Appendix A-1

Survey Instrument – Ambulatory Care Pharmacists Survey on Specialty Recognition

Ambulatory Care Pharmacists Survey on Specialty Recognition

Dear Ambulatory Care Pharmacist:

Thank you for taking the time to provide background information to assist in the consideration of a proposed specialty certification of pharmacists who have distinguished themselves in the care of ambulatory patients by gaining specialized knowledge, skills, and abilities.

The American College of Clinical Pharmacy (ACCP), the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP) have partnered to develop and submit a petition to the Board of Pharmaceutical Specialties (BPS) to recognize ambulatory care pharmacy practice as a specialty. The petitioning organizations believe that while ambulatory patients may be cared for by pharmacists in a number of different practice settings, some pharmacists have developed a specialized body of knowledge, skills, and abilities and a unique practice beyond the scope of pharmacy practice defined by licensure examination. As such, the associations believe there is tremendous value in recognizing and credentialing pharmacists who attain the skills to actively manage medication use over the long-term; educate patients in adherence; engage them in preventive strategies to improve outcomes, maintain wellness, and slow chronic disease progression; and partner with other members of the health care team to coordinate and integrate care.

Definition of Ambulatory Care Pharmacy Practice – A Specialty in Medication Use for Preventive and Chronic Care

Ambulatory care pharmacy practice is the provision of integrated, accessible health care services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.

Please complete the 14-item survey below **by Friday, August 29, 2008**. Your individual responses will be confidential. Collectively, all pharmacist responses will be compiled to provide support for this specialty in a petition to the Board of Pharmaceutical Specialties. If questions arise, contact <u>pmanolakis@gmail.com</u>.

Thank you for your time and assistance in this effort.

Cindi Brennan, PharmD, MHA

Director of Clinical Excellence UW Medicine Pharmacy Services Clinical Professor, University of Washington School of Pharmacy American Society of Health System Pharmacists

Jean-Venable "Kelly" R. Goode, PharmD, BCPS, FAPhA, FCCP Professor, Virginia Commonwealth University, School of Pharmacy Director, Community Pharmacy Practice and Residency Program American Pharmacists Association

Stuart T. Haines, PharmD, BCPS, FCCP, FASHP, FAPhA

Professor and Pharmacotherapy Specialist University of Maryland School of Pharmacy American College of Clinical Pharmacy

1. Which of the following best describes your ambulatory care practice setting?

- Academic-teaching and practice (ambulatory care clinic)
- Academic-teaching and practice (community pharmacy)
- Academic-teaching and practice (physicians' office-based)
- Academic-teaching and practice (managed care)
- Ambulatory care clinic
- Physicians' office-based practice
- Managed care practice
- Community pharmacy practice
- I do not have an ambulatory care practice
- Other (please describe)

2. On average, how many HOURS per week do you practice in your ambulatory care practice site?

- Full-time: 40 or more hours per week
- 31 39 hours per week
- 25 30 hours per week
- 21 24 hours per week
- 15 20 hours per week
- 10 14 hours per week
- 1 9 hours per week
- I do not practice in ambulatory care

3. Do you believe that you currently practice in the area of specialization as defined above?

Yes No

4. If yes, in an average week, what <u>PERCENTAGE</u> of your time do you estimate is devoted exclusively to practicing according to this definition?

90% - 100% 80% - 89% 70% - 79% 60% - 69% 50% - 59% 40% - 49% 30% - 39% 20% - 29% 10% - 19% 1% - 9%

In questions 5 - 7 below, please ensure that your combined responses do not exceed ~100%.

5. In an average week, what <u>PERCENTAGE</u> of your time IN PRACTICE do you spend engaged in direct patient care activities such as: managing medication use; developing/implementing individualized treatment goals and plans; gathering information from and assessing patients; integrating care of acute illnesses in the context of patients' underlying chronic disease(s) and health status; performing roles in patient education, health promotion, wellness and/or self-management; coordinating care among members of the health care team; and advocating for patients?

| 90% - 100% |
|---|
| 80% - 89% |
| 70% - 79% |
| 60% - 69% |
| 50% - 59% |
| 40% - 49% |
| 30% - 39% |
| 20% - 29% |
| 10% - 19% |
| 1% - 9% |
| I do not perform any of these functions |

6. In an average week, what <u>PERCENTAGE</u> of your time IN PRACTICE do you spend engaged in the following activities and functions: practice-based research; retrieving and interpreting biomedical literature and evidence; establishing clinical services; establishing systems for patient referral and follow-up.

| _ | |
|---|---|
| | 90% - 100% |
| | 80% - 89% |
| | 70% - 79% |
| | 60% - 69% |
| | 50% - 59% |
| | 40% - 49% |
| | 30% - 39% |
| | 20% - 29% |
| | 10% - 19% |
| | 1% - 9% |
| | I do not perform any of these functions |

7. In an average week, what <u>PERCENTAGE</u> of your time IN PRACTICE do you spend engaged in the following non-patient care activities: administrative functions, dispensing functions, precepting students and/or residents, staff-management activities.

 90% - 100%

 80% - 89%

 70% - 79%

 60% - 69%

 50% - 59%

 40% - 49%

 30% - 39%

 20% - 29%

 10% - 19%

 1% - 9%

 I do not perform any of these functions

8. Does your practice currently "bill" third parties for clinical services?

Yes No

9. If yes, of the bills submitted what PERCENTAGE of your claims are paid?

90% - 100% 80% - 89% 70% - 79% 60% - 69%

| 50% - 59% |
|-------------------------|
| 40% - 49% |
| 30% - 39% |
| 20% - 29% |
| 10% - 19% |
| 1% - 9% |
| I don't know |
| Other (Please specify.) |

10. Does your practice currently collect cash payments from patients who receive clinical services?

Yes No

11. Please indicate which of the following credentials you have earned. (Check all that apply.)

| BCPS |
|---|
| BCOP |
| BCNSP |
| ВСРР |
| CGP |
| CDE |
| CDM |
| No advanced credentials beyond entry-level degree |
| Other (please list) |

12. Have you completed a residency or fellowship?

| Yes |
|-----|
| No |

13. If yes, please check all residencies/fellowships completed. (Please use the text box provided to describe or specify as needed.)

- PGY1 Pharmacy Practice Residency
- PGY1 Community Pharmacy Residency
- PGY1 Managed Care Residency
- PGY2 Ambulatory Care Residency
- PGY2 Residency-Other

Fellowship

Other (please specify)

14. If the petition to recognize ambulatory care pharmacy practice as a specialty is approved, how likely would you be to pursue this specialty recognition within the next 5 years?

| Highly likely | |
|-----------------|--|
| Likely | |
| Somewhat likely | |
| Unlikely | |
| Highly unlikely | |

(Optional.) Please add any additional comments (e.g., about your responses, the proposed specialty) and/or your contact information below.

Note: IF YOU WANT TO SUPPORT THIS RECOGNITION EFFORT... After submitting your survey response, you will have an opportunity to add your signature to the petition in support of this proposed specialty. If interested, please see link in the "Success Page" that appears after your survey response has been received.

Appendix B-1

Joint Commission of Pharmacy Practitioners (JCPP)

Vision Statement – Pharmacy Practice in 2015

Joint Commission of Pharmacy Practitioners

Vision Statement

Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.

Pharmacy Practice in 2015

<u>The Foundations of Pharmacy Practice.</u> Pharmacy education will prepare pharmacists to provide patient-centered and population-based care that optimizes medication therapy; to manage health care system resources to improve therapeutic outcomes; and to promote health improvement, wellness, and disease prevention. Pharmacists will develop and maintain:

- a commitment to care for, and care about, patients
- an in-depth knowledge of medications, and the biomedical, sociobehavioral, and clinical sciences
- the ability to apply evidence-based therapeutic principles and guidelines, evolving sciences and emerging technologies, and relevant legal, ethical, social, cultural, economic, and professional issues to contemporary pharmacy practice.

<u>How Pharmacists Will Practice.</u> Pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients' therapeutic outcomes. In doing so, they will communicate and collaborate with patients, care givers, health care professionals, and qualified support personnel. As experts regarding medication use, pharmacists will be responsible for:

- rational use of medications, including the measurement and assurance of medication therapy outcomes
- promotion of wellness, health improvement, and disease prevention
- design and oversight of safe, accurate, and timely medication distribution systems.

Working cooperatively with practitioners of other disciplines to care for patients, pharmacists will be:

- the most trusted and accessible source of medications, and related devices and supplies
- the primary resource for unbiased information and advice regarding the safe, appropriate, and cost-effective use of medications
- valued patient care providers whom health care systems and payers recognize as having responsibility for assuring the desired outcomes of medication use.

<u>How Pharmacy Practice Will Benefit Society</u>. Pharmacists will achieve public recognition that they are essential to the provision of effective health care by ensuring that:

- medication therapy management is readily available to all patients
- desired patient outcomes are more frequently achieved
- overuse, underuse and misuse of medications are minimized
- medication-related public health goals are more effectively achieved
- cost-effectiveness of medication therapy is optimized.

Academy of Managed Care Pharmacy 703-683-8416 Judith A. Cahill Executive Director

American College of Apothecaries 901-383-8119 D. C. Huffman, Jr. Executive Vice President

> American College of Clinical Pharmacy 816-531-2177 Michael S. Maddux Executive Director

American Pharmacists Association 202-628-4410 John A. Gans Executive Vice President

American Society of Consultant Pharmacists 703-739-1300 John Feather Executive Director

American Society of Health-System Pharmacists 301-657-3000 Henri R. Manasse, Jr. Executive Vice President

> National Community Pharmacists Association 703-683-8200 Bruce T. Roberts Executive Vice President

> > Liaison Members

American Association of Colleges of Pharmacy 703-739-2330 Lucinda L. Maine Executive Vice President

Accreditation Council for Pharmacy Education 312-664-3575 Peter H. Vlasses Executive Director

National Association of Boards of Pharmacy 847-391-4400 Carmen A. Catizone Executive Director

National Alliance of State Pharmacy Associations 804-285-4431 Rebecca P. Snead Executive Vice President

Appendix B-2

Statements from Non-pharmacist Health Professional Leaders, Planners and/or Administrators



1155 21st Street, NW Suite 202 Washington, DC 20036 T 202.331.5790 • F 202.331.9334 www.ahqa.org

October 28, 2008

Richard J. Bertin, PhD, RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street N.W. Suite 400 Washington, DC 20005

Dear Dr. Bertin,

I am pleased to write in support of recognition by the Board of Pharmaceutical Specialties of pharmacist specialists practicing in ambulatory care.

As the Executive Vice President of the American Health Quality Association (AHQA), I am privileged to represent thousands of physicians, nurses, pharmacists and other health professionals who are improving health care outcomes and patient safety in communities across America. My work within the health care policy and quality arenas, and particularly with the profession of pharmacy, has persuaded me of the great value of pharmacists working with patients, physicians, and other professionals in the management of chronic illnesses.

Pharmacists who can satisfy the requirements for the proposed specialty will be a valuable resource to individuals and organizations working to improve the value of drug therapy and the quality of health care. As AHQA's member Quality Improvement Organizations (QIOs) expand their work with prescription drug plans and health professionals to improve the safety and effectiveness of pharmacotherapy, I am confident they will seek out pharmacist specialists who are skilled in working with patients, identifying and reducing clinically significant adverse events, and preventing the costly consequences of poorly coordinated treatment.

I hope you will take this opportunity to strengthen clinical pharmacy by recognizing an ambulatory care pharmacist specialty.

David G. Schulke Executive Vice President

November 13, 2008

Richard J. Bertin, PhD, RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW Suite 400 Washington, DC 20005

Dear Dr. Bertin:

I am very pleased to write in support of recognition of ambulatory care pharmacist specialists by the Board of Pharmaceutical Specialties.

I am currently the Medical Director for the Daily Planet which is a comprehensive health services and activity center that serves the homeless and underprivileged people of the greater Richmond area. This clinic was established in 1969 with a mission to enable homeless or near homeless individuals reach a level of self sustainability.

Recently, the VCU School of Pharmacy and the Daily Planet were accepted as part of the Health Resources and Services Administration Patient Safety and Clinical Pharmacy Services Collaborative (PSPC). We have been partnering to increase clinical pharmacy services in our clinic. Through the Collaborative we have already increased the number of hours the pharmacists are in the clinic and hope to expand to other patient populations.

These pharmacists with specialized skills in ambulatory care practice are invaluable to the care of our patients. The pharmacists actively manage medication use over the long term in complex patients; educate patients in adherence; engage them in preventative strategies for improving outcomes, maintaining wellness, and slowing disease progression; and partner with other members of our clinic to coordinate and integrate care.

Recognizing ambulatory care pharmacist specialists will help improve the care of patients in multiple settings. This is reflective of the Virginia Board of Health Professions which ensures protection of the public through all that they do.

Thank you in advance for consideration of this petition.

Diame Reyolds Core MD

Diane Reynolds-Cane, MD Medical Director Daily Planet Health Care for the Homeless Clinic A Federally Qualified Health Center

Appendix B-3

Statements of Pharmacists Not Practicing In Ambulatory Care Practice



Roger W. Anderson, Dr.P.H. Senior Vice President & Chief Pharmacist Medco Health Solutions, Inc. 100 Parsons Pond Drive Franklin Lakes, NJ 07417

tel 201-269-6339 fax 201-269-1226 www.medco.com

August 19, 2008

Richard J. Bertin, PhD RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW Suite 400 Washington, DC 20005

Dear Dick,

I am pleased to write a letter of support for the development of BPS recognition for pharmacist specialists practicing in ambulatory care pharmacy. As you know, I have been a long term supporter of specialist recognition for many years, and have served on the BPS Board in the past. In addition to supporting all specialist categories, I was particularly active in the recruitment of BPS credentialed pharmacists, and supportive of our staff at M.D. Anderson to obtain BPS recognition in Oncology. This support has continued with me during my years at Medco, and now is the right time to move in the creation of recognition within the ambulatory care practice area.

Even though I have retired from my Senior Vice President and Chief Pharmacist position at Medco on August 1, 2008, I would like to take this opportunity to write a letter of support relating to my experience during the past four years at Medco. Bruce Scott will replace me at Medco, but doesn't assume his position until September 8, 2008.

There is a tremendous need for advancing the level of practice in the ambulatory setting throughout the country, but at Medco, we have the responsibility of caring for over 65 million patients who are on chronic medication therapies. We have advanced the level of care by stratifying all our patients by disease category, and have created Therapeutic Resource Centers for nine different chronic disease areas. We have conducted training in each of these areas, but want to elevate further the level of practice. This new potential credential fits perfectly with our vision and strategy. We want our pharmacists to practice at an elevated level, and need for this enhanced level of care is certainly apparent given the complexity of chronic therapies.

I am not sure of the overall number of pharmacists practicing in this area, but I assume it is very large given the overall retail opportunities, outpatient clinic pharmacies, and those like Medco, in the PBM/Mail Service pharmacy practice settings. At Medco, we have over 2,500 pharmacists and over 1,100 of these are practicing in our Therapeutic Resource Centers.

Just as I did at M.D. Anderson, we at Medco intend to provide additional practice opportunities and enhanced compensation for those pharmacists with additional credential such as BPS specialist certification.

While we do not yet have such a credential from BPS, we at Medco have already been having our advance trained pharmacists interacting with patients and physicians to identify themselves as being from each of our specialized Therapeutic Resource Centers. The response from patients and physicians has been extremely positive. This is very similar to the response and respect our specialists pharmacists experienced at M.D. Anderson.

In conclusion, I am confident that this is the path to follow in this very critical practice area. I would be pleased to correspond further as this process proceed and know that Bruce Scott will also be very supportive as he assumes his new role at Medco.

Roger W. Anderson, Dr.P.H. R.Ph., FASHP Former Senior Vice President and Chief Pharmacist



August 21, 2008

Richard J. Bertin, PhD, RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW Suite 400 Washington, DC 20005

Re: Recognition of Ambulatory Care Pharmacy Practice as a Specialty

Dear Dr. Bertin:

As the healthcare delivery model in this country has evolved with a much greater focus and extent of care provided to ambulatory patients, so have pharmacy practice models evolved. Technologies enabling many surgical and diagnostic procedures to be safely conducted in non-hospital settings, especially laparoscopic devices and advances in information technology, along with the rising costs of hospitalization have been and continue to be major factors impacting the US healthcare system.

Many pharmacists with excellent clinical training now practice in ambulatory settings, some under collaborative practice agreements, whereby the pharmacist is assessing and triaging patients while monitoring and refining drug therapy regimens. The clinical, therapeutic and communication skills required in this environment are both significant and unique. Many of these practice settings have implemented outcomes measures; often showing improvement over similar functions when performed by other members of the healthcare team. Practitioners with the ability to perform at these established levels will continue to be crucial to healthcare organizations, administrators and payors.

Current predictors of competency to perform ambulatory clinical skills at the high levels required have consisted primarily of pharmacy residency training, in community pharmacy, ambulatory care or specialty areas; or BCPS certification. Most organizations employing this type of pharmacist have some type of on-thejob training programs tailored to the individual pharmacist's experience and skills. Reliance primarily with on-the-job training increases costs and may result in applicant pool shrinkage. Several of the clients I currently consult with would welcome a growing pool of applicants with BPS certification in ambulatory care.

I have appreciated the approach and methods that BPS utilizes in developing an area for board certification and the rigor of its examination process. On several occasions I have hired and actively sought out individuals with BPS certification;

finding them to be able to perform at high levels immediately. In a prior position, I contracted to bring a BPS review course "in-house" with several clinical staff ultimately earning BPS certification of various types.

With the introduction of Part D, Medicare requires Medication Therapy Management Programs (MTMP) of all Part D plan sponsors. Free- standing Prescription Drug Plans (PDPs) have little incentive to offer these services except to meet the currently minimal requirements of CMS while Medicare-Advantage drug plans (MA-PDs) and Special Needs Plans (SNPs) have major incentives to leverage drug therapy in chronic diseases to decrease hospitalization rates and lengths of stay. I am currently working with some MA and SNP Medicare plan sponsors to implement local networks consisting of physicians and pharmacists to provide high-level and sophisticated care management activities. Many of the functions now being performed under Part D are "MTM-light" in my view and below the competency level required for BPS certification.

My views have been influenced by the fact that my daughter recently completed an ambulatory care residency and has now embarked on a career in ambulatory care pharmacy practice. Her description of her patients, their response to the pharmacist-run clinics at the Veteran's Administration and the measurement of patient's clinical responses and impact on healthcare outcomes have been gratifying to me both as a parent and a pharmacist.

I believe that an opportunity exists for BPS to consider splitting the BCPS certification into two components; acute care and chronic care with a common base from which each is built. While I am sure that BPS is already considering this, my comment is related to the timing which I believe is now ideal based upon increasing implementation of on-line medical records and renewed focus on continuum of care issues.

I appreciate the opportunity to comment on this important matter. Please let me know if I might provide any clarification or additional perspective.

Sincerely. Michad & Lapta

Michael S. Flagstad, MS, RPh Principal



August 21, 2008

Richard J. Bertin, PhD RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW, Suite 400 Washington, DC 20005

Dear Dr. Bertin:

I am writing this letter in support of a petition to the Board of Pharmaceutical Specialties (BPS) to recognize Ambulatory Care Pharmacy Practice as a specialty. As you know, we require BPS certification as a condition of employment for Clinical Pharmacy Specialists (CPS) at Kaiser Permanente Colorado. Currently 82 BPS certified pharmacists (mostly BCPS) are employed by our department. These CPS actively manage medication use over the long-term; educate patients in adherence; engage them in preventive strategies for improving outcomes, maintaining wellness, and slowing chronic disease progression; and partner with other members of the health care team to coordinate and integrate care.

Demand for BPS credentialed pharmacy positions increased by over 1,600% in our organization during the past 15 years (from 5 to 86 positions). The number of pharmacists practicing in ambulatory care clinical pharmacy settings in other health systems has also increased steadily and will continue to do so. This demand is fueled in part by the growing proportion of society suffering from chronic, generally incurable illnesses or conditions such as asthma, heart disease, diabetes, kidney disease, and cancer. <u>By 2025, an estimated 164 million Americans—nearly half the population—will</u> <u>by affected by chronic disease</u>. Recent publications from our department have *conclusively demonstrated the dramatic reductions in morbidity and mortality ambulatory care pharmacists can have on patient populations afflicted with these types of chronic diseases* (see CHEST 2005;127:1515-1522, and Pharmacotherapy 2007;27:1370-1378).

Specialty certification in Ambulatory Care Pharmacy Practice will be extremely attractive to the growing numbers of clinical pharmacists caring for the chronically ill. Clinical pharmacy leadership in our organization believes that approximately 25% of our CPS will seek certification in Ambulatory Care *in addition* to their current BCPS status. A method facilitating the transition from BCPS to Ambulatory Care Pharmacy Practice certification would further increase the demand.

I continue to actively support the mission of BPS to improve patient care through recognition and promotion of specialized training, knowledge, and skills in pharmacy and specialty board certification of pharmacists. I urge BPS to consider the recognition of Ambulatory Care Pharmacy Practice as a specialty to highlight the unique qualifications of that subset of pharmacists in outpatient settings that have distinguished



themselves in the care of ambulatory patients by gaining specialized knowledge, skills, and abilities, and creating a unique practice beyond the scope of pharmacy practice defined by licensure examination.

Jennis K. Helling

Dennis K. Helling, PharmD, DSc, FCCP, FASHP Executive Director, Pharmacy Operations & Therapeutics Kaiser Permanente Colorado Region Clinical Professor, UCDHSC School of Pharmacy



UNIVERSITY OF MARYLAND

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August 22, 2008

Richard J. Bertin, PhD RPh Executive Director **Board of Pharmaceutical Specialties** 1100 15th Street NW. Suite 400 Washington, DC 20005

Dear Dr. Bertin:

I write in support of recognition of Ambulatory Care Pharmacy Practice as a Specialty. This letter focuses on the quantitative need for specialized ambulatory pharmacy services (as defined in the petition) in the United States.

Data released earlier this month by the National Center for Health Statistics (NCHS)¹ show that an estimated 1.1 billion visits to physician offices and hospital outpatient departments (OPDs) and emergency departments (EDs) were made in 2006. This is a rate of 381.9 visits per 100 persons annually. From 1996-2006, the number of visits increased by 26%, faster than the growth of the US population, which grew by 11 %. OPD visits increased by 52%, and ED visits by 32%, during that period. NCHS attributes the disproportionate growth to the aging of the population and higher utilization by older persons. Since the leading edge of the baby boom generation only now is reaching 65, utilization of ambulatory care services is likely to continue to grow unabated for another 20-30 years.

NCHS also noted that 71.6% of all ambulatory care visits in 2006 reported medication therapy. "An estimated 2.6 billion medications [of all types]... were provided, prescribed or continued at ambulatory care visits."²

The Medicare Program recognizes the need for differentiated professional services for the elderly with complex medical issues through its Medication Therapy Management (MTM) program requirement for high risk beneficiaries. Roughly 11% of the beneficiaries enrolled in a Medicare plan with a MTMP met the high risk criteria in 2008.³

¹ Schappert SM, Rechsteiner EA. Ambulatory medical care utilization estimates for 2006. National health statistics reports: no 8. Hyattsville, MD: National Center for Health Statistics. 2008.

² *Ibid*, p 4.

These numbers provide quantitative evidence of the very large and growing number of patients who are being treated in ambulatory care settings for complex conditions requiring multiple medications. It is apparent that the complex pharmaceutical care services needed by these patients could be offered most appropriately by specialists in ambulatory pharmacy.

At a conference I convened and facilitated in 2001⁴, two dozen experts from around the US estimated the quantity of pharmaceutical services that they believed would best serve the health care needs of society in 2020. One focus of their deliberations was to estimate need for those ambulatory patients receiving four or more prescriptions, a group defined as requiring complex primary care pharmaceutical services. The experts assumed that one pharmacist would be required to meet the needs of 1000 such patients or about 130,000 primary (ambulatory) care pharmacists by 2020.

An alternative estimate of need was based upon the experience of Kaiser Permanente/Denver, which operates a closed system that provides its 350,000 patients with highly managed medication therapy. It estimates its needs for primary (ambulatory) care pharmacists for its complex patients at 1.1 to 1000. If this ratio were extended to the US population in 2020, over 300,000 such pharmacists would be needed.

Note that these estimates *exclude* pharmacists providing order fulfillment functions in community pharmacies.

In conclusion, a significant proportion of the US population is being cared for in the ambulatory environment, and over 70% are treated with medications. A large and growing number receive multiple medications from not only office-based physicians, but also hospital outpatient departments and emergency rooms. These patients are being served increasingly by pharmacists concentrating their practices on ambulatory pharmacy. Recognizing ambulatory pharmacy as a specialty and establishing a mechanism to certify specialists in this area would provide an effective mechanism for developing leadership and cohesion in a practice focus that inevitably will become even more critical to patient care and the health of our population.

David Allerapp

David A. Knapp, PhD

³ Medicare Part D Medication Therapy Management (MTM) Programs: 2008 Fact Sheet. Baltimore, MD: Centers for Medicare and Medicaid. March 19, 2008

⁴ Knapp DA. Professionally determined need for pharmacy services in 2020. Am. J. Pharm. Educ., **66**, 421-429(2002).

DEPARTMENT OF HEALTH & HUMAN SERVICES



Healthcare Systems Bureau

SEP 2 2008

Rockville, Maryland 20857

Richard J. Bertin, PhD, RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street, NW Suite 400 Washington, DC 20005

Dear Dr. Bertin:

The mission of the Office of Pharmacy Affairs (OPA) is to promote access to clinically and cost effective pharmacy services to patients of the more than 13,000 safety net clinics and hospitals that participate in the 340B Drug Pricing Program. OPA is part of the Health Resources and Services Administration (HRSA), the nation's federal agency for improving access to healthcare services for people who are uninsured, isolated or medically vulnerable. HRSA-supported safety-net providers serve populations that have a higher prevalence of chronic diseases than do other populations of similar age and gender. This makes drug safety and effectiveness crucial elements of care in these populations.

Problems associated with polypharmacy, duplication of therapy, drug interactions, incorrect drug or dosage, and lack of patient understanding have become much more prevalent in the outpatient setting. The number and costs of outpatient adverse drug events (ADEs) will also increase unless effective interventions to improve outpatient safety are implemented.

Clinical pharmacy services in the outpatient/ambulatory setting have proven benefits to patients, health centers and to colleges and schools of pharmacy. The integration of clinical pharmacy services into primary health care improves patient health outcomes, increases patient safety and reduces cost to the health care system.

In recognition of these proven benefits, HRSA has initiated a Patient Safety and Clinical Pharmacy Services Collaborative (Collaborative). The primary emphasis of the Collaborative is the improvement of healthcare delivery systems which integrate use of clinical pharmacy services and safe medication practices. These practices will ultimately result in improved patient outcomes. HRSA believes that the outcomes/demonstrated improvements of the Collaborative will generate broader interest and demand for ambulatory clinical pharmacy services.

The Collaborative will also increase awareness of the benefits of clinical pharmacy services among healthcare providers and promote the integration of clinical pharmacy services into the interdisciplinary healthcare team. Page 2 – Richard J. Bertin, PhD, RPh

The OPA supports credentialing pharmacists who are trained to capably coordinate patient care among members of interdisciplinary healthcare teams. Training specific in the Ambulatory Care Pharmacy specialty will prepare clinical pharmacists to build effective partnerships within the healthcare teams and ultimately improve patient outcomes. Recognizing and credentialing pharmacists with the specialized knowledge, skills and abilities to implement and manage medication use in ambulatory patients will further improve the practice of pharmacy and patient care.

Jimmy R. Mitchell, RPh, MPH, MS Director Office of Pharmacy Affairs

August 25, 2008

Richard J. Bertin, PhD RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street, NW, Suite 400 Washington, D.C. 20005

Dear Dr. Bertin:

The purpose of this letter is to petition the Board of Pharmaceutical Specialties (BPS) for recognition of Ambulatory Care Pharmacy Practice as a specialty.

A subset of pharmacists in outpatient settings have distinguished themselves in the care of ambulatory patients by gaining specialized knowledge, skills, and abilities, and creating a unique practice beyond the scope of pharmacy practice defined by the licensure examination. These pharmacists actively manage medication use over the long term; educate patients in adherence; engage them in preventative strategies for improving outcomes, maintaining wellness, and slowing disease progression; and partner with other members of the healthcare team to coordinate and integrate care.

An excellent example of the efforts outlined above is our own Ukrop's Pharmacy Immunization Program. This program, which has fostered multidisciplinary collaboration, developed innovations in the area of pharmacybased immunization delivery, and focused on advocacy and education, was recognized in June with one of APhA's Pinnacle Awards for improving the medication use process. Ukrop's pharmacists administer more than 35,000 vaccines each year. The immunization program has improved the lives of our patients by protecting them from vaccine-preventable diseases.

Beyond immunizations, Ukrop's Pharmacy offers many different types of patient care services such as medication therapy management, smoking cessation, wellness and prevention, and diabetes education and management. Our patients have benefited immensely from these services. Several patients have sent letters stating that the Ukrop's pharmacist saved their life.

Ukrop's needs pharmacists who are better prepared to develop and improve patient care services for the benefit of our patients. Currently, Ukrop's employs approximately 5 pharmacists who would meet the criteria of an Ambulatory Care Pharmacy Specialist. However, I anticipate a need to hire more pharmacists with these credentials as our services expand. Ukrop's will probably hire 5 more pharmacists with these skills in the next 5 years with an ultimate goal of having one specialist in each pharmacy (currently 22 pharmacies).

With Ukrop's involvement and on going commitment to patient care initiatives such as immunizations, I feel strongly that there is tremendous value in recognizing and credentialing pharmacists as medication use specialists in preventive and chronic care.

Thank you for your consideration. Please contact me if I can provide additional information.

Sincerely,

John O. Beckner Director of Pharmacy and Health Services Ukrop's Super Markets, Inc. (804) 340-4057



Dean's Office

Phoenix Campus 445 N. 5th St. Phoenix, AZ 85004 Tel: (602) 293-3222 Fax: (602) 293-3632 Tucson Campus 1295 N. Martin Ave. P.O. Box 210202 Tucson, AZ 85721-0202 Tel: (520) 626-1657 Fax: (520) 626-0546

September 13, 2008

Richard J. Bertin, Ph.D., R.Ph. Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW, Suite 400 Washington, DC 20005

Dear Dr. Bertin:

As Founding and Executive Director of the University of Arizona Center for Health Outcomes and PharmacoEconomic (HOPE) Research, and Co-Chair of the Committee on Identifying and Preventing Medication Errors, Institute of Medicine (IOM) of the National Academies – I urge the Board of Pharmaceutical Specialties to recognize that **Ambulatory Care Pharmacy Practice is a specialty.**

The recognition of specialized pharmacy practice in ambulatory care will further delineate an important subset of practice that contributes significantly to positive medication assessment and outcomes for patients. There is tremendous value in recognizing and credentialing pharmacists enabling certified ambulatory care pharmacists to perform roles in patient education, health promotion, wellness and medication management including self management. This will assist in not only maintaining but further strengthening patient to pharmacist relationships; fostering ongoing management of medication use in ambulatory-based patients; and integrating care for both acute and chronic illnesses that is essential to achieving optimal patient care.

We need to participate actively and effectively as a multidisciplinary health team within the ambulatory care setting to provide improved therapeutic planning and achievement of patient outcomes. There are numerous pharmacy related health care issues for ambulatory patients, in regards to compliance, patient education, cost-effectiveness and nonprescription drug use and overall drug related morbidity and mortality. This would enhance inpatient and outpatient drug therapy, particularly with regard to follow-up of response, side effects, and compliance after discharge from a hospital or long-term care facility.

- On average a hospital patient is subject to at least one medication error per day;
- Substantial variations in error rates are found across facilities;
- At least 1.5 million preventable ADEs occur each year;
- Current estimates as to the cost of drug related morbidity in the US may be in excess of 200 billion dollars annually with estimates that more than 60% can be prevented.

In essence, supporting a specialty level for ambulatory care pharmacy practice is important to reinforce advanced pharmacy practice for optimal, cost-effective patient care. Efforts are needed

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within all care settings in order to improve medication safety and use, cost-effectiveness, qualityof-life improvement, and patient outcomes. This specialty of pharmacy practice may be the exact prescription to achieve and insure the value of drug therapy in the ambulatory setting.

Additionally, the certified ambulatory care pharmacist would become the key source of information and collection of data with regard to the incidence and prevalence of side effects, contraindications, management of adverse reactions, and other post-marketing information that is so essential to assuring drug therapy value. Ultimately, I believe this will lead to improve communications between pharmacy specialty providers in all settings including ambulatory, acute care and long term care. In the past 40 years we have made significant improvement in the long term care and acute care settings relative to the ambulatory setting due in part to the specialty advances within those settings. It is time to move forward similarly in the ambulatory setting so to improve the quality, safety and overall cost-effectiveness of drug therapy.

I support the cohort petition efforts of the American College of Clinical Pharmacy (ACCP); the American Pharmacists Association (APhA); and, the American Society of Health-System Pharmacists (ASHP). Recognizing ambulatory care pharmacy practice as a specialty is a necessity and I urge you to strongly consider the petition to establish **ambulatory care pharmacy practice as a specialty.** As the complexities of patient care expand and the access to health care becomes more restricted, the need for pharmacists with focused and defined skills in these areas are critical if not essential to achieving value with regard to drug therapy.

J. Lyle Bootman, Ph.D., Sc.D.
Dean, College of Pharmacy
Professor of Pharmacy, Medicine, and Public Health
Founding and Executive Director, The University of Arizona
Center for Health Outcomes and PharmacoEconomic (HOPE) Research
Co-Chair, Committee on Identifying and Preventing Medication Errors, Institute of Medicine of the National Academies

September 3, 2008

Richard J. Bertin, PhD RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW, Suite 400 Washington, DC 20005

Dr. Bertin,

I am writing this letter in support of the petition for a new specialty recognition program for Ambulatory Care Pharmacists. There is a need for recognition of this specialty and I will offer support for this assertion in the following paragraphs. I have been a pharmacist for nearly 20 years and have practiced in various settings. I have also conducted research on ambulatory pharmacy services and recently served as Director of Practice Improvement for the Pharmacy Quality Alliance (PQA). I am currently employed by Humana but the opinions that I express in this letter are my personal opinions and do not represent the official position of my employer.

There are several reasons that I support the petition submitted by APhA, ASHP and ACCP. These reasons include: 1) a lack of differentiation between ambulatory care clinicians and community pharmacists; 2) the growing demand for ambulatory specialists who can demonstrate competence in medication-therapy management; and 3) the pharmacotherapy exam focuses on inpatient care and lacks depth in ambulatory and preventive care. Further detail follows.

The healthcare market has changed considerably in recent decades and this change has accelerated in recent years due, in part, to the creation of the Medicare Part D drug benefit. This benefit requires that drug plans provide medication-therapy management (MTM) services to the millions of Medicare patients with chronic diseases and poly-pharmacy. Furthermore, employers have begun to recognize that ambulatory pharmacists can have a profound effect on health outcomes for employed patients with chronic diseases and have started to demand medication-therapy management services for the commercially-insured population.

Health plans and drug plans have sought to create meaningful MTM programs through recruitment of pharmacists to work within the drug plan or through contracts with external pharmacists. However, the lack of an ambulatory pharmacist credentialing process creates difficulties in identifying pharmacists who have the requisite clinical skills to provide ambulatory-based MTM services. If BPS created a specialty recognition program for ambulatory care pharmacists, there would be great demand for pharmacists who achieved this recognition.

The current pharmacotherapy recognition program is useful but fails to provide the necessary focus on disease prevention, health promotion and patient counseling that are cornerstones of ambulatory care. Given that the majority of healthcare is delivered in an ambulatory setting and since the appropriate treatment of chronic disease is largely shaped in the ambulatory setting, there is a need to identify pharmacists who have the knowledge and skills to help physicians select appropriate treatment and therapeutic monitoring for ambulatory patients and to help patients use and self-monitor their chronic medications. An exam and recognition criteria that are tailored to the ambulatory role of clinicians is needed.

I believe that addition of Ambulatory Care to the list of pharmacist specialties will provide incentive for some community pharmacists to elevate their knowledge and skills. As health plans search for highly-skilled pharmacists to provide MTM, they will increasingly turn to pharmacists who possess advanced credentials. This will further expand the clinical opportunities for pharmacists who practice in ambulatory settings. The increased availability of these specialists will further raise the level of care. Thus, an upward spiral towards better care may be created through recognition of the specialty of ambulatory care pharmacist.

I appreciate your consideration of the petition, and I look forward to further discussion and debate on this topic.

Sincerely,

David P. Nau, Ph.D., R.Ph., CPHQ

Telephone: 859-232-8562 Email: <u>dnau@humana.com</u>

Appendix B-4

Statements from Members of the Public

34 East StreetAnnapolis, MD 2140114 August 2008

Dr. Richard J. Berlin Executive Director Board of Pharmaceutical Specialties 1100 15 Street Suite 400 Washington, D. C. 20005

Letter of Support

Dear Dr. Berlin,

This letter is to voice my support for the establishment of the "Ambulatory Care Pharmacy Practice" as a specialty.

As background, I am 73 years old and have been a diabetic for 50 years; 17 years ago I had my first heart attack; and 14 years ago I was diagnosed with Interstitial Cystitis. Lastly, by accepted standards, I have been anemic for over 40 years.

For these health challenges, I currently take 10 different medications that are prescribed by eight different doctors. Not only do the health conditions interact with one another, so do the prescribed medications. Often medical doctors do not have an appreciation for these interactions or the effects of a given medication on what I will call quality of life. As examples, statins make me feel so lethargic that I don't want to get out of bed. Many of the other medications prescribed for me have as a possible side effect that of being dizzy, others give me diarrhea. It has been a difficult task to sort out which medications are the correct ones for me. A large portion of my health care is rendered by the staff of the Veterans Hospital (VA) in Baltimore, Maryland. Fortunately, the VA has an arrangement with the University of Maryland Hospital next door to interchange health care professionals as patient needs require. Through this arrangement, I have acquired the assistance of Dr. Stuart T. Haines, Pharm.D, FCCP, FASHP. Not only has Dr. Haines helped me sort out my medications during the last three years, he made two of his graduate students at the University of Maryland available to help me devise a procedure to properly take my insulin with a syringe when I have an insulin pump failure. Dr. Haines oversaw this whole process.

Lastly, through Dr. Haines's easy-going but positive leadership, my wife and I have also established a close relationship with our local drug store pharmacist. She also does a thorough job of researching all aspects of the medication challenges of our lives.

In summary, I now consider the pharmacist a vital member of my health care team. I endorse having a specialty that will make this aspect of patient care an every day standard.

Very truly yours,

John Paul Berry

Richard J Bertin, PhD Rph Executive Director Board of Pharmaceutical Specialities 1100 15th Street NW, Suite 400 Washington, DC 20005

Dear Dr.Bertin:

I would like to add my voice to the requests to recognize Ambulatory Care Pharmacy as a specialty. I believe my experiences with the Veterans Administration Hospital in Middleton, WI are noteworthy.

Of specific and personal, 'hands-on'service to me has been the efforts of Dr.Arthur Schuna at the VA facility. My experience at this hospital dates to February of 1991 when I had quintuple bypass heart surgery. Art Schuna at that time not only demonstrated extra-ordinary efforts to heal . but went out of his way to give me his E-mail address, which has enabled me to be in continuing and constant contact whenever I had any questions.

Since that first date I have had many opportunities to avail myself of this hospital, and Art's, services. I was seen for high blood pressure, stroke, eye damage (from the stroke), prostate surgery, knee replacement and heart followup.

I have contacted Art Schuna many, many times for advice. He has always been prompt in response and offered me opinions which have benefited me and prolonged my life. He has even called me from his home on weekends, when he felt immediate action was called for. He has made it possible for me to obtain, on short notice, changes or refills on many needed drugs. In addition, the policy of this VA facility-and most directly Art Schuna, to offer needed help have been outstanding.

I am presently 80 years old and look forward to many more years of usefulness. Much of this feeling of projected accomplishment can, in my estimation, be attributed to the great care of Art and the facility he represents.

For additional questions I can be reached at the following addresses. 1324 Bennett Street, Janesville, WI 53545. Telephone: 608-756-2528. E-mail: <u>fbd@charter.net</u>.

Sincerely. 7 Labela ank H. Daniels

Richard W. Taylor 2015 Vineyard Road Annapolis, MD 21401

August 14, 2008

Richard J. Bertin, PhD RPh Executive Director Board of Pharmaceutical Specialties 1100 15th Street NW Suite 400 Washington, DC 20005

Re: Letter of Support

Dear Dr. Bertin:

This letter is in support of the development of a certification process for pharmacists who practice at a high level in ambulatory care clinics. For the past fifteen years, I have personally received this high level of care in managing my Type 1 diabetes from Dr. Stuart Haines at the VA clinic in Baltimore.

From 1968 through 1993 I saw a different doctor at nearly every VA clinic appointment. For twenty-five years I felt I was just a folder, a number. In 1993 I was placed under the care of Dr. Haines. Dr. Hines educated me in what I needed to do to get control of my diabetes, (i.e. log my numbers, track my blood pressure readings, etc.), something that the doctors before him had not done or had not followed through. Additionally, Dr. Haines made himself available to me at all times, not just during clinic appointments. Whenever I had a question, a concern, needed advice or direction, Dr. Haines was available to me, often addressing my concerns or answering my questions the same day. It was his dedication to me, and our relationship over the years, which increased my knowledge and my ability to maintain my health.

Specifically, Dr. Haines' patience and persistence with me has enabled me to improve my A1C readings from a poorly controlled A1C9 to a current and consistent range of A1C5.9 to A1C6.4. Dr. Haines was instrumental in my decision to go on an insulin pump in 2000. He told me I would be a good candidate and that it would benefit me tremendously. Once the decision was made Dr. Haines had to make a special request on my behalf for the pump. Once the pump became a reality, Dr. Haines and I were in constant contact day and night for weeks, while he walked me through the adjustments, intricacies and interpretation of my results. Over time when some adjustments were needed, Dr. Haines would review the pump results and advise some changes. He was instrumental in giving me additional control over my life. This would not have been possible without his ongoing support over the years. Dr. Haines' active role in adjusting my blood pressure medications over the years has resulted in good control. These adjustments were always made with explanations. If the desired results were not achieved within a reasonable period of time, changes were made until the desired results were reached. If it were deemed that a particular medication, not readily available at the VA was in my best interest, Dr. Haines would petition for the medication for me. Helping me to obtain the proper medications and helping me to manage these medications is another reason for my well-being.

During my fifteen years under Dr. Haines' care I have had several hospitalization. When the doctors treating me questioned some of my medications, or wanted to make changes, I asked that Dr. Haines be included in the decision-making. This coordination between all the doctors facilitated my recovery. I value and respect Dr. Haines' knowledge of me and feel that his input was effective in my recuperation.

I feel that Dr. Haines knows me as well as I do, due to our long-term relationship. He sincerely cares about my well-being and my life. I firmly believe that this has been possible only because of his hands on involvement in my medical life. Dr. Haines has been a Godsend to me and to my physical well-being.

Very truly yours,

Kichan W. Taya

Richard W. Taylor

To: The American Society Health System Pharmacists

Subject: Ambulatory Care Pharmacists

To Whom It May Concern:

The purpose of this letter is to express my beliefs regarding the excellent care and services provided from the pharmacists at a local hospitals' outpatient Coumadin clinic.

In addition to our monthly INR testing and adjusting Coumadin dosages, they have educated my husband and me on correct dosage schedules, drug actions and drug interactions, diet and abnormal effects. They have also requested we promptly notify them of any life style changes or have any new or changed medications. We rely on the clinic pharmacists as a primary resource for all other drug information. I can always depend on them to take the time to answer and/or research my questions.

As a retired Emergency Department Registered Nurse I had many patients come in with shoeboxes of medications which many were repeated or expired. Many of the patients had no idea what the drugs were nor why they were taking them. I have also seen that some of the medications were taken incorrectly or not at all.

Along with an outstanding patient rapport, I believe education is the key to desired therapeutic drug use. I believe this can best be provided by pharmacists. Physicians do not seem to have or take the time to educate their patients. I believe the worth of an ambulatory care pharmacists could be very measurable and even life saving.

I am grateful for the services, education and care, the clinic pharmacist provides to me and my husband.

gave Thuman

Jane Thurman 202 Center Street Erlanger, Ky 41018₂₀₀₈

Mo. Vouald, My family would like to thank you + your most capable + caring pharmacy staff at the anticoagulation clinic. Thy mother was recently (may 07) diagnosed à a-fib + started on cormadien : monthly follow ups. Her many health problems, medications, and all the upo + downs shis experienced lately resulted in dangerondy high INR levels - That is until we were referred to your OP service. Hank you for your part in burgeryevenbetters clinic to Hamilton.

Page 37

ats a relief to have such a valuable resource and to feel that someone really cares about my mother's safety a well being. Plus time spert out of the laboratory on the registration room each uset is a real bonus. Thank you for serving (and of believe, saving) my mother and those in her same situation. Thank yn so very much.

Nanny Puckett

Appendix B-5 Task Group Employer Survey

Ambulatory Care Pharmacist Employer Survey

Dear Employer:

Thank you for taking the time to provide background information to assist in the consideration of a proposed specialty certification of pharmacists who have distinguished themselves in the care of ambulatory patients by gaining specialized knowledge, skills, and abilities. Several of these individuals practice throughout your organization today.

The American College of Clinical Pharmacy (ACCP), the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP) have partnered to develop a petition to the Board of Pharmaceutical Specialties (BPS) to recognize ambulatory care pharmacy practice as a specialty. The petitioning organizations believe that while ambulatory patients may be cared for by pharmacists in a number of different practice settings, some pharmacists have developed a specialized body of knowledge, skills, and abilities and a unique practice beyond the scope of pharmacy practice defined by licensure examination. As such, the associations believe there is tremendous value in recognizing and credentialing pharmacists who attain the skills to actively manage medication use over the long-term; educate patients in adherence; engage them in preventive strategies to improve outcomes, maintain wellness, and slow chronic disease progression; and partner with other members of the health care team to coordinate and integrate care.

Definition of Ambulatory Care Pharmacy Practice --A Specialty in Medication Use for Preventive and Chronic Care

Ambulatory care pharmacy practice is the provision of integrated, accessible health care services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.

Please complete the 13-item survey below by Wednesday, September 3, 2008. Your individual responses will be confidential. Collectively, all employers' responses will be compiled to demonstrate demand for this specialty in a petition to the Board of Pharmaceutical Specialties. If questions arise, contact <u>pmanolakis@gmail.com</u>.

Thank you for your time and assistance in this effort.

ACCP/APhA/ASHP Joint Task Group

1. What is the total number of practicing pharmacists (i.e., non-administrative pharmacists) that are employed by your organization?

2. How many of these pharmacists do you believe are currently practicing in the area of specialization as defined above?

3. How many of these pharmacists practicing in the area of specialization are currently required to have advanced clinical training (e.g., residency training)?

4. How many of these pharmacist positions in the area of specialization currently require BPS specialty certification or other earned credentials (e.g., certified diabetes educator [CDE], certified geriatric pharmacist [CGP])?

5. Please specify the <u>desired</u> level of training for pharmacists practicing in the area of specialization [check all that apply].

PGY-1 Residency-Pharmacy Practice

PGY-1 Residency-Community Pharmacy Practice

PGY-1 Residency with Ambulatory Care emphasis

PGY-2 Residency-Ambulatory Care

PGY-2 Residency-Other

Certificate training program(s)

Employer-provided training program

None required or desired

Other (please list)

6. Please specify the <u>desired</u> credentials for pharmacists practicing in the area of specialization. [Check all that apply.]

BCPS - Board Certified Pharmacotherapy Specialist

BCOP-Board Certified Oncology Pharmacist

BCNSP-Board Certified Nutritional Support Pharmacist

BCPP-Board Certified Psychiatric Pharmacist

CGP-Certified Geriatric Pharmacist

CDE-Certified Diabetes Educator

CDM-Certified Disease Manager

No additional credentials sought

Other (please specify)

7. Which of the following best describes the type of ambulatory care practice in your company or institution?

Community Pharmacy (Chain or Independent)

Ambulatory Clinic

Managed Care Practice

Academia With Practice Site

Other (Please specify.)

8. Which of the following ranges represents your organization's anticipated growth in total pharmacist staff over the next 5 years?

Projected decrease 0%–5% 5%-10% 10%–20% >20%

9. Which of the following ranges best describes your organization's anticipated growth in the number of ambulatory care pharmacy specialists (as described above) over the next 5 years?

Projected decrease

__0%–5% __5%-10%

10%–20%

>20%

10. What proportion of your pharmacist staff do you estimate are projected to be practicing at a specialty level of ambulatory care in the next 5 years?

| 0%-5% |
|---------|
| 6%-10% |
| 11%-19% |
| 20%-25% |
| 26%-33% |

34%-50% 51%-66% 67%-75% 76%-80% 81%-90% 91%-100%

11. How many positions for ambulatory care pharmacy specialists (as defined above) has your organization recruited over the past 3 years, from July 1, 2005 to June 30, 2008?

12. What percentage of these positions were filled?

13. How many positions for ambulatory care pharmacy specialists (as defined above) do you estimate you will hire from July 1, 2008 through June 30, 2011?

Please add any additional comments and/or your contact information (optional) below.

Appendix D-1

Report of the Role Delineation Study of Ambulatory Care Pharmacists

Report of the Role Delineation Study of Ambulatory Care Pharmacists

Prepared for

Board of Pharmaceutical Specialties 1100 15th Street, NW, Suite 400 Washington, DC 20005-1707



Prepared by

Professional Examination Service Department of Research and Development 475 Riverside Drive New York, NY 10115

June 2007

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INTRODUCTION

In 2006, the Board of Pharmaceutical Specialties (BPS) contracted with Professional Examination Service (PES) to conduct a role delineation of ambulatory care¹ pharmacy practice. Previous exploratory research by BPS indicated a potential interest by pharmacists in certifying in this area of pharmacy practice.

The conduct of a role delineation study is a widely recognized and legally defensible strategy for establishing the content validity of a certification program. The ambulatory care pharmacy role delineation that PES conducted for BPS is consistent with current testing and measurement requirements for the validation of certification examinations as found in *Standards for Educational and Psychological Testing* (1999); *Uniform Guidelines on Employee Selection Procedures* (1978); and PES Guidelines for the Development, Use, and Evaluation of Licensure and Certification Programs (1995).

Through the role delineation process, the tasks performed and the knowledge required for professional practice in the role is identified and validated. The content outline of the certification examination is then linked to this empirical description of practice, creating a framework for an examination that is practice-related and content-valid.

The role delineation of the practice of ambulatory care pharmacy described in this report was conducted during 2006 – 2007. The goal of the study was to describe and empirically validate the domains, tasks, and knowledge that comprise the practice of ambulatory care pharmacy.

The research was conducted in two phases. In the first phase ambulatory care pharmacy was defined and in the second phase a survey was administered to practicing pharmacists in order to validate the practice definition and develop hypothetical test specifications for a potential new certification examination.

METHODOLOGY

Delineation of Ambulatory Care Practice

Nomination of Subject-Matter experts

At the outset of the study, BPS invited ACCP, ASHP, and APhA executives to nominate subject-matter experts to participate in the study. Nominators were requested to indicate which of three potential activities a nominee would be willing to participate in:

¹ BPS initially requested that PES delineate "ambulatory care/primary care" pharmacy practice. After deliberation by the project task force, it was agreed that primary care was a subset of ambulatory care, and that the term ambulatory care would be used to encompass both.

service on the project task force, review of task force work products, or a telephone interview.

Task Force Meeting 1

From the pool of nominees, BPS selected a 10-member task force of subject-matter experts to serve on the project task force. The task force met three times during the course of the study. A list of the task force members can be found in Appendix 1.

The task force was charged with creating a description of the major domains of practice and the tasks performed by pharmacists specializing in ambulatory care, as well as the knowledge base that supports performance of the tasks. The task force met twice to perform their work. During the first task force meeting the membership identified five major domains of ambulatory care practice and drafted task statements and knowledge statements related to each domain. Prior to the second task force meeting, PES conducted telephone critical incidents interviews with additional subject matter experts and circulated the work of the task force to independent reviewers for comment.

Independent Reviews

Prior to the second task force meeting, PES circulated the work of the task force to ten independent reviewers for comment. The participants were selected from the pool of individuals who had volunteered or were nominated for the study in response to the BPS call for nominations. Reviewers were asked to evaluate the document for completeness and clarity. Four of the ten invited participants completed the review. Appendix 2 contains the instructions provided to the independent reviewers, as well as a description of the demographic characteristics of participants.

Telephone Interviews

Also prior to the second task force meeting, PES conducted telephone critical incidents interviews with an additional nine subject-matter experts who were selected from the pool of nominees assembled at the outset of the study. The interviews were designed to generate an independent set of critical tasks and knowledge relevant to ambulatory care pharmacy. A protocol was developed to guide discussion. All of the questions were designed to elicit descriptions of tasks performed and knowledge used during "critical incidents," or instances of very successful and highly unsuccessful job performance. Appendix 3 contains the interview protocol and a description of the participants.

Task Force Meeting 2

At their second meeting, the task force reviewed the results of the two data collection activities (i.e., independent reviews and telephone interviews), and finalized the delineation of ambulatory care practice. The delineation consisted of five domains, with tasks and knowledge statements specific to each domain. The five domains of practice and the number of task and knowledge statements delineated within each one are shown in Table 1.

| Domain | # of Tasks | # of Knowledge Statements |
|--|------------|------------------------------|
| Direct Patient Care | 44 | 50 |
| Practice Management | 20 | 25 |
| Public Health | 9 | 10 |
| Medical Informatics & Professional Development | 12 | 27 |
| Patient Advocacy | 12 | 11 |
| TOTAL | 97 | 123 |

Table 1. Elements of the Delineation of Ambulatory Care Practice

Conduct of Survey to Validate Delineation

PES conducted a Web-based survey to collect validation ratings on the contribution of each of the domains, tasks, and knowledge areas to the practice of ambulatory care pharmacy. A draft survey instrument was reviewed by the project task force at its second meeting, and a pilot test of the survey instrument was conducted prior to its large scale dissemination.

Validation rating scales for the domains of ambulatory care practice focused on the percentage of time spent in each domain and the importance of each domain to achieving optimal outcomes for patients. The *% of Time* rating was:

Considering the time you spend providing ambulatory care pharmacy services (excluding basic prescription processing), what percentage of your work time do you spend performing the tasks related to each domain?

The *Importance* rating scale was:

How important is this domain to achieving optimal outcomes for patients? 1 = Not important, 2 = Minimally important, 3 = Moderately important, 4 = Highly important

The validation rating scales for the task statements focused on the frequency of performing each task and the importance of each task to achieving optimal outcomes for patients. The *Frequency* rating scale was:

How frequently did you perform the task during the past year? 1 = Never, 2 = Less than monthly, 3 = At least monthly, 4 = At least weekly, 5 = At least daily

The *Importance* rating scale was:

How important is the task to achieving optimal outcomes for patients? 1 = Not important, 2 = Minimally important, 3 = Moderately important, 4 = Highly important

The validation rating scales for the knowledge statements focused on the frequency of use of each knowledge area and the importance of each knowledge area to achieving optimal outcomes for patients. The *Frequency* rating scale was:

How frequently did you use the knowledge during the past year? 1 = *Never,* 2 = *Less than monthly,* 3 = *At least monthly,* 4 = *At least weekly,* 5 = *At least daily*

The *Importance* rating scale was:

How important is the knowledge to achieving optimal outcomes for patients? 1 = Not important, 2 = Minimally important, 3 = Moderately important, 4 = Highly important

To reduce time demands on participants, two versions of the survey were created: one containing the knowledge ratings and the other containing the task ratings. Both versions contained the domains ratings, a background questionnaire, and open-ended questions regarding the completeness of the delineation. Screen shots of the survey can be found in Appendix 4.

No single database of ambulatory care pharmacists exists. A number of prominent pharmacy professional organizations participated in the validation effort by providing contact information from their databases of members who they could identify as ambulatory care pharmacists. The participants were:

- the American Pharmacists Association (APhA)
- the American Society of Health-System Pharmacists (ASHP)
- the American College of Clinical Pharmacy (ACCP)

Each organization employed their own selection criteria to identify potential participants. APhA provided contact information for 6891 pharmacists, ACCP for 1575 pharmacists, and ASHP for 2140 pharmacists.

After duplicates were removed across databases, the final set of potential participants consisted of 10,376 pharmacists. Initially, PES selected a sample of 3000 pharmacists from this dataset and invited them to participate. Early survey returns from this group indicated a low participation rate; therefore, PES invited all remaining individuals to participate for a total pool of 10, 376 invitees.

RESULTS

Return Rate

The return rate for the survey was 9%, as shown in Table 2

| Invitations | Not | Number | Return |
|-------------|-----------|-----------|--------|
| Sent | Eligible* | Completed | Rate |
| 10376 | 1345 | 828 | 9.2% |

Table 2.Survey Return Rate

* Undeliverable email or no longer practicing

This is a low return rate for a job analysis survey. The return rate was not entirely unexpected, and may be the result of a number of factors operating simultaneously.

(1) The precision of the selection criteria used to identify potential survey participants is unknown. While each participating organization used its best available selection criteria to identify potential participants, it is not known how precise those selection criteria were. It may be that some of the survey recipients were not practicing in ambulatory care, were only peripherally interested in ambulatory care practice, or were retired.

- (2) It is not atypical to obtain a low return rate when conducting an initial role delineation for a potential new certification. Response rates are typically much higher when conducting a follow-up role delineation for an existing certification. This is because individuals who already earned the certification are surveyed. These individuals have a vested interest in specialty area and participate at much higher rates.
- (3) It is not known how many e-mail invitations were treated as spam. The increased use of spam filters makes it difficult to determine how many survey invitations were actually received by the intended participants.

It is important to note that while the return rate is low, the absolute number of respondents is sufficient for analysis purposes. As seen in Table 3, there were over 400 completed surveys per version.

| Version | Completed | Percent |
|---------------|-----------|---------|
| A (Tasks) | 423 | 51% |
| B (Knowledge) | 405 | 49% |
| Total | 828 | 100% |

Table 3. Percent of Respondents Completing Each Survey Version

Respondent Demographics

Survey respondents represented a range of work settings, as seen in Table 4. The largest percentage of respondents (32%) worked in primary care settings (defined as family medicine practice, primary care clinic, federal hospital/institution, or managed care). Another 25% worked in community pharmacies, 17% worked in academic institutions, and 12% worked in community or university hospitals. No more than 9% of respondents worked in any "other" setting.

| | Ν | % |
|------------------------------------|-----|------|
| Academic Institution | 137 | 17% |
| Call Center | 8 | 1% |
| Chain Community Pharmacy | 125 | 15% |
| Community Hospital, For Profit | 16 | 2% |
| Community Hospital, Not-For-Profit | 49 | 6% |
| Drug Information Center | 6 | 1% |
| Family Medicine Practice | 40 | 5% |
| Federal Hospital/Institution | 96 | 12% |
| Forensic Institution | 0 | 0% |
| Home Health Care | 11 | 1% |
| Independent Community Pharmacy | 83 | 10% |
| Independent Consulting | 6 | 1% |
| Long-Term Care/Assisted Living | 9 | 1% |
| Mail-Order Pharmacy | 1 | 0% |
| Managed Health Care | 44 | 5% |
| Pharmaceutical Industry | 3 | 0% |
| Primary Care Clinic | 83 | 10% |
| State Psychiatric Hospital/Clinic | 0 | 0% |
| University-Affiliated Hospital | 33 | 4% |
| Other | 75 | 9% |
| Total | 825 | 100% |

Table 4. Primary Work Setting

The task force, on reviewing the respondent work setting distribution, stated that while the settings represented were generally consistent with expectations, the representation of community pharmacies and academic institutions was slightly higher than expected. In the interest of exploring possible work setting differences in respondents' ratings, demographics are presented separately by work setting. The task force recommended use of the work setting grouping illustrated in Table 5.

| | Ν | % |
|--|-----|-------|
| Community Pharmacy, Chain | 125 | 15.2 |
| Community Pharmacy, Independent | 83 | 10.1 |
| Primary Care (Family Medicine Practice, Federal Hospital/Institution, Managed Care, Primary Care Clinic) | 263 | 31.9 |
| Hospital (Community Hospital, University-Affiliated Hospital) | 98 | 11.9 |
| Academic Institution | 137 | 16.6 |
| Other (Call Center, Drug Information Center, Home Health Care, Independent Consulting, Long-Term Care/Assisted Living, Mail-Order Pharmacy, Pharmaceutical Industry) | 119 | 14.4 |
| Total | 825 | 100.0 |

Table 5. Work Setting Groupings

The total respondent group reported spending an average of 55% of their time engaged in direct patient care, as seen in Table 6. On average, respondents in academic institutions (43%) and other settings (48%) spent less time in direct patient care than respondents in the remaining work settings (59 – 62%). On average, the total respondent group spent less than one fourth of their time performing basic prescription processing (excluding patient education, counseling, and advocacy). However, while respondents in chain (61%) and independent (52%) community pharmacies spent more than half of their work time performing basic prescription processing, respondents in primary care spent only 7% of their time performing prescription processing, as did 15% of those in hospitals and 5% of those in academic institutions (see Table 6).

| | Mean Percentage of Work Time | | |
|---------------------------------|------------------------------|--|--|
| Setting | In Direct Patient Care | Performing Basic Prescription Processing | |
| Community Pharmacy, Chain | 59% | 61% | |
| Community Pharmacy, Independent | 60% | 52% | |
| Primary Care | 60% | 7% | |
| Hospital | 62% | 15% | |
| Academic Institution | 43% | 5% | |
| Other | 48% | 25% | |
| Total Sample | 55% | 23% | |

Table 6. Time Spent in Aspects of Practice

Note: Respondents were asked these two questions separately. Given that community pharmacists reported spending more time in basic prescription processing than in direct patient care, and that the combined percentages exceed 100, it may be that these respondents were including basic prescription processing in their definition of direct patient care.

As shown in Table 7, respondents spent an average of 77% of their work time in an outpatient setting. The median of 100% indicates that a majority of the sample spent *all* of their time in an outpatient setting. Respondents in hospital settings spent the least time in an outpatient setting (52%) and Community pharmacists, chain spent the most (86%).

| | Percentage of Time | | |
|---------------------------------|--------------------|--------|--|
| Setting | Mean | Median | |
| Community Pharmacy, Chain | 86% | 100% | |
| Community Pharmacy, Independent | 79% | 100% | |
| Primary Care | 84% | 100% | |
| Hospital | 52% | 50% | |
| Academic Institution | 74% | 100% | |
| Other | 71% | 100% | |
| Total Sample | 77% | 100% | |

Table 7. Time Spent in an Outpatient Setting

Respondents had an average of 14 years of experience as a licensed pharmacist, and 9 years as an ambulatory care pharmacist. As seen in Table 8, respondents working in independent community pharmacies had the most experience both overall and in ambulatory care; respondents in primary care settings had the least experience.

| | Mean Number of Years of Experience | | | | | |
|---------------------------------|-------------------------------------|-----------------------------|--|--|--|--|
| Setting | As an Ambulatory Care Pharmacist | As a Licensed Pharmacist | | | | |
| Community Pharmacy, Chain | 10 | 15 | | | | |
| Community Pharmacy, Independent | 15 | 21 | | | | |
| Primary Care | 7 | 11 | | | | |
| Hospital | 8 | 14 | | | | |
| Academic Institution | 8 | 13 | | | | |
| Other | 11 | 17 | | | | |
| Total Sample | 9 | 14 | | | | |

 Table 8. Years of Experience

Fifty-nine percent of the total sample reported having completed a residency training program, as seen in Table 9. Respondents in community settings were far less likely than respondents in primary care, hospitals, or academic institutions to have completed an ambulatory care residency. While independent community pharmacists had more experience than respondents in all other settings, they were the least likely to have completed a residency in an area related to ambulatory or primary care.

| Setting | Ν | % |
|---------------------------------|-----|-----|
| Community Pharmacy, Chain | 22 | 18% |
| Community Pharmacy, Independent | 16 | 20% |
| Primary Care | 205 | 78% |
| Hospital | 65 | 66% |
| Academic Institution | 112 | 82% |
| Other | 64 | 54% |
| Total Sample | 484 | 59% |

Table 9. Percent of Respondents Completing Ambulatory Care Residency

Of those respondents who completed a residency training program, the largest percentage (46%) completed a program in pharmacy practice and another 38% completed a program in primary care/ambulatory care (see Table 10).

| | n | % |
|------------------------------|-----|-----|
| Community Care | 32 | 7% |
| Family Medicine | 46 | 10% |
| Geriatrics | 13 | 3% |
| Managed Care | 16 | 3% |
| Pediatrics | 8 | 2% |
| Pharmacy Practice | 223 | 46% |
| Primary Care/Ambulatory Care | 183 | 38% |
| Other | 78 | 16% |

Table 10. Type of Residency Training Program

As seen in Table 11, half of the respondents received a Bachelor's degree as their entrylevel pharmacy degree and half received the PharmD. Respondents in primary care settings were most likely to have received the PharmD as their entry level degree and community pharmacists (chain) were least likely.

| | | Work Setting | | | | | | | |
|-------------------|----------------------------------|---------------------------------|-----------------|----------|-------------------------|--------|--------|--|--|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total | | |
| Bachelor's degree | 71 | 65 | 91 | 46 | 58 | 77 | 408 | | |
| - | 56.8% | 78.3% | 34.7% | 47.9% | 43.0% | 64.7% | 49.8% | | |
| Pharm.D. | 51 | 18 | 170 | 50 | 76 | 41 | 406 | | |
| | 40.8% | 21.7% | 64.9% | 52.1% | 56.3% | 34.5% | 49.5% | | |
| Other | 3 | 0 | 1 | 0 | 1 | 1 | 6 | | |
| | 2.4% | .0% | .4% | .0% | .7% | .8% | .7% | | |
| Total | 125 | 83 | 262 | 96 | 135 | 119 | 820 | | |
| | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | | |

 Table 11. Entry Level Pharmacy-Related Degree

Overall, 74% of the survey respondents reported having earned a PharmD degree as their *highest* degree in pharmacy. As seen in Table 12, respondents in community (chain) settings were much less likely than respondents in primary care, hospitals, or academic institutions to have earned a PharmD degree as their highest pharmacy related degree.

| | Work Setting | | | | | | | |
|-------------------|----------------------------------|---------------------------------|-----------------|----------|-------------------------|--------|--------|--|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total | |
| Bachelor's degree | 58 | 52 | 12 | 12 | 3 | 29 | 166 | |
| | 47.5% | 64.2% | 4.7% | 12.5% | 2.3% | 25.2% | 20.6% | |
| Master's degree | 5 | 2 | 10 | 4 | 1 | 13 | 35 | |
| | 4.1% | 2.5% | 3.9% | 4.2% | .8% | 11.3% | 4.4% | |
| Pharm.D. | 56 | 27 | 236 | 80 | 126 | 73 | 598 | |
| | 45.9% | 33.3% | 91.5% | 83.3% | 95.5% | 63.5% | 74.4% | |
| Ph.D. | 3 | 0 | 0 | 0 | 2 | 0 | 5 | |
| | 2.5% | .0% | .0% | .0% | 1.5% | .0% | .6% | |
| Total | 122 | 81 | 258 | 96 | 132 | 115 | 804 | |
| | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | |

Table 12. Respondents' Highest Pharmacy-Related Degrees

The type of PharmD program completed by respondents as their highest level of pharmacy-related education is shown in Table 13.

| | | | Woi | k Setting | | | |
|---------------------|----------------------------------|---------------------------------|-----------------|-----------|-------------------------|-----------|------------|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total |
| 6 year, entry-level | 37 | 10 | 111 | 29 | 39 | 27 | 253 |
| | 66.1% | 37.0% | 46.1% | 36.7% | 30.7% | 37.0% | 42.0% |
| 6 year, track-in | 9 | 5 | 51 | 21 | 30 | 9 | 125 |
| | 16.1% | 18.5% | 21.2% | 26.6% | 23.6% | 12.3% | 20.7% |
| 1 year, post BS | 0 | 0 | 7 | 5 | 3 | 2 | 17 |
| | .0% | .0% | 2.9% | 6.3% | 2.4% | 2.7% | 2.8% |
| 2 year, post-BS | 4 | 5 | 42 | 17 | 44 | 19 | 131 |
| | 7.1% | 18.5% | 17.4% | 21.5% | 34.6% | 26.0% | 21.7% |
| 3 year, post-BS | 3 5.4% | 2 7.4% | $10 \\ 4.1\%$ | 1 1.3% | 4 3.1% | 6 8.2% | 26 4.3% |
| Non-traditional | 3 | 5 | 20 | 6 | 7 | 10 | 51 |
| program | 5.4% | 18.5% | 8.3% | 7.6% | 5.5% | 13.7% | 8.5% |
| Total | 56 | 27 | 241 | 79 | 127 | 73 | 603 |
| | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Table 13. Type of PharmD Program Completed

Only 6% of respondents reported completing a fellowship training program, as seen Table 14. Respondents in academic institutions were most likely to have completed a fellowship training program and respondents in independent community pharmacies were least likely.

| | Work Setting | | | | | | | |
|-------|----------------------------------|---------------------------------|-----------------|----------|-------------------------|--------|--------|--|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total | |
| Yes | 2 | 4 | 19 | 5 | 12 | 8 | 50 | |
| | 1.6% | 4.9% | 7.3% | 5.1% | 9.0% | 6.8% | 6.1% | |
| No | 122 | 78 | 243 | 93 | 122 | 110 | 768 | |
| | 98.4% | 95.1% | 92.7% | 94.9% | 91.0% | 93.2% | 93.9% | |
| Total | 124 | 82 | 262 | 98 | 134 | 118 | 818 | |
| | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | |

Table 14. Completion of Fellowship Training Program

Thirty two percent of respondents were BPS certified in pharmacotherapy, as seen in Table 15. Respondents in primary care and academic institutions were most likely to be certified in pharmacotherapy, and respondents in community pharmacy (chain) were least likely. Community pharmacists (chain) were most likely to hold disease-specific certifications.

| | Work Setting | | | | | | |
|--|----------------------------------|---------------------------------|-----------------|----------|-------------------------|--------|--------|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total |
| BPS Pharmacotherapy | 1.0% | 6.2% | 49.0% | 24.4% | 49.6% | 23.5% | 31.9% |
| BPS Nuclear | 2.0% | .0% | .0% | 1.2% | .0% | .0% | .4% |
| BPS Nutrition Support | .0% | 1.5% | .4% | 2.4% | .0% | 1.0% | .7% |
| BPS Oncology | .0% | .0% | .8% | 2.4% | 2.4% | 6.1% | 1.8% |
| BPS Psychiatric | .0% | 1.5% | 1.3% | 1.2% | .0% | .0% | .7% |
| Certified Geriatric Pharmacist | 2.0% | 4.6% | 1.3% | 1.2% | 6.5% | 5.1% | 3.1% |
| Certified Diabetes Educator | 3.9% | 6.2% | 10.5% | 8.5% | 8.9% | 9.2% | 8.5% |
| Certified Anticoagulation Care Provider | .0% | .0% | 3.8% | 12.2% | 3.3% | 1.0% | 3.4% |
| Disease specific certifications | 16.7% | 35.4% | 8.4% | 7.3% | 15.4% | 9.2% | 13.3% |
| None | 62.7% | 49.2% | 27.6% | 43.9% | 27.6% | 45.9% | 39.1% |
| Other | 17.6% | 16.9% | 10.5% | 8.5% | 10.6% | 15.3% | 12.6% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Table 15. Other Certifications Held by Respondents

The demographic information provided by respondents suggests that the respondent group is not homogeneous. Rather, there are a variety of practice patterns and backgrounds of the pharmacists completing the survey, all of whom self-identified as ambulatory care pharmacists.

Domain Ratings

The mean percentage of time spent in domains is shown in Table 16. Respondents spent nearly half of their ambulatory care work time in direct patient care. They spent similar amounts of time (17 – 18%) in Practice Management, and Medical Informatics and Professional Development. Another 11% was spent in Patient Advocacy, and 4% was spent in Public Health. Respondents reported spending only 2% of their ambulatory care work time (excluding basic prescription processing) in "other" domains. This low percentage attests to the completeness of the domain structure developed by the task force. See Appendix 6 for the "other" domains specified by respondents. The "other" domains cited by 5 or more respondents (e.g., teaching, dispensing, administration) are already reflected by specific tasks within the delineation of practice

Respondents in primary care and in hospital settings spent more time in direct patient care than respondents in community pharmacies and academic institutions. Respondents in community settings spent more time in patient advocacy than respondents in the other settings.

| | | Work Setting | | | | | | |
|--------------------------|-----------|--------------|---------|----------|-------------|--------|--------|--|
| | Community | Community | Primary | Hospital | Academic | Other | Total | |
| | Pharmacy, | Pharmacy, | Care | | Institution | | | |
| | Indep. | Chain | | | | | | |
| Direct Patient Care | 45.1% | 41.9% | 54.9% | 50.4% | 43.3% | 42.1% | 47.8% | |
| | (25.0) | (24.4) | (22.2) | (24.0) | (21.4) | (27.0) | (24.2) | |
| Practice Management | 15.3% | 22.4% | 16.1% | 18.1% | 14.0% | 24.1% | 17.6% | |
| - | (13.2) | (18.8) | (14.3) | (16.0) | (14.7) | (21.6) | (16.5) | |
| Public Health | 6.0% | 5.0% | 3.2% | 4.0% | 4.9% | 4.5% | 4.4% | |
| | (6.2) | (5.2) | (4.0) | (4.2) | (5.9) | (5.9) | (5.2) | |
| Medical Informatics and | 13.9% | 11.8% | 15.7% | 13.6% | 27.1% | 16.8% | 16.9% | |
| Professional Development | (14.1) | (13.7) | (12.6) | (9.8) | (20.7) | (16.7) | (15.6) | |
| Patient Advocacy | 15.8% | 15.3% | 9.1% | 9.6% | 9.8% | 9.8% | 11.0% | |
| , | (16.3) | (16.5) | (7.9) | (7.9) | (9.5) | (9.3) | (11.3) | |
| Other | 4.0% | 3.7% | 1.0% | 4.3% | .8% | 2.7% | 2.3% | |
| | (16.3) | (14.5) | (6.8) | (15.3) | (5.6) | (13.1) | (11.6) | |

Table 16. Percent of Time Spent in Each Domain

The mean *Importance* ratings for the domains for the total sample and for subgroups based on BCPS certification and residency training status are shown in Table 17. The domain of *Direct Patient Care* was rated highly important. Three domains (*Practice Management, Medical Informatics and Professional Development,* and *Patient Advocacy*) were rated moderately to highly important. The fifth domain, *Public Health,* was rated slightly less than moderately important. There were no substantive differences in the domain ratings made by BCPS certified and non-certified respondents, or by respondents who did complete a residency training program and those who did not.

| | | Work Setting | | | | | | |
|--------------------------|----------------------------------|---------------------------------|-----------------|----------|-------------------------|-------|-------|--|
| | Community Pharmacy, Indep. | Community Pharmacy, Chain | Primary Care | Hospital | Academic Institution | Other | Total | |
| Direct Patient Care | 3.8 | 3.6 | 3.9 | 3.8 | 3.9 | 3.8 | 3.8 | |
| | (.5) | (.6) | (.3) | (.5) | (.4) | (.5) | (.5) | |
| Practice Management | 3.4 | 3.3 | 3.5 | 3.4 | 3.3 | 3.6 | 3.4 | |
| | (.7) | (.7) | (.6) | (.7) | (.8) | (.7) | (.7) | |
| Public Health | 3.0 | 2.7 | 2.7 | 2.8 | 2.9 | 2.9 | 2.8 | |
| | (.8) | (.9) | (.8) | (.8) | (.9) | (.8) | (.8) | |
| Medical Informatics and | 3.3 | 3.0 | 3.6 | 3.4 | 3.5 | 3.5 | 3.4 | |
| Professional Development | (.8) | (.8) | (.5) | (.7) | (.7) | (.7) | (.7) | |
| Patient Advocacy | 3.4 | 3.2 | 3.4 | 3.2 | 3.4 | 3.3 | 3.3 | |
| | (.7) | (.8) | (.7) | (.9) | (.8) | (.8) | (.8) | |
| Other | 2.8 | 3.1 | 3.2 | 2.3 | 3.0 | 3.3 | 2.9 | |
| | (1.3) | (1.0) | (1.0) | (1.3) | (1.2) | (1.1) | (1.2) | |

Table 17. Domain Importance Ratings Mean and (Standard Deviation)

Task Ratings

Task *Frequency* ratings can be found in Appendix 7. Ratings ranged from a low of 1.6 (between never and less than monthly) for four tasks to a high of 4.5 (between weekly and daily) for one task. The task performed most frequently by respondents was:

• Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems)

The tasks performed least frequently by respondents were:

- Administer appropriate immunizations to specific patients
- *Identify and report suspected public health threats (for example, disasters, infectious diseases)*
- Facilitate appropriate care for patients affected by public health threats and disasters
- Participate in disaster response preparation and planning

Task *Importance* ratings can be found in Appendix 8. Ratings ranged from a low of 2.7 (minimally to moderately important) for one task to a high of 3.9 (highly important) for three tasks. The tasks rated most important by respondents were:

- Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions
- Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy
- Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems)

The task rated least important by respondents was:

• Administer appropriate immunizations to specific patients

A series of analysis of variance (ANOVA) tests was conducted to explore work setting differences in the frequency of task performance. Numerous tasks were performed significantly more frequently by respondents in primary care settings, hospitals, and academic institutions than by respondents in community pharmacies (both chain and independent). These tasks are presented in Exhibit 1. This suggests that there may be subsets or subtypes of ambulatory care pharmacy practice.

Exhibit 1. Ambulatory Care Pharmacy Tasks Performed More Frequently in Primary Care Settings, Hospitals, and Academic Institutions than in Community Pharmacies

Direct Patient Care

- Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results).
- Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers.
- Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit).
- Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain).
- Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate.
- Define treatment goals in collaboration with the patient and other healthcare providers.
- Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes.
- Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes.
- Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety.
- Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient.
- Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety.
- Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted
- Modify patient-specific treatment plan based on follow up assessment.
- Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy.
- Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers).
- Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection).

Medical Informatics and Professional Development

- Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions.
- Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine.
- Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice.

Patient Advocacy

• Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs).

Respondents' write-in responses regarding tasks missing from the survey can be found in Appendix 9. It appears that the specified tasks are already reflected in the existing task statements. In addition, no single missing task was specified by more than 5 respondents. This suggests that the ambulatory care pharmacy task list developed by the task force was complete.

Knowledge Ratings

Knowledge *Frequency* ratings are found in Appendix 10. Ratings ranged from a low of 2.0 (less than monthly) for two knowledge areas to a high of 4.9 (at least daily) for one knowledge area.

The knowledge area used most frequently by respondents was:

• pharmacotherapy²

The knowledge areas used least frequently by respondents were:

- granting agencies and their application procedures
- uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals

Knowledge *Importance* ratings are found in Appendix 11. Ratings ranged from a low of 2.4 (less than monthly to at least monthly) for one knowledge area to a high of 3.9 (at least weekly) for two knowledge areas.

The knowledge areas rated most important by respondents were:

- pharmacotherapy
- how to effectively communicate with the patient

The knowledge area rated leas important by respondents was:

• *uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals*

A series of ANOVAs was run to explore differences in the frequency of knowledge use by respondents in different work settings. As was the case with tasks, there were several knowledge areas that were used significantly more frequently by respondents in primary care settings, hospitals, and academic institutions than by respondents in community pharmacies. These knowledge areas are presented in Exhibit 2. Again this suggests the possible existence of different types of ambulatory care pharmacy practice.

 $^{^{2}}$ The term pharmacotherapy in this study is used in its generic sense to mean drug therapy. It is not intended to convey knowledge of the BPS specialty certification in pharmacotherapy.

Exhibit 2. Ambulatory Care Pharmacy Knowledge Used More Frequently by Respondents in Primary Care Settings, Hospitals, and Academic Institutions than in Community Pharmacies

Direct Patient Care

- Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy
- Knowledge of the clinical assessment process
- Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines)
- Knowledge of the principles and practice of evidence-based medicine
- Knowledge of how to develop an effective, individualized treatment plan
- Knowledge of how to implement an effective, individualized treatment plan

Medical Informatics and Professional Development

- Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references
- Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature
- Knowledge of principles and methods of educating health care students, residents, and professionals
- Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis)
- Knowledge of strengths and limitations of various study methods
- Knowledge of clinical versus statistical significance in order to interpret medical literature
- Knowledge of appropriate research methodology to design studies to assess a research hypothesis
- Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment

Write in responses related to knowledge missing from the survey can be found in Appendix 12. There were very few responses overall, and no single knowledge are was cited by more than 5 respondents. This suggests the knowledge delineation developed by the task force was complete.

Additional Data Analyses

In preparation for presentation of the survey results to the task force, PES conducted a number of exploratory data analyses. PES compared the domain, task, and knowledge ratings of pharmacists who were more experienced (.i.e. 4+ years) and less experienced (1-3 years) in ambulatory care. This analysis yielded little to no difference between groups. PES also conducted an analysis comparing the ratings of respondents who were BPS certified in Pharmacotherapy with those who were not, and another analysis comparing respondents who had completed an ambulatory care-related residency training program with those who had not. These latter two analyses did reveal some

ratings differences, but these findings were deemed by the task force to be less relevant than those related to practice setting. For information purposes, these results are included in Appendix 13.

DEVELOPMENT OF HYPOTHETICAL TEST SPECIFICATIONS

Should an organization petition BPS to develop a specialty certification examination in ambulatory care pharmacy, PES recommends that the data from this study be used to derive the test specifications for the examination. There are two elements to test specifications: (1) domain weights and (2) validated tasks and knowledge. Domain weights describe the relative emphasis of each domain of practice, indicating the percentage of items on an examination form to assess each domain. The hypothetical test weights in Table 18 were developed in the same manner as was done for other BPS specialties. That is, PES derived weights for the domains by equally weighting respondents' % of *Time* and *Importance* ratings for the domains.

| Domain | % of Exam |
|---|-----------|
| Direct Patient Care | 50% |
| Practice Management | 18% |
| Public Health | 4% |
| Medical Informatics and Professional Development | 17% |
| Patient Advocacy | 11% |

Table 18. Hypothetical Test Specifications

It should be noted that these weights were derived using the data for the entire respondent group. Survey results, however, suggested the possibility of different subtypes of ambulatory care practice. The examination sponsor would need to review the survey results to determine whether the test specifications should be based on the total respondent group's data or on data from one or more subgroups.

The second element of the test specifications for a BPS certification examination is the set of validated tasks and knowledge that describe specialty practice. PES recommends the establishment of the following validation thresholds. First, PES recommends that all tasks that are performed at least monthly be included in the test outline. PES further recommends that any task performed less than monthly on average (<3.0) be included if it received an *Importance* rating greater than or equal to 3.0, indicating moderate

importance. All but three tasks in the delineation created by the task force meet these criteria.

Similar thresholds would apply to the knowledge areas. That is, knowledge used at least monthly should be included, and any knowledge used less frequently than that must be rated at least moderately important in order to be included. The majority (102 of 123) of the knowledge areas created by the task force meet these criteria. More than half of the eliminated knowledge areas are research-related areas in the Medical Informatics and Professional Development domain.

The tasks and knowledge meeting the validation thresholds are shown in Exhibit 3. Again, it should be noted that the validation thresholds were applied to the data for the entire respondent group. An examination sponsor would need to determine whether this is the appropriate group's data to use for the purpose of test specifications development.

DOMAIN 1: Direct Patient Care

Tasks:

- 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management.
- 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness).
- 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions.
- 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records.
- 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results).
- 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection).
- 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow).
- 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues.
- 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care.
- 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors.
- 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy.
- 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition).
- 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist.
- 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based education).
- 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems).
- 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections).
- 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia).
- 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations).
- 1.19 Recommend appropriate immunizations to specific patients.
- 1.20 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs).

| 1.21 | Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. |
|------|--|
| 1.22 | Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). |
| 1.23 | Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). |
| 1.24 | Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). |
| 1.25 | Identify situations in which OTC treatment may be appropriate, and recommend treatment options. |
| 1.26 | Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. |
| 1.27 | Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). |
| 1.28 | Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). |
| 1.29 | Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) |
| 1.30 | Define treatment goals in collaboration with the patient and other healthcare providers. |
| 1.31 | Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses). |
| 1.32 | Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. |
| 1.33 | Develop a patient-specific plan to address prioritized patient needs and identified drug- related problems to improve patient outcomes. |
| 1.34 | Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. |
| 1.35 | Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. |
| 1.36 | Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. |
| 1.37 | Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). |
| 1.38 | Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. |
| 1.39 | Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted. |
| 1.40 | Modify patient-specific treatment plan based on follow up assessment. |
| 1.41 | Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. |
| 1.42 | Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). |

Knowledge of:

- 1 anatomy and physiology
- 2 pathophysiology
- 3 laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy
- 4 the clinical assessment process
- 5 physical assessment techniques
- 6 pharmacology
- 7 pharmacotherapy
- 8 the principles of both focused and integrated disease-state management
- 9 the principles of and regulations governing collaborative drug therapy management
- 10 OTC medications
- 11 the principles of self-care
- 12 herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine
- 13 common immunizations
- 14 clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines)
- 15 the principles and practice of evidence-based medicine
- 16 recent advances related to pharmacotherapy in ambulatory practice
- 17 factors affecting medication and treatment adherence
- 18 effective interventions to address medication and treatment nonadherence
- 19 the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR)
- 20 patient interviewing skills
- 21 motivational interviewing techniques
- 22 how to assess the patient's readiness and/or willingness to participate in their own care
- 23 how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes
- 24 barriers to patient education and interventions to overcome them
- cultural diversity and how it may impact the care of the patient
- 26 humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient
- 27 how to obtain a medication history
- 28 the principles and process of medication reconciliation
- 29 how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient
- 30 how to collaborate with other healthcare professionals to optimize patient care outcomes
- 31 how to prioritize patient needs and/or drug-related problems
- 32 the scope of practice of the ambulatory care pharmacy specialist
- 33 how to apply pharmacoeconomic principles when designing a treatment plan
- 34 how to develop an effective, individualized treatment plan
- 35 how to implement an effective, individualized treatment plan
- 36 patient education principles and techniques (for example, group classes, individual patient counseling).
- 37 the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes)
- 38 the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests)

- 39 the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors)
- 40 the process of determining appropriateness of over-the-counter treatments for individualized patients
- 41 how to effectively communicate treatment recommendations to the appropriate healthcare provider(s)
- 42 how to effectively communicate with the patient
- 43 the principles and practices of wellness and prevention
- 44 lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications
- 45 the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections)
- 46 State and Federal regulations regarding protection of patient information
- 47 the steps involved in continuity of care between healthcare settings (i.e., transitioning)
- 48 appropriate writing techniques for composing patient education materials
- 49 appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs

DOMAIN 2: Practice Management

Tasks:

- 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics).
- 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics).
- 2.3 Establish relationships and/or collaborative practice agreements with other health care providers.
- 2.4 Promote and market patient care services to patients and health care providers.
- 2.5 Establish and maintain a system for patient referral.
- 2.6 Establish and maintain a system for patient follow up.
- 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of costeffective care (for example, medication use evaluation, ADR reporting, incident report evaluation).
- 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services.
- 2.9 Participate as an integral member of an interdisciplinary health care team.
- 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff).
- 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication dispensing functions).
- 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis).
- 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services.

- 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements.
- 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice.
- 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA).
- 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs).
- 2.18 Ensure timely and accurate delivery of medication to patients.
- 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical necessity.
- 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures.

Knowledge of:

- 1 the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice
- 2 effective interdisciplinary communication strategies
- 3 the regulations surrounding collaborative drug therapy agreements
- 4 the strategies and resources necessary for establishing a collaborative care agreement and referral process
- 5 needs assessment techniques for prospective ambulatory care pharmacy services
- 6 implementation strategies for ambulatory care pharmacy services
- 7 the continuous quality improvement process
- 8 business principles to effectively manage the practice (for example, accounting, purchasing, resource utilization, work flow, profit analysis)
- 9 procedures for coding and billing as relevant to pharmacy practice
- 10 tasks involved in managing the implementation of a new service or program
- 11 effective marketing strategies for initiating or expanding ambulatory pharmacy services
- 12 systems for patient referral and follow up
- 13 special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide)
- 14 how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics)
- 15 formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process)
- 16 cost-effective alternative and therapeutic interchange options
- 17 State and Federal regulations regarding protection of patient information
- 18 scope of practice for ambulatory care pharmacy practice
- 19 process necessary for evaluation, analysis, and justification of services
- 20 compensation strategies and funding sources
- 21 the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria)
- 22 legislative and regulatory issues that impact the practice of ambulatory care pharmacy

DOMAIN 3: Public Health

Tasks:

- 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations).
- 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues.
- 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society).
- 3.4 Participate in community health screening programs.
- 3.5 Serve as a public advocate regarding preventive health issues.
- 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice.
- 3.7 Facilitate appropriate care for patients affected by public health threats and disasters.
- 3.8 Participate in disaster response preparation and planning.

Knowledge of:

- 1 the role of ambulatory care pharmacists in public health
- 2 resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI)
- 3 disease prevention strategies
- 4 disease screening guidelines
- 5 complementary and alternative medicine treatments for the prevention and treatment of diseases
- 6 information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines)

DOMAIN 4: Medical Informatics and Professional Development

Tasks:

- 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice.
- 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs).
- 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions.
- 4.4 Respond to drug information requests from patients and healthcare professionals.
- 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine.
- 4.6 Provide health and medication-related education to healthcare professionals.
- 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice.
- 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice
- 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences.

- 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge.
- 4.11 Participate in local, state, and/or national professional organizations.
- 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education.

Knowledge of:

- 1 principles of evidence-based medicine
- 2 common resources of biomedical literature applicable to ambulatory pharmacy practice
- 3 primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references
- 4 how to formulate a search strategy to retrieve information from the biomedical literature
- 5 process for identifying educational needs of healthcare professionals in ambulatory care practice
- 6 principles and methods of educating health care students, residents, and professionals
- 7 research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis)
- 8 strengths and limitations of various study methods
- 9 clinical versus statistical significance in order to interpret medical literature
- 10 appropriate research methodology to design studies to assess a research hypothesis
- 11 the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities
- 12 the role and benefits of professional organizations for ambulatory care pharmacy practice
- 13 certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certified Asthma Educator).
- 14 the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment

DOMAIN 5: Patient Advocacy

Tasks:

- 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes.
- 5.2 Facilitate access to Patient and/or Medication Assistance Programs.
- 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes.
- 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy.
- 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting).
- 5.6 Ensure the patient has access to and understands the importance of maintaining an upto-date medication list and emphasize the importance of sharing the list with all healthcare providers.
- 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care.

- 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs).
- 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist.
- 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes.
- 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient.
- 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments).

Knowledge of:

- 1 assertive and persuasive communication techniques for representing a patient's healthcare needs and interests
- 2 patient-specific factors which may impact access to medications (for example, socioeconomic)
- 3 the structure, guidelines, and process of patient and/or medication assistance programs
- 4 the structure, including benefits and limitations, of prescription drug plans/formularies for patients in ambulatory care
- 5 resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting
- 6 medication reconciliation skills and techniques
- 7 the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services).
- 8 collaborative relationships necessary to enable case management of ambulatory care patients
- 9 the scope and limitations of ambulatory care pharmacy practice
- 10 legislative and regulatory issues that impact patient outcomes
- 11 conflict management and negotiation skills

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Appendix 1. Members of the Ambulatory Care Role Delineation Task Force

BPS Ambulatory Care Task Force Members

Doug Covey, PharmD, MHA Tampa VA Medical Center Pharmacy Tampa, FL

Steven Chen, PharmD School of Pharmacy, USC Los Angeles, CA Alvin Goo, PharmD Dept. of Pharmacy & Family Medicine Harborview Medical Center Seattle, WA

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Winnie A. Landis, Pharmacist Lafayette, IN Ray E. Marcrom, PharmD Manchester, TN

Kelly Brock, PharmD College of Pharmacy Western University of Health Sciences Pomona, CA

Beverly A. Kroner, PharmD, BCPS Pharmacy Dept. Kaiser Permanente Aurora, CO Appendix 2. Independent Review Instructions and Participant Demographics

Email Invitation for Independent Review

To the Reviewers for the BPS Practice Analysis of Ambulatory Care Pharmacists:

The Board of Pharmaceutical Specialties (BPS) is considering a new credential to recognize pharmacists who are specifically focused on achieving optimal drug therapy outcomes in patients in a variety of ambulatory care settings. It is envisioned that these pharmacists provide personalized services to patients based on their unique clinical status.

BPS has contracted with my company, Professional Examination Service, to conduct a role delineation study of the ambulatory care practice area. If a decision is made to move forward with a new specialty certification in ambulatory care, then the results of the study will be used to create a content outline for the examination.

A Practice Analysis Task Force met in August of 2006 to create a draft description of the work of ambulatory care pharmacists. To build on the work of the Practice Analysis Task Force, we are now circulating the draft document to a select group of subject-matter experts for review and comment.

This summer, you volunteered (or were nominated) to perform this review activity. We selected you from the group of nominees because you represent a specific type of pharmacy practice setting. Therefore, your participation is vital to ensuring representation of practices in your setting.

The draft description of the practice of ambulatory care pharmacists is attached for your review. It consists of three sections: (1) domains, (2) tasks performed within domains, and (3) knowledge statements. Suggestions for performing your review are included in this document. Our goal is to create tasks and knowledge listings that are complete, concise, and clearly understood by ambulatory care pharmacists across the range of practice settings.

You can make your edits in the Word document and e-mail it back to us. (We have turned the Word tracking feature on so we can easily identify your edits). Alternatively, you can print out the document, make changes on the printed version, and fax your edits back to us. Return your edits to Professional Examination Service, HRCI contractor, no later than **November 24**, **2006**. Return via e-mail: npapadimos@proexam.org or by fax: (212) 367-4266, Attn: Nicole Papadimos.

We greatly appreciate your contribution of time and professional expertise to this endeavor. If you have difficulty either opening or printing the document or if you have any questions about this independent review or about the practice analysis in general, please free to contact:

Nicole E. Papadimos Research Associate Professional Examination Service

Instructions for Ambulatory Care Pharmacist Independent Review

Five major domains of ambulatory care pharmacy practice form the basic structure for the delineation of practice. On the following pages, you will be reviewing lists of tasks and knowledge, which are organized within these five practice areas. The five domains are:

Direct Patient Care Practice Management Public Health and Professional Advocacy Education and Medical Informatics Patient Advocacy

Instructions for reviewing the tasks appear on page 2; instructions for reviewing the domains appear on page 11; instructions for reviewing the knowledge appear on page 12.

Please make your edits right in the document, and return them to PES by email at <u>npapadimos@proexam.org</u>, or by fax at (212) 367-4266 by Friday November 24, 2006.

Review of BPS Ambulatory Care Pharmacy Task Statements

This section contains the Ambulatory Care Pharmacy task list drafted by the Practice Analysis Task Force. The tasks listed on pages 3 - 10 are organized within the five domains.

Think about the following as you review the tasks in each domain:

Check for completeness

Do the task statements describe the full range of work performed by ambulatory care pharmacists in the domain? Add/delete/modify the task statements to create a comprehensive listing.

Check for redundancy

Does each task statement describe a unique behavior? Delete or modify the task statements within the area in order to create a non-redundant listing.

Check for clarity

Is each task phrased as accurately and concisely as possible? Revise language, as needed, to improve the clarity of statements. Add examples, if useful.

Check for consistency

Is the level of detail and specificity consistent within the domain? Edit (or endorse) the tasks within each area.

Check for sequence

Is the sequence of statements logical? Edit (or endorse) the sequence of task statements within each domain.

In addition to responding to these questions, please feel free to make any other editorial suggestions that come to mind.

Review of Ambulatory Care Domains

Listed below are the five domains of responsibility for Ambulatory Care Pharmicists.

Direct Patient Care Practice Management Public Health and Professional Advocacy Education and Medical Informatics Patient Advocacy

Think about the following as you review each domain:

Is each domain title clear and unambiguous? Depending on the answer, modify the domain title in order to create a clear and concise title.

Do the domain titles reflect the range of tasks associated with the functional area? After referring back to the tasks associated with each domain (pp. 2 - 9), review the areas to see if they reflect the range of tasks associated with each domain. Depending on your answer, modify the domain.

Suggestions for Reviewing the Draft Knowledge

This section contains the knowledge listing drafted by the BPS Ambulatory Care Practice Analysis Task Force.

The knowledge list on pages 13 - 21 consists of knowledge related to each of the five domains (i.e., Direct Patient Care, Practice Management, Public Health and Professional Advocacy, Education and Medical Informatics, and Patient Advocacy).

As you review the knowledge statements, ask yourself the following:

Check for completeness

Do the knowledge statements describe the complete set of knowledge required to perform the responsibilities in the domain? Add/delete/modify the knowledge statements in order to create a comprehensive listing.

Check for redundancy

Does each knowledge statement describe a unique knowledge base? Delete or modify the knowledge statements in order to create a non-redundant listing.

Check for clarity

Is each knowledge statement phrased as accurately and concisely as possible? Revise language, as needed, to improve the clarity of statements. Add examples, if useful.

Check for consistency

Is the level of detail and specificity consistent within each domain? Edit (or endorse) the knowledge within each domain.

Check for sequence

Is the sequence of statements logical? Edit (or endorse) the sequence of knowledge statements within each domain.

In addition to responding to these questions, please feel free make any other editorial suggestions that come to mind.

Professional and Demographic Background of Independent Reviewers

Primary Role

| | n |
|--|---|
| Associate Professor | 2 |
| Clinical Pharmacist/Clinical Associate Professor | 1 |
| Clinical Pharmacy Supervisor- Specialties | 1 |
| Total | 4 |

Primary Setting

| | n |
|---|---|
| Ambulatory Care | 2 |
| Managed Health Care | 1 |
| Other: Academia w/Community Pharmacy Practice Site | 1 |
| Total | 4 |

Percent of time providing direct educational or consultative services to patients

2

| | n |
|----------|---|
| 1 - 20 | 0 |
| 21 - 40 | 1 |
| 41 - 60 | 2 |
| 61 - 100 | 0 |
| Total | 3 |

Percent of time providing direct educational or consultative services to patients

| | Mean | SD |
|---|------|------|
| Percent of time providing direct educational or consultative services to patients | 50.0 | 10.0 |

Years of Experience

| | n |
|---------|---|
| 1 - 5 | 0 |
| 6 - 10 | 2 |
| 11 - 20 | 2 |
| 21 - 30 | 0 |
| Total | 4 |

Years of Experience

| | Mean | SD |
|---------------------|------|-----|
| Years of Experience | 13.0 | 5.2 |

Patient Populations in Last Year

| | n |
|-------------------------------|---|
| All adult age groups (21-65+) | 3 |
| Adult (21-65) | 0 |
| Adult (65+) | 1 |
| Total | 4 |

BPS Certifications

| | n |
|-----------------|---|
| None | 1 |
| Pharmacotherapy | 3 |
| Total | 4 |

Gender

| | n |
|--------|---|
| Female | 1 |
| Male | 3 |
| Total | 4 |

Appendix 3. Telephone Interview Script and Participant Demographics

- 1. To start out, please describe your job. What are your major duties and responsibilities?
- 2. Describe what you see as the differences between ambulatory care specialty practice and entry-level pharmacy practice. What tasks are performed in an ambulatory care setting that are unique to that setting? What specialized knowledge is required?
- 3. If you were going to train a newly licensed pharmacist to practice in the specialty of ambulatory care, what training would you provide? What topics would you cover?
- 4. Think of a time when you felt particularly effective in your work as an ambulatory care pharmacist -- a time when you felt good about your own performance. Describe the situation. What specific knowledge and skills made you particularly effective in that situation?

(*For Trainers/Educators:* Think of one or more times when an ambulatory care pharmacists you trained or supervised was particularly effective in his/her work.)

- 5. Now think of a time when you felt particularly ineffective in your work as an ambulatory care pharmacist, maybe a time when something went wrong. Describe the situation. What specific knowledge and skills would have helped you in that situation?
- 6. What changes do you anticipate in the practice of ambulatory care pharmacy in the next 3 to 5 years?

Professional and Demographic Description of Interviewees

| | n |
|---------------------------------------|---|
| Clinical Coordinator | 2 |
| Clinical Pharmacy Specialist | 2 |
| Community Pharmacist/Managing Partner | 1 |
| Director, Pharmacy Management | 1 |
| Manager | 1 |
| Professor | 2 |
| Total | 9 |

Primary Setting

| | n |
|--------------------------------|---|
| Academic Institution | 1 |
| Ambulatory Care | 1 |
| Chain Community Pharmacy | 1 |
| Home Health Care | 1 |
| Independent Community Pharmacy | 1 |
| Long-Term Care | 1 |
| Managed Health Care | 2 |
| Other: Care Management | 1 |
| Total | 9 |

Percent of time providing direct educational or consultative services to patients

| | n |
|----------|---|
| 0 | 0 |
| 1 - 20 | 3 |
| 21 - 40 | 1 |
| 41 - 60 | 4 |
| 61 - 100 | 0 |
| Total | 8 |

Percent of time providing direct educational or consultative services to patients

| | Mean | SD |
|---|------|------|
| Percent of time providing direct educational or consultative services to patients | 33.1 | 17.7 |

Years of Experience

| | n |
|---------|---|
| 1 - 5 | 1 |
| 6 - 10 | 2 |
| 11 - 20 | 3 |
| 21 - 30 | 3 |
| Total | 9 |

Patient Populations in Last Year

| | n |
|---------------------------------|---|
| All adult age groups (21 - 65+) | 8 |
| Adult (21 - 65) | 1 |
| Adult (65+) | 0 |
| Total | 9 |

BPS Certifications

| | n |
|-----------------|---|
| None | 4 |
| Pharmacotherapy | 5 |
| Total | 9 |

Gender

| | n |
|--------|---|
| Female | 7 |
| Male | 2 |
| Total | 9 |

Appendix 4. Screen Shots of Survey Instrument (Composite)

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| elcome and thank you for your v structions are provided for each owledge related to ambulatory | h section of the survey; it is imp | | rmacists. a carefully. You will be asked to a | use your experience as a pharn | nacist to rate either tasks <i>or</i> |
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| you are unable to complete the u were provided. | entire survey in one sitting, yo | u may exit and return later. Us | e the "Save and Exit" button at t | he top of each screen. To retu | rn to the survey, use the link |
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| The survey consists of five sections that address your work experiences during the past year. We are interested in <i>your</i> work and <i>your</i> opinions. Therefore, please answer each question on the basis of experience. | of your own | |
| Some questions have special instructions. Failure to follow the instructions will result in error messages in red text at the top of the screen. You will have to revise your response before continuing with | h the survey. | |
| How to View the Survey | | |
| The survey has been designed to be viewed at a screen resolution of at least 1024 x 768. Click here for your screen resolution. If it is not set at 1024 x 768, adjust it as follows: RIGHT-click on your d PROPERTIES, select SETTINGS, and move the slide bar to 1024 x 768. Then, return to the survey. | esktop, selec | :t |
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| Section 1 — Tasks | | | | | | | | | | | | | | |
| asks listed in this section | are related to Direct Pa | i tient Care. For each ambula | atory care | nharmary ta | sk in this se | ction, nlea | se make th | ne follow | ina two | ratinos: | | | | |
| | | | | | | | | | | 2 | | | | |
| | | task during the past year? Imp ast weekly, At least daily M | | —How impor nt, Minimally | | | | | | | s? | | | |
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| Establish a caregiver rela communication, and enco | | that fosters trust and open agement. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
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| | | elevant to the patient's care | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| (for example, chief comp | laint, history of present il | lness). | <u> </u> | | | | | | | | Ŭ | | | |
| Obtain the patient's medi | cation history, including o | over the counter (OTC) | | | | | | | | | | | | |
| medications, prescription supplements, adherence, | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | | 16 11 12 1 | | | | | | | | | | | | |
| interview, patient's health | ncare provider(s), patient | ned from patient/caregiver t's documented medication | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| profiles, and medical reco | ords. | | | | | | | | | | | | | |
| | | ily, medical, psychosocial, | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| lifestyle, substances of al | ouse, diagnostic test resu | ilts). | 0 | | | | | | | | | | | |
| Perform pertinent physica | al assessments as they re | elate to patient's current | | | | | | | | | | | | |
| | is (for example, vital sign | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
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| interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | 0 | • | 0 | • | 0 | 0 | 0 | 0 | 0 | |
| Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | • | 0 | • | • | 0 | • | • | • | 0 | |
| Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | 0 | • | • | • | • | 0 | • | • | 0 | |
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| or each ambulatory care pharmacy task in this section, please make the follow | ing two rati | ings: | | | | | | | | | |
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| Assess the information gathered to identify non-drug factors that may affect | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| atient outcomes (for example, tobacco, activity level, nutrition). | Ŭ | Ŭ | Ť | Ť | Ŭ | Ĩ | Ŭ | Ŭ | Ŭ | | |
| dentify and refer (i.e. triage) patients with needs beyond the scope of the | | | | | | | | | | | |
| ambulatory care pharmacy specialist. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Recognize patient-specific barriers to successful drug therapy (for example, | | | | | | | | | | | |
| social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| interpreter, picture-based education). | | | | | | | | | | | |
| Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid | | | | | | | | | | | |
| while taking the medication, potential side effects and when to report | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| problems). | | | | | | | | | | | |
| Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| drops, subcutaneous injections). | | | | | | | | | | | |
| Provide disease-related patient education/counseling (for example, diabetes, | | | | | | | | | | | |
| asthma, hypertension, dyslipidemia). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| valuate the patient's administration technique for medications that are not idministered orally (for example, nasal inhalers, oral inhalers, eye drops, ear irops, subcutaneous injections). | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | |
| Provide disease-related patient education/counseling (for example, diabetes, isthma, hypertension, dyslipidemia). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Provide wellness and prevention education/counseling (for example, lifestyle nodifications, immunizations). | 0 | 0 | 0 | 0 | • | 0 | • | 0 | 0 | |
| Recommend appropriate immunizations to specific patients. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Administer appropriate immunizations to specific patients. | • | 0 | • | • | • | 0 | 0 | 0 | 0 | |
| Provide OTC education/counseling (for example, herbals, non-herbal dietary upplements, vitamins, non-prescription drugs). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | • | • | 0 | • | • | 0 | 0 | • | 0 | |
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| Provide integrated disease-state management (for exa clinics, primary care clinics where more than one dise in a visit). | | 0 | • | • | • | 0 | 0 | • | • | • | | |
| Provide focused disease-state management (for exam hypertension, asthma, heart failure, anticoagulation, c health, chronic pain). | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Provide wellness and preventive programs for individu weight management program, tobacco cessation prog program). | | • | • | • | • | 0 | 0 | • | 0 | 0 | | |
| Identify situations in which OTC treatment may be app recommend treatment options. | propriate, and | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Make recommendations to manage drug therapy whic modification, or discontinuation of medication therapy | | • | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Recommend appropriate self-care devices for monitor example, blood glucose meters, peak flow meters, blo | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| / situations in which UTC treatment may be appropriate, and mend treatment options. | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ecommendations to manage drug therapy which may include initia ation, or discontinuation of medication therapy as appropriate. | ation, (| • | 0 | • | • | • | 0 | 0 | 0 | • | |
| mend appropriate self-care devices for monitoring chronic disease le, blood glucose meters, peak flow meters, blood pressure monit | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| patients how to use self-care devices for monitoring chronic disea ample, blood glucose meters, peak flow meters, blood pressure rs). | | • | 0 | • | • | • | 0 | 0 | • | 0 | |
| mend appropriate health-related screening tests (for example, ho ncy tests, hemoccult tests) |)me (| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| patients how to use appropriate health-related screening tests (fo le, home pregnancy tests, hemoccult tests). | or (| • | • | • | • | • | 0 | • | • | 0 | |
| treatment goals in collaboration with the patient and other health ers. | care (| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| nine patient's ability and willingness to pay for services (for examp nce coverage, out of pocket expenses). | ole, (| • | 0 | • | • | • | 0 | 0 | 0 | 0 | |
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| r each ambulatory care pharmac requency— How frequently did yo <i>Never, Less than monthly, At leas</i> | ou perform the ta | sk during the past year? Im | - portance | - | | | | | | | | re and exit Responses for all previous pages saved. | will be |
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| imphasize affordability and cost-e herapy or designing a drug treatm | | n recommending drug | 0 | 0 | • | • | • | 0 | 0 | 0 | 0 | | |
| evelop a patient-specific plan to a dentified drug-related problems to | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| evelop a patient-specific monitor esponse to both drug and non-dru | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Communicate patient-specific findi Ither healthcare professionals invo | | | • | 0 | • | 0 | • | 0 | 0 | 0 | 0 | | |
| Communicate patient-specific findi atient/caregiver in language they erbal communication). | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| esponse to both drug and non-drug therapy and assure safety. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | • | • | • | • | • | 0 | • | • | 0 | |
| Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Conduct follow-up visits in order to assess response to both drug and non- drug therapy and assure safety. | 0 | 0 | • | • | • | 0 | • | • | • | |
| Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Modify patient-specific treatment plan based on follow up assessment. | • | 0 | • | • | • | 0 | • | • | 0 | |
| Determine patient-specific reasons for lack of adherence to recommended reatment and in collaboration with the patient develop a plan for improving adherence to therapy. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). | 0 | • | • | 0 | • | 0 | 0 | 0 | 0 | |
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| ntify the need for ambulatory clinical pharmacy services in response to | | | | | | | | | | | |
| ient care needs and/or business potential (for example, Medication erapy Management, focused or integrated disease-state management | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| ablish relationships and/or collaborative practice agreements with other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| lith care providers. | | | Ŭ | Ŭ | Ŭ | | | | Ŭ | | |
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| evelop systems for ongoing quality improvement, patient safety, and ovision of cost-effective care (for example, medication use evaluation, ADR porting, incident report evaluation). | 0 | • | • | • | 0 | • | 0 | • | 0 | |
| erform ongoing evaluations of quality, value, and need to justify, modify, sband, or expand ambulatory care pharmacy services. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| articipate as an integral member of an interdisciplinary health care team. | 0 | 0 | • | 0 | • | 0 | 0 | 0 | 0 | |
| sure time, space and resources necessary to provide patient care services or example, patient education materials, immunization supplies, office uipment and space, ancillary personnel, staff). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication dispensing functions). | 0 | • | • | • | • | • | • | • | 0 | |
| Vlanage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | • | 0 | • | • | • | 0 | • | • | 0 | |
| Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | 0 | 0 | 0 | 0 | 0 | 0 | • | • | 0 | |
| Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |

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| rovide a system for drug procurement (for example, contracts, buying roups, special order drugs, patient assistance programs). | 0 | 0 | • | • | • | 0 | 0 | 0 | • | |
| nsure timely and accurate delivery of medication to patients. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| articipate in formulary management (for example, participate on P&T mmittee, develop criteria for use protocols, design cost-effective treatment otocols, develop system for obtaining prior authorization and nonformulary ugs based on medical necessity). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | |
| eport medication errors and develop systems to track and analyze these for sssible intervention measures. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| rovide general information to the public regarding preventive health issues for example, cardiovascular disease, tobacco cessation, immunizations). | 0 | • | 0 | 0 | • | • | • | 0 | 0 | | |
| rovide information to, and/or collaborate with other healthcare professionals o design intervention strategies that address preventive health issues. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| dvise and direct the public and consumers to appropriate resource groups, irganizations, and agencies (for example, Alzheimer's Association, American ancer Society). | 0 | • | 0 | 0 | • | 0 | 0 | 0 | 0 | | |
| 'articipate in community health screening programs. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Serve as a public advocate regarding preventive health issues. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| Advocate to ensure appropriate healthcare policy for ambulatory care wharmacy practice. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| dentify and report suspected public health threats (for example, disasters, nfectious diseases). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |

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| dvocate to ensure appropriate healthcare policy for ambulatory care narmacy practice. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| entify and report suspected public health threats (for example, disasters, fectious diseases). | 0 | • | • | 0 | 0 | • | 0 | 0 | 0 | |
| acilitate appropriate care for patients affected by public health threats and sasters. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| articipate in disaster response preparation and planning. | 0 | • | • | 0 | 0 | • | 0 | 0 | 0 | |
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| Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Respond to drug information requests from patients and healthcare professionals. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Provide health and medication-related education to healthcare professionals. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| Respond to drug information requests from patients and healthcare professionals. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Provide experiential training to pharmacy students and residents in ambulatory are pharmacy practice. | 0 | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | |
| Conduct research as principal investigator or co-investigator to generate nowledge applicable to ambulatory care pharmacy practice | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to ocal, regional, and national audiences. | 0 | • | 0 | 0 | 0 | • | 0 | 0 | 0 | |
| Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Participate in local, state, and/or national professional organizations. | 0 | 0 | • | 0 | • | • | 0 | 0 | • | |
| Provide ongoing staff training and development, and opportunities/support for redentialing and continuing education. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Knowledge of how to apply p treatment plan | harmacoeconomic pri | nciples when designing a | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | 0 | | | | |
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| Knowledge of how to obtain a medication history | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| nowledge of how to develop effective collaborative rel. lealthcare professionals in order to access health-relat issential to the care of the patient | | 0 | • | 0 | 0 | • | 0 | 0 | 0 | 0 | |
| (nowledge of how to collaborate with other healthcare ptimize patient care outcomes | professionals to | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of how to prioritize patient needs and/or dru | ug-related problems | 0 | • | • | 0 | • | 0 | 0 | • | • | |
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| nowledge of how to develop an effective, individualized | d treatment plan | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| (nowledge of how to implement an effective, individual | ized treatment plan | 0 | 0 | • | 0 | 0 | 0 | 0 | • | • | |
| (nowledge of patient education principles and technique classes, individual patient counseling). | es (for example, group | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Knowledge of the format for and recommendations (for e | | ent care activities, plans | 0 | 0 | • | 0 | • | 0 | 0 | • | • | | | |
| Knowledge of the types, indi (for example, home pregnar | | ealth-related screening tests sts) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| Knowledge of the types, indi monitoring chronic diseases meters, blood pressure mor | (for example, blood gl | | 0 | • | • | 0 | 0 | 0 | 0 | 0 | • | | | |
| Knowledge of the process of treatments for individualized | | ateness of over-the-counter | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| Knowledge of how to effecti the appropriate healthcare p | | tment recommendations to | 0 | • | • | • | • | • | • | 0 | 0 | | | |
| Knowledge of how to effecti | vely communicate with | the patient | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| Knowledge of the principles | and practices of wellne | ess and prevention | 0 | • | • | 0 | 0 | 0 | • | 0 | • | | | |
| Knowledge of lifestyle behav dietary factors, exercise, tob | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| Knowledge of the proper ad immunizations (for example, | | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
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| Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Knowledge of the principles and practices of wellness and prevention | 0 | 0 | 0 | 0 | • | • | • | 0 | • | |
| Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| <nowledge administration="" and<br="" drugs="" for="" of="" proper="" techniques="" the="" various="">mmunizations (for example, eye drops, inhalers, injections)</nowledge> | 0 | 0 | • | • | • | • | • | • | • | |
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| Knowledge of appropriate writing techniques for composing patient education materials | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs | 0 | 0 | 0 | 0 | 0 | • | • | 0 | 0 | |
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| Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | 0 | • | • | 0 | 0 | 0 | 0 | 0 | 0 | | |
| (nowledge of effective interdisciplinary communication strategies | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| <pre>śnowledge of the regulations surrounding collaborative drug therapy agreements</pre> | 0 | 0 | • | 0 | • | 0 | • | 0 | 0 | | |
| (nowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | 0 | • | • | • | 0 | 0 | 0 | 0 | 0 | | |
| Knowledge of implementation strategies for ambulatory care pharmacy services | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Knowledge of the continuous quality improvement process | 0 | • | • | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of procedures for coding and billing as relevant to pharmacy practice | 0 | 0 | 0 | 0 | • | • | 0 | 0 | • | |
| Knowledge of tasks involved in managing the implementation of a new service or program | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services | 0 | 0 | • | • | 0 | 0 | • | 0 | • | |
| Knowledge of systems for patient referral and follow up | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | 0 | 0 | 0 | 0 | • | • | • | • | • | |
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| ior each ambulatory care pharmacy knowledge statement in this section, please F requency —How frequently did you use the knowledge task during the past ye <i>Never, Less than monthly, At least monthly, At least weekly, At least daily</i> | ar? Impor | | / important | | | | | | nes for pa | and exit Responses for all previous pages will b saved. |
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| Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | |
| Knowledge of work flow efficiencies and process improvement analyses | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| (nowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of cost-effective alternative and therapeutic interchange options | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | |
| Knowledge of State and Federal regulations regarding protection of patient information | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | 0 | |
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| ogle C → Go Integrate patient care services within an amoulatory ispensing pharmacy practice (for example, medication adherence programs, ledication Therapy Management services, and disease management clinics) | (ay VC | heck 👻 🐴 Au | itoLink 👻 🍯 | AutoFill | Send to▼ | 0 | 0 | 0 | 0 | Setting |
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| nowledge of scope of practice for ambulatory care pharmacy practice | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| nowledge of process necessary for evaluation, analysis, and justification of ervices | 0 | 0 | • | • | • | 0 | • | • | • | |
| nowledge of compensation strategies and funding sources | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| nowledge of the literature evaluating medication errors and patient safety for example, IOM report, Beers criteria) | 0 | 0 | • | • | • | 0 | 0 | • | 0 | |
| nowledge of legislative and regulatory issues that impact the practice of mbulatory care pharmacy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| nowledge of the role of ambulatory care pharmacists in public health | • | 0 | 0 | 0 | 0 | 0 | 0 | • | • | | | |
| nowledge of resources available through relevant groups, organizations, and igencies (for example, ADA, AHA, NIH, CDC, AAAAI) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
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| nowledge of disease screening guidelines | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| nowledge of complementary and alternative medicine treatments for the revention and treatment of diseases | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | | | |
| nowledge of legislative and regulatory issues that impact the prevention and reatment of diseases | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| nowledge of information that is accessible to the public regarding the revention and treatment of diseases (for example, reliable internet websites, oll-free information hotlines) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | • | | | |
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| nowledge of surveillance methods and surveillance resources for public ealth threats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
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| Knowledge of processes for delivery and implementation strategies for public nealth services | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
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| Knowledge of principles of evidence-based medicine | 0 | 0 | 0 | 0 | • | 0 | 0 | 0 | 0 | | | | |
| Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | • | • | • | • | 0 | 0 | • | • | 0 | | | | |
| Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | 0 | 0 | 0 | 0 | • | 0 | • | • | 0 | | | | |
| Knowledge of principles and methods of educating health care students, residents, and professionals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
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| Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedica journals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
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| nowledge of staff development principles and avenues for providing ontinuing education | 0 | • | • | 0 | 0 | 0 | 0 | 0 | 0 | |
| nowledge of certifications available to the ambulatory care pharmacy pecialist (for example, Certified Diabetes Educator, Board Certified 'harmacotherapy Specialist, Certified Gerlatric Pharmacist, Certified anticoagulation Pharmacy Specialist, Certified Asthma Educator). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 0 | • | • | • | 0 | 0 | • | • | • | |
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| (nowledge of the structure, guidelines, and process of patient and/or nedication assistance programs | 0 | • | 0 | 0 | 0 | 0 | 0 | 0 | • | |
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| Direct Patient Care: Drug therapy management activities are the focus of this domain. This includes taking subjective and objective information to make an assessment; setting treatment goals; and developing a patient specific plan with monitoring parameters, and altering the plan based on patient follow-up. Implementing recognize guidelines, developing and implementing collaborative drug therapy management protocols, providing patient education and counseling, engaging the patient in self-management, and documenting these activities are also part drug therapy management. | % | 0 | 0 | 0 | 0 | | |
| Practice Management: Providing an infrastructure that supports drug therapy management is the focus of this domain. Included are: establishing relationships and contracts with other healthcare providers; developing and maintaining systems for drug procurement, patient referral, and patient follow-up; formulary management, medication use evaluations, and adverse drug reaction reporting; creating viable business plans to develop, implement, continuously assess, and justify clinical services with methods for compensation; and intelligent management of resources and workflow. | <u> </u> | 0 | 0 | 0 | 0 | | |
| Public Health and Professional Advocacy: Preventive health services, public health information, advocacy for healthcare policy and response to public health threats and disasters are the focus of this domain. | % | 0 | 0 | 0 | 0 | | |
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| Public Health and Professional Advocacy: Preventive health services, public health information, advocacy for healthcare policy and response to public health threats and disasters are the focus of this domain. | % | 0 | 0 | 0 | 0 | |
| Medical Informatics and Professional Development: This domain focuses on: the retrieval, interpretation, and application of the medical literature to clinical practice; participation in research; education and training of students and residents; education and training of staff; participation in continuing education; and participation in professional pharmacy organizations. | <u> </u> | 0 | 0 | 0 | 0 | |
| Patient Advocacy: The focus of this domain is patient empowerment, coordination of care, and effective communication and collaboration with patients and other healthcare professionals to optimize drug therapy outcomes for patients. | % | 0 | • | 0 | 0 | |
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| Academic Institution | Federal Hospital/Institution | O Managed Health Care | |
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| Community Hospital, For Profit | Independent Community Pharmacy | State Psychiatric Hospital/Clinic | |
| Community Hospital, Not-For-Profit Drug Information Center | Independent Consulting Long-Term Care/Assisted Living | Ouniversity-Affiliated Hospital | _ |
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| What is the <mark>HIGHEST</mark> pharmacy-related degree | e you have earned? | | |
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| What is the HIGHEST pharmacy-related degree you have earned? | <u>^</u> |
| Bachelor's degree Master's degree Pharm.D. Ph.D. Other (<i>Please specify.</i>) | |
| In which year were you first licensed as a pharmacist? | |
| 4 digit year (e.g., 1995) | |
| What percentage of your work time is spent performing basic prescription processing (excluding patient education, counseling, and advocacy)? | |
| % | |
| Have you completed a residency training program? | |
| ○ Yes ○ No | |
| | |
| Have you completed a fellowship training program? | |
| O Yes | |
| | |
| How many years have you been practicing as a licensed pharmacist? | |
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| Have you completed a fellowship training program? | ~ |
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| How many years have you been practicing as a licensed pharmacist? | |
| years | |
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| How many years have you been practicing as an ambulatory care pharmacist? | |
| years | |
| | |
| What other certifications do you have? | |
| BPS Pharmacotherapy | |
| BPS Nuclear | |
| BPS Nutrition Support | |
| BPS Oncology BPS Psychiatric | |
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| CACP (Certified Anticoagulation Care Provider) | |
| Disease specific certifications | |
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Appendix 5. Survey Invitation and Reminder E-mails

Dear Colleague:

The Board of Pharmaceutical Specialties (BPS) needs your help! We are conducting an important study of ambulatory care pharmacy. The purpose of the study is to identify the responsibilities performed by ambulatory care pharmacists, as well as the specific knowledge base required to perform these responsibilities. This process is called a role delineation study. It will yield the first national description of this pharmacy practice area, and it may be used by the pharmacy profession in the creation of a new specialty certification examination for ambulatory care pharmacists.

As a pharmacist involved in ambulatory care, you are one of a limited group of individuals who has been selected to participate in the study. Please note that your practice need not be 100% ambulatory in order to participate. Your response will describe your own unique practice pattern with respect to ambulatory care pharmacy. As a reward for participating, upon completion of the survey, you will be included in a random drawing for one of four \$100 gift certificates from Amazon.com.

Please click here http://www.surveywriter.net/in/survey/survey310/bps.asp?pw=giw68gd to fill out the survey. Your participation is voluntary and your answers are confidential.

We anticipate the survey taking approximately 30 minutes to complete. If you are unable to complete the entire survey in one sitting, you may exit and return later. To return to the survey, use the above URL. Please complete the survey by Wednesday, March 21, 2007.

If you experience difficulty completing the survey or would like to be removed from future mailings, please contact bps_ambcare@proexam.org or call (212) 367-4275 for assistance.

Thank you in advance for your contribution to furthering the ambulatory care pharmacy profession.

Sincerely,

Jannet M. Carmichael, PharmD, BCPS Chairman of the Board of Pharmaceutical Specialties Dear Colleague:

Last week, I invited you to participate in a study of ambulatory care pharmacy sponsored by the Board of Pharmaceutical Specialties. The study will yield the first national description of this pharmacy specialty area. Your participation is essential to ensuring that the study accurately reflects the practice of pharmacists involved in ambulatory care.

Your practice need not be 100% ambulatory in order to participate. Your response will describe your own unique practice pattern with respect to ambulatory care pharmacy. As a reward for participating, upon completion of the survey, you will be included in a random drawing for one of four \$100 gift certificates from Amazon.com.

Please remember to complete the survey by the March 23, 2007 deadline. The survey link is provided below, in case you misplaced the original email message. Please note that this link is individualized to you and cannot be forwarded or transmitted to others.

http://www.surveywriter.net/in/survey/survey310/bps.asp?pw=s26h74xw33e

Your participation is voluntary and your answers are confidential.

We anticipate the survey taking approximately 30 minutes to complete. If you are unable to complete the entire survey in one sitting, you may exit and return later. To return to the survey, use the above URL.

If you experience difficulty completing the survey or would like to be removed from future mailings, please contact bps_ambcare@proexam.org or call (212) 367-4207 for assistance.

Thank you in advance for your contribution to furthering the ambulatory care pharmacy profession.

Sincerely,

Jannet M. Carmichael, PharmD, BCPS Chairman of the Board of Pharmaceutical Specialties Appendix 6. Write-In Responses: "Other" Domains of Practice

Other Domains of Practice

- Academia
- Administration (5)
- Administration; CE Planning
- Administrative/professional organizations
- Advocacy for profession which is my full time job.
- Background legal and company policy/procedure paperwork
- Basic prescription processing & consultation
- Basic prescription processing (verifying but not dispensing)
- Battling insurance companies
- Book keeping
- Business and personnel management
- Business management
- chat with customers
- Clinical research
- Computer documentation
- Cost effectiveness and drug appropriateness
- Departmental and Corporate administration
- Development of technology to support all of the above
- Direct patient assistance with daily living
- Direct patient interaction
- Dispensing (14)
- Dispensing, counseling, and insurance billing
- Dispensing, staffing
- Education for health care professionals
- Education of pharmacists and students to develop skills and idea sharing
- Faculty
- Filling prescriptions/resolving insurance problems
- Filling prescriptions, answering questions
- Finding things unrelated to pharmacy for patient
- Formulary adherence fill and check process
- Formulary or administrative etc.
- General rx work & managing the business
- Governmental authority of state medical district
- Handling problems with PBMs due to long hold times on the phone and understaffing by pharmacy management.
- Health screen
- Innovation
- Inpatient activities (2)
- Insurance billing and calling
- Learning new computer systems e.g. XP Word Excel e-mail etc
- Management activities
- MD's/intern's/resident's questions on dosing, drug interaction, drug formulary, and recommendations on all of theses
- Medication assistance program and drug dispensing
- Misc
- New computer system preparation for accreditation/survey
- NIMH sponsored research on improving adherence in elderly mentally ill

Other Domains of Practice

- Order entry
- Other academic responsibilities not encompassed in student teaching
- Other duties on quality teams other committees
- Other teaching committees etc.
- Patient empowerment and increased patient health literacy
- Pharmacy resident training
- Policy and procedure work
- Preparation of chemotherapy
- Prescription checking, counseling
- Protect out patients by making sure chemo orders are correctly dosed appropriate and made correctly
- Regular duties of a retail pharmacist; filling prescriptions counseling patients answering phone calls/questions billing problems working out patient financial problems preparing reports networking with other clinic staff dealing with co-workers
- Research (4)
- Research/teaching
- Residency/student training
- Rx processing
- Screening, filling, counseling
- Staffing
- Student and resident training and admin time /planning
- Students
- Supervising clinical pharmacy specialist
- TAKE CARE OF INDIVIDUAL PAITENT'S NEEDS PRN
- Teaching (12)
- Technical functions processing
- Training student pharmacists and residents
- University related service teaching and scholarship
- Verifying prescriptions/calling physicians for clarifications
- Work with agents from insurance carriers on issues with specific patients and there population as a whole.

Appendix 7. Task Frequency Ratings

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Direct Patient Care | | | | | | | |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open | 4.4 | 4.5 | 4.5 | 4.2 | 4.5 | 4.1 | 4.4 |
| communication, and encourages patient self-management. | (1.0) | (.9) | (1.0) | (1.1) | (1.0) | (1.5) | (1.1) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for | 4.2 | 4.0 | 4.5 | 4.2 | 4.4 | 3.8 | 4.2 |
| example, chief complaint, history of present illness). | (1.1) | (1.2) | (1.0) | (1.2) | (1.1) | (1.4) | (1.2) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, | 4.0 | 4.0 | 4.5 | 4.3 | 4.5 | 3.9 | 4.2 |
| prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | (1.3) | (1.1) | (1.0) | (1.1) | (1.0) | (1.4) | (1.2) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, | 3.7 | 3.7 | 4.4 | 4.2 | 4.2 | 4.1 | 4.1 |
| patient's healthcare provider(s), patient's documented medication profiles, and medical records. | (1.4) | (1.4) | (1.1) | (1.1) | (1.3) | (1.3) | (1.3) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, | 3.0 | 2.8 | 4.2 | 3.7 | 4.2 | 3.9 | 3.8 |
| substances of abuse, diagnostic test results). | (1.5) | (1.4) | (1.1) | (1.4) | (1.1) | (1.4) | (1.4) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition | 2.3 | 2.0 | 3.7 | 3.2 | 3.5 | 2.7 | 3.0 |
| and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | (1.6) | (1.2) | (1.4) | (1.6) | (1.4) | (1.5) | (1.6) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone | 2.1 | 2.2 | 2.6 | 2.8 | 2.8 | 2.1 | 2.5 |
| mineral density, peak flow). | (1.3) | (1.2) | (1.7) | (1.7) | (1.7) | (1.5) | (1.6) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist | 2.6 | 2.3 | 4.1 | 3.3 | 3.9 | 3.2 | 3.4 |
| on health and medication-related issues. | (1.6) | (1.1) | (1.2) | (1.4) | (1.3) | (1.5) | (1.5) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness | 3.8 | 3.6 | 4.4 | 3.9 | 4.3 | 3.8 | 4.0 |
| and ability to actively participate in his/her own care. | (1.3) | (1.2) | (1.1) | (1.3) | (1.1) | (1.4) | (1.3) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant | 4.1 | 4.1 | 4.6 | 4.5 | 4.6 | 4.2 | 4.4 |
| disease states, other medication, and other patient specific factors. | (1.2) | (1.0) | (1.0) | (.8) | (1.0) | (1.2) | (1.1) |
| 1.11 Assess the available information to identify drug related problems (for example, no | 4.3 | 4.1 | 4.5 | 4.6 | 4.6 | 4.3 | 4.4 |
| drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | (1.1) | (1.1) | (1.0) | (.8) | (.9) | (1.2) | (1.0) |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient | 3.5 | 3.2 | 4.4 | 4.1 | 4.3 | 3.8 | 4.0 |
| tcomes (for example, tobacco, activity level, nutrition). | (1.2) | (1.2) | (1.1) | (1.2) | (1.1) | (1.4) | (1.2) |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.7 | 3.0 | 3.9 | 3.5 | 3.9 | 3.4 | 3.7 |
| bulatory care pharmacy specialist. | (1.3) | (1.2) | (1.1) | (1.2) | (1.2) | (1.5) | (1.3) |
| 14 Recognize patient-specific barriers to successful drug therapy (for example, social | 3.7 | 3.3 | 4.1 | 4.0 | 4.3 | 3.8 | 3.9 |
| situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based | (1.4) | (1.3) | (1.2) | (1.2) | (1.1) | (1.4) | (1.3) |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of | 4.7 | 4.7 | 4.5 | 4.4 | 4.4 | 4.3 | 4.5 |
| medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | (.8) | (.6) | (1.0) | (1.1) | (1.0) | (1.2) | (1.0) |
| 1.16 Evaluate the patient's administration technique for medications that are not | 3.7 | 3.8 | 3.2 | 3.2 | 3.5 | 3.2 | 3.4 |
| administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | (1.4) | (1.1) | (1.3) | (1.3) | (1.2) | (1.4) | (1.3) |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, | 3.9 | 4.0 | 4.4 | 4.0 | 4.3 | 3.7 | 4.1 |
| hypertension, dyslipidemia). | (1.3) | (1.1) | (1.0) | (1.2) | (1.2) | (1.4) | (1.2) |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle | 3.6 | 3.3 | 4.0 | 3.2 | 3.8 | 3.1 | 3.6 |
| modifications, immunizations). | (1.3) | (1.2) | (1.2) | (1.4) | (1.4) | (1.6) | (1.3) |
| 1.19 Recommend appropriate immunizations to specific patients. | 2.6 | 2.3 | 2.9 | 2.6 | 3.4 | 2.5 | 2.8 |
| | (1.3) | (1.2) | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.20 Administer appropriate immunizations to specific patients. | 1.9 | 1.9 | 1.4 | 1.3 | 1.7 | 1.5 | 1.6 |
| | (1.3) | (1.3) | (.9) | (.8) | (1.2) | (1.1) | (1.1) |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary | 4.6 | 4.3 | 3.9 | 3.7 | 3.9 | 3.8 | 4.0 |
| supplements, vitamins, non-prescription drugs). | (.8) | (.9) | (1.2) | (1.3) | (1.2) | (1.3) | (1.2) |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative | 1.9 | 2.2 | 4.3 | 4.0 | 3.7 | 3.3 | 3.4 |
| ements with healthcare providers. | (1.4) | (1.3) | (1.3) | (1.5) | (1.6) | (1.7) | (1.7) |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, | 1.9 | 1.7 | 3.9 | 2.9 | 3.3 | 2.7 | 2.9 |
| nary care clinics where more than one disease may be addressed in a visit). | (1.4) | (.9) | (1.4) | (1.6) | (1.6) | (1.7) | (1.7) |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, | 2.3 | 2.2 | 4.3 | 3.6 | 3.9 | 3.4 | 3.5 |
| asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | (1.5) | (1.1) | (1.1) | (1.5) | (1.4) | (1.6) | (1.6) |
| 1.25 Provide wellness and preventive programs for individual patients (for example, | 2.1 | 2.0 | 2.6 | 2.2 | 2.6 | 2.2 | 2.3 |
| weight management program, tobacco cessation program, immunization program). | (1.3) | (1.2) | (1.4) | (1.4) | (1.5) | (1.4) | (1.4) |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend | 4.6 | 4.4 | 3.9 | 3.7 | 4.0 | 3.8 | 4.0 |
| treatment options. | (.8) | (.9) | (1.2) | (1.2) | (1.2) | (1.3) | (1.2) |
| 1.27 Make recommendations to manage drug therapy which may include initiation, | 3.6 | 3.4 | 4.5 | 4.3 | 4.4 | 4.1 | 4.2 |
| modification, or discontinuation of medication therapy as appropriate. | (1.3) | (1.1) | (.9) | (1.0) | (1.0) | (1.3) | (1.1) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for | 4.0 | 3.8 | 3.5 | 3.1 | 3.8 | 3.2 | 3.6 |
| example, blood glucose meters, peak flow meters, blood pressure monitors). | (1.0) | (1.0) | (1.3) | (1.3) | (1.3) | (1.5) | (1.3) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for | 3.6 | 3.6 | 3.1 | 2.8 | 3.3 | 2.5 | 3.1 |
| example, blood glucose meters, peak flow meters, blood pressure monitors). | (1.2) | (.9) | (1.3) | (1.4) | (1.2) | (1.5) | (1.3) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.30 Recommend appropriate health-related screening tests (for example, home | 3.0 | 2.7 | 2.2 | 2.1 | 2.4 | 2.4 | 2.4 |
| pregnancy tests, hemoccult tests) | (1.2) | (1.1) | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, | 2.8 | 2.5 | 1.7 | 1.7 | 2.1 | 2.0 | 2.1 |
| home pregnancy tests, hemoccult tests). | (1.3) | (1.2) | (1.0) | (1.1) | (1.1) | (1.3) | (1.2) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare | 2.5 | 2.3 | 4.3 | 3.9 | 4.3 | 3.7 | 3.7 |
| providers. | (1.5) | (1.0) | (1.1) | (1.3) | (1.0) | (1.5) | (1.5) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance | 3.8 | 3.6 | 2.6 | 3.2 | 3.8 | 3.5 | 3.3 |
| coverage, out of pocket expenses). | (1.5) | (1.6) | (1.6) | (1.6) | (1.4) | (1.7) | (1.6) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or | 4.0 | 3.9 | 4.2 | 4.0 | 4.3 | 3.9 | 4.1 |
| designing a drug treatment plan. | (1.4) | (1.0) | (1.2) | (1.1) | (1.1) | (1.4) | (1.2) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified | 2.9 | 2.9 | 4.4 | 3.9 | 4.4 | 3.9 | 3.9 |
| drug-related problems to improve patient outcomes. | (1.5) | (1.2) | (1.1) | (1.3) | (1.0) | (1.4) | (1.4) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified | 2.9 | 2.6 | 4.3 | 3.9 | 4.4 | 3.8 | 3.8 |
| drug-related problems to improve patient outcomes. | (1.5) | (1.2) | (1.2) | (1.4) | (1.0) | (1.4) | (1.4) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response | 2.6 | 2.1 | 4.4 | 3.9 | 4.4 | 3.6 | 3.7 |
| to both drug and non-drug therapy and assure safety. | (1.4) | (1.1) | (1.2) | (1.3) | (1.0) | (1.5) | (1.5) |
| 1.38 Communicate patient-specific findings and treatment recommendations to other | 3.1 | 2.7 | 4.5 | 4.3 | 4.4 | 4.0 | 4.0 |
| healthcare professionals involved in the care of the patient. | (1.4) | (1.2) | (1.0) | (1.1) | (1.0) | (1.4) | (1.3) |
| 1.39 Communicate patient-specific findings and treatment recommendations to the | 3.6 | 3.2 | 4.5 | 4.1 | 4.4 | 3.6 | 4.0 |
| patient/caregiver in language they can understand (includes both written and verbal communication). | (1.4) | (1.4) | (1.0) | (1.2) | (1.0) | (1.5) | (1.3) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug | 2.3 | 2.0 | 4.2 | 3.7 | 3.9 | 2.9 | 3.4 |
| herapy and assure safety. | (1.4) | (.9) | (1.2) | (1.5) | (1.3) | (1.6) | (1.6) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver | 1.9 | 1.8 | 4.5 | 4.2 | 4.3 | 3.6 | 3.6 |
| function tests, cholesterol results) and other diagnostic results (for example, ECHO results, bulmonary function tests) to determine if and when adjustments to dru | (1.2) | (1.1) | (1.0) | (1.2) | (1.1) | (1.5) | (1.6) |
| .42 Modify patient-specific treatment plan based on follow up assessment. | 2.1 | 1.9 | 4.4 | 3.9 | 4.2 | 3.7 | 3.6 |
| | (1.4) | (1.1) | (1.1) | (1.4) | (1.1) | (1.4) | (1.6) |
| .43 Determine patient-specific reasons for lack of adherence to recommended treatment | 2.9 | 2.6 | 4.3 | 3.7 | 4.3 | 3.6 | 3.7 |
| in collaboration with the patient develop a plan for improving adherence to therapy. | (1.4) | (1.5) | (1.1) | (1.2) | (1.0) | (1.4) | (1.4) |
| .44 Document all patient care activities (for example, patient-specific findings, detailed | 2.5 | 2.6 | 4.6 | 4.1 | 4.3 | 3.7 | 3.8 |
| reatment recommendations and communications with patient and other healthcare providers). | (1.5) | (1.5) | (1.0) | (1.4) | (1.2) | (1.6) | (1.5) |
| Practice Management | | | | | | | |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care | 2.4 | 2.4 | 2.7 | 2.8 | 2.8 | 2.7 | 2.6 |
| needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (1.5) | (1.3) | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs | 2.0 | 2.2 | 2.1 | 2.3 | 2.2 | 2.1 | 2.1 |
| and/or business potential (for example, Medication Therapy Management, focused or ntegrated disease-state management programs/clinics). | (1.4) | (1.2) | (.9) | (1.3) | (1.0) | (1.2) | (1.1) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care | 2.1 | 2.5 | 2.9 | 3.0 | 2.7 | 2.6 | 2.7 |
| providers. | (1.5) | (1.4) | (1.3) | (1.5) | (1.3) | (1.6) | (1.4) |
| 2.4 Promote and market patient care services to patients and health care providers. | 2.4 | 2.5 | 2.6 | 2.5 | 2.5 | 2.5 | 2.5 |
| | (1.5) | (1.4) | (1.3) | (1.3) | (1.4) | (1.4) | (1.4) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 2.5 Establish and maintain a system for patient referral. | 2.0 | 1.9 | 3.3 | 2.7 | 2.8 | 2.6 | 2.7 |
| | (1.4) | (1.3) | (1.5) | (1.5) | (1.5) | (1.7) | (1.6) |
| 2.6 Establish and maintain a system for patient follow up. | 2.1 | 2.0 | 3.7 | 3.3 | 3.3 | 3.1 | 3.1 |
| | (1.4) | (1.4) | (1.4) | (1.5) | (1.6) | (1.6) | (1.6) |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of | 2.8 | 2.1 | 2.6 | 2.9 | 2.8 | 2.8 | 2.7 |
| cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | (1.6) | (1.3) | (1.1) | (1.3) | (1.2) | (1.4) | (1.3) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or | 2.5 | 2.1 | 2.5 | 2.7 | 2.6 | 2.6 | 2.5 |
| expand ambulatory care pharmacy services. | (1.6) | (1.3) | (1.2) | (1.4) | (1.1) | (1.4) | (1.3) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 2.7 | 2.6 | 4.5 | 4.3 | 4.5 | 3.9 | 3.9 |
| | (1.6) | (1.5) | (1.0) | (1.2) | (.9) | (1.5) | (1.5) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for | 2.8 | 3.1 | 3.1 | 3.0 | 3.1 | 2.9 | 3.0 |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | (1.6) | (1.5) | (1.4) | (1.4) | (1.4) | (1.5) | (1.5) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of | 2.9 | 2.5 | 3.5 | 3.2 | 3.0 | 3.0 | 3.1 |
| care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | (1.7) | (1.6) | (1.3) | (1.5) | (1.3) | (1.6) | (1.5) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash | 2.9 | 3.2 | 1.5 | 2.3 | 1.7 | 2.3 | 2.1 |
| payment systems, insurance contracting, accounting systems, pricing, expense analysis). | (1.7) | (1.8) | (1.0) | (1.5) | (1.1) | (1.5) | (1.5) |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 1.9 | 2.3 | 1.5 | 2.0 | 1.7 | 2.1 | 1.8 |
| | (1.3) | (1.4) | (1.0) | (1.4) | (1.0) | (1.4) | (1.2) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the | 2.2 | 2.1 | 2.5 | 2.4 | 2.2 | 2.4 | 2.3 |
| provider and/or institution, and in accordance with legal and regulatory requirements. | (1.4) | (1.3) | (1.2) | (1.3) | (1.0) | (1.5) | (1.3) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted | 2.6 | 2.5 | 2.6 | 2.6 | 2.4 | 2.6 | 2.6 |
| guidelines and standards of practice. | (1.6) | (1.5) | (1.3) | (1.3) | (1.0) | (1.4) | (1.3) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for | 2.3 | 2.3 | 1.9 | 2.4 | 2.0 | 2.0 | 2.1 |
| example, OSHA, CLIA). | (1.6) | (1.4) | (1.4) | (1.7) | (1.4) | (1.5) | (1.5) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, | 2.4 | 3.3 | 1.4 | 2.1 | 1.6 | 2.3 | 2.0 |
| special order drugs, patient assistance programs). | (1.7) | (1.6) | (.9) | (1.5) | (1.1) | (1.4) | (1.4) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 4.5 | 4.7 | 2.8 | 3.3 | 2.2 | 3.8 | 3.4 |
| | (1.1) | (.8) | (1.7) | (1.7) | (1.6) | (1.6) | (1.7) |
| 2.19 Participate in formulary management (for example, participate on P&T committee, | 1.9 | 2.2 | 2.7 | 2.6 | 1.9 | 2.6 | 2.4 |
| develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | (1.3) | (1.5) | (1.3) | (1.3) | (1.0) | (1.4) | (1.3) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible | 3.2 | 3.0 | 2.6 | 3.0 | 2.8 | 3.1 | 2.9 |
| intervention measures. | (1.5) | (1.3) | (1.2) | (1.3) | (1.3) | (1.4) | (1.3) |
| Public Health | | | | | | | |
| 3.1 Provide general information to the public regarding preventive health issues (for | 3.3 | 3.2 | 2.4 | 2.6 | 2.6 | 2.4 | 2.7 |
| example, cardiovascular disease, tobacco cessation, immunizations). | (1.3) | (1.3) | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to | 2.5 | 2.3 | 2.6 | 2.7 | 2.7 | 2.8 | 2.6 |
| design intervention strategies that address preventive health issues. | (1.5) | (1.1) | (1.3) | (1.3) | (1.3) | (1.4) | (1.4) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, | 2.7 | 3.0 | 2.1 | 2.2 | 2.3 | 2.4 | 2.4 |
| organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | (1.3) | (1.2) | (1.0) | (1.2) | (1.2) | (1.2) | (1.2) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 3.4 Participate in community health screening programs. | 2.3 | 2.0 | 1.7 | 1.7 | 2.0 | 1.9 | 1.9 |
| | (1.2) | (.8) | (.7) | (.8) | (.8) | (1.1) | (.9) |
| 3.5 Serve as a public advocate regarding preventive health issues. | 2.6 | 2.4 | 1.9 | 1.8 | 2.3 | 2.0 | 2.1 |
| | (1.5) | (1.4) | (1.1) | (1.1) | (1.1) | (1.2) | (1.2) |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy | 2.3 | 2.2 | 1.9 | 2.2 | 2.2 | 2.2 | 2.1 |
| practice. | (1.4) | (1.3) | (1.1) | (1.3) | (1.1) | (1.3) | (1.2) |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious | 1.8 | 1.9 | 1.4 | 1.6 | 1.5 | 1.7 | 1.6 |
| diseases). | (1.2) | (1.1) | (.6) | (1.1) | (.8) | (1.1) | (1.0) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 1.8 | 1.7 | 1.4 | 1.5 | 1.5 | 1.7 | 1.6 |
| | (1.2) | (1.1) | (.6) | (.9) | (.8) | (1.1) | (.9) |
| 3.9 Participate in disaster response preparation and planning. | 1.6 | 1.8 | 1.4 | 1.6 | 1.5 | 1.7 | 1.6 |
| | (1.0) | (.9) | (.7) | (.9) | (.7) | (.9) | (.8) |
| Medical Informatics and Professional Development | | | | | | | |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy | 3.4 | 3.0 | 3.9 | 3.6 | 3.8 | 3.7 | 3.7 |
| practice. | (1.2) | (1.2) | (.9) | (1.1) | (1.1) | (1.1) | (1.1) |
| 4.2 Practice ongoing self-managed continuing professional development (for example, | 3.6 | 3.4 | 3.6 | 3.5 | 3.8 | 3.6 | 3.6 |
| continuing education programs, practice self-evaluation, attend study or journal clubs). | (1.0) | (.8) | (.7) | (1.0) | (1.0) | (.9) | (.9) |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, | 2.6 | 2.1 | 3.5 | 3.3 | 3.7 | 3.2 | 3.2 |
| statistical analysis, and significance and applicability of reported data and conclusions. | (1.2) | (1.1) | (.9) | (1.1) | (1.0) | (1.1) | (1.2) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 4.3 | 4.4 | 4.3 | 4.4 | 4.1 | 4.3 | 4.3 |
| | (.9) | (.8) | (.9) | (.9) | (1.1) | (.9) | (.9) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and | 2.7 | 2.7 | 3.8 | 3.8 | 4.0 | 3.7 | 3.5 |
| sidents in the principles and practice of evidence-based medicine. | (1.4) | (1.3) | (1.2) | (1.2) | (1.1) | (1.3) | (1.3) |
| 4.6 Provide health and medication-related education to healthcare professionals. | 2.9 | 3.3 | 3.7 | 3.7 | 4.0 | 3.9 | 3.6 |
| | (1.4) | (1.1) | (1.1) | (1.2) | (1.0) | (1.0) | (1.2) |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care | 2.7 | 2.6 | 3.8 | 3.6 | 4.0 | 3.2 | 3.4 |
| pharmacy practice. | (1.4) | (1.4) | (1.4) | (1.5) | (1.2) | (1.6) | (1.5) |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge | 1.7 | 1.3 | 2.1 | 2.1 | 2.9 | 1.9 | 2.1 |
| applicable to ambulatory care pharmacy practice | (1.2) | (.6) | (1.1) | (1.3) | (1.4) | (1.3) | (1.3) |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, | 1.5 | 1.3 | 1.8 | 1.9 | 2.3 | 1.8 | 1.8 |
| abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | (1.0) | (.7) | (.7) | (1.1) | (1.0) | (1.2) | (1.0) |
| 4.10 Document and report adverse drug-related events as appropriate (for example, | 2.3 | 2.1 | 2.4 | 2.6 | 2.6 | 2.4 | 2.4 |
| adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | (1.3) | (1.0) | (1.0) | (1.2) | (1.2) | (1.2) | (1.2) |
| 4.11 Participate in local, state, and/or national professional organizations. | 2.8 | 3.0 | 2.7 | 2.8 | 3.1 | 2.9 | 2.9 |
| | (1.3) | (1.0) | (1.0) | (1.2) | (1.0) | (1.2) | (1.1) |
| 4.12 Provide ongoing staff training and development, and opportunities/support for | 2.9 | 2.3 | 2.5 | 2.6 | 2.6 | 2.8 | 2.6 |
| credentialing and continuing education. | (1.5) | (1.0) | (1.1) | (1.1) | (1.0) | (1.3) | (1.2) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|--------------|-------------------------|--------------|--------------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Patient Advocacy | | | | | | | |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 3.6 (1.4) | 3.5 (1.1) | 4.1 (1.2) | 3.8 (1.1) | 4.0 (1.1) | 4.0 (1.3) | 3.9 (1.2) |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 3.1 | 2.9 | 2.2 | 3.0 | 2.8 | 2.7 | 2.7 |
| | (1.4) | (1.4) | (1.3) | (1.2) | (1.4) | (1.5) | (1.4) |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal | 3.6 | 4.0 | 2.2 | 2.5 | 2.9 | 2.9 | 2.9 |
| prescription drug coverage and facilitate best outcomes. | (1.4) | (1.3) | (1.4) | (1.4) | (1.5) | (1.4) | (1.5) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.9 | 4.2 | 3.5 | 3.2 | 3.0 | 3.2 | 3.5 |
| | (1.5) | (1.2) | (1.4) | (1.3) | (1.5) | (1.5) | (1.5) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care | 2.9 | 3.2 | 2.9 | 3.2 | 3.1 | 2.7 | 3.0 |
| (for example, transition from acute to ambulatory care setting). | (1.5) | (1.3) | (1.3) | (1.2) | (1.5) | (1.5) | (1.4) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an | 3.6 | 3.5 | 4.0 | 3.7 | 4.0 | 3.3 | 3.7 |
| up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | (1.3) | (1.3) | (1.2) | (1.1) | (1.2) | (1.5) | (1.3) |
| 5.7 Establish a system for two-way communication between the pharmacist and the | 3.4 | 3.4 | 4.1 | 3.6 | 3.8 | 3.4 | 3.7 |
| patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | (1.6) | (1.4) | (1.3) | (1.4) | (1.4) | (1.5) | (1.4) |
| 5.8 Collaborate with other healthcare professionals to provide case management (for | 2.5 | 2.5 | 3.9 | 3.5 | 3.7 | 3.4 | 3.4 |
| example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | (1.5) | (1.3) | (1.2) | (1.4) | (1.2) | (1.4) | (1.4) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care | 2.8 | 2.4 | 3.5 | 2.8 | 3.4 | 3.0 | 3.1 |
| pharmacist. | (1.6) | (1.2) | (1.3) | (1.2) | (1.3) | (1.4) | (1.4) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 2.8 | 2.4 | 2.6 | 2.5 | 2.8 | 2.9 | 2.7 |
| | (1.5) | (1.4) | (1.2) | (1.4) | (1.3) | (1.5) | (1.4) |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to | 2.5 | 2.5 | 3.1 | 3.0 | 3.3 | 3.0 | 2.9 |
| optimize care for the patient | (1.5) | (1.4) | (1.1) | (1.3) | (1.3) | (1.4) | (1.3) |
| 5.12 Encourage patients to openly communicate health and medication related concerns | 3.8 | 4.0 | 3.9 | 4.0 | 4.1 | 3.5 | 3.9 |
| with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | (1.3) | (1.2) | (1.2) | (1.1) | (1.2) | (1.4) | (1.2) |

Appendix 8. Task Importance Ratings by Work Setting

| · · · · · · · · · · · · · · · · · · · | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|--|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Direct Patient Care | | | | | | | |
| 1 Establish a caregiver relationship with the patient that fosters trust and open | 3.8 | 3.8 | 3.9 | 3.7 | 3.9 | 3.8 | 3.8 |
| ommunication, and encourages patient self-management. | (.4) | (.5) | (.3) | (.6) | (.3) | (.5) | (.4) |
| .2 Interview patient/caregiver to obtain information relevant to the patient's care (for | 3.7 | 3.7 | 3.9 | 3.8 | 3.9 | 3.7 | 3.8 |
| xample, chief complaint, history of present illness). | (.5) | (.5) | (.4) | (.6) | (.3) | (.5) | (.5) |
| 3 Obtain the patient's medication history, including over the counter (OTC) medications, rescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | 3.8 | 3.7 | 3.9 | 3.9 | 3.9 | 3.8 | 3.9 |
| | (.4) | (.5) | (.4) | (.5) | (.3) | (.5) | (.4) |
| 4 Reconcile medications based on information obtained from patient/caregiver interview | 3.7 | 3.5 | 3.8 | 3.8 | 3.7 | 3.7 | 3.7 |
| atient's healthcare provider(s), patient's documented medication profiles, and medical ecords. | (.5) | (.6) | (.5) | (.5) | (.6) | (.5) | (.5) |
| .5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, | 3.4 | 3.2 | 3.6 | 3.6 | 3.6 | 3.7 (.5) 3.8 (.5) 3.7 (.5) 3.7 (.5) 3.7 (.5) 3.7 (.5) 3.7 (.5) 3.5 (.7) 2.9 (.9) 2.8 (1.1) | 3.5 |
| ubstances of abuse, diagnostic test results). | (.7) | (.7) | (.6) | (.6) | (.5) | | (.6) |
| .6 Perform pertinent physical assessments as they relate to patient's current condition | 3.1 | 2.7 | 3.3 | 3.3 | 3.2 | 2.9 | 3.1 |
| nd/or therapies (for example, vital signs, weight, palpation, auscultation, visual spection). | (.8) | (.8) | (.8) | (.8) | (.7) | (.9) | (.8) |
| .7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone | 3.2 | 3.0 | 3.0 | 3.1 | 3.1 | 2.8 | 3.0 |
| nineral density, peak flow). | (.8) | (.7) | (.9) | (1.0) | (.8) | (1.1) | (.9) |
| .8 Determine patient's willingness to work with an ambulatory care pharmacy specialist | 3.3 | 3.0 | 3.5 | 3.3 | 3.4 | 3.1 | 3.3 |
| n health and medication-related issues. | (.8) | (.9) | (.7) | (.9) | (.7) | (.9) | (.8) |
| .9 Assess patient's self-management knowledge, understanding, skills, and willingness | 3.7 | 3.3 | 3.8 | 3.6 | 3.8 | 3.6 | 3.7 |
| nd ability to actively participate in his/her own care. | (.6) | (.7) | (.5) | (.8) | (.4) | (.7) | (.6) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant | 3.7 | 3.5 | 3.9 | 3.9 | 3.9 | 3.7 | 3.8 |
| disease states, other medication, and other patient specific factors. | (.5) | (.7) | (.3) | (.4) | (.4) | (.6) | (.5) |
| .11 Assess the available information to identify drug related problems (for example, no | 3.8 | 3.6 | 3.9 | 3.9 | 4.0 | 3.8 | 3.9 |
| Irug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | (.5) | (.7) | (.4) | (.3) | (.2) | (.6) | (.4) |
| .12 Assess the information gathered to identify non-drug factors that may affect patient | 3.5 | 3.1 | 3.6 | 3.5 | 3.6 | 3.5 | 3.5 |
| omes (for example, tobacco, activity level, nutrition). | (.7) | (.7) | (.5) | (.7) | (.5) | (.7) | (.6) |
| .13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.6 | 3.1 | 3.6 | 3.5 | 3.6 | 3.4 | 3.5 |
| bulatory care pharmacy specialist. | (.7) | (.8) | (.6) | (.6) | (.6) | (.7) | (.7) |
| Recognize patient-specific barriers to successful drug therapy (for example, social | 3.5 | 3.3 | 3.7 | 3.6 | 3.7 | 3.6 | 3.6 |
| ituations, patient denial, literacy, mental capacity, culture, language) and implement a lan to overcome these (for example, home visits, interpreter, picture-based | (.6) | (8.) | (.6) | (.7) | (.6) | (.7) | (.6) |
| .15 Provide drug-related patient education/counseling (for example, purpose of | 3.9 | 3.8 | 3.9 | 3.9 | 3.9 | 3.8 | 3.9 |
| nedication, proper administration, directions for use, foods or drugs to avoid while taking he medication, potential side effects and when to report problems). | (.4) | (.5) | (.4) | (.3) | (.3) | (.5) | (.4) |
| .16 Evaluate the patient's administration technique for medications that are not | 3.7 | 3.7 | 3.6 | 3.6 | 3.8 | 3.5 | 3.6 |
| dministered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, ubcutaneous injections). | (.5) | (.5) | (.6) | (.6) | (.5) | (.7) | (.6) |
| .17 Provide disease-related patient education/counseling (for example, diabetes, asthma, | 3.7 | 3.6 | 3.8 | 3.9 | 3.8 | 3.6 | 3.8 |
| ypertension, dyslipidemia). | (.6) | (.6) | (.4) | (.3) | (.4) | (.6) | (.5) |
| .18 Provide wellness and prevention education/counseling (for example, lifestyle | 3.5 | 3.3 | 3.5 | 3.4 | 3.6 | 3.4 | 3.5 |
| nodifications, immunizations). | (.7) | (.7) | (.6) | (.7) | (.6) | (.7) | (.7) |
| .19 Recommend appropriate immunizations to specific patients. | 3.2 | 2.9 | 3.2 | 3.2 | 3.4 | 3.0 | 3.2 |
| | (.9) | (1.0) | (.7) | (.8) | (.6) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.20 Administer appropriate immunizations to specific patients. | 3.0 | 2.7 | 2.6 | 2.8 | 2.7 | 2.6 | 2.7 |
| | (1.0) | (1.1) | (.9) | (1.0) | (1.0) | (1.0) | (1.0) |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary | 3.7 | 3.4 | 3.6 | 3.7 | 3.7 | 3.6 | 3.6 |
| supplements, vitamins, non-prescription drugs). | (.5) | (.8) | (.6) | (.5) | (.6) | (.7) | (.6) |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative | 3.3 | 3.2 | 3.8 | 3.9 | 3.8 | 3.5 | 3.6 |
| greements with healthcare providers. | (.9) | (1.0) | (.5) | (.3) | (.5) | (.8) | (.7) |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, | 3.2 | 2.9 | 3.7 | 3.6 | 3.6 | 3.4 | 3.5 |
| imary care clinics where more than one disease may be addressed in a visit). | (.8) | (.8) | (.6) | (.6) | (.6) | (.8) | (.8) |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, | 3.4 | 3.3 | 3.8 | 3.7 | 3.7 | 3.6 | 3.6 |
| asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | (.7) | (.7) | (.5) | (.5) | (.5) | (.7) | (.6) |
| 1.25 Provide wellness and preventive programs for individual patients (for example, | 3.3 | 3.2 | 3.3 | 3.3 | 3.4 | 3.2 | 3.3 |
| weight management program, tobacco cessation program, immunization program). | (.8) | (.8) | (.7) | (.8) | (.8) | (.9) | (.8) |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend | 3.8 | 3.5 | 3.6 | 3.5 | 3.5 | 3.5 | 3.6 |
| treatment options. | (.4) | (.6) | (.6) | (.6) | (.6) | (.7) | (.6) |
| 1.27 Make recommendations to manage drug therapy which may include initiation, | 3.6 | 3.5 | 3.9 | 3.8 | 3.9 | 3.7 | 3.8 |
| modification, or discontinuation of medication therapy as appropriate. | (.5) | (.6) | (.4) | (.5) | (.3) | (.7) | (.5) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for | 3.7 | 3.4 | 3.5 | 3.3 | 3.6 | 3.5 | 3.5 |
| example, blood glucose meters, peak flow meters, blood pressure monitors). | (.6) | (.6) | (.6) | (.7) | (.6) | (.8) | (.7) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for | 3.6 | 3.5 | 3.4 | 3.3 | 3.5 | 3.2 | 3.4 |
| example, blood glucose meters, peak flow meters, blood pressure monitors). | (.6) | (.6) | (.7) | (.8) | (.7) | (.9) | (.7) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|--|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.30 Recommend appropriate health-related screening tests (for example, home | 3.2 | 3.0 | 2.8 | 3.0 | 3.0 | 3.0 | 3.0 |
| pregnancy tests, hemoccult tests) | (.7) | (.7) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, | 3.3 | 2.9 | 2.6 | 2.9 | 2.9 | 3.0 | 2.9 |
| home pregnancy tests, hemoccult tests). | (.8) | (.7) | (.9) | (.8) | (.9) | (.9) | (.9) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare | 3.3 | 2.9 | 3.8 | 3.7 | 3.8 | 3.0 (.9) 3.0 | 3.6 |
| providers. | (.8) | (1.0) | (.5) | (.6) | (.5) | (.8) | (.7) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance | 3.4 | 3.2 | 3.0 | 3.2 | 3.5 | 3.4 | 3.3 |
| overage, out of pocket expenses). | (.8) | (1.0) | (1.0) | (.9) | (.6) | (.9) | (.9) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or | 3.6 | 3.6 | 3.6 | 3.7 | 3.7 | 3.6 | 3.6 |
| designing a drug treatment plan. | (.6) | (.6) | (.7) | (.6) | (.5) | (.8) | (.6) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified | 3.6 | 3.4 | 3.8 | 3.7 | 3.8 | 3.8 | 3.7 |
| drug-related problems to improve patient outcomes. | (.6) | (.7) | (.4) | (.5) | (.5) | 3.0 (.9) 3.0 (.9) 3.5 (.8) 3.4 (.9) 3.6 (.8) 3.8 (.5) 3.7 (.6) 3.6 (.9) 3.6 (.9) 3.6 (.9) 3.6 (.9) 3.6 (.8) 3.6 (.8) 3.6 | (.5) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified | 3.5 | 3.2 | 3.8 | 3.7 | 3.8 | 3.7 | 3.7 |
| drug-related problems to improve patient outcomes. | (.7) | (.7) | (.4) | (.6) | (.5) | (.6) | (.6) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response | 3.4 | 3.2 | 3.9 | 3.7 | 3.7 | 3.6 | 3.6 |
| to both drug and non-drug therapy and assure safety. | (.7) | (.8) | (.4) | (.6) | (.5) | (.9) | (.7) |
| 1.38 Communicate patient-specific findings and treatment recommendations to other | 3.6 | 3.4 | 3.9 | 3.9 | 3.9 | 3.6 | 3.8 |
| healthcare professionals involved in the care of the patient. | (.6) | (.7) | (.3) | (.3) | (.4) | (.8) | (.5) |
| 1.39 Communicate patient-specific findings and treatment recommendations to the | 3.6 | 3.5 | 3.9 | 3.7 | 3.9 | 3.6 | 3.7 |
| patient/caregiver in language they can understand (includes both written and verbal communication). | (.6) | (.6) | (.3) | (.6) | (.4) | (.8) | (.6) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug | 3.3 | 3.0 | 3.8 | 3.6 | 3.7 | 3.3 | 3.5 |
| therapy and assure safety. | (.7) | (.8) | (.5) | (.6) | (.4) | (1.0) | (.7) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver | 3.3 | 3.1 | 3.8 | 3.8 | 3.8 | 3.5 | 3.6 |
| function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | (.8) | (.9) | (.4) | (.5) | (.4) | (.8) | (.7) |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 3.3 | 2.9 | 3.9 | 3.7 | 3.9 | 3.6 | 3.6 |
| | (.8) | (.9) | (.4) | (.5) | (.4) | (.7) | (.7) |
| ¹³ Determine patient-specific reasons for lack of adherence to recommended treatment d in collaboration with the patient develop a plan for improving adherence to therapy. | 3.5 | 3.3 | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (.7) | (.8) | (.4) | (.6) | (.4) | (.7) | (.6) |
| .44 Document all patient care activities (for example, patient-specific findings, detailed | 3.4 | 3.2 | 3.9 | 3.8 | 3.9 | 3.5 | 3.7 |
| reatment recommendations and communications with patient and other healthcare providers). | (.8) | (.9) | (.3) | (.6) | (.4) | (.8) | (.7) |
| Practice Management | | | | | | | |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care | 3.4 | 3.1 | 3.5 | 3.5 | 3.5 | 3.3 | 3.4 |
| needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (.8) | (.9) | (.7) | (.6) | (.7) | (.8) | (.8) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs | 3.3 | 3.1 | 3.4 | 3.6 | 3.5 | 3.2 | 3.4 |
| and/or business potential (for example, Medication Therapy Management, focused or ntegrated disease-state management programs/clinics). | (.8) | (1.0) | (.6) | (.7) | (.7) | (.9) | (.8) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care | 3.5 | 3.3 | 3.7 | 3.8 | 3.7 | 3.5 | 3.6 |
| providers. | (.7) | (.9) | (.5) | (.4) | (.5) | (.8) | (.6) |
| 2.4 Promote and market patient care services to patients and health care providers. | 3.4 | 3.2 | 3.4 | 3.5 | 3.4 | 3.2 | 3.4 |
| | (.8) | (.9) | (.7) | (.7) | (.8) | (1.0) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 2.5 Establish and maintain a system for patient referral. | 3.3 | 2.8 | 3.5 | 3.4 | 3.4 | 3.2 | 3.3 |
| | (.8) | (1.1) | (.7) | (.8) | (.8) | (1.0) | (.9) |
| 2.6 Establish and maintain a system for patient follow up. | 3.4 | 3.1 | 3.7 | 3.6 | 3.5 | 3.3 | 3.5 |
| | (.8) | (.9) | (.6) | (.7) | (.6) | (.9) | (.7) |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of | 3.5 | 3.1 | 3.4 | 3.6 | 3.5 | 3.4 | 3.4 |
| cost-effective care (for example, medication use evaluation, ADR reporting, incident repor evaluation). | (.7) | (.9) | (.6) | (.5) | (.6) | (.7) | (.7) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or | 3.4 | 3.0 | 3.4 | 3.5 | 3.4 | 3.4 | 3.4 |
| expand ambulatory care pharmacy services. | (.8) | (.9) | (.6) | (.7) | (.7) | (.9) | (.7) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 3.6 | 3.2 | 3.9 | 3.8 | 3.9 | 3.7 | 3.7 |
| | (.7) | (1.0) | (.4) | (.5) | (.4) | (.7) | (.6) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for | 3.5 | 3.3 | 3.3 | 3.5 | 3.5 | 3.3 | 3.4 |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | (.8) | (.9) | (.8) | (.7) | (.7) | (.9) | (.8) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of | 3.6 | 3.1 | 3.5 | 3.5 | 3.3 | 3.3 | 3.4 |
| care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | (.7) | (.9) | (.6) | (.6) | (.8) | (.9) | (.7) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash | 3.5 | 3.3 | 3.0 | 3.4 | 3.2 | 3.3 | 3.2 |
| payment systems, insurance contracting, accounting systems, pricing, expense analysis). | (.7) | (.8) | (.9) | (.8) | (.9) | (.9) | (.9) |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 3.4 | 3.3 | 3.4 | 3.5 | 3.4 | 3.2 | 3.4 |
| | (.8) | (.8) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the | 3.4 | 3.0 | 3.6 | 3.6 | 3.6 | 3.3 | 3.5 |
| provider and/or institution, and in accordance with legal and regulatory requirements. | (.7) | (.9) | (.6) | (.7) | (.6) | (.9) | (.7) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|--|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted | 3.5 | 3.2 | 3.6 | 3.6 | 3.5 | 3.5 | 3.5 |
| guidelines and standards of practice. | (.8) | (1.0) | (.6) | (.5) | (.7) | (.8) | (.7) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for | 3.4 | 3.0 | 3.0 | 3.2 | 3.2 | 3.1 | 3.2 |
| example, OSHA, CLIA). | (.9) | (.9) | (.9) | (1.0) | (.9) | (.9) | (.9) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, | 3.2 | 3.2 | 2.7 | 3.2 | 2.8 | 9) (.9) .8 3.1 .0) (.9) .3 3.7 .0) (.6) .2 3.4 | 3.0 |
| special order drugs, patient assistance programs). | (.9) | (.9) | (.9) | (.9) | (1.0) | (.9) | (.9) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 3.8 | 3.7 | 3.3 | 3.4 | 3.3 | 3.7 | 3.5 |
| | (.5) | (.5) | (.9) | (.8) | (1.0) | (.6) | (.8) |
| Participate in formulary management (for example, participate on P&T committee, | 3.3 | 2.7 | 3.4 | 3.5 | 3.2 | 3.4 | 3.3 |
| develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | (.8) | (1.0) | (.7) | (.8) | (.8) | (.9) | (.8) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible | 3.7 | 3.3 | 3.5 | 3.6 | 3.5 | 3.6 | 3.5 |
| intervention measures. | (.6) | (.8) | (.7) | (.6) | (.7) | (.7) | (.7) |
| Public Health | | | | | | | |
| 3.1 Provide general information to the public regarding preventive health issues (for | 3.4 | 3.2 | 3.2 | 3.4 | 3.3 | 3.2 | 3.3 |
| example, cardiovascular disease, tobacco cessation, immunizations). | (.7) | (.8) | (.7) | (.6) | (.7) | (.8) | (.7) |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to | 3.3 | 2.9 | 3.3 | 3.5 | 3.3 | 3.3 | 3.3 |
| design intervention strategies that address preventive health issues. | (.7) | (.8) | (.7) | (.5) | (.8) | (.8) | (.7) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, | 3.2 | 3.0 | 2.8 | 3.2 | 3.1 | 3.0 | 3.0 |
| organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | (.7) | (.8) | (.8) | (.7) | (.7) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 3.4 Participate in community health screening programs. | 3.2 | 2.9 | 2.9 | 3.0 | 3.0 | 2.9 | 3.0 |
| | (.9) | (.8) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 3.5 Serve as a public advocate regarding preventive health issues. | 3.3 | 3.1 | 2.9 | 3.1 | 3.0 | 3.0 | 3.1 |
| | (.8) | (.9) | (.8) | (.9) | (.8) | (.9) | (.8) |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy | 3.3 | 3.0 | 3.2 | 3.3 | 3.3 | 3.3 | 3.2 |
| practice. | (.8) | (.9) | (.7) | (.7) | (.8) | (.9) | (.8) |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious | 3.2 | 3.0 | 2.7 | 3.1 | 2.9 | 3.0 | 2.9 |
| diseases). | (.8) | (.9) | (.9) | (.9) | (.9) | (.9) | (.9) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 3.2 | 2.9 | 2.8 | 3.0 | 3.0 | 3.1 | 3.0 |
| | (.8) | (.9) | (.8) | (.9) | (.9) | (.9) | (.9) |
| 3.9 Participate in disaster response preparation and planning. | 3.1 | 2.9 | 2.8 | 3.1 | 3.0 | 3.1 | 3.0 |
| | (.8) | (.8) | (.9) | (.9) | (.9) | (.9) | (.9) |
| Medical Informatics and Professional Development | | | | | | | |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy | 3.6 | 3.2 | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 |
| practice. | (.7) | (.8) | (.5) | (.5) | (.5) | (.6) | (.6) |
| 4.2 Practice ongoing self-managed continuing professional development (for example, | 3.8 | 3.5 | 3.8 | 3.8 | 3.8 | 3.6 | 3.7 |
| continuing education programs, practice self-evaluation, attend study or journal clubs). | (.5) | (.6) | (.4) | (.4) | (.5) | (.6) | (.5) |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, | 3.2 | 2.7 | 3.6 | 3.6 | 3.7 | 3.5 | 3.4 |
| statistical analysis, and significance and applicability of reported data and conclusions. | (.8) | (.9) | (.6) | (.7) | (.6) | (.7) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 3.7 | 3.6 | 3.8 | 3.9 | 3.7 | 3.7 | 3.7 |
| | (.5) | (.6) | (.4) | (.3) | (.6) | (.5) | (.5) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and | 3.3 | 3.2 | 3.7 | 3.8 | 3.7 | 3.7 | 3.6 |
| residents in the principles and practice of evidence-based medicine. | (.8) | (.8) | (.5) | (.4) | (.5) | (.6) | (.6) |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.4 | 3.3 | 3.7 | 3.7 | 3.8 | 3.8 | 3.6 |
| | (.7) | (.7) | (.5) | (.5) | (.5) | (.5) | (.6) |
| rovide experiential training to pharmacy students and residents in ambulatory care | 3.5 | 3.3 | 3.7 | 3.7 | 3.8 | 3.6 | 3.6 |
| pharmacy practice. | (.7) | (.8) | (.5) | (.5) | (.5) | (.7) | (.6) |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge | 2.9 | 2.5 | 3.0 | 3.2 | 3.3 | 3.1 | 3.0 |
| applicable to ambulatory care pharmacy practice | (.9) | (.9) | (.7) | (.7) | (.7) | (1.0) | (.8) |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, | 2.8 | 2.4 | 3.0 | 3.3 | 3.2 | 2.9 | 3.0 |
| abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | (1.0) | (.9) | (.7) | (.8) | (.7) | (1.0) | (.9) |
| 4.10 Document and report adverse drug-related events as appropriate (for example, | 3.5 | 2.9 | 3.3 | 3.5 | 3.4 | 3.5 | 3.4 |
| adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | (.8) | (.9) | (.7) | (.6) | (.7) | (.8) | (.7) |
| 4.11 Participate in local, state, and/or national professional organizations. | 3.4 | 3.3 | 3.3 | 3.4 | 3.4 | 3.4 | 3.4 |
| | (.7) | (.8) | (.7) | (.7) | (.7) | (.7) | (.7) |
| 4.12 Provide ongoing staff training and development, and opportunities/support for | 3.4 | 3.1 | 3.2 | 3.6 | 3.2 | 3.5 | 3.3 |
| credentialing and continuing education. | (.8) | (.9) | (.7) | (.6) | (.7) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------------|-------------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Patient Advocacy | | | | | | | |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 3.6 (.7) | 3.4 (.7) | 3.6 (.6) | 3.6 (.6) | 3.6 (.6) | 3.6 (.6) | 3.6 (.6) |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 3.4 | 3.0 | 2.9 | 3.3 | 3.2 | 3.1 | 3.1 |
| | (.8) | (.9) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal | 3.3 | 3.0 | 3.0 | 3.2 | 3.2 | 3.2 | 3.1 |
| prescription drug coverage and facilitate best outcomes. | (.8) | (.9) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.5 | 3.0 | 3.3 | 3.5 | 3.3 | 3.3 | 3.3 |
| | (.7) | (.8) | (.7) | (.5) | (.7) | (.8) | (.7) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care | 3.3 | 3.1 | 3.4 | 3.6 | 3.5 | 3.2 | 3.4 |
| (for example, transition from acute to ambulatory care setting). | (.8) | (.9) | (.7) | (.5) | (.7) | (.9) | (.8) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an | 3.6 | 3.5 | 3.7 | 3.7 | 3.7 | 3.5 | 3.6 |
| up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | (.6) | (.6) | (.5) | (.5) | (.5) | (.7) | (.6) |
| 5.7 Establish a system for two-way communication between the pharmacist and the | 3.7 | 3.5 | 3.7 | 3.7 | 3.7 | 3.6 | 3.7 |
| patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | (.6) | (.6) | (.5) | (.4) | (.5) | (.6) | (.5) |
| 5.8 Collaborate with other healthcare professionals to provide case management (for | 3.4 | 3.2 | 3.6 | 3.5 | 3.5 | 3.5 | 3.5 |
| example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | (.7) | (.7) | (.6) | (.7) | (.7) | (.8) | (.7) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care | 3.3 | 3.0 | 3.4 | 3.3 | 3.4 | 3.2 | 3.3 |
| pharmacist. | (.9) | (.9) | (.7) | (.8) | (.6) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 3.3 | 2.9 | 3.2 | 3.3 | 3.2 | 3.3 | 3.2 |
| | (.9) | (.9) | (.7) | (.8) | (.8) | (.8) | (.8) |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to | 3.3 | 2.8 | 3.3 | 3.3 | 3.3 | 3.2 | 3.2 |
| optimize care for the patient | (.9) | (.9) | (.7) | (.7) | (.8) | (.9) | (.8) |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | 3.6 | 3.4 | 3.5 | 3.7 | 3.6 | 3.4 | 3.5 |
| | (.6) | (.8) | (.6) | (.5) | (.7) | (.8) | (.7) |

Appendix 9. Write- In Responses: Tasks Missing from Survey

Tasks Missing From Survey

24 hour ambulatory blood pressure monitoring service - working collaboratively with subspecialists (Cardio) to optimize drug therapy and patient outcomes - serving on and chairing committees (R&D, etc.)

Explaining the patient's drug plan to the patient-copays, deductible, policy, etc. *Managing stafffostering a patient-friendly environment

Advice on: missing a dose, take more than prescribed, poison control questions

Advise new residents about formulary and drug conflicts that they are not aware of (clinic setting)

Analyze patient drug regimes on an emergency basis as part of a Fire Department Rescue team

Answering questions regarding medical treatment, testing, disease states, etc. Many patients tell me their physician won't take the time to explain things, so we try to help. Many times I spend 10-15 minutes trying to help patients understand their medicines & medical problems.

Assess/address health literacy and cultural diversity issues understand and apply patient adherence/compliance models to improve patient compliance (e.g. Health Belief Model, Stages of change, etc.) identify/address general and disease specific health/medication beliefs that impair patient partnership/adherence

Assist/direct with medical emergencies within the clinic... CPR, anaphylaxis....

CareCompanion is a telemonitoring device we use to monitor diabetes and/or hypertension patients. They input blood glucose, blood pressure, and pulse values, which we then evaluate via the internet. We intervene if we start seeing a negative trend. Interventions range from contacting the patient to contacting the physician with a recommendation. I think telemonitoring will play a bigger role in health care as the technology advances.

Collaborate with contracted home infusion agency to ensure appropriate delivery of care and cooperation and communication between the two facilities.

Compounding medication to suit patient desire

Decreasing prescribing variability within our healthcare setting

Develop and implement performance measures and metrics that improve patient outcomes.

Diabetic monofilament exams

Dispensing of prescriptions, which is still the base of our professional practice and must not be undervalued.

Faculty, medical resident, medical student education; group patient education sessions

Getting ambulatory care medications approved by patients' insurance companies by spending hours on the phone and knowing Byzantine codifications.

I am a relief pharmacist so I'm not able to develop a comprehensive practice. I am a trained immunizer, however, and provide them as part of my work.

Tasks Missing From Survey

I check chemo orders and help prepare them along with a tech for an out patient infusion center. Making sure chemo regimens are correct and timely is a major part of my job right now.

I facilitate support groups for HIV infected patients on therapy

I found this survey to be too drug-centric. Effective practitioners think of the patient more holistically and recognize drug therapy as only part of patient care. They also have to recognize when not to use drugs.

I often see newly discharged patients post open heart surgery or from cardiac wards and often see various problems with cardiovascular drugs during the first 1-3 weeks. I work with a cardiology service and detect many of these problems in patients who are being followed for their anticoagulant therapy.

I work in a BMT clinic. Patients' needs are a little different. I provide chemotherapy teaching to patients and family, medication discharge counsel. I write chemotherapy orders, and daily update medication lists

I work primarily with insurance carriers. We are expanding services into a more case management format. These questions will most likely be answered very differently in 6-12 months.

I work primarily with terminally ill hospice patients. I'm strictly a clinical consultant, and am not involved in marketing, 3rd party reimbursement, etc. Hence in many areas I scored myself zero but also think it's very important for the profession.

I work under a scope of practice (rather than protocol) I have prescribing privileges and use them daily I evaluate and approve (or deny) non-formulary medications I contribute written medical CE

Keep current on Information Technology advancements (i.e., electronic patient record)

Legislative advocacy, grant writing, oversight of clinical pharmacy technicians

Much of the business component- inventory management, dealing with vendors, evaluating third party contracts, utilizing co-ops, networks, etc. Effective advertising. You have to know the dollars and numbers to stay in business to do the fun clinical stuff.

Monitor authenticity of prescription, loss prevention

Not only do I review labs for my patients - I also have the authority to request them and do so to facilitate optimal patient care.

Oncology practice, so all oncology related items such as checking chemo protocols, doses, monitoring reactions, etc...

Optimize patient compliance through selection with physician of a cost-effective medication, especially in light of chronic disease states and acute antibiotic therapies.

Participation in institutional efforts and committees to improve medication safety (ambulatory clinic part of academic hospital).

PBM formulary management has come to take more of my time than any other function I perform except for new prescription counseling/education

Tasks Missing From Survey

Perform prior authorizations for medications. Evaluate patients for enrollment into clinical trials

Preparation of chemotherapy treatments

Prescriptive authority in VA system

Provision of product to patient, supervision of staff to ensure appropriate delivery of product

Pursue opportunities to speak with federal, state and local officials about the practice of pharmacy and what it can do to assist in patient care and in research to improve patient care

Recommending drug therapy in certain disease states

Seek funding opportunities to advance ambulatory care pharmacy research

Serve as resource person for physicians acquiring latest information and adverse events. Searching for the newest data relating to cancer diagnosis and treatment. Care plan development on PPO's and EMR system. Developing and start up of satellite facilities.

Staff meetings/managerial functions with ambulatory care clinic staff to maintain and improve functionality of our clinic.

Support refill service staff

Teach patients how to use home tele-health equipment and review their results daily

Telephone calls to insurance companies to work out rx coverage. Faxes, phone call for refills.

The increased requirement of prior-authorizations from insurance companies for drug therapy. Once the phone call is made to the physician to do the PA, we rarely are kept in the loop. Thus necessitating multiple phone calls to follow up with the physician.

Unfortunately a lot of administrative work, such as patient scheduling, visit prep, paperwork.

We are PCP to many of these patients.

We currently have clinics run by ambulatory care pharmacists that include hypertension, cholesterol, and asthma management as well travel immunizations, hepatitis C, congestive heart failure, anticoagulation, and smoking cessation. We have our own DEA numbers and are able to write our own prescriptions under protocol with our medical group physicians for any medications related to the above problems. We have two medical assistants who check in the patients at time of appointment and front desk personnel in charge of making appointments and receiving phone calls. Some of our services are fee for service such as travel and smoking cessation while other services are being billed under incident to billing under the primary care physician.

We often help patients by financing prescriptions while patients get prior authorization from insurance so they can begin treatment immediately when necessary

Appendix 10. Knowledge Frequency Ratings by Work Setting

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Direct Patient Care | | | | | | | |
| 1 Knowledge of anatomy and physiology | 3.9 | 3.9 | 4.1 | 4.2 | 4.1 | 4.1 | 4.1 |
| | (1.1) | (1.0) | (1.0) | (1.0) | (1.0) | (.9) | (1.0) |
| 2 Knowledge of pathophysiology | 4.1 | 4.0 | 4.6 | 4.5 | 4.5 | 4.1 | 4.4 |
| | (1.1) | (1.0) | (.7) | (1.0) | (.7) | (1.1) | (.9) |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their | 3.9 | 3.8 | 4.9 | 4.8 | 4.7 | 4.3 | 4.5 |
| interpretation as they relate to drug therapy | (1.0) | (1.2) | (.3) | (.5) | (.6) | (1.0) | (.9) |
| 4 Knowledge of the clinical assessment process | 3.7 | 3.7 | 4.7 | 4.6 | 4.6 | 4.3 | 4.4 |
| | (1.1) | (1.2) | (.6) | (.7) | (.7) | (1.1) | (.9) |
| 5 Knowledge of physical assessment techniques | 3.6 | 3.2 | 3.8 | 4.0 | 3.8 | 3.6 | 3.7 |
| | (1.2) | (1.2) | (1.1) | (1.0) | (1.1) | (1.3) | (1.2) |
| 6 Knowledge of pharmacology | 4.6 | 4.5 | 4.7 | 4.9 | 4.5 | 4.6 | 4.7 |
| | (.8) | (.7) | (.6) | (.3) | (.8) | (.8) | (.7) |
| 7 Knowledge of pharmacotherapy | 4.8 | 4.8 | 5.0 | 5.0 | 4.8 | 4.7 | 4.9 |
| | (.5) | (.5) | (.2) | (.2) | (.5) | (.7) | (.5) |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 4.2 | 4.2 | 4.7 | 4.8 | 4.6 | 4.3 | 4.5 |
| | (1.1) | (1.1) | (.5) | (.5) | (.7) | (.9) | (.8) |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy | 3.5 | 3.3 | 4.0 | 4.2 | 3.5 | 3.2 | 3.7 |
| management | (1.3) | (1.4) | (1.2) | (1.1) | (1.2) | (1.5) | (1.3) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 10 Knowledge of OTC medications | 4.9 | 4.9 | 4.4 | 4.5 | 4.3 | 4.2 | 4.5 |
| | (.3) | (.4) | (.8) | (.6) | (.8) | (.9) | (.7) |
| 11 Knowledge of the principles of self-care | 4.8 | 4.8 | 4.4 | 4.3 | 4.2 | 4.0 | 4.4 |
| | (.6) | (.5) | (.8) | (.9) | (1.0) | (1.1) | (.9) |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | 4.6 | 4.1 | 4.0 | 4.1 | 3.8 | 3.6 | 4.0 |
| used in complementary and alternative medicine | (.7) | (1.1) | (.8) | (.8) | (.9) | (1.0) | (.9) |
| 13 Knowledge of common immunizations | 3.3 | 3.0 | 3.4 | 3.4 | 3.4 | 3.2 | 3.3 |
| | (1.1) | (1.1) | (1.1) | (1.2) | (1.0) | (1.2) | (1.1) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III | 3.3 | 3.1 | 4.8 | 4.4 | 4.5 | 3.8 | 4.2 |
| guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (1.3) | (1.4) | (.5) | (.9) | (.8) | (1.3) | (1.2) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 3.6 | 3.6 | 4.7 | 4.6 | 4.6 | 4.1 | 4.3 |
| | (1.2) | (1.2) | (.5) | (.6) | (.7) | (1.2) | (1.0) |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 4.2 | 4.1 | 4.4 | 4.2 | 4.1 | 4.0 | 4.2 |
| | (1.0) | (.9) | (.7) | (1.0) | (1.0) | (1.1) | (.9) |
| 17 Knowledge of factors affecting medication and treatment adherence | 4.4 | 4.5 | 4.6 | 4.4 | 4.4 | 4.3 | 4.5 |
| | (.7) | (.8) | (.7) | (.8) | (.9) | (.9) | (.8) |
| 18 Knowledge of effective interventions to address medication and treatment | 4.2 | 4.1 | 4.4 | 4.3 | 4.3 | 4.0 | 4.3 |
| nonadherence | (.9) | (.9) | (.7) | (.9) | (.9) | (1.1) | (.9) |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood | 4.1 | 4.2 | 3.5 | 3.9 | 3.5 | 3.2 | 3.7 |
| glucose, cholesterol, INR) | (1.0) | (.8) | (1.5) | (1.3) | (1.3) | (1.3) | (1.3) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for | 2.7 | 2.9 | 2.5 | 3.2 | 2.6 | 2.5 | 2.7 |
| example, OSHA, CLIA) | (1.4) | (1.4) | (1.3) | (1.4) | (1.3) | (1.2) | (1.3) |
| 21 Knowledge of patient interviewing skills | 4.5 | 4.5 | 4.7 | 4.6 | 4.6 | 4.1 | 4.5 |
| | (.9) | (.8) | (.7) | (.9) | (.9) | (1.2) | (.9) |
| 22 Knowledge of motivational interviewing techniques | 3.9 | 3.6 | 4.2 | 4.1 | 3.8 | 3.4 | 3.9 |
| | (1.2) | (1.3) | (1.0) | (1.0) | (1.2) | (1.5) | (1.2) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in | 4.1 | 3.9 | 4.4 | 4.2 | 4.0 | 3.6 | 4.1 |
| their own care | (1.1) | (1.1) | (.9) | (1.1) | (1.1) | (1.3) | (1.1) |
| 24 Knowledge of how to develop effective collaborative partnerships with individual | 4.0 | 4.0 | 4.4 | 4.1 | 3.9 | 3.5 | 4.1 |
| patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | (1.2) | (1.2) | (.9) | (1.2) | (1.2) | (1.5) | (1.2) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 4.4 | 4.0 | 4.4 | 4.2 | 4.1 | 3.7 | 4.2 |
| | (.9) | (1.0) | (.8) | (1.0) | (1.0) | (1.3) | (1.0) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.7 | 3.5 | 3.7 | 3.9 | 3.5 | 3.4 | 3.6 |
| | (1.2) | (1.2) | (1.1) | (1.0) | (1.1) | (1.3) | (1.1) |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may | 4.2 | 4.0 | 4.0 | 4.1 | 3.5 | 3.8 | 3.9 |
| impact the care of the patient | (1.0) | (1.0) | (1.0) | (1.0) | (1.1) | (1.2) | (1.0) |
| 28 Knowledge of how to obtain a medication history | 4.2 | 3.9 | 4.6 | 4.6 | 4.5 | 4.1 | 4.4 |
| | (1.0) | (1.1) | (.8) | (.9) | (.9) | (1.2) | (1.0) |
| 29 Knowledge of the principles and process of medication reconciliation | 3.8 | 3.7 | 4.3 | 4.5 | 3.7 | 3.6 | 4.0 |
| | (1.3) | (1.3) | (1.0) | (1.0) | (1.4) | (1.4) | (1.2) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare | 4.1 | 4.1 | 4.5 | 4.8 | 4.2 | 4.2 | 4.3 |
| professionals in order to access health-related patient information essential to the care of the patient | (1.1) | (1.2) | (.9) | (.7) | (1.1) | (1.1) | (1.0) |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize | 4.2 | 4.3 | 4.7 | 4.8 | 4.5 | 4.5 | 4.5 |
| patient care outcomes | (1.0) | (1.0) | (.7) | (.7) | (.9) | (1.0) | (.9) |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | 4.4 | 4.3 | 4.8 | 4.6 | 4.6 | 4.3 | 4.6 |
| | (.8) | (.7) | (.5) | (.8) | (.8) | (1.1) | (.8) |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 3.7 | 3.6 | 4.5 | 4.3 | 4.0 | 3.8 | 4.1 |
| | (1.3) | (1.3) | (.9) | (1.0) | (1.1) | (1.4) | (1.2) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment | 3.7 | 4.0 | 4.2 | 4.3 | 3.8 | 3.7 | 4.0 |
| plan | (1.4) | (1.1) | (1.0) | (.9) | (1.2) | (1.3) | (1.2) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 3.4 | 3.8 | 4.7 | 4.6 | 4.5 | 4.0 | 4.3 |
| | (1.4) | (1.2) | (.7) | (.8) | (.8) | (1.3) | (1.1) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 3.5 | 3.8 | 4.7 | 4.6 | 4.5 | 3.9 | 4.3 |
| | (1.4) | (1.2) | (.7) | (.9) | (.8) | (1.3) | (1.1) |
| 37 Knowledge of patient education principles and techniques (for example, group classes, | 3.6 | 3.7 | 4.2 | 4.1 | 4.0 | 3.7 | 4.0 |
| individual patient counseling). | (1.5) | (1.3) | (1.0) | (1.1) | (1.1) | (1.4) | (1.2) |
| 38 Knowledge of the format for documentation of patient care activities, plans and | 2.6 | 3.0 | 4.7 | 4.3 | 4.5 | 3.8 | 4.0 |
| recommendations (for example, SOAP notes) | (1.4) | (1.5) | (.7) | (1.2) | (1.0) | (1.4) | (1.4) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for | 3.7 | 3.5 | 3.2 | 3.0 | 2.9 | 2.9 | 3.2 |
| example, home pregnancy tests, hemoccult tests) | (1.1) | (1.0) | (1.2) | (1.3) | (1.1) | (1.2) | (1.2) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring | 4.3 | 4.1 | 4.0 | 3.8 | 3.9 | 3.4 | 3.9 |
| chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (.9) | (1.0) | (1.0) | (1.2) | (1.1) | (1.3) | (1.1) |
| 41 Knowledge of the process of determining appropriateness of over-the-counter | 5.0 | 4.7 | 4.1 | 4.1 | 4.0 | 3.7 | 4.2 |
| eatments for individualized patients | (.2) | (.4) | (.9) | (1.0) | (.9) | (1.2) | (1.0) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the | 4.5 | 4.3 | 4.8 | 4.8 | 4.6 | 4.3 | 4.6 |
| appropriate healthcare provider(s) | (.8) | (.9) | (.6) | (.6) | (.7) | (1.0) | (.8) |
| 43 Knowledge of how to effectively communicate with the patient | 4.9 | 4.8 | 4.8 | 4.8 | 4.6 | 4.3 | 4.7 |
| | (.2) | (.6) | (.5) | (.5) | (.8) | (1.1) | (.7) |
| 44 Knowledge of the principles and practices of wellness and prevention | 4.5 | 4.2 | 4.3 | 4.2 | 4.1 | 3.8 | 4.2 |
| | (.8) | (1.0) | (.9) | (1.0) | (1.0) | (1.2) | (1.0) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary | 4.7 | 4.4 | 4.6 | 4.3 | 4.4 | 3.9 | 4.4 |
| factors, exercise, tobacco use) and appropriate modifications | (.6) | (.8) | (.8) | (.9) | (1.0) | (1.2) | (.9) |
| 46 Knowledge of the proper administration techniques for various drugs and | 4.7 | 4.6 | 3.9 | 3.9 | 3.8 | 4.1 | 4.1 |
| immunizations (for example, eye drops, inhalers, injections) | (.7) | (.6) | (1.2) | (1.3) | (1.1) | (1.2) | (1.1) |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | 4.8 | 4.4 | 4.6 | 4.7 | 4.1 | 4.2 | 4.5 |
| | (.6) | (1.1) | (.8) | (.7) | (1.1) | (1.0) | (.9) |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., | 3.5 | 3.4 | 3.8 | 4.2 | 3.3 | 3.6 | 3.6 |
| transitioning) | (1.4) | (1.3) | (1.1) | (1.0) | (1.2) | (1.4) | (1.2) |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | 2.9 | 2.8 | 3.3 | 3.3 | 2.9 | 3.0 | 3.1 |
| | (1.6) | (1.2) | (1.1) | (1.3) | (1.2) | (1.2) | (1.3) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 2.7 | 2.8 | 3.3 | 3.4 | 3.4 | 3.1 | 3.2 |
| handouts) for delivering educational programs | (1.4) | (1.1) | (1.1) | (1.3) | (1.0) | (1.2) | (1.2) |
| Practice Management | | | | | | | |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the | 3.4 | 3.2 | 4.1 | 4.2 | 3.7 | 3.5 | 3.8 |
| pharmacist's role in a successful ambulatory care practice | (1.4) | (1.3) | (1.1) | (1.0) | (1.3) | (1.4) | (1.3) |
| 2 Knowledge of effective interdisciplinary communication strategies | 3.5 | 3.9 | 4.5 | 4.5 | 4.1 | 3.9 | 4.1 |
| | (1.3) | (1.2) | (.8) | (.8) | (1.1) | (1.3) | (1.1) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 2.6 | 2.8 | 3.5 | 4.0 | 2.9 | 2.8 | 3.1 |
| | (1.4) | (1.3) | (1.3) | (1.1) | (1.2) | (1.4) | (1.4) |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative | 2.4 | 2.8 | 3.2 | 3.7 | 2.8 | 2.6 | 2.9 |
| care agreement and referral process | (1.3) | (1.2) | (1.3) | (1.3) | (1.2) | (1.4) | (1.3) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy | 2.5 | 2.8 | 2.9 | 3.3 | 2.7 | 2.7 | 2.8 |
| services | (1.3) | (1.2) | (1.3) | (1.3) | (1.2) | (1.3) | (1.3) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | 2.5 | 2.9 | 3.0 | 3.4 | 2.7 | 2.8 | 2.9 |
| | (1.2) | (1.3) | (1.2) | (1.4) | (1.1) | (1.4) | (1.3) |
| 7 Knowledge of the continuous quality improvement process | 3.0 | 3.3 | 3.5 | 4.1 | 2.9 | 3.4 | 3.4 |
| | (1.5) | (1.3) | (1.1) | (1.0) | (1.2) | (1.3) | (1.3) |
| Knowledge of business principles to effectively manage the practice (for example, | 3.5 | 4.1 | 2.4 | 3.0 | 1.9 | 3.3 | 2.8 |
| knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | (1.4) | (1.3) | (1.3) | (1.3) | (1.1) | (1.4) | (1.5) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 3.0 | 3.7 | 3.0 | 3.1 | 2.7 | 3.1 | 3.1 |
| | (1.6) | (1.4) | (1.6) | (1.6) | (1.5) | (1.6) | (1.6) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 10 Knowledge of tasks involved in managing the implementation of a new service or | 2.8 | 3.4 | 2.8 | 3.1 | 2.6 | 2.9 | 2.9 |
| program | (1.4) | (1.2) | (1.2) | (1.4) | (1.2) | (1.3) | (1.3) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory | 2.5 | 3.2 | 2.5 | 2.7 | 2.2 | 2.6 | 2.5 |
| pharmacy services | (1.4) | (1.3) | (1.3) | (1.3) | (1.1) | (1.3) | (1.3) |
| 12 Knowledge of systems for patient referral and follow up | 2.7 | 3.2 | 3.6 | 3.6 | 3.2 | 3.1 | 3.3 |
| | (1.4) | (1.3) | (1.2) | (1.3) | (1.3) | (1.5) | (1.4) |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, | 3.7 | 3.5 | 2.3 | 2.7 | 2.4 | 2.9 | 2.8 |
| Accutane®, Enbrel®, Clozaril®, thalidomide) | (1.3) | (1.2) | (1.3) | (1.3) | (1.1) | (1.4) | (1.4) |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, | 2.9 | 3.3 | 2.4 | 3.1 | 2.5 | 2.4 | 2.7 |
| CLIA, state Board of Pharmacy, other state laws) | (1.4) | (1.4) | (1.3) | (1.4) | (1.2) | (1.3) | (1.4) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 3.5 | 3.3 | 2.8 | 3.3 | 2.2 | 3.0 | 2.9 |
| | (1.4) | (1.2) | (1.3) | (1.3) | (1.2) | (1.4) | (1.3) |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing | 2.9 | 3.1 | 2.9 | 3.1 | 2.4 | 2.6 | 2.8 |
| pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | (1.5) | (1.4) | (1.5) | (1.5) | (1.5) | (1.5) | (1.5) |
| 17 Knowledge of formulary management systems (for example, P&T committee function, | 3.5 | 3.3 | 3.9 | 3.8 | 2.7 | 3.3 | 3.5 |
| therapeutic interchange, prior authorization, nonformulary process) | (1.5) | (1.5) | (1.2) | (1.3) | (1.2) | (1.4) | (1.4) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 4.3 | 4.3 | 4.3 | 4.2 | 3.8 | 3.9 | 4.1 |
| | (1.0) | (1.0) | (.9) | (1.0) | (1.3) | (1.3) | (1.1) |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | 4.5 | 4.1 | 4.3 | 4.2 | 3.6 | 4.1 | 4.1 |
| | (.9) | (1.2) | (1.1) | (1.1) | (1.3) | (1.1) | (1.1) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 20 Knowledge of service development process (for example, needs assessment, business | 2.1 | 2.8 | 2.2 | 2.6 | 2.0 | 2.5 | 2.3 |
| plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | (1.2) | (1.3) | (1.2) | (1.3) | (1.0) | (1.3) | (1.2) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.3 | 3.7 | 4.2 | 3.8 | 3.7 | 3.2 | 3.7 |
| | (1.5) | (1.2) | (1.1) | (1.2) | (1.3) | (1.5) | (1.3) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 2.7 | 3.0 | 3.1 | 3.6 | 2.7 | 2.6 | 2.9 |
| | (1.4) | (1.1) | (1.3) | (1.4) | (1.1) | (1.3) | (1.3) |
| 23 Knowledge of compensation strategies and funding sources | 2.5 | 3.2 | 2.5 | 3.3 | 2.5 | 2.6 | 2.7 |
| | (1.4) | (1.2) | (1.4) | (1.3) | (1.2) | (1.5) | (1.4) |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for | 2.8 | 3.4 | 3.3 | 3.6 | 3.1 | 3.3 | 3.3 |
| example, IOM report, Beers criteria) | (1.5) | (1.1) | (1.2) | (1.3) | (1.2) | (1.2) | (1.2) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory | 3.1 | 3.6 | 2.9 | 3.3 | 2.8 | 2.9 | 3.0 |
| care pharmacy | (1.4) | (1.1) | (1.3) | (1.3) | (1.1) | (1.4) | (1.3) |
| Public Health | | | | | | | |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 3.4 | 3.2 | 2.9 | 3.1 | 2.6 | 2.7 | 2.9 |
| | (1.5) | (1.3) | (1.4) | (1.2) | (1.2) | (1.3) | (1.4) |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies | 3.1 | 3.3 | 3.6 | 3.2 | 3.2 | 3.0 | 3.3 |
| (for example, ADA, AHA, NIH, CDC, AAAAI) | (1.4) | (1.3) | (1.2) | (1.4) | (1.1) | (1.3) | (1.2) |
| 3 Knowledge of disease prevention strategies | 3.9 | 3.7 | 4.2 | 4.0 | 3.9 | 3.4 | 3.9 |
| | (1.1) | (1.0) | (1.0) | (1.1) | (1.0) | (1.3) | (1.1) |
| 4 Knowledge of disease screening guidelines | 3.7 | 3.4 | 4.1 | 3.7 | 3.6 | 3.1 | 3.7 |
| | (1.3) | (1.1) | (1.0) | (1.3) | (1.2) | (1.3) | (1.2) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention | 3.7 | 3.4 | 3.6 | 3.5 | 3.3 | 3.1 | 3.5 |
| and treatment of diseases | (1.2) | (1.2) | (1.0) | (1.1) | (1.1) | (1.3) | (1.1) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment | 2.9 | 3.2 | 2.8 | 3.1 | 2.7 | 2.7 | 2.8 |
| of diseases | (1.4) | (1.4) | (1.2) | (1.2) | (1.2) | (1.4) | (1.3) |
| 7 Knowledge of information that is accessible to the public regarding the prevention and | 3.6 | 3.6 | 3.4 | 3.4 | 3.2 | 3.3 | 3.4 |
| treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | (1.2) | (1.1) | (1.2) | (1.0) | (1.0) | (1.2) | (1.1) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.5 | 2.4 | 2.1 | 2.3 | 1.9 | 2.2 | 2.2 |
| | (1.3) | (1.0) | (1.1) | (1.0) | (1.0) | (1.2) | (1.1) |
| 9 Knowledge of prevention and treatment of public health threats | 2.6 | 2.4 | 2.3 | 2.3 | 2.0 | 2.5 | 2.3 |
| | (1.4) | (1.1) | (1.2) | (1.1) | (1.0) | (1.3) | (1.2) |
| 10 Knowledge of processes for delivery and implementation strategies for public health | 2.5 | 2.5 | 2.2 | 2.3 | 1.9 | 2.3 | 2.2 |
| services | (1.3) | (1.3) | (1.1) | (1.0) | (1.0) | (1.2) | (1.2) |
| Medical Informatics and Professional Development | | | | | | | |
| 1 Knowledge of principles of evidence-based medicine | 3.4 | 3.8 | 4.7 | 4.5 | 4.3 | 3.9 | 4.2 |
| | (1.3) | (1.2) | (.5) | (.8) | (.9) | (1.3) | (1.1) |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory | 3.1 | 3.2 | 4.2 | 3.9 | 3.9 | 3.6 | 3.8 |
| pharmacy practice | (1.5) | (1.3) | (1.0) | (1.2) | (1.1) | (1.4) | (1.3) |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, | 2.9 | 3.1 | 4.4 | 4.1 | 4.4 | 3.9 | 3.9 |
| indexing and abstracting services), and tertiary (for example, textbook review articles) references | (1.4) | (1.3) | (.8) | (1.0) | (.8) | (1.2) | (1.2) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the | 3.0 | 3.2 | 4.1 | 4.1 | 4.1 | 3.7 | 3.8 |
| biomedical literature | (1.4) | (1.3) | (.9) | (1.0) | (1.0) | (1.3) | (1.2) |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in | 2.5 | 2.9 | 3.5 | 3.6 | 3.2 | 3.2 | 3.2 |
| ambulatory care practice | (1.3) | (1.3) | (1.1) | (1.2) | (1.3) | (1.3) | (1.3) |
| 6 Knowledge of principles and methods of educating health care students, residents, and | 2.7 | 3.2 | 4.2 | 4.3 | 4.4 | 3.4 | 3.8 |
| professionals | (1.4) | (1.4) | (1.0) | (.9) | (.9) | (1.3) | (1.3) |
| 7 Knowledge of research methodology to interpret study validity (for example, study | 2.5 | 2.5 | 3.8 | 3.7 | 3.9 | 3.2 | 3.4 |
| design, population selection, blinding, statistical analysis) | (1.2) | (1.2) | (1.0) | (1.1) | (1.0) | (1.4) | (1.2) |
| 8 Knowledge of strengths and limitations of various study methods | 2.6 | 2.5 | 3.7 | 3.7 | 3.8 | 3.0 | 3.4 |
| | (1.3) | (1.2) | (.9) | (1.0) | (.9) | (1.2) | (1.1) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | 2.7 | 2.6 | 3.8 | 3.8 | 4.0 | 3.2 | 3.5 |
| | (1.3) | (1.2) | (.9) | (.9) | (.8) | (1.2) | (1.2) |
| 10 Knowledge of appropriate research methodology to design studies to assess a research | 2.3 | 2.1 | 3.2 | 3.3 | 3.2 | 2.7 | 2.9 |
| hypothesis | (1.3) | (1.2) | (1.1) | (1.2) | (1.2) | (1.2) | (1.3) |
| 11 Knowledge of granting agencies and their application procedures | 1.6 | 1.9 | 2.1 | 1.9 | 2.2 | 2.0 | 2.0 |
| | (.9) | (1.0) | (1.2) | (1.0) | (1.1) | (1.0) | (1.1) |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, | 2.1 | 2.0 | 2.4 | 2.5 | 2.5 | 2.3 | 2.4 |
| HIPAA, IRB, OSHA) | (1.4) | (1.3) | (1.2) | (1.1) | (1.1) | (1.1) | (1.2) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 1.9 | 1.9 | 2.6 | 2.7 | 2.6 | 2.3 | 2.4 |
| | (1.1) | (1.0) | (1.2) | (1.3) | (1.1) | (1.2) | (1.2) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 14 Knowledge of elements of informed consent | 2.4 | 2.2 | 2.6 | 2.8 | 2.6 | 2.7 | 2.6 |
| | (1.5) | (1.3) | (1.2) | (1.3) | (1.1) | (1.4) | (1.3) |
| 15 Knowledge of survey procedures | 1.7 | 2.2 | 2.1 | 2.3 | 2.3 | 2.2 | 2.1 |
| | (.9) | (1.0) | (1.0) | (1.1) | (.9) | (1.0) | (1.0) |
| 16 Knowledge of data management | 2.1 | 2.5 | 2.7 | 3.1 | 2.6 | 2.9 | 2.6 |
| | (1.3) | (1.3) | (1.3) | (1.3) | (1.1) | (1.4) | (1.3) |
| 17 Knowledge of data analysis and statistical methods | 2.1 | 2.1 | 2.7 | 2.7 | 2.6 | 2.7 | 2.6 |
| | (1.2) | (1.1) | (1.1) | (1.1) | (1.1) | (1.4) | (1.2) |
| 18 Knowledge of the uniform requirements (developed by the International Committee of | 1.5 | 1.6 | 2.1 | 1.8 | 2.2 | 2.1 | 2.0 |
| Medical Journal Editors) for manuscripts submitted to biomedical journals | (.8) | (.8) | (.9) | (.8) | (.9) | (1.2) | (1.0) |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | 1.9 | 2.0 | 2.7 | 2.7 | 2.5 | 2.5 | 2.4 |
| | (1.0) | (1.0) | (1.1) | (1.1) | (1.0) | (1.2) | (1.1) |
| 20 Knowledge of techniques for presentation of research findings | 1.8 | 1.8 | 2.4 | 2.3 | 2.4 | 2.3 | 2.2 |
| | (1.0) | (.9) | (1.0) | (1.0) | (.8) | (1.2) | (1.0) |
| 21 Knowledge of the content of an effective research presentation | 1.7 | 2.0 | 2.4 | 2.4 | 2.4 | 2.3 | 2.2 |
| | (1.0) | (.9) | (1.0) | (1.0) | (.9) | (1.2) | (1.0) |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy | 2.1 | 2.3 | 2.5 | 2.6 | 2.6 | 2.4 | 2.4 |
| organization conferences, journals) | (1.1) | (1.0) | (1.0) | (1.0) | (.8) | (1.1) | (1.0) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine | 2.4 | 2.3 | 2.7 | 2.8 | 2.4 | 2.7 | 2.6 |
| events and problems observed with drug/vaccine products to appropriate governmental entities | (1.2) | (.7) | (1.1) | (1.0) | (1.0) | (1.1) | (1.1) |

| | Work Setting | | | | | | | |
|--|---------------------------------|----------------------------------|-----------------|----------|-------------------------|-------|-------|--|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total | |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care | 2.3 | 2.8 | 2.9 | 2.9 | 2.9 | 2.7 | 2.8 | |
| pharmacy practice | (1.1) | (1.0) | (1.1) | (1.1) | (1.0) | (1.2) | (1.1) | |
| 25 Knowledge of staff development principles and avenues for providing continuing | 2.3 | 2.7 | 2.9 | 3.0 | 2.7 | 2.8 | 2.7 | |
| education | (1.1) | (1.1) | (1.0) | (1.0) | (1.0) | (1.1) | (1.0) | |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for | 2.2 | 2.5 | 2.9 | 2.8 | 2.6 | 2.5 | 2.6 | |
| example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (1.2) | (1.1) | (1.2) | (1.2) | (1.0) | (1.1) | (1.1) | |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and | 2.6 | 2.7 | 4.3 | 3.9 | 4.1 | 3.6 | 3.8 | |
| protocols in the ambulatory care environment | (1.3) | (1.2) | (1.0) | (1.2) | (1.1) | (1.4) | (1.3) | |
| Patient Advocacy | | | | | | | | |
| Knowledge of assertive and persuasive communication techniques for representing a | 3.8 | 3.5 | 4.1 | 4.1 | 3.6 | 3.2 | 3.8 | |
| patient's healthcare needs and interests | (1.3) | (1.3) | (1.1) | (1.0) | (1.2) | (1.3) | (1.2) | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for | 4.0 | 3.9 | 4.2 | 4.3 | 4.1 | 3.7 | 4.1 | |
| example, socioeconomic) | (1.3) | (1.2) | (1.1) | (1.0) | (1.0) | (1.3) | (1.1) | |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication | 3.5 | 3.2 | 2.8 | 3.4 | 2.9 | 3.0 | 3.0 | |
| assistance programs | (1.3) | (1.2) | (1.4) | (1.1) | (1.2) | (1.3) | (1.3) | |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug | 4.3 | 4.0 | 4.0 | 3.7 | 3.4 | 3.7 | 3.9 | |
| plans/ formularies for patients in ambulatory care | (1.1) | (1.2) | (1.3) | (1.3) | (1.3) | (1.4) | (1.3) | |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to | 2.8 | 3.3 | 3.7 | 4.0 | 2.8 | 3.0 | 3.3 | |
| and from the ambulatory care setting | (1.5) | (1.3) | (1.2) | (1.1) | (1.2) | (1.4) | (1.4) | |
| 6 Knowledge of medication reconciliation skills and techniques | 3.0 | 3.4 | 3.8 | 4.3 | 3.0 | 3.1 | 3.5 | |
| | (1.4) | (1.4) | (1.2) | (.9) | (1.3) | (1.5) | (1.4) | |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 7 Knowledge of the healthcare resources and services available to ambulatory care | 3.4 | 3.5 | 3.6 | 3.8 | 3.3 | 3.3 | 3.5 |
| patients (for example, disease specific websites, medication assistance programs social services). | (1.3) | (1.2) | (1.1) | (1.2) | (1.0) | (1.3) | (1.2) |
| 8 Knowledge of collaborative relationships necessary to enable case management of | 2.7 | 2.8 | 3.8 | 3.8 | 3.2 | 2.9 | 3.3 |
| ambulatory care patients | (1.3) | (1.3) | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.1 | 3.2 | 4.1 | 3.8 | 3.6 | 3.2 | 3.6 |
| | (1.4) | (1.4) | (1.1) | (1.3) | (1.1) | (1.3) | (1.3) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 3.0 | 3.1 | 3.3 | 2.9 | 2.7 | 3.0 |
| | (1.3) | (1.3) | (1.1) | (1.2) | (1.0) | (1.2) | (1.2) |
| 11 Knowledge of conflict management and negotiation skills | 3.4 | 3.3 | 3.6 | 3.8 | 3.3 | 3.2 | 3.5 |
| | (1.5) | (1.3) | (1.2) | (1.2) | (1.3) | (1.3) | (1.3) |

Appendix 11. Knowledge Importance Ratings by Work Setting

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| Direct Patient Care | | | | | | | |
| 1 Knowledge of anatomy and physiology | 3.3 | 3.4 | 3.3 | 3.3 | 3.3 | 3.5 | 3.3 |
| | (.7) | (.7) | (.7) | (.7) | (.7) | (.6) | (.7) |
| 2 Knowledge of pathophysiology | 3.4 | 3.6 | 3.6 | 3.7 | 3.8 | 3.6 | 3.6 |
| | (.7) | (.6) | (.6) | (.6) | (.4) | (.6) | (.6) |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their | 3.5 | 3.5 | 3.9 | 4.0 | 3.9 | 3.8 | 3.8 |
| interpretation as they relate to drug therapy | (.6) | (.6) | (.3) | (.2) | (.3) | (.5) | (.4) |
| 4 Knowledge of the clinical assessment process | 3.2 | 3.3 | 3.8 | 3.7 | 3.8 | 3.6 | 3.6 |
| | (.8) | (.7) | (.5) | (.5) | (.5) | (.6) | (.6) |
| 5 Knowledge of physical assessment techniques | 3.1 | 2.9 | 3.1 | 3.2 | 3.1 | 3.0 | 3.1 |
| | (.9) | (.8) | (.7) | (.7) | (.7) | (.8) | (.8) |
| 6 Knowledge of pharmacology | 3.7 | 3.7 | 3.8 | 3.9 | 3.7 | 3.8 | 3.8 |
| | (.6) | (.5) | (.5) | (.3) | (.5) | (.5) | (.5) |
| 7 Knowledge of pharmacotherapy | 3.8 | 3.9 | 4.0 | 3.9 | 4.0 | 4.0 | 3.9 |
| | (.4) | (.3) | (.3) | (.3) | (.1) | (.2) | (.3) |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 3.5 | 3.6 | 3.8 | 3.8 | 3.8 | 3.6 | 3.7 |
| | (.7) | (.7) | (.5) | (.4) | (.4) | (.6) | (.5) |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy | 3.2 | 3.2 | 3.4 | 3.5 | 3.3 | 3.2 | 3.3 |
| management | (.9) | (.8) | (.8) | (.7) | (.7) | (.7) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 10 Knowledge of OTC medications | 3.9 | 3.9 | 3.6 | 3.7 | 3.7 | 3.6 | 3.7 |
| | (.2) | (.2) | (.5) | (.6) | (.5) | (.6) | (.5) |
| 11 Knowledge of the principles of self-care | 3.8 | 3.9 | 3.6 | 3.6 | 3.6 | 3.4 | 3.6 |
| | (.5) | (.3) | (.6) | (.6) | (.7) | (.7) | (.6) |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | 3.6 | 3.4 | 3.4 | 3.4 | 3.4 | 3.3 | 3.4 |
| used in complementary and alternative medicine | (.7) | (.7) | (.7) | (.7) | (.7) | (.7) | (.7) |
| 13 Knowledge of common immunizations | 3.2 | 3.0 | 3.0 | 3.0 | 3.2 | 3.1 | 3.1 |
| | (.8) | (.8) | (.7) | (.9) | (.7) | (.8) | (.8) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III | 3.2 | 3.1 | 3.9 | 3.6 | 3.9 | 3.5 | 3.6 |
| guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (1.0) | (.9) | (.3) | (.6) | (.4) | (.7) | (.7) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 3.2 | 3.2 | 3.8 | 3.7 | 3.8 | 3.5 | 3.6 |
| | (.8) | (.8) | (.4) | (.6) | (.4) | (.7) | (.6) |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 3.7 | 3.4 | 3.7 | 3.5 | 3.7 | 3.6 | 3.6 |
| | (.6) | (.7) | (.5) | (.6) | (.6) | (.7) | (.6) |
| 17 Knowledge of factors affecting medication and treatment adherence | 3.7 | 3.8 | 3.7 | 3.6 | 3.8 | 3.8 | 3.7 |
| | (.5) | (.4) | (.5) | (.7) | (.5) | (.4) | (.5) |
| 18 Knowledge of effective interventions to address medication and treatment | 3.6 | 3.6 | 3.7 | 3.6 | 3.7 | 3.7 | 3.7 |
| nonadherence | (.6) | (.5) | (.5) | (.7) | (.6) | (.5) | (.6) |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood | 3.7 | 3.7 | 3.2 | 3.5 | 3.3 | 3.1 | 3.3 |
| glucose, cholesterol, INR) | (.6) | (.5) | (.8) | (.7) | (.7) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for | 2.8 | 2.8 | 2.6 | 2.9 | 2.8 | 2.7 | 2.7 |
| example, OSHA, CLIA) | (1.0) | (1.0) | (.8) | (.8) | (.8) | (.7) | (.8) |
| 21 Knowledge of patient interviewing skills | 3.8 | 3.7 | 3.9 | 3.8 | 3.9 | 3.8 | 3.8 |
| | (.5) | (.5) | (.3) | (.4) | (.4) | (.5) | (.4) |
| 22 Knowledge of motivational interviewing techniques | 3.4 | 3.2 | 3.4 | 3.3 | 3.2 | 3.3 | 3.3 |
| | (.9) | (.7) | (.7) | (.7) | (.7) | (.8) | (.7) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 | 3.5 | 3.5 |
| their own care | (.7) | (.6) | (.6) | (.8) | (.8) | (.7) | (.7) |
| 24 Knowledge of how to develop effective collaborative partnerships with individual | 3.5 | 3.5 | 3.7 | 3.4 | 3.5 | 3.5 | 3.5 |
| patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | (.7) | (.7) | (.5) | (.8) | (.7) | (.7) | (.7) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 3.6 | 3.4 | 3.7 | 3.5 | 3.6 | 3.6 | 3.6 |
| | (.7) | (.6) | (.5) | (.8) | (.6) | (.6) | (.6) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.2 | 3.1 | 3.1 | 3.3 | 3.1 | 3.2 | 3.2 |
| | (.7) | (.8) | (.7) | (.7) | (.7) | (.7) | (.7) |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may | 3.5 | 3.4 | 3.3 | 3.2 | 3.2 | 3.3 | 3.3 |
| impact the care of the patient | (.7) | (.8) | (.7) | (.7) | (.7) | (.8) | (.7) |
| 28 Knowledge of how to obtain a medication history | 3.7 | 3.5 | 3.8 | 3.8 | 3.9 | 3.7 | 3.8 |
| | (.6) | (.7) | (.4) | (.5) | (.4) | (.6) | (.5) |
| 29 Knowledge of the principles and process of medication reconciliation | 3.4 | 3.2 | 3.6 | 3.6 | 3.3 | 3.3 | 3.5 |
| | (.9) | (.8) | (.6) | (.6) | (.7) | (.8) | (.7) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare | 3.7 | 3.6 | 3.8 | 3.8 | 3.7 | 3.7 | 3.7 |
| professionals in order to access health-related patient information essential to the care of the patient | (.6) | (.7) | (.5) | (.4) | (.6) | (.5) | (.6) |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize | 3.7 | 3.9 | 3.9 | 3.8 | 3.8 | 3.7 | 3.8 |
| patient care outcomes | (.6) | (.4) | (.4) | (.4) | (.5) | (.5) | (.4) |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | 3.7 | 3.7 | 3.8 | 3.8 | 3.9 | 3.7 | 3.8 |
| | (.5) | (.5) | (.5) | (.5) | (.5) | (.5) | (.5) |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 3.2 | 3.4 | 3.6 | 3.4 | 3.4 | 3.4 | 3.4 |
| | (1.0) | (.8) | (.7) | (.7) | (.7) | (.8) | (.8) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment | 3.4 | 3.6 | 3.5 | 3.4 | 3.3 | 3.4 | 3.4 |
| plan | (.8) | (.7) | (.7) | (.7) | (.8) | (.8) | (.7) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 3.4 | 3.5 | 3.8 | 3.8 | 3.9 | 3.6 | 3.7 |
| | (.7) | (.8) | (.4) | (.6) | (.3) | (.7) | (.6) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 3.5 | 3.5 | 3.8 | 3.8 | 3.9 | 3.6 | 3.7 |
| | (.7) | (.8) | (.4) | (.4) | (.3) | (.7) | (.6) |
| 37 Knowledge of patient education principles and techniques (for example, group classes, | 3.4 | 3.4 | 3.6 | 3.5 | 3.5 | 3.4 | 3.5 |
| individual patient counseling). | (.9) | (.8) | (.6) | (.8) | (.7) | (.7) | (.7) |
| 38 Knowledge of the format for documentation of patient care activities, plans and | 2.9 | 3.0 | 3.7 | 3.5 | 3.6 | 3.4 | 3.4 |
| recommendations (for example, SOAP notes) | (1.0) | (.9) | (.6) | (.6) | (.7) | (.8) | (.8) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for | 3.5 | 3.3 | 2.9 | 3.1 | 3.0 | 3.0 | 3.1 |
| example, home pregnancy tests, hemoccult tests) | (.6) | (.7) | (.8) | (.7) | (.8) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring | 3.7 | 3.6 | 3.5 | 3.4 | 3.6 | 3.4 | 3.5 |
| chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (.6) | (.6) | (.6) | (.6) | (.7) | (.8) | (.6) |
| 41 Knowledge of the process of determining appropriateness of over-the-counter | 3.9 | 3.9 | 3.5 | 3.6 | 3.6 | 3.5 | 3.6 |
| treatments for individualized patients | (.3) | (.3) | (.6) | (.6) | (.6) | (.7) | (.6) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the | 3.8 | 3.8 | 3.8 | 3.8 | 3.9 | 3.7 | 3.8 |
| appropriate healthcare provider(s) | (.5) | (.4) | (.4) | (.5) | (.3) | (.6) | (.4) |
| 43 Knowledge of how to effectively communicate with the patient | 4.0 | 3.9 | 3.9 | 3.8 | 3.9 | 3.9 | 3.9 |
| | (.1) | (.3) | (.2) | (.4) | (.4) | (.4) | (.3) |
| 44 Knowledge of the principles and practices of wellness and prevention | 3.7 | 3.7 | 3.5 | 3.6 | 3.5 | 3.5 | 3.6 |
| | (.5) | (.5) | (.5) | (.6) | (.7) | (.7) | (.6) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary | 3.8 | 3.7 | 3.7 | 3.7 | 3.7 | 3.6 | 3.7 |
| factors, exercise, tobacco use) and appropriate modifications | (.5) | (.5) | (.5) | (.5) | (.6) | (.6) | (.5) |
| 46 Knowledge of the proper administration techniques for various drugs and | 3.9 | 3.8 | 3.6 | 3.6 | 3.6 | 3.7 | 3.7 |
| immunizations (for example, eye drops, inhalers, injections) | (.4) | (.4) | (.6) | (.7) | (.6) | (.5) | (.6) |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | 3.6 | 3.4 | 3.6 | 3.6 | 3.4 | 3.5 | 3.5 |
| | (.7) | (.8) | (.7) | (.7) | (.7) | (.8) | (.7) |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., | 3.2 | 3.1 | 3.2 | 3.5 | 3.0 | 3.3 | 3.2 |
| transitioning) | (.9) | (1.0) | (.7) | (.7) | (.8) | (.8) | (.8) |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | 3.0 | 2.8 | 3.2 | 3.3 | 2.9 | 3.0 | 3.1 |
| | (.9) | (.9) | (.7) | (.8) | (.7) | (.9) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 2.9 | 2.8 | 3.2 | 3.2 | 3.2 | 3.1 | 3.1 |
| handouts) for delivering educational programs | (1.0) | (.9) | (.7) | (.8) | (.7) | (.8) | (.8) |
| Practice Management | | | | | | | |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the | 3.1 | 3.2 | 3.5 | 3.5 | 3.4 | 3.3 | 3.4 |
| pharmacist's role in a successful ambulatory care practice | (.9) | (.8) | (.7) | (.8) | (.7) | (.7) | (.8) |
| 2 Knowledge of effective interdisciplinary communication strategies | 3.1 | 3.4 | 3.6 | 3.5 | 3.5 | 3.5 | 3.5 |
| | (1.0) | (.7) | (.6) | (.7) | (.7) | (.7) | (.7) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 2.7 | 3.0 | 3.3 | 3.4 | 3.3 | 3.3 | 3.2 |
| | (1.0) | (.8) | (.7) | (.8) | (.7) | (.8) | (.8) |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative | 2.6 | 3.0 | 3.3 | 3.4 | 3.2 | 3.1 | 3.2 |
| care agreement and referral process | (1.0) | (.8) | (.8) | (.8) | (.7) | (.8) | (.8) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy | 2.9 | 2.9 | 3.2 | 3.3 | 3.1 | 3.1 | 3.1 |
| services | (1.0) | (.7) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | 2.9 | 3.1 | 3.4 | 3.3 | 3.2 | 3.2 | 3.2 |
| | (1.0) | (.8) | (.7) | (.8) | (.8) | (.8) | (.8) |
| 7 Knowledge of the continuous quality improvement process | 3.2 | 3.2 | 3.3 | 3.5 | 3.2 | 3.4 | 3.3 |
| | (.9) | (.8) | (.7) | (.7) | (.8) | (.8) | (.8) |
| 8 Knowledge of business principles to effectively manage the practice (for example, | 3.3 | 3.6 | 2.8 | 3.0 | 2.6 | 3.1 | 3.0 |
| knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | (.8) | (.6) | (.8) | (.8) | (.9) | (.8) | (.8) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 3.2 | 3.3 | 3.1 | 3.2 | 3.1 | 3.2 | 3.2 |
| | (1.0) | (.9) | (.9) | (.8) | (.9) | (.9) | (.9) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 10 Knowledge of tasks involved in managing the implementation of a new service or | 3.0 | 3.3 | 3.2 | 3.2 | 3.1 | 3.2 | 3.2 |
| program | (1.0) | (.8) | (.7) | (.8) | (.7) | (.7) | (.8) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory | 2.9 | 3.3 | 3.1 | 3.0 | 2.9 | 3.0 | 3.0 |
| pharmacy services | (1.0) | (.7) | (.9) | (.9) | (.8) | (.9) | (.9) |
| 12 Knowledge of systems for patient referral and follow up | 2.9 | 3.3 | 3.3 | 3.2 | 3.1 | 3.0 | 3.1 |
| | (1.1) | (.8) | (.8) | (1.0) | (.8) | (.9) | (.9) |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, | 3.5 | 3.4 | 2.8 | 3.0 | 2.8 | 3.0 | 3.0 |
| Accutane®, Enbrel®, Clozaril®, thalidomide) | (.7) | (.7) | (.9) | (.9) | (1.0) | (.8) | (.9) |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, | 3.0 | 3.3 | 2.7 | 3.0 | 2.8 | 2.9 | 2.9 |
| CLIA, state Board of Pharmacy, other state laws) | (1.0) | (.8) | (.8) | (.8) | (.8) | (.8) | (.9) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 3.1 | 3.1 | 2.8 | 3.0 | 2.6 | 2.9 | 2.9 |
| | (.9) | (.8) | (.9) | (.8) | (.8) | (.8) | (.8) |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing | 3.3 | 3.3 | 3.1 | 3.1 | 3.1 | 3.1 | 3.2 |
| pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | (1.0) | (.8) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 17 Knowledge of formulary management systems (for example, P&T committee function, | 3.1 | 3.1 | 3.3 | 3.2 | 3.0 | 3.2 | 3.2 |
| therapeutic interchange, prior authorization, nonformulary process) | (.9) | (.8) | (.7) | (.8) | (.7) | (.8) | (.8) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 3.6 | 3.6 | 3.6 | 3.4 | 3.4 | 3.5 | 3.5 |
| | (.6) | (.7) | (.6) | (.7) | (.7) | (.7) | (.7) |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | 3.4 | 3.3 | 3.4 | 3.3 | 3.2 | 3.5 | 3.4 |
| | (.8) | (.8) | (.8) | (.8) | (.8) | (.7) | (.8) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 20 Knowledge of service development process (for example, needs assessment, business | 2.6 | 2.8 | 2.6 | 2.7 | 2.6 | 2.6 | 2.6 |
| plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | (1.0) | (.9) | (.9) | (.9) | (.8) | (.8) | (.9) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.1 | 3.2 | 3.4 | 3.3 | 3.2 | 3.3 | 3.3 |
| | (1.0) | (.8) | (.7) | (.8) | (.7) | (.8) | (.8) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 2.9 | 3.1 | 3.2 | 3.3 | 3.1 | 3.0 | 3.1 |
| | (1.0) | (.7) | (.8) | (.9) | (.7) | (.9) | (.8) |
| 23 Knowledge of compensation strategies and funding sources | 2.8 | 3.2 | 3.1 | 3.1 | 3.2 | 3.2 | 3.1 |
| | (1.0) | (.8) | (.8) | (.9) | (.7) | (.8) | (.9) |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for | 3.1 | 3.2 | 3.3 | 3.2 | 3.2 | 3.3 | 3.2 |
| example, IOM report, Beers criteria) | (1.1) | (.8) | (.7) | (.7) | (.8) | (.8) | (.8) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory | 3.2 | 3.5 | 3.2 | 3.3 | 3.2 | 3.3 | 3.2 |
| care pharmacy | (.9) | (.6) | (.8) | (.8) | (.6) | (.8) | (.8) |
| Public Health and Professional Advocacy | | | | | | | |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 3.2 | 3.0 | 2.9 | 3.0 | 2.9 | 2.9 | 3.0 |
| | (.9) | (.8) | (.8) | (.9) | (.8) | (.8) | (.8) |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies | 3.0 | 3.2 | 3.2 | 2.9 | 3.0 | 3.0 | 3.1 |
| (for example, ADA, AHA, NIH, CDC, AAAAI) | (.9) | (.8) | (.8) | (1.0) | (.8) | (.8) | (.8) |
| 3 Knowledge of disease prevention strategies | 3.5 | 3.5 | 3.6 | 3.4 | 3.5 | 3.4 | 3.5 |
| | (.7) | (.7) | (.6) | (.8) | (.6) | (.8) | (.7) |
| 4 Knowledge of disease screening guidelines | 3.4 | 3.3 | 3.4 | 3.2 | 3.4 | 3.2 | 3.3 |
| | (.8) | (.7) | (.7) | (.9) | (.7) | (.7) | (.7) |

| | | | Wo | ork Setting | | | |
|---|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention | 3.4 | 3.0 | 3.1 | 3.1 | 3.0 | 3.0 | 3.1 |
| and treatment of diseases | (.8) | (.8) | (.7) | (.9) | (.8) | (.9) | (.8) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment | 2.9 | 2.9 | 2.8 | 2.9 | 2.7 | 2.9 | 2.8 |
| of diseases | (.9) | (.9) | (.9) | (.8) | (.8) | (.8) | (.8) |
| 7 Knowledge of information that is accessible to the public regarding the prevention and | 3.3 | 3.2 | 3.1 | 3.1 | 2.9 | 3.2 | 3.1 |
| treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | (.8) | (.8) | (.8) | (.8) | (.9) | (.8) | (.8) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.9 | 2.8 | 2.5 | 2.7 | 2.3 | 2.8 | 2.6 |
| | (.9) | (.9) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 9 Knowledge of prevention and treatment of public health threats | 3.0 | 2.8 | 2.7 | 2.8 | 2.5 | 3.0 | 2.8 |
| | (1.0) | (.8) | (.8) | (.8) | (.9) | (.8) | (.9) |
| 10 Knowledge of processes for delivery and implementation strategies for public health | 2.9 | 2.8 | 2.6 | 2.8 | 2.3 | 2.8 | 2.7 |
| services | (.9) | (.9) | (.7) | (.8) | (.8) | (.8) | (.8) |
| Medical Informatics and Professional Development | | | | | | | |
| 1 Knowledge of principles of evidence-based medicine | 3.3 | 3.3 | 3.8 | 3.7 | 3.7 | 3.6 | 3.6 |
| | (.8) | (.8) | (.4) | (.6) | (.6) | (.7) | (.6) |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory | 3.1 | 3.2 | 3.6 | 3.3 | 3.5 | 3.3 | 3.4 |
| pharmacy practice | (1.0) | (.9) | (.7) | (.8) | (.9) | (.9) | (.8) |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, | 2.9 | 3.1 | 3.7 | 3.5 | 3.7 | 3.4 | 3.5 |
| indexing and abstracting services), and tertiary (for example, textbook review articles) references | (1.0) | (.9) | (.6) | (.8) | (.5) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the | 3.1 | 3.1 | 3.6 | 3.4 | 3.6 | 3.4 | 3.4 |
| biomedical literature | (1.0) | (.9) | (.6) | (.8) | (.7) | (.8) | (.8) |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in | 2.7 | 3.0 | 3.2 | 3.1 | 3.0 | 3.1 | 3.1 |
| ambulatory care practice | (1.1) | (.8) | (.8) | (.8) | (.9) | (.9) | (.9) |
| 6 Knowledge of principles and methods of educating health care students, residents, and | 2.9 | 3.2 | 3.4 | 3.4 | 3.4 | 3.3 | 3.3 |
| professionals | (1.0) | (.8) | (.7) | (.7) | (.7) | (.9) | (.8) |
| 7 Knowledge of research methodology to interpret study validity (for example, study | 2.8 | 2.8 | 3.5 | 3.4 | 3.5 | 3.3 | 3.3 |
| design, population selection, blinding, statistical analysis) | (1.1) | (1.0) | (.7) | (.9) | (.7) | (.9) | (.9) |
| 8 Knowledge of strengths and limitations of various study methods | 2.9 | 2.7 | 3.5 | 3.3 | 3.5 | 3.3 | 3.3 |
| | (1.0) | (.9) | (.7) | (.7) | (.6) | (.9) | (.8) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | 3.0 | 2.8 | 3.6 | 3.4 | 3.7 | 3.4 | 3.4 |
| | (1.1) | (.9) | (.6) | (.8) | (.5) | (.9) | (.8) |
| 10 Knowledge of appropriate research methodology to design studies to assess a research | 2.7 | 2.6 | 3.3 | 3.2 | 3.2 | 3.0 | 3.1 |
| nypothesis | (1.0) | (1.0) | (.8) | (.9) | (.9) | (.9) | (.9) |
| 11 Knowledge of granting agencies and their application procedures | 2.2 | 2.3 | 2.6 | 2.5 | 2.4 | 2.6 | 2.5 |
| | (.9) | (.9) | (.9) | (1.0) | (.9) | (.8) | (.9) |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, | 2.5 | 2.4 | 2.7 | 2.8 | 2.6 | 2.8 | 2.7 |
| HIPAA, IRB, OSHA) | (1.1) | (1.0) | (.9) | (.8) | (.9) | (.9) | (.9) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 2.5 | 2.6 | 2.9 | 2.9 | 3.0 | 3.0 | 2.8 |
| | (1.1) | (1.0) | (.9) | (.9) | (.9) | (1.0) | (1.0) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 14 Knowledge of elements of informed consent | 2.6 | 2.7 | 2.9 | 3.0 | 2.9 | 3.1 | 2.9 |
| | (1.2) | (.9) | (.9) | (.9) | (.9) | (.9) | (1.0) |
| 15 Knowledge of survey procedures | 2.2 | 2.5 | 2.5 | 2.6 | 2.5 | 2.7 | 2.5 |
| | (.8) | (.9) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 16 Knowledge of data management | 2.4 | 2.5 | 2.7 | 2.9 | 2.5 | 2.9 | 2.7 |
| | (1.0) | (.9) | (.9) | (.8) | (.8) | (.9) | (.9) |
| 17 Knowledge of data analysis and statistical methods | 2.5 | 2.4 | 2.8 | 2.9 | 2.6 | 3.0 | 2.7 |
| | (.9) | (1.0) | (.8) | (.9) | (.8) | (.9) | (.9) |
| 18 Knowledge of the uniform requirements (developed by the International Committee of | 2.1 | 2.2 | 2.6 | 2.4 | 2.3 | 2.6 | 2.4 |
| Medical Journal Editors) for manuscripts submitted to biomedical journals | (.9) | (.9) | (.9) | (.9) | (.8) | (1.0) | (.9) |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | 2.5 | 2.4 | 2.9 | 2.8 | 2.7 | 2.9 | 2.8 |
| | (1.0) | (1.0) | (.9) | (.9) | (.8) | (.8) | (.9) |
| 20 Knowledge of techniques for presentation of research findings | 2.4 | 2.4 | 2.8 | 2.7 | 2.5 | 2.8 | 2.6 |
| | (1.0) | (1.0) | (.9) | (.9) | (.8) | (1.0) | (.9) |
| 21 Knowledge of the content of an effective research presentation | 2.5 | 2.4 | 2.8 | 2.8 | 2.6 | 2.9 | 2.7 |
| | (1.0) | (.9) | (.9) | (.9) | (.8) | (1.0) | (.9) |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy | 2.5 | 2.7 | 2.8 | 2.9 | 2.7 | 2.8 | 2.7 |
| organization conferences, journals) | (1.0) | (.8) | (.8) | (.8) | (.8) | (.9) | (.9) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine | 3.0 | 3.0 | 3.2 | 3.2 | 3.3 | 3.4 | 3.2 |
| events and problems observed with drug/vaccine products to appropriate governmental entities | (1.0) | (1.0) | (.8) | (.8) | (.7) | (.8) | (.8) |

| | | | Wo | ork Setting | | | |
|--|---------------------------------|----------------------------------|-----------------|-------------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care | 2.8 | 3.0 | 3.0 | 3.1 | 3.0 | 2.9 | 3.0 |
| pharmacy practice | (.9) | (.8) | (.8) | (.9) | (.8) | (.9) | (.8) |
| 25 Knowledge of staff development principles and avenues for providing continuing | 2.6 | 2.8 | 3.0 | 2.9 | 2.8 | 2.9 | 2.9 |
| education | (.9) | (.8) | (.8) | (.8) | (.9) | (.8) | (.9) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for | 2.8 | 3.0 | 3.1 | 3.1 | 2.9 | 3.0 | 3.0 |
| example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (.9) | (.9) | (.8) | (.9) | (.9) | (.8) | (.9) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 2.9 | 3.1 | 3.7 | 3.5 | 3.7 | 3.5 | 3.5 |
| | (1.0) | (1.0) | (.6) | (.8) | (.6) | (.7) | (.8) |
| Patient Advocacy | | | | | | | |
| 1 Knowledge of assertive and persuasive communication techniques for representing a | 3.4 | 3.1 | 3.4 | 3.3 | 3.2 | 3.1 | 3.3 |
| patient's healthcare needs and interests | (.9) | (1.0) | (.7) | (.8) | (.8) | (.8) | (.8) |
| 2 Knowledge of patient-specific factors which may impact access to medications (for | 3.4 | 3.4 | 3.5 | 3.4 | 3.4 | 3.4 | 3.5 |
| example, socioeconomic) | (.9) | (.8) | (.6) | (.7) | (.7) | (.8) | (.7) |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication | 3.2 | 3.0 | 3.0 | 3.1 | 3.0 | 3.1 | 3.0 |
| assistance programs | (.9) | (1.0) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug | 3.4 | 3.2 | 3.4 | 3.2 | 3.1 | 3.3 | 3.3 |
| plans/ formularies for patients in ambulatory care | (.8) | (.9) | (.7) | (.8) | (.7) | (.8) | (.8) |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to | 2.9 | 3.1 | 3.4 | 3.3 | 2.9 | 3.3 | 3.2 |
| and from the ambulatory care setting | (1.0) | (.9) | (.7) | (.7) | (.8) | (.7) | (.8) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.0 | 3.2 | 3.4 | 3.3 | 3.1 | 3.4 | 3.3 |
| | (.9) | (.9) | (.7) | (.7) | (.8) | (.8) | (.8) |

| | Work Setting | | | | | | |
|--|---------------------------------|----------------------------------|-----------------|----------|-------------------------|-------|-------|
| | Community Pharmacy, Chain | Community Pharmacy, Indep. | Primary Care | Hospital | Academic Institution | Other | Total |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | 3.1 | 3.3 | 3.2 | 3.2 | 3.0 | 3.2 | 3.2 |
| | (.9) | (.9) | (.7) | (.8) | (.7) | (.8) | (.8) |
| 8 Knowledge of collaborative relationships necessary to enable case management of | 2.9 | 2.9 | 3.2 | 3.3 | 3.0 | 3.1 | 3.1 |
| ambulatory care patients | (1.0) | (.9) | (.7) | (.8) | (.8) | (.8) | (.8) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.0 | 3.2 | 3.4 | 3.2 | 3.2 | 3.2 | 3.2 |
| | (.9) | (.8) | (.8) | (.9) | (.8) | (.8) | (.8) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 3.1 | 2.9 | 3.0 | 2.8 | 2.9 | 2.9 |
| | (.9) | (.8) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 11 Knowledge of conflict management and negotiation skills | 3.1 | 3.1 | 3.2 | 3.2 | 3.1 | 3.1 | 3.2 |
| | (.9) | (.8) | (.8) | (.8) | (.9) | (.8) | (.8) |

Appendix 12. Write-in Responses: Knowledge Missing from Survey

Knowledge Missing From Survey

Ability to utilize community resources to help with overall health, i.e., exercise programs, elder services, social groups

Cat and canine anatomy physiology

Collaborative nutrition management with the dieticians in DM patients

Communication skills and development of patient education

Dealing with grief and loss

Evidence based health care

Fitness and nutrition services

Home health nurse and transportation needs for ambulatory patients.

How to connect with department of health or provide response during times of natural disaster.

How to effectively use ancillary personnel (technicians, LVN's, clerks, etc)

How to locate practice sites in a desired area of employment, i.e., am care clinics, diabetes clinics, lipid clinics.

Knowledge of effective patient-pharmacist engagement techniques - In my setting we have developed a unique telephonic reach out system that has provided highly positive results; Pharmacy practice should be aware that effective ambulatory practice does not require a pharmacist to face-to-face encounter.

Managed care, prior authorizations, formulary interchange, tiered benefit plans, SOAP notes

Medicaid/Medicare prescribing limitations and service limit restrictions.

Methods to bring about change to enable implementation of patient-focused activities. For me, this is a daily activity of high importance.

NCQA and quality improvement marker achievement was barely touched....Could we have more on evidence based care and outcomes of care nation wide. We need to know how health care is working in order to improve it.

Patient counseling about different drugs and diseased especially chronic ones, e.g. diabetes and hypertension.

Patient health-belief models e.g. wellness behavior, illness behavior. Cultural and religious beliefs also affect accessibility, adherence and concordance.

Peer review, supervisory, coaching and mentoring

Pharmacotherapy and its application to patients

Precepting students and ambulatory care residents.

Proficiency in cardiopulmonary resuscitation (or equivalent)

Project management -- How to take a project idea, get appropriate approvals, generate buyin, set time line, achieve goals and complete/achieve goals

Knowledge Missing From Survey

Psychological and sociological principles necessary to relate to patients, practitioners and other pharmacists alike. All parties involved need to come to a common understanding of what's really important to each other. Setting aside egos, indifference, apathy is essential.

Role of clinic directors in assuring competency of staff, continuous quality initiatives and reporting of quality, clinical, economic and humanistic outcomes management.

Scope of practice relating to device therapy management

Technology (computer) skills

Technology and development of software applications to capture and report on outcomes. Data mining and analytical tools such as crystal reports, other tools such as Excel, Powerpoint, possibly html presentation of data via the various databases

The economics and daily operation needs of an ambulatory clinic.

The importance of handheld PDAs for information gathering

The knowledge that care fragmentation can be a real issue when physicians focus solely on their piece, and how best to proceed in these situations.

There was not enough emphasis on chief complaint history taking , how to manage a patient visit, and how interview a patient returning for a follow up visit for a chronic disease

Time management programs

Time management skills, documentation to support level of billing

Use of new technology (treo phone, wireless internet, barcode scanning equipment, etc...)

We need a resource to consolidate the variability in patient care based scopes of practice per licensure within individual states. there is a lot of emphasis placed on certification and programmatic activity that does not translate to consistent standards of care and patient access

Within Medical Informatics: its good to understand Excel, Access and other databases to be able to know what they can and can't do to move ahead in offering pharmacy programs.

You did not address teaching and precepting of students and residents. This is at the core of many family medicine practice/residency sites. My students include/have included pharmacy, medical, physician assistant, and nurse practitioner.

Appendix 13. Subgroup Analyses Based on BCPS Certification and Residency Training Status In this appendix, the ratings for the domains, tasks, and knowledge are presented for subgroups based on:

- (1) By whether or not the respondent is a Board Certified Pharmacotherapy Specialist (BCPS) 226 of 823 respondents (32%) held the BCPS certification.
- (2) By whether or not the respondent completed an ambulatory care-related residency program 485 of 823 respondents (59%) had completed a residency.

Note that 40% of the respondents were both BCPS certified and had completed a residency.

| | | PS cation | Resid | lency | Total |
|--|--------|--------------|--------|--------|--------|
| | Yes | No | Yes | No | Yes |
| Direct Patient Care | 49.7% | 47.1% | 50.5% | 44.0% | 47.8% |
| | (22.3) | (24.9) | (23.0) | (25.4) | (24.2) |
| Practice Management | 16.2% | 18.2% | 16.1% | 20.0% | 17.7% |
| | (14.9) | (17.0) | (15.0) | (18.2) | (16.5) |
| Public Health | 3.6% | 4.7% | 4.0% | 4.9% | 4.4% |
| | (4.4) | (5.4) | (4.8) | (5.7) | (5.2) |
| Medical Informatics and Professional Development | 20.3% | 15.5% | 18.3% | 14.7% | 16.8% |
| | (17.4) | (14.7) | (15.2) | (16.0) | (15.6) |
| Patient Advocacy | 9.5% | 11.6% | 9.7% | 12.7% | 11.0% |
| | (9.3) | (12.0) | (9.3) | (13.5) | (11.3) |
| Other | .7% | 2.9% | 1.4% | 3.7% | 2.3% |
| | (5.1) | (13.2) | (8.3) | (15.1) | (11.6) |

Percentage of Time Spent in Domains by BCPS Certification and Residency Training Status: Mean and (Standard Deviation)

Domain Importance Ratings by BCPS Certification and Residency Training Status: Mean and (Standard Deviation)

| | | PS cation | Residency on | | , | | Residency | | Total |
|--|-------|--------------|-----------------|-------|-------|--|-----------|--|-------|
| | Yes | No | Yes | No | Yes | | | | |
| 1 Direct Patient Care | 3.9 | 3.8 | 3.9 | 3.7 | 3.9 | | | | |
| | (.2) | (.5) | (.3) | (.6) | (.5) | | | | |
| 2 Practice Management | 3.4 | 3.5 | 3.4 | 3.4 | 3.4 | | | | |
| | (.7) | (.7) | (.6) | (.7) | (.7) | | | | |
| 3 Public Health | 2.8 | 2.8 | 2.8 | 2.8 | 2.8 | | | | |
| | (.8) | (.8) | (.8) | (.9) | (.8) | | | | |
| 4 Medical Informatics and Professional Development | 3.6 | 3.4 | 3.5 | 3.3 | 3.4 | | | | |
| | (.6) | (.7) | (.6) | (.8) | (.7) | | | | |
| 5 Patient Advocacy | 3.4 | 3.3 | 3.4 | 3.3 | 3.3 | | | | |
| | (.7) | (.8) | (.7) | (.8) | (.8) | | | | |
| 6 Other | 3.0 | 2.9 | 3.0 | 2.9 | 2.9 | | | | |
| | (1.1) | (1.2) | (1.2) | (1.2) | (1.2) | | | | |

Frequency Ratings for Tasks by BCPS Certification and Residency Training Status: Mean and (Standard Deviation)

| | | BCPS Certification | | 5 | | Total |
|---|-------|-----------------------|-------|-------|-------|-------|
| - | Yes | No | Yes | No | | |
| Direct Patient Care | | | | | | |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open | 4.5 | 4.3 | 4.5 | 4.3 | 4.4 | |
| communication, and encourages patient self-management. | (1.1) | (1.1) | (1.1) | (1.1) | (1.1) | |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's | 4.5 | 4.1 | 4.4 | 4.1 | 4.2 | |
| care (for example, chief complaint, history of present illness). | (1.0) | (1.2) | (1.1) | (1.2) | (1.2) | |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) | 4.4 | 4.2 | 4.3 | 4.1 | 4.2 | |
| medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | (1.1) | (1.2) | (1.1) | (1.2) | (1.2) | |
| 1.4 Reconcile medications based on information obtained from patient/caregiver | 4.5 | 3.9 | 4.3 | 3.8 | 4.1 | |
| interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | (1.0) | (1.3) | (1.1) | (1.4) | (1.3) | |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, | 4.3 | 3.6 | 4.1 | 3.3 | 3.8 | |
| lifestyle, substances of abuse, diagnostic test results). | (1.1) | (1.4) | (1.2) | (1.5) | (1.4) | |
| 1.6 Perform pertinent physical assessments as they relate to patient's current | 3.6 | 2.8 | 3.5 | 2.5 | 3.0 | |
| condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | (1.4) | (1.6) | (1.5) | (1.6) | (1.6) | |
| .7 Perform point of care testing (for example, blood glucose, cholesterol, INR, pone mineral density, peak flow). | 2.6 | 2.4 | 2.7 | 2.1 | 2.5 | |
| | (1.6) | (1.6) | (1.6) | (1.4) | (1.6) | |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy | 3.9 | 3.2 | 3.8 | 2.8 | 3.4 | |
| specialist on health and medication-related issues. | (1.2) | (1.5) | (1.3) | (1.5) | (1.5) | |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and | 4.3 | 3.9 | 4.3 | 3.7 | 4.0 | |
| willingness and ability to actively participate in his/her own care. | (1.1) | (1.3) | (1.2) | (1.4) | (1.3) | |
| 1.10 Assess benefits and risks of drug therapy for patients considering | 4.7 | 4.3 | 4.6 | 4.1 | 4.4 | |
| concomitant disease states, other medication, and other patient specific factors. | (.8) | (1.1) | (.9) | (1.2) | (1.1) | |
| 1.11 Assess the available information to identify drug related problems (for | 4.6 | 4.4 | 4.5 | 4.3 | 4.4 | |
| example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | (.9) | (1.0) | (1.0) | (1.1) | (1.0) | |
| 1.12 Assess the information gathered to identify non-drug factors that may | 4.4 | 3.8 | 4.3 | 3.6 | 4.0 | |
| affect patient outcomes (for example, tobacco, activity level, nutrition). | (1.0) | (1.3) | (1.1) | (1.3) | (1.2) | |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.9 | 3.5 | 3.8 | 3.4 | 3.7 | |
| ambulatory care pharmacy specialist. | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) | |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, | 4.2 | 3.8 | 4.1 | 3.6 | 3.9 | |
| social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based education). | (1.1) | (1.3) | (1.1) | (1.4) | (1.3) | |

Frequency Ratings for Tasks by BCPS Certification and Residency Training Status: Mean and (Standard Deviation)

| _ | | BCPS Re Certification | | | | dency | Total |
|--|-------|--------------------------|-------|-------|-------|-------|-------|
| _ | Yes | No | Yes | No | | | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of | 4.4 | 4.5 | 4.5 | 4.5 | 4.5 | | |
| medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | (1.1) | (1.0) | (1.0) | (.9) | (1.0) | | |
| 1.16 Evaluate the patient's administration technique for medications that are not | 3.2 | 3.5 | 3.3 | 3.5 | 3.4 | | |
| administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | (1.3) | (1.3) | (1.3) | (1.3) | (1.3) | | |
| 1.17 Provide disease-related patient education/counseling (for example, | 4.3 | 4.0 | 4.3 | 3.8 | 4.1 | | |
| diabetes, asthma, hypertension, dyslipidemia). | (1.1) | (1.2) | (1.1) | (1.3) | (1.2) | | |
| 1.18 Provide wellness and prevention education/counseling (for example, | 3.9 | 3.5 | 3.8 | 3.3 | 3.6 | | |
| lifestyle modifications, immunizations). | (1.3) | (1.4) | (1.3) | (1.4) | (1.3) | | |
| 1.19 Recommend appropriate immunizations to specific patients. | 3.2 | 2.6 | 3.0 | 2.5 | 2.8 | | |
| | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) | | |
| 1.20 Administer appropriate immunizations to specific patients. | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 | | |
| | (1.0) | (1.1) | (1.1) | (1.1) | (1.1) | | |
| .21 Provide OTC education/counseling (for example, herbals, non-herbal ietary supplements, vitamins, non-prescription drugs). | 3.9 | 4.1 | 3.9 | 4.1 | 4.0 | | |
| dietary supplements, vitamins, non-prescription drugs). | (1.2) | (1.2) | (1.2) | (1.1) | (1.2) | | |
| 22 Perform collaborative drug therapy management via protocol or signed | 4.2 | 3.1 | 4.0 | 2.6 | 3.4 | | |
| collaborative agreements with healthcare providers. | (1.4) | (1.7) | (1.5) | (1.7) | (1.7) | | |
| 1.23 Provide integrated disease-state management (for example, | 3.7 | 2.6 | 3.5 | 2.1 | 2.9 | | |
| pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | (1.5) | (1.6) | (1.5) | (1.5) | (1.7) | | |
| 1.24 Provide focused disease-state management (for example, diabetes, | 4.1 | 3.2 | 4.0 | 2.7 | 3.5 | | |
| hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | (1.2) | (1.6) | (1.3) | (1.6) | (1.6) | | |
| 1.25 Provide wellness and preventive programs for individual patients (for | 2.5 | 2.3 | 2.5 | 2.1 | 2.3 | | |
| example, weight management program, tobacco cessation program, immunization program). | (1.4) | (1.4) | (1.4) | (1.3) | (1.4) | | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and | 4.0 | 4.1 | 3.9 | 4.2 | 4.0 | | |
| recommend treatment options. | (1.1) | (1.2) | (1.2) | (1.1) | (1.2) | | |
| 1.27 Make recommendations to manage drug therapy which may include | 4.6 | 4.0 | 4.4 | 3.8 | 4.2 | | |
| initiation, modification, or discontinuation of medication therapy as appropriate. | (.9) | (1.2) | (1.0) | (1.2) | (1.1) | | |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases | 3.7 | 3.5 | 3.6 | 3.6 | 3.6 | | |
| (for example, blood glucose meters, peak flow meters, blood pressure monitors). | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) | | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases | 3.2 | 3.1 | 3.1 | 3.1 | 3.1 | | |
| (for example, blood glucose meters, peak flow meters, blood pressure monitors). | (1.2) | (1.4) | (1.3) | (1.3) | (1.3) | | |

| | | BCPS Residency | | Total | |
|---|--------------|----------------|--------------|--------------|--------------|
| | Yes | No | Yes | No | . otur |
| 1.30 Recommend appropriate health-related screening tests (for example, home | 2.1 | 2.5 | 2.2 | 2.6 | 2.4 |
| pregnancy tests, hemoccult tests) | (1.2) | (1.2) | (1.2) | (1.2) | (1.2) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for | 1.7 | 2.2 | 1.9 | 2.3 | 2.1 |
| example, home pregnancy tests, hemoccult tests). | (1.0) | (1.3) | (1.1) | (1.3) | (1.2) |
| 1.32 Define treatment goals in collaboration with the patient and other | 4.4 | 3.4 | 4.2 | 2.9 | 3.7 |
| nealthcare providers. | (1.0) | (1.5) | (1.2) | (1.6) | (1.5) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, | 3.2 | 3.3 | 3.3 | 3.3 | 3.3 |
| nsurance coverage, out of pocket expenses). | (1.6) | (1.6) | (1.6) | (1.7) | (1.6) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug | 4.4 | 4.0 | 4.2 | 3.9 | 4.1 |
| herapy or designing a drug treatment plan. | (1.1) | (1.2) | (1.1) | (1.3) | (1.2) |
| .35 Develop a patient-specific plan to address prioritized patient needs and | 4.5 | 3.6 | 4.3 | 3.2 | 3.8 |
| dentified drug-related problems to improve patient outcomes. | (1.0) | (1.4) | (1.1) | (1.5) | (1.4) |
| .36 Implement a patient-specific plan to address prioritized patient needs and | 4.5 | 3.5 | 4.2 | 3.1 | 3.8 |
| ntified drug-related problems to improve patient outcomes. | (.9) | (1.5) | (1.1) | (1.5) | (1.4) |
| 37 Develop a patient-specific monitoring and follow-up plan in order to assess | 4.5 | 3.4 | 4.2 | 2.9 | 3.7 |
| response to both drug and non-drug therapy and assure safety. | (.9) | (1.5) | (1.2) | (1.6) | (1.5) |
| 1.38 Communicate patient-specific findings and treatment recommendations to | 4.5 | 3.8 | 4.4 | 3.4 | 4.0 |
| other healthcare professionals involved in the care of the patient. | (.9) | (1.4) | (1.1) | (1.5) | (1.3) |
| 1.39 Communicate patient-specific findings and treatment recommendations to | 4.4 | 3.9 | 4.3 | 3.6 | 4.0 |
| he patient/caregiver in language they can understand (includes both written and verbal communication). | (1.0) | (1.4) | (1.1) | (1.4) | (1.3) |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non- | 4.1 | 3.1 | 3.9 | 2.7 | 3.4 |
| drug therapy and assure safety. | (1.2) | (1.6) | (1.4) | (1.6) | (1.6) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, | 4.5 | 3.2 | 4.2 | 2.7 | 3.6 |
| NR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted. | (1.0) | (1.6) | (1.3) | (1.6) | (1.6) |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 4.4 | 3.3 | 4.2 | 2.7 | 3.6 |
| | (1.0) | (1.6) | (1.2) | (1.6) | (1.6) |
| .43 Determine patient-specific reasons for lack of adherence to recommended | 4.4 | 3.5 | 4.1 | 3.1 | 3.7 |
| reatment and in collaboration with the patient develop a plan for improving adherence to therapy. | (.9) | (1.5) | (1.2) | (1.5) | (1.4) |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other nealthcare providers). | 4.6 (1.0) | 3.5 (1.6) | 4.3 (1.2) | 3.0 (1.6) | 3.8 (1.5) |

Frequency Ratings for Tasks by BCPS Certification and Residency Training Status: Mean and (Standard Deviation)

| | BCPS Certification | | 5 | | Total |
|---|-----------------------|--------------|--------------|--------------|--------------|
| - | Yes | No | Yes | No | |
| Practice Management | | | | | |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to | 2.7 | 2.6 | 2.7 | 2.5 | 2.6 |
| patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (1.4) | (1.4) | (1.4) | (1.4) | (1.4) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient | 2.1 | 2.1 | 2.2 | 2.0 | 2.1 |
| care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (1.1) | (1.2) | (1.1) | (1.2) | (1.1) |
| 2.3 Establish relationships and/or collaborative practice agreements with other | 2.9 | 2.6 | 2.8 | 2.5 | 2.7 |
| health care providers. | (1.3) | (1.4) | (1.4) | (1.5) | (1.4) |
| 2.4 Promote and market patient care services to patients and health care | 2.7 | 2.4 | 2.6 | 2.4 | 2.5 |
| providers. | (1.4) | (1.4) | (1.3) | (1.4) | (1.4) |
| 2.5 Establish and maintain a system for patient referral. | 3.3 | 2.5 | 3.1 | 2.2 | 2.7 |
| | (1.4) | (1.6) | (1.5) | (1.5) | (1.6) |
| 2.6 Establish and maintain a system for patient follow up. | 3.6 | 2.9 | 3.5 | 2.6 | 3.1 |
| | (1.4) | (1.6) | (1.5) | (1.6) | (1.6) |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and | 2.8 | 2.6 | 2.7 | 2.7 | 2.7 |
| provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | (1.2) | (1.4) | (1.2) | (1.5) | (1.3) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 2.5 | 2.5 | 2.5 | 2.4 | 2.5 |
| disband, or expand ambulatory care pharmacy services. | (1.3) | (1.3) | (1.2) | (1.5) | (1.3) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 4.6 | 3.6 | 4.3 | 3.3 | 3.9 |
| | (.9) | (1.6) | (1.2) | (1.7) | (1.5) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office | 3.1 | 3.0 | 3.1 | 2.9 | 3.0 |
| equipment and space, ancillary personnel, staff). | (1.4) | (1.5) | (1.4) | (1.5) | (1.5) |
| 2.11 Organize the practice in a manner that supports efficient work flow, | 3.4 | 3.0 | 3.3 | 2.9 | 3.1 |
| integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication dispensing functions). | (1.3) | (1.5) | (1.4) | (1.6) | (1.5) |
| 2.12 Manage a financially viable practice (for example, cash flow management, | 1.7 | 2.3 | 1.8 | 2.6 | 2.1 |
| cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | (1.2) | (1.6) | (1.3) | (1.7) | (1.5) |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 1.6 (1.0) | 1.9 (1.3) | 1.8 (1.1) | 1.9 (1.3) | 1.8 (1.2) |
| | (1.0) | (1.5) | (1.1) | (1.5) | (1.2) |

| Frequency Ratings for Tasks by BCPS Certification and Residency Training Status: |
|--|
| Mean and (Standard Deviation) |

| | BCPS Certification | | Resid | dency | Total |
|---|-----------------------|-------|-------|-------|-------|
| | Yes | No | Yes | No | |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by | 2.4 | 2.3 | 2.4 | 2.3 | 2.3 |
| the provider and/or institution, and in accordance with legal and regulatory requirements. | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |
| 2.15 Develop and implement policy and procedures that are in accordance with | 2.5 | 2.6 | 2.6 | 2.5 | 2.6 |
| accepted guidelines and standards of practice. | (1.2) | (1.4) | (1.2) | (1.4) | (1.3) |
| 2.16 Manage point of care testing in accordance with regulatory requirements | 1.9 | 2.2 | 2.0 | 2.3 | 2.1 |
| (for example, OSHA, CLIA). | (1.3) | (1.5) | (1.4) | (1.6) | (1.5) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying | 1.5 | 2.2 | 1.7 | 2.5 | 2.0 |
| groups, special order drugs, patient assistance programs). | (.9) | (1.5) | (1.2) | (1.6) | (1.4) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 2.4 | 3.7 | 2.8 | 4.1 | 3.4 |
| | (1.6) | (1.6) | (1.7) | (1.5) | (1.7) |
| 2.19 Participate in formulary management (for example, participate on P&T | 2.4 | 2.3 | 2.5 | 2.2 | 2.3 |
| committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical necessity. | (1.2) | (1.4) | (1.2) | (1.4) | (1.3) |
| 2.20 Report medication errors and develop systems to track and analyze these | 2.6 | 3.0 | 2.7 | 3.1 | 2.9 |
| for possible intervention measures. | (1.2) | (1.4) | (1.3) | (1.4) | (1.3) |
| Public Health | | | | | |
| 3.1 Provide general information to the public regarding preventive health issues | 2.4 | 2.8 | 2.5 | 2.9 | 2.7 |
| (for example, cardiovascular disease, tobacco cessation, immunizations). | (1.1) | (1.3) | (1.2) | (1.3) | (1.3) |
| 3.2 Provide information to, and/or collaborate with other healthcare | 2.7 | 2.6 | 2.7 | 2.5 | 2.6 |
| professionals to design intervention strategies that address preventive health issues. | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, | 2.1 | 2.5 | 2.2 | 2.6 | 2.4 |
| organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | (1.0) | (1.2) | (1.1) | (1.3) | (1.2) |
| 3.4 Participate in community health screening programs. | 1.8 | 1.9 | 1.9 | 2.0 | 1.9 |
| | (.6) | (1.0) | (.8) | (1.0) | (.9) |
| 3.5 Serve as a public advocate regarding preventive health issues. | 1.9 | 2.2 | 2.0 | 2.3 | 2.1 |
| | (1.0) | (1.3) | (1.2) | (1.3) | (1.2) |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care | 2.0 | 2.2 | 2.1 | 2.2 | 2.1 |
| pharmacy practice. | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |
| 3.7 Identify and report suspected public health threats (for example, disasters, | 1.4 | 1.6 | 1.5 | 1.7 | 1.6 |
| infectious diseases). | (.7) | (1.0) | (.8) | (1.1) | (1.0) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and | 1.4 | 1.6 | 1.4 | 1.7 | 1.6 |
| disasters. | (.6) | (1.0) | (.8) | (1.0) | (.9) |

| | BCPS Certification | | BCPS Reside Certification | | 5 | | Total |
|---|-----------------------|-------|------------------------------|-------|-------|--|-------|
| | Yes | No | Yes | No | | | |
| 3.9 Participate in disaster response preparation and planning. | 1.4 | 1.6 | 1.5 | 1.7 | 1.6 | | |
| | (.6) | (.9) | (.7) | (.9) | (.8) | | |
| Medical Informatics and Professional Development | | | | | | | |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care | 4.1 | 3.5 | 3.8 | 3.4 | 3.7 | | |
| pharmacy practice. | (.9) | (1.1) | (1.0) | (1.2) | (1.1) | | |
| 4.2 Practice ongoing self-managed continuing professional development (for | 3.7 | 3.5 | 3.6 | 3.5 | 3.6 | | |
| example, continuing education programs, practice self-evaluation, attend study or journal clubs). | (.8) | (.9) | (.9) | (.9) | (.9) | | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design | 3.7 | 2.9 | 3.5 | 2.7 | 3.2 | | |
| methodology, statistical analysis, and significance and applicability of reported data and conclusions. | (.8) | (1.2) | (1.0) | (1.3) | (1.2) | | |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 4.4 | 4.2 | 4.2 | 4.3 | 4.3 | | |
| | (.8) | (1.0) | (1.0) | (.9) | (.9) | | |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 3.9 | 3.4 | 3.8 | 3.1 | 3.5 | | |
| | (1.1) | (1.3) | (1.2) | (1.4) | (1.3) | | |
| 4.6 Provide health and medication-related education to healthcare professionals. | 4.0 | 3.5 | 3.8 | 3.4 | 3.6 | | |
| | (1.1) | (1.2) | (1.1) | (1.3) | (1.2) | | |
| 4.7 Provide experiential training to pharmacy students and residents in | 3.8 | 3.2 | 3.7 | 3.0 | 3.4 | | |
| ambulatory care pharmacy practice. | (1.4) | (1.5) | (1.4) | (1.5) | (1.5) | | |
| 4.8 Conduct research as principal investigator or co-investigator to generate | 2.5 | 1.9 | 2.3 | 1.7 | 2.1 | | |
| knowledge applicable to ambulatory care pharmacy practice | (1.2) | (1.3) | (1.2) | (1.3) | (1.3) | | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, | 2.1 | 1.7 | 1.9 | 1.6 | 1.8 | | |
| abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | (.9) | (1.0) | (.9) | (1.0) | (1.0) | | |
| 4.10 Document and report adverse drug-related events as appropriate (for | 2.4 | 2.4 | 2.4 | 2.4 | 2.4 | | |
| example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | (1.1) | (1.2) | (1.1) | (1.2) | (1.2) | | |
| 4.11 Participate in local, state, and/or national professional organizations. | 2.9 | 2.8 | 2.9 | 2.8 | 2.9 | | |
| | (1.0) | (1.1) | (1.1) | (1.2) | (1.1) | | |
| 4.12 Provide ongoing staff training and development, and opportunities/support | 2.6 | 2.6 | 2.6 | 2.7 | 2.6 | | |
| for credentialing and continuing education. | (1.0) | (1.2) | (1.1) | (1.2) | (1.2) | | |
| Patient Advocacy | | | | | | | |
| 5.1 Communicate patient-related information to healthcare professionals that | 4.1 | 3.8 | 4.0 | 3.7 | 3.9 | | |
| advocates for optimal patient outcomes. | (1.1) | (1.2) | (1.2) | (1.3) | (1.2) | | |

| | BCPS Certification | | 5 | | Total |
|--|-----------------------|-------|-------|-------|-------|
| - | Yes | No | Yes | No | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 2.5 | 2.8 | 2.6 | 2.8 | 2.7 |
| | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 5.3 Assist patients with understanding of prescription drug plans that provide | 2.6 | 3.0 | 2.6 | 3.3 | 2.9 |
| optimal prescription drug coverage and facilitate best outcomes. | (1.4) | (1.5) | (1.5) | (1.5) | (1.5) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.4 | 3.5 | 3.3 | 3.7 | 3.5 |
| | (1.4) | (1.5) | (1.4) | (1.4) | (1.4) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | 2.9 | 3.0 | 2.9 | 3.0 | 3.0 |
| | (1.2) | (1.4) | (1.4) | (1.4) | (1.4) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | 3.9 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |
| 5.7 Establish a system for two-way communication between the pharmacist and | 4.0 | 3.6 | 3.8 | 3.5 | 3.7 |
| the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | (1.3) | (1.5) | (1.4) | (1.5) | (1.4) |
| 5.8 Collaborate with other healthcare professionals to provide case management | 3.8 | 3.2 | 3.7 | 3.0 | 3.4 |
| (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | (1.3) | (1.5) | (1.3) | (1.5) | (1.4) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the | 3.5 | 2.9 | 3.3 | 2.7 | 3.1 |
| ambulatory care pharmacist. | (1.2) | (1.4) | (1.3) | (1.4) | (1.4) |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient | 2.8 | 2.6 | 2.7 | 2.6 | 2.7 |
| outcomes. | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 5.11 Manage conflict and differences of opinions with other healthcare | 3.3 | 2.8 | 3.1 | 2.6 | 2.9 |
| professionals to optimize care for the patient | (1.1) | (1.4) | (1.2) | (1.4) | (1.3) |
| 5.12 Encourage patients to openly communicate health and medication related | 4.1 | 3.8 | 3.9 | 3.8 | 3.9 |
| concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |

| | BCPS Certification | | BCPS Residency Certification | | Total |
|---|-----------------------|------|---------------------------------|------|-------|
| _ | Yes | No | Yes | No | |
| Direct Patient Care | | | | | |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open | 3.9 | 3.8 | 3.9 | 3.8 | 3.8 |
| communication, and encourages patient self-management. | (.4) | (.4) | (.3) | (.5) | (.4) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's | 3.9 | 3.8 | 3.9 | 3.7 | 3.8 |
| care (for example, chief complaint, history of present illness). | (.3) | (.5) | (.3) | (.6) | (.5) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) | 3.9 | 3.8 | 3.9 | 3.8 | 3.9 |
| medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | (.4) | (.4) | (.3) | (.5) | (.4) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver | 3.9 | 3.7 | 3.8 | 3.6 | 3.7 |
| interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | (.4) | (.6) | (.4) | (.7) | (.5) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, | 3.6 | 3.5 | 3.6 | 3.4 | 3.5 |
| lifestyle, substances of abuse, diagnostic test results). | (.5) | (.7) | (.5) | (.7) | (.6) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | 3.4 | 3.1 | 3.3 | 2.9 | 3.1 |
| | (.7) | (.9) | (.7) | (.9) | (.8) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, | 2.9 | 3.1 | 3.1 | 2.9 | 3.0 |
| bone mineral density, peak flow). | (.9) | (.9) | (.9) | (.9) | (.9) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy | 3.4 | 3.3 | 3.5 | 3.1 | 3.3 |
| specialist on health and medication-related issues. | (.7) | (.8) | (.7) | (.9) | (.8) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and | 3.8 | 3.6 | 3.8 | 3.5 | 3.7 |
| willingness and ability to actively participate in his/her own care. | (.5) | (.7) | (.4) | (.8) | (.6) |
| 1.10 Assess benefits and risks of drug therapy for patients considering | 4.0 | 3.7 | 3.9 | 3.6 | 3.8 |
| concomitant disease states, other medication, and other patient specific factors. | (.2) | (.6) | (.3) | (.7) | (.5) |
| 1.11 Assess the available information to identify drug related problems (for | 3.9 | 3.8 | 3.9 | 3.7 | 3.9 |
| example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | (.3) | (.5) | (.2) | (.6) | (.4) |
| 1.12 Assess the information gathered to identify non-drug factors that may | 3.6 | 3.5 | 3.6 | 3.4 | 3.5 |
| affect patient outcomes (for example, tobacco, activity level, nutrition). | (.6) | (.7) | (.5) | (.7) | (.6) |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.7 | 3.4 | 3.6 | 3.4 | 3.5 |
| ambulatory care pharmacy specialist. | (.6) | (.7) | (.6) | (.8) | (.7) |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, | 3.7 | 3.5 | 3.7 | 3.5 | 3.6 |
| social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based education). | (.5) | (.7) | (.6) | (.7) | (.6) |

| | | BCPS Certification | | | | | | dency | _ Total |
|--|------|-----------------------|-------|-------|-------|--|--|-------|---------|
| | Yes | No | Yes | No | | | | | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of | 3.9 | 3.9 | 3.9 | 3.8 | 3.9 | | | | |
| medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | (.4) | (.4) | (.4) | (.5) | (.4) | | | | |
| 1.16 Evaluate the patient's administration technique for medications that are not | 3.6 | 3.7 | 3.7 | 3.6 | 3.6 | | | | |
| administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | (.6) | (.6) | (.6) | (.6) | (.6) | | | | |
| 1.17 Provide disease-related patient education/counseling (for example, | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 | | | | |
| diabetes, asthma, hypertension, dyslipidemia). | (.5) | (.5) | (.4) | (.6) | (.5) | | | | |
| 1.18 Provide wellness and prevention education/counseling (for example, | 3.5 | 3.5 | 3.6 | 3.4 | 3.5 | | | | |
| ifestyle modifications, immunizations). | (.5) | (.7) | (.6) | (.7) | (.7) | | | | |
| 1.19 Recommend appropriate immunizations to specific patients. | 3.3 | 3.1 | 3.2 | 3.1 | 3.2 | | | | |
| | (.6) | (.9) | (.7) | (.9) | (.8) | | | | |
| 1.20 Administer appropriate immunizations to specific patients. | 2.7 | 2.7 | 2.7 | 2.7 | 2.7 | | | | |
| | (.9) | (1.0) | (1.0) | (1.0) | (1.0) | | | | |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal | 3.6 | 3.6 | 3.7 | 3.6 | 3.6 | | | | |
| dietary supplements, vitamins, non-prescription drugs). | (.5) | (.6) | (.6) | (.7) | (.6) | | | | |
| 1.22 Perform collaborative drug therapy management via protocol or signed | 3.8 | 3.5 | 3.8 | 3.4 | 3.6 | | | | |
| collaborative agreements with healthcare providers. | (.4) | (.8) | (.5) | (.9) | (.7) | | | | |
| 1.23 Provide integrated disease-state management (for example, | 3.7 | 3.4 | 3.7 | 3.2 | 3.5 | | | | |
| pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | (.5) | (.8) | (.6) | (.9) | (.8) | | | | |
| 1.24 Provide focused disease-state management (for example, diabetes, | 3.7 | 3.6 | 3.8 | 3.4 | 3.6 | | | | |
| hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | (.5) | (.7) | (.5) | (.7) | (.6) | | | | |
| 1.25 Provide wellness and preventive programs for individual patients (for | 3.3 | 3.3 | 3.3 | 3.2 | 3.3 | | | | |
| example, weight management program, tobacco cessation program, immunization program). | (.7) | (.8) | (.8) | (.8) | (.8) | | | | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and | 3.6 | 3.6 | 3.6 | 3.6 | 3.6 | | | | |
| recommend treatment options. | (.5) | (.6) | (.6) | (.6) | (.6) | | | | |
| 1.27 Make recommendations to manage drug therapy which may include | 3.9 | 3.7 | 3.9 | 3.6 | 3.8 | | | | |
| initiation, modification, or discontinuation of medication therapy as appropriate. | (.2) | (.6) | (.3) | (.6) | (.5) | | | | |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases | 3.6 | 3.5 | 3.5 | 3.4 | 3.5 | | | | |
| (for example, blood glucose meters, peak flow meters, blood pressure monitors). | (.6) | (.7) | (.6) | (.7) | (.7) | | | | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases | 3.5 | 3.4 | 3.4 | 3.4 | 3.4 | | | | |
| (for example, blood glucose meters, peak flow meters, blood pressure monitors). | (.6) | (.8) | (.7) | (.7) | (.7) | | | | |

| | BCPS Certification | | 5 | | _ Total |
|--|-----------------------|------|------|------|---------|
| - | Yes | No | Yes | No | |
| 1.30 Recommend appropriate health-related screening tests (for example, home | 2.9 | 3.0 | 2.9 | 3.1 | 3.0 |
| pregnancy tests, hemoccult tests) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for | 2.7 | 3.0 | 2.8 | 3.0 | 2.9 |
| example, home pregnancy tests, hemoccult tests). | (.8) | (.9) | (.8) | (.9) | (.9) |
| 1.32 Define treatment goals in collaboration with the patient and other | 3.8 | 3.5 | 3.8 | 3.3 | 3.6 |
| healthcare providers. | (.4) | (.8) | (.5) | (.9) | (.7) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, | 3.3 | 3.2 | 3.3 | 3.2 | 3.3 |
| insurance coverage, out of pocket expenses). | (.8) | (.9) | (.9) | (.9) | (.9) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug | 3.7 | 3.6 | 3.7 | 3.5 | 3.6 |
| therapy or designing a drug treatment plan. | (.5) | (.7) | (.6) | (.7) | (.6) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (.4) | (.6) | (.4) | (.7) | (.5) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and | 3.8 | 3.6 | 3.8 | 3.5 | 3.7 |
| identified drug-related problems to improve patient outcomes. | (.4) | (.6) | (.5) | (.7) | (.6) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess | 3.8 | 3.6 | 3.8 | 3.4 | 3.6 |
| response to both drug and non-drug therapy and assure safety. | (.4) | (.7) | (.5) | (.8) | (.7) |
| 1.38 Communicate patient-specific findings and treatment recommendations to | 3.9 | 3.7 | 3.9 | 3.5 | 3.8 |
| other healthcare professionals involved in the care of the patient. | (.3) | (.6) | (.3) | (.7) | (.5) |
| 1.39 Communicate patient-specific findings and treatment recommendations to | 3.9 | 3.7 | 3.9 | 3.5 | 3.7 |
| the patient/caregiver in language they can understand (includes both written and verbal communication). | (.3) | (.6) | (.4) | (.7) | (.6) |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non- | 3.7 | 3.4 | 3.7 | 3.2 | 3.5 |
| drug therapy and assure safety. | (.5) | (.8) | (.5) | (.9) | (.7) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, | 3.9 | 3.5 | 3.8 | 3.3 | 3.6 |
| INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted. | (.3) | (.7) | (.4) | (.8) | (.7) |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 3.9 | 3.5 | 3.8 | 3.3 | 3.6 |
| | (.3) | (.7) | (.4) | (.8) | (.7) |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended | 3.8 | 3.6 | 3.8 | 3.4 | 3.7 |
| treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | (.4) | (.7) | (.4) | (.8) | (.6) |
| 1.44 Document all patient care activities (for example, patient-specific findings, | 3.9 | 3.6 | 3.9 | 3.4 | 3.7 |
| detailed treatment recommendations and communications with patient and other healthcare providers). | (.3) | (.7) | (.4) | (.8) | (.7) |

| | | BCPS Certification | | | | | | | | dency | Total |
|---|------|-----------------------|------|-------|------|--|--|--|--|-------|-------|
| | Yes | No | Yes | No | | | | | | | |
| Practice Management | | | | | | | | | | | |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 | | | | | | |
| patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (.7) | (.8) | (.7) | (.8) | (.8) | | | | | | |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient | 3.5 | 3.4 | 3.5 | 3.2 | 3.4 | | | | | | |
| care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | (.6) | (.8) | (.7) | (.9) | (.8) | | | | | | |
| 2.3 Establish relationships and/or collaborative practice agreements with other | 3.7 | 3.6 | 3.7 | 3.4 | 3.6 | | | | | | |
| health care providers. | (.5) | (.7) | (.5) | (.7) | (.6) | | | | | | |
| 2.4 Promote and market patient care services to patients and health care | 3.4 | 3.3 | 3.4 | 3.2 | 3.4 | | | | | | |
| providers. | (.7) | (.8) | (.7) | (.9) | (.8) | | | | | | |
| 2.5 Establish and maintain a system for patient referral. | 3.6 | 3.2 | 3.5 | 3.1 | 3.3 | | | | | | |
| | (.7) | (.9) | (.7) | (1.0) | (.9) | | | | | | |
| 2.6 Establish and maintain a system for patient follow up. | 3.7 | 3.4 | 3.6 | 3.3 | 3.5 | | | | | | |
| | (.6) | (.8) | (.6) | (.8) | (.7) | | | | | | |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and | 3.5 | 3.4 | 3.5 | 3.4 | 3.4 | | | | | | |
| provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | (.6) | (.7) | (.6) | (.8) | (.7) | | | | | | |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 3.4 | 3.4 | 3.5 | 3.3 | 3.4 | | | | | | |
| disband, or expand ambulatory care pharmacy services. | (.6) | (.8) | (.7) | (.8) | (.7) | | | | | | |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 3.9 | 3.6 | 3.9 | 3.5 | 3.7 | | | | | | |
| | (.3) | (.7) | (.4) | (.8) | (.6) | | | | | | |
| 2.10 Assure time, space and resources necessary to provide patient care | 3.4 | 3.4 | 3.5 | 3.3 | 3.4 | | | | | | |
| services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | (.6) | (.8) | (.7) | (.8) | (.8) | | | | | | |
| 2.11 Organize the practice in a manner that supports efficient work flow, | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 | | | | | | |
| integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication dispensing functions). | (.6) | (.8) | (.6) | (.8) | (.7) | | | | | | |
| 2.12 Manage a financially viable practice (for example, cash flow management, | 3.1 | 3.3 | 3.2 | 3.4 | 3.2 | | | | | | |
| cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | (.8) | (.9) | (.9) | (.8) | (.9) | | | | | | |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy | 3.3 | 3.4 | 3.4 | 3.3 | 3.4 | | | | | | |
| services. | (.8) | (.8) | (.8) | (.9) | (.8) | | | | | | |

| | | BCPS Certification | | | | | | dency | Total |
|---|------|-----------------------|------|-------|------|--|--|-------|-------|
| | Yes | No | Yes | No | | | | | |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by | 3.6 | 3.4 | 3.6 | 3.3 | 3.5 | | | | |
| the provider and/or institution, and in accordance with legal and regulatory requirements. | (.6) | (.8) | (.6) | (.8) | (.7) | | | | |
| 2.15 Develop and implement policy and procedures that are in accordance with | 3.5 | 3.5 | 3.6 | 3.4 | 3.5 | | | | |
| accepted guidelines and standards of practice. | (.7) | (.7) | (.6) | (.8) | (.7) | | | | |
| 2.16 Manage point of care testing in accordance with regulatory requirements | 3.1 | 3.2 | 3.1 | 3.2 | 3.2 | | | | |
| (for example, OSHA, CLIA). | (.9) | (.9) | (.9) | (1.0) | (.9) | | | | |
| 2.17 Provide a system for drug procurement (for example, contracts, buying | 2.7 | 3.1 | 2.9 | 3.1 | 3.0 | | | | |
| groups, special order drugs, patient assistance programs). | (.9) | (.9) | (.9) | (.9) | (.9) | | | | |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 3.2 | 3.6 | 3.3 | 3.7 | 3.5 | | | | |
| | (.9) | (.7) | (.9) | (.6) | (.8) | | | | |
| 2.19 Participate in formulary management (for example, participate on P&T | 3.4 | 3.2 | 3.3 | 3.2 | 3.3 | | | | |
| committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical necessity. | (.7) | (.9) | (.7) | (.9) | (.8) | | | | |
| 2.20 Report medication errors and develop systems to track and analyze these | 3.5 | 3.6 | 3.5 | 3.6 | 3.5 | | | | |
| for possible intervention measures. | (.7) | (.7) | (.7) | (.7) | (.7) | | | | |
| Public Health | | | | | | | | | |
| 3.1 Provide general information to the public regarding preventive health issues | 3.2 | 3.3 | 3.3 | 3.3 | 3.3 | | | | |
| (for example, cardiovascular disease, tobacco cessation, immunizations). | (.7) | (.7) | (.7) | (.7) | (.7) | | | | |
| 3.2 Provide information to, and/or collaborate with other healthcare | 3.3 | 3.3 | 3.3 | 3.2 | 3.3 | | | | |
| professionals to design intervention strategies that address preventive health issues. | (.7) | (.8) | (.7) | (.8) | (.7) | | | | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, | 2.9 | 3.1 | 3.0 | 3.1 | 3.0 | | | | |
| organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | (.7) | (.8) | (.8) | (.8) | (.8) | | | | |
| 3.4 Participate in community health screening programs. | 2.8 | 3.0 | 3.0 | 3.0 | 3.0 | | | | |
| | (.8) | (.9) | (.8) | (.9) | (.8) | | | | |
| 3.5 Serve as a public advocate regarding preventive health issues. | 2.9 | 3.1 | 3.0 | 3.1 | 3.1 | | | | |
| | (.8) | (.9) | (.8) | (.9) | (.8) | | | | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care | 3.3 | 3.2 | 3.3 | 3.2 | 3.2 | | | | |
| pharmacy practice. | (.7) | (.9) | (.8) | (.9) | (.8) | | | | |
| 3.7 Identify and report suspected public health threats (for example, disasters, | 2.8 | 3.0 | 2.9 | 3.0 | 2.9 | | | | |
| infectious diseases). | (.8) | (.9) | (.9) | (.9) | (.9) | | | | |
| 3.8 Facilitate appropriate care for patients affected by public health threats and | | | | | | | | | |
| 3 .8 Facilitate appropriate care for patients affected by public health threats and disasters. | 2.8 | 3.0 | 2.9 | 3.1 | 3.0 | | | | |

| | BCPS Certification | | | | | | | | | | | | Resid | lency | _ Total |
|--|-----------------------|------|------|------|--------|--|--|--|--|--|--|--|-------|-------|---------|
| | Yes | No | Yes | No | . otai | | | | | | | | | | |
| 3.9 Participate in disaster response preparation and planning. | 2.9 | 3.0 | 2.9 | 3.1 | 3.0 | | | | | | | | | | |
| | (.8) | (.9) | (.9) | (.9) | (.9) | | | | | | | | | | |
| Medical Informatics and Professional Development | | | | | | | | | | | | | | | |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care | 3.8 | 3.6 | 3.8 | 3.5 | 3.7 | | | | | | | | | | |
| pharmacy practice. | (.4) | (.7) | (.5) | (.7) | (.6) | | | | | | | | | | |
| 4.2 Practice ongoing self-managed continuing professional development (for | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 | | | | | | | | | | |
| example, continuing education programs, practice self-evaluation, attend study or journal clubs). | (.4) | (.5) | (.4) | (.6) | (.5) | | | | | | | | | | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design | 3.7 | 3.3 | 3.6 | 3.1 | 3.4 | | | | | | | | | | |
| methodology, statistical analysis, and significance and applicability of reported data and conclusions. | (.5) | (.8) | (.6) | (.9) | (.8) | | | | | | | | | | |
| 4.4 Respond to drug information requests from patients and healthcare | 3.8 | 3.7 | 3.8 | 3.7 | 3.7 | | | | | | | | | | |
| professionals. | (.4) | (.5) | (.5) | (.5) | (.5) | | | | | | | | | | |
| 1.5 Educate pharmacists, physicians, other allied health care professionals, tudents, and residents in the principles and practice of evidence-based nedicine. | 3.8 | 3.5 | 3.7 | 3.4 | 3.6 | | | | | | | | | | |
| | (.4) | (.7) | (.5) | (.7) | (.6) | | | | | | | | | | |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.8 | 3.6 | 3.7 | 3.5 | 3.6 | | | | | | | | | | |
| | (.4) | (.6) | (.5) | (.7) | (.6) | | | | | | | | | | |
| 4.7 Provide experiential training to pharmacy students and residents in | 3.8 | 3.6 | 3.8 | 3.4 | 3.6 | | | | | | | | | | |
| ambulatory care pharmacy practice. | (.5) | (.6) | (.5) | (.7) | (.6) | | | | | | | | | | |
| 4.8 Conduct research as principal investigator or co-investigator to generate | 3.2 | 2.9 | 3.2 | 2.8 | 3.0 | | | | | | | | | | |
| knowledge applicable to ambulatory care pharmacy practice | (.7) | (.9) | (.7) | (.9) | (.8) | | | | | | | | | | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, | 3.2 | 2.9 | 3.2 | 2.7 | 3.0 | | | | | | | | | | |
| abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | (.7) | (.9) | (.7) | (.9) | (.9) | | | | | | | | | | |
| 4.10 Document and report adverse drug-related events as appropriate (for | 3.4 | 3.3 | 3.4 | 3.3 | 3.3 | | | | | | | | | | |
| example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | (.6) | (.8) | (.7) | (.8) | (.7) | | | | | | | | | | |
| 4.11 Participate in local, state, and/or national professional organizations. | 3.4 | 3.4 | 3.4 | 3.3 | 3.4 | | | | | | | | | | |
| | (.7) | (.8) | (.7) | (.8) | (.7) | | | | | | | | | | |
| 4.12 Provide ongoing staff training and development, and opportunities/support | 3.4 | 3.3 | 3.4 | 3.3 | 3.3 | | | | | | | | | | |
| for credentialing and continuing education. | (.7) | (.8) | (.7) | (.8) | (.8) | | | | | | | | | | |
| Patient Advocacy | | | | | | | | | | | | | | | |
| 5.1 Communicate patient-related information to healthcare professionals that | 3.7 | 3.6 | 3.6 | 3.6 | 3.6 | | | | | | | | | | |
| advocates for optimal patient outcomes. | (.6) | (.6) | (.6) | (.6) | (.6) | | | | | | | | | | |

| Task Importance Ratings by BCPS Certification and Residency Training Status: | |
|--|--|
| Mean and (Standard Deviation) | |

| _ | BCPS Certification | | | | | | | | Resid | lency | _ Total |
|---|-----------------------|------|------|------|------|--|--|--|-------|-------|---------|
| - | Yes | No | Yes | No | | | | | | | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | | | | | | |
| | (.7) | (.8) | (.8) | (.8) | (.8) | | | | | | |
| 5.3 Assist patients with understanding of prescription drug plans that provide | 3.2 | 3.1 | 3.1 | 3.1 | 3.1 | | | | | | |
| optimal prescription drug coverage and facilitate best outcomes. | (.7) | (.8) | (.8) | (.9) | (.8) | | | | | | |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.3 | 3.3 | 3.3 | 3.3 | 3.3 | | | | | | |
| | (.6) | (.8) | (.7) | (.8) | (.7) | | | | | | |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning | 3.5 | 3.3 | 3.4 | 3.3 | 3.4 | | | | | | |
| f care (for example, transition from acute to ambulatory care setting). | (.6) | (.8) | (.7) | (.8) | (.8) | | | | | | |
| 5.6 Ensure the patient has access to and understands the importance of | 3.7 | 3.6 | 3.7 | 3.6 | 3.6 | | | | | | |
| intaining an up-to-date medication list and emphasize the importance of aring the list with all healthcare providers. | (.5) | (.6) | (.6) | (.6) | (.6) | | | | | | |
| 5.7 Establish a system for two-way communication between the pharmacist and | 3.7 | 3.7 | 3.7 | 3.6 | 3.7 | | | | | | |
| the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | (.5) | (.6) | (.5) | (.6) | (.5) | | | | | | |
| 5.8 Collaborate with other healthcare professionals to provide case management | 3.6 | 3.5 | 3.5 | 3.4 | 3.5 | | | | | | |
| (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | (.6) | (.7) | (.7) | (.7) | (.7) | | | | | | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the | 3.4 | 3.3 | 3.4 | 3.2 | 3.3 | | | | | | |
| ambulatory care pharmacist. | (.7) | (.8) | (.7) | (.9) | (.8) | | | | | | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient | 3.2 | 3.2 | 3.2 | 3.2 | 3.2 | | | | | | |
| outcomes. | (.7) | (.8) | (.8) | (.9) | (.8) | | | | | | |
| 5.11 Manage conflict and differences of opinions with other healthcare | 3.3 | 3.2 | 3.3 | 3.1 | 3.2 | | | | | | |
| professionals to optimize care for the patient | (.7) | (.8) | (.7) | (.9) | (.8) | | | | | | |
| 5.12 Encourage patients to openly communicate health and medication related | 3.6 | 3.5 | 3.6 | 3.4 | 3.5 | | | | | | |
| concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | (.6) | (.7) | (.6) | (.7) | (.7) | | | | | | |

| | | PS cation | Resid | lency | _ Total |
|---|-------|--------------|-------|-------|---------|
| | Yes | No | Yes | No | |
| Direct Patient Care | | | | | |
| 1 Knowledge of anatomy and physiology | 4.1 | 4.1 | 4.0 | 4.2 | 4.1 |
| | (1.0) | (1.0) | (1.0) | (.9) | (1.0) |
| 2 Knowledge of pathophysiology | 4.6 | 4.3 | 4.5 | 4.2 | 4.4 |
| | (.8) | (1.0) | (.8) | (1.0) | (.9) |
| Knowledge of laboratory and disease/drug monitoring parameters and their terpretation as they relate to drug therapy | 4.9 | 4.4 | 4.8 | 4.2 | 4.5 |
| | (.5) | (.9) | (.6) | (1.0) | (.9) |
| 4 Knowledge of the clinical assessment process | 4.7 | 4.3 | 4.6 | 4.1 | 4.4 |
| | (.5) | (1.0) | (.8) | (1.1) | (.9) |
| 5 Knowledge of physical assessment techniques | 3.7 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (1.2) | (1.1) | (1.1) | (1.2) | (1.2) |
| 6 Knowledge of pharmacology | 4.6 | 4.7 | 4.7 | 4.7 | 4.7 |
| | (.7) | (.7) | (.7) | (.6) | (.7) |
| 7 Knowledge of pharmacotherapy | 4.9 | 4.8 | 4.9 | 4.8 | 4.9 |
| | (.4) | (.5) | (.5) | (.5) | (.5) |
| 8 Knowledge of the principles of both focused and integrated disease-state | 4.7 | 4.4 | 4.7 | 4.3 | 4.5 |
| management | (.6) | (.8) | (.6) | (1.0) | (.8) |
| 9 Knowledge of the principles of and regulations governing collaborative drug | 3.8 | 3.6 | 3.7 | 3.6 | 3.7 |
| therapy management | (1.2) | (1.3) | (1.3) | (1.4) | (1.3) |
| 10 Knowledge of OTC medications | 4.4 | 4.5 | 4.4 | 4.7 | 4.5 |
| | (.7) | (.7) | (.8) | (.6) | (.7) |
| 11 Knowledge of the principles of self-care | 4.4 | 4.4 | 4.4 | 4.5 | 4.4 |
| | (.8) | (.9) | (.9) | (.9) | (.9) |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and | 4.0 | 4.0 | 4.0 | 4.1 | 4.0 |
| treatments used in complementary and alternative medicine | (.9) | (.9) | (.9) | (1.0) | (.9) |
| 13 Knowledge of common immunizations | 3.5 | 3.2 | 3.4 | 3.3 | 3.3 |
| | (1.0) | (1.1) | (1.1) | (1.1) | (1.1) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, | 4.7 | 4.0 | 4.6 | 3.6 | 4.2 |
| NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (.7) | (1.2) | (.9) | (1.2) | (1.1) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 4.7 | 4.2 | 4.6 | 3.9 | 4.3 |
| | (.6) | (1.1) | (.7) | (1.2) | (1.0) |

| | | PS ication | Resid | lency | Total |
|---|-------------|---------------|--------------|--------------|--------------|
| - | Yes | No | Yes | No | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory | 4.3 | 4.2 | 4.3 | 4.1 | 4.2 |
| practice | (.9) | (.9) | (.9) | (1.0) | (.9) |
| 17 Knowledge of factors affecting medication and treatment adherence | 4.5 | 4.4 | 4.5 | 4.4 | 4.4 |
| | (.8) | (.8) | (.8) | (.8) | (.8) |
| 18 Knowledge of effective interventions to address medication and treatment | 4.3 | 4.2 | 4.3 | 4.2 | 4.3 |
| adherence | (.9) | (.9) | (.9) | (.9) | (.9) |
| 19 Knowledge of the techniques for use of point of care testing (for example, | 3.3 | 3.8 | 3.5 | 3.8 | 3.7 |
| blood glucose, cholesterol, INR) | (1.5) | (1.3) | (1.4) | (1.1) | (1.3) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing | 2.3 | 2.8 | 2.6 | 2.8 | 2.7 |
| (for example, OSHA, CLIA) | (1.3) | (1.3) | (1.4) | (1.3) | (1.3) |
| 21 Knowledge of patient interviewing skills | 4.6 | 4.5 | 4.6 | 4.4 | 4.5 |
| | (.8) | (.9) | (.8) | (1.0) | (.9) |
| 22 Knowledge of motivational interviewing techniques | 3.9 | 3.9 | 4.0 | 3.8 | 3.9 |
| | (1.2) | (1.2) | (1.2) | (1.2) | (1.2) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to | 4.1 | 4.1 | 4.2 | 4.0 | 4.1 |
| participate in their own care | (1.1) | (1.1) | (1.1) | (1.1) | (1.1) |
| 24 Knowledge of how to develop effective collaborative partnerships with | 4.3 | 4.0 | 4.1 | 3.9 | 4.1 |
| individual patients in order to maximize trust, encourage patient self- management, and optimize treatment outcomes | (1.1) | (1.2) | (1.2) | (1.2) | (1.2) |
| 25 Knowledge of barriers to patient education and interventions to overcome | 4.2 | 4.2 | 4.2 | 4.1 | 4.2 |
| them | (1.0) | (1.0) | (1.0) | (1.0) | (1.0) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.6 | 3.6 | 3.6 | 3.6 | 3.6 |
| | (1.1) | (1.2) | (1.1) | (1.2) | (1.1) |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how | 3.9 | 3.9 | 3.9 | 4.0 | 3.9 |
| they may impact the care of the patient | (1.0) | (1.0) | (1.0) | (1.0) | (1.0) |
| 28 Knowledge of how to obtain a medication history | 4.5 | 4.3 | 4.6 | 4.1 | 4.4 |
| | (.9) | (1.0) | (.9) | (1.1) | (1.0) |
| 29 Knowledge of the principles and process of medication reconciliation | 4.1 | 3.9 | 4.1 | 3.8 | 4.0 |
| | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient | 4.4 (.9) | 4.3 (1.1) | 4.4 (1.0) | 4.2 (1.0) | 4.3 (1.0) |

| | | BCPS Residency Certification | | lency | Total |
|--|-------|---------------------------------|-------|-------|-------|
| | Yes | No | Yes | No | |
| 31 Knowledge of how to collaborate with other healthcare professionals to | 4.7 | 4.5 | 4.6 | 4.4 | 4.5 |
| optimize patient care outcomes | (.7) | (.9) | (.8) | (.9) | (.9) |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | 4.7 | 4.5 | 4.6 | 4.4 | 4.6 |
| | (.6) | (.8) | (.7) | (.8) | (.8) |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy | 4.3 | 4.0 | 4.3 | 3.8 | 4.1 |
| alist | (1.0) | (1.2) | (1.1) | (1.2) | (1.2) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a | 4.1 | 3.9 | 4.1 | 3.8 | 4.0 |
| treatment plan | (1.1) | (1.2) | (1.1) | (1.2) | (1.2) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 4.6 | 4.2 | 4.6 | 3.8 | 4.3 |
| | (.8) | (1.2) | (.8) | (1.3) | (1.1) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 4.6 | 4.1 | 4.6 | 3.8 | 4.3 |
| | (.8) | (1.2) | (.9) | (1.3) | (1.1) |
| 37 Knowledge of patient education principles and techniques (for example, | 4.1 | 3.9 | 4.1 | 3.8 | 4.0 |
| group classes, individual patient counseling). | (1.1) | (1.3) | (1.1) | (1.3) | (1.2) |
| 38 Knowledge of the format for documentation of patient care activities, plans | 4.7 | 3.8 | 4.5 | 3.3 | 4.0 |
| and recommendations (for example, SOAP notes) | (.8) | (1.5) | (1.0) | (1.5) | (1.4) |
| 39 Knowledge of the types, indications, and uses of health-related screening | 3.0 | 3.2 | 3.1 | 3.3 | 3.2 |
| tests (for example, home pregnancy tests, hemoccult tests) | (1.1) | (1.2) | (1.2) | (1.2) | (1.2) |
| 40 Knowledge of the types, indications, and uses of self-care devices for | 3.9 | 3.9 | 3.9 | 3.9 | 3.9 |
| monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (1.0) | (1.1) | (1.1) | (1.1) | (1.1) |
| 41 Knowledge of the process of determining appropriateness of over-the- | 4.0 | 4.3 | 4.1 | 4.4 | 4.2 |
| counter treatments for individualized patients | (.9) | (1.0) | (1.0) | (.9) | (1.0) |
| 42 Knowledge of how to effectively communicate treatment recommendations | 4.7 | 4.5 | 4.7 | 4.5 | 4.6 |
| to the appropriate healthcare provider(s) | (.6) | (.8) | (.7) | (.8) | (.8) |
| 43 Knowledge of how to effectively communicate with the patient | 4.7 | 4.7 | 4.7 | 4.7 | 4.7 |
| | (.7) | (.7) | (.7) | (.7) | (.7) |
| 44 Knowledge of the principles and practices of wellness and prevention | 4.2 | 4.2 | 4.2 | 4.2 | 4.2 |
| | (.9) | (1.0) | (1.0) | (1.0) | (1.0) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, | 4.5 | 4.4 | 4.4 | 4.4 | 4.4 |
| dietary factors, exercise, tobacco use) and appropriate modifications | (.9) | (.9) | (1.0) | (.8) | (.9) |

| Frequency Ratings for Knowledge by BCPS Certification and Residency Training Status: |
|--|
| Mean and (Standard Deviation) |

| | | BCPS Residency Certification | | lency | Total |
|---|-------|---------------------------------|-------|-------|-------|
| | Yes | No | Yes | No | |
| 46 Knowledge of the proper administration techniques for various drugs and | 3.8 | 4.2 | 3.9 | 4.4 | 4.1 |
| immunizations (for example, eye drops, inhalers, injections) | (1.2) | (1.1) | (1.2) | (1.0) | (1.1) |
| 47 Knowledge of State and Federal regulations regarding protection of patient | 4.3 | 4.5 | 4.4 | 4.6 | 4.5 |
| information | (1.0) | (.9) | (1.0) | (.8) | (.9) |
| 48 Knowledge of the steps involved in continuity of care between healthcare | 3.7 | 3.6 | 3.7 | 3.6 | 3.6 |
| settings (i.e., transitioning) | (1.2) | (1.2) | (1.2) | (1.2) | (1.2) |
| Knowledge of appropriate writing techniques for composing patient | 3.0 | 3.1 | 3.2 | 2.9 | 3.1 |
| education materials | (1.1) | (1.3) | (1.2) | (1.3) | (1.3) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual | 3.2 | 3.2 | 3.4 | 2.9 | 3.2 |
| aids, handouts) for delivering educational programs | (1.0) | (1.2) | (1.1) | (1.2) | (1.2) |
| Practice Management | | | | | |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of | 4.1 | 3.6 | 3.9 | 3.5 | 3.8 |
| the pharmacist's role in a successful ambulatory care practice | (1.1) | (1.3) | (1.2) | (1.4) | (1.3) |
| 2 Knowledge of effective interdisciplinary communication strategies | 4.4 | 4.0 | 4.4 | 3.8 | 4.1 |
| | (.9) | (1.2) | (.9) | (1.3) | (1.1) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy | 3.2 | 3.1 | 3.3 | 2.9 | 3.1 |
| agreements | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 4 Knowledge of the strategies and resources necessary for establishing a | 2.8 | 3.0 | 3.1 | 2.8 | 2.9 |
| collaborative care agreement and referral process | (1.3) | (1.4) | (1.3) | (1.3) | (1.3) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care | 2.7 | 2.8 | 2.9 | 2.7 | 2.8 |
| pharmacy services | (1.1) | (1.3) | (1.3) | (1.3) | (1.3) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy | 2.9 | 2.9 | 3.0 | 2.7 | 2.9 |
| services | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) |
| 7 Knowledge of the continuous quality improvement process | 3.3 | 3.4 | 3.4 | 3.4 | 3.4 |
| | (1.2) | (1.3) | (1.2) | (1.3) | (1.2) |
| 8 Knowledge of business principles to effectively manage the practice (for | 2.1 | 3.1 | 2.4 | 3.4 | 2.8 |
| mple, knowledge of accounting, purchasing, resource utilization, work flow, fit analysis) | (1.1) | (1.5) | (1.3) | (1.5) | (1.5) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 2.8 | 3.1 | 2.8 | 3.4 | 3.1 |
| | (1.5) | (1.6) | (1.5) | (1.6) | (1.6) |
| 10 Knowledge of tasks involved in managing the implementation of a new | 2.7 | 2.9 | 2.8 | 3.0 | 2.8 |
| service or program | (1.1) | (1.3) | (1.3) | (1.3) | (1.3) |

| | | BCPS Certification | | lency | Total |
|--|-------|-----------------------|-------|-------|-------|
| | Yes | No | Yes | No | |
| 11 Knowledge of effective marketing strategies for initiating or expanding | 2.5 | 2.6 | 2.5 | 2.6 | 2.5 |
| ambulatory pharmacy services | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) |
| 12 Knowledge of systems for patient referral and follow up | 3.5 | 3.2 | 3.4 | 3.1 | 3.3 |
| | (1.2) | (1.4) | (1.3) | (1.4) | (1.4) |
| 13 Knowledge of special order drug systems (for example, patient assistant | 2.2 | 2.9 | 2.4 | 3.2 | 2.7 |
| programs, Accutane [®] , Enbrel [®] , Clozaril [®] , thalidomide) | (1.1) | (1.4) | (1.3) | (1.4) | (1.4) |
| 14 Knowledge of regulations with regard to point of care testing (for example, | 2.3 | 2.8 | 2.5 | 2.9 | 2.7 |
| OSHA, CLIA, state Board of Pharmacy, other state laws) | (1.2) | (1.4) | (1.3) | (1.4) | (1.4) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 2.4 | 3.1 | 2.7 | 3.3 | 2.9 |
| | (1.2) | (1.4) | (1.3) | (1.3) | (1.3) |
| 16 Knowledge of how to integrate patient care services within an ambulatory | 2.5 | 2.9 | 2.7 | 2.9 | 2.8 |
| dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | (1.5) | (1.5) | (1.5) | (1.5) | (1.5) |
| 17 Knowledge of formulary management systems (for example, P&T committee | 3.3 | 3.5 | 3.4 | 3.5 | 3.5 |
| function, therapeutic interchange, prior authorization, nonformulary process) | (1.4) | (1.4) | (1.3) | (1.4) | (1.4) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 4.2 | 4.1 | 4.2 | 4.1 | 4.1 |
| | (1.0) | (1.1) | (1.1) | (1.2) | (1.1) |
| 19 Knowledge of State and Federal regulations regarding protection of patient | 4.0 | 4.2 | 4.0 | 4.3 | 4.1 |
| information | (1.2) | (1.1) | (1.2) | (1.1) | (1.1) |
| 20 Knowledge of service development process (for example, needs assessment, | 2.1 | 2.3 | 2.2 | 2.4 | 2.3 |
| business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | (1.2) | (1.2) | (1.2) | (1.2) | (1.2) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.8 | 3.7 | 3.9 | 3.5 | 3.7 |
| | (1.2) | (1.4) | (1.3) | (1.4) | (1.3) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of | 2.9 | 3.0 | 3.0 | 2.9 | 2.9 |
| services | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) |
| 23 Knowledge of compensation strategies and funding sources | 2.5 | 2.8 | 2.6 | 2.8 | 2.7 |
| | (1.3) | (1.4) | (1.4) | (1.4) | (1.4) |
| 24 Knowledge of the literature evaluating medication errors and patient safety | 3.2 | 3.3 | 3.3 | 3.2 | 3.3 |
| (for example, IOM report, Beers criteria) | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of | 2.8 | 3.1 | 2.9 | 3.2 | 3.0 |
| ambulatory care pharmacy | (1.2) | (1.3) | (1.2) | (1.3) | (1.3) |

| | | BCPS Residency Certification | | lency | Total |
|--|-------|---------------------------------|-------|-------|-------|
| | Yes | No | Yes | No | |
| Public Health | | | | | |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 2.8 | 3.0 | 2.8 | 3.1 | 2.9 |
| | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 2 Knowledge of resources available through relevant groups, organizations, and | 3.5 | 3.2 | 3.4 | 3.2 | 3.3 |
| agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | (1.2) | (1.3) | (1.3) | (1.2) | (1.2) |
| 3 Knowledge of disease prevention strategies | 4.1 | 3.8 | 4.0 | 3.8 | 3.9 |
| | (1.0) | (1.1) | (1.1) | (1.1) | (1.1) |
| 4 Knowledge of disease screening guidelines | 3.9 | 3.6 | 3.8 | 3.5 | 3.7 |
| | (1.2) | (1.2) | (1.2) | (1.2) | (1.2) |
| 5 Knowledge of complementary and alternative medicine treatments for the | 3.6 | 3.4 | 3.5 | 3.5 | 3.5 |
| prevention and treatment of diseases | (1.1) | (1.2) | (1.1) | (1.2) | (1.1) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and | 2.7 | 2.9 | 2.8 | 2.9 | 2.8 |
| treatment of diseases | (1.2) | (1.3) | (1.2) | (1.3) | (1.3) |
| 7 Knowledge of information that is accessible to the public regarding the | 3.3 | 3.4 | 3.3 | 3.5 | 3.4 |
| prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | (1.1) | (1.2) | (1.1) | (1.2) | (1.1) |
| 8 Knowledge of surveillance methods and surveillance resources for public | 2.0 | 2.3 | 2.1 | 2.3 | 2.2 |
| health threats | (1.0) | (1.2) | (1.1) | (1.2) | (1.1) |
| 9 Knowledge of prevention and treatment of public health threats | 2.1 | 2.4 | 2.2 | 2.5 | 2.3 |
| | (1.0) | (1.2) | (1.1) | (1.3) | (1.2) |
| 10 Knowledge of processes for delivery and implementation strategies for public | 2.1 | 2.3 | 2.1 | 2.5 | 2.2 |
| health services | (1.0) | (1.2) | (1.1) | (1.3) | (1.1) |
| Medical Informatics and Professional Development | | | | | |
| 1 Knowledge of principles of evidence-based medicine | 4.6 | 4.1 | 4.5 | 3.9 | 4.2 |
| | (.8) | (1.1) | (.9) | (1.2) | (1.1) |
| 2 Knowledge of common resources of biomedical literature applicable to | 4.1 | 3.7 | 4.0 | 3.5 | 3.8 |
| ambulatory pharmacy practice | (1.0) | (1.3) | (1.1) | (1.4) | (1.3) |
| 3 Knowledge of primary (for example, original research reports), secondary (for | 4.4 | 3.8 | 4.3 | 3.5 | 3.9 |
| example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | (.8) | (1.2) | (.9) | (1.3) | (1.2) |
| 4 Knowledge of how to formulate a search strategy to retrieve information from | 4.1 | 3.7 | 4.0 | 3.4 | 3.8 |
| the biomedical literature | (.9) | (1.2) | (1.0) | (1.3) | (1.2) |

| | BCPS Certification | | Resid | dency | _ Total |
|--|-----------------------|-------|-------|-------|---------|
| | Yes | No | Yes | No | |
| 5 Knowledge of process for identifying educational needs of healthcare | 3.3 | 3.2 | 3.4 | 3.1 | 3.2 |
| professionals in ambulatory care practice | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |
| 6 Knowledge of principles and methods of educating health care students, | 4.2 | 3.7 | 4.2 | 3.3 | 3.8 |
| residents, and professionals | (1.0) | (1.4) | (1.1) | (1.4) | (1.3) |
| 7 Knowledge of research methodology to interpret study validity (for example, | 3.9 | 3.2 | 3.7 | 2.9 | 3.4 |
| design, population selection, blinding, statistical analysis) | (1.0) | (1.3) | (1.0) | (1.4) | (1.2) |
| 8 Knowledge of strengths and limitations of various study methods | 3.8 | 3.2 | 3.7 | 3.0 | 3.4 |
| | (.9) | (1.2) | (1.0) | (1.3) | (1.1) |
| 9 Knowledge of clinical versus statistical significance in order to interpret | 3.9 | 3.3 | 3.8 | 3.1 | 3.5 |
| medical literature | (.9) | (1.2) | (.9) | (1.3) | (1.2) |
| 10 Knowledge of appropriate research methodology to design studies to assess | 3.2 | 2.8 | 3.2 | 2.6 | 2.9 |
| a research hypothesis | (1.2) | (1.3) | (1.2) | (1.3) | (1.3) |
| 11 Knowledge of granting agencies and their application procedures | 2.0 | 2.0 | 2.1 | 1.9 | 2.0 |
| | (1.0) | (1.1) | (1.0) | (1.1) | (1.1) |
| 12 Knowledge of regulatory requirements for the coordination of research (for | 2.3 | 2.4 | 2.4 | 2.3 | 2.4 |
| example, HIPAA, IRB, OSHA) | (1.0) | (1.3) | (1.0) | (1.4) | (1.2) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 2.4 | 2.4 | 2.5 | 2.2 | 2.4 |
| | (.9) | (1.3) | (1.1) | (1.3) | (1.2) |
| 14 Knowledge of elements of informed consent | 2.4 | 2.6 | 2.6 | 2.6 | 2.6 |
| | (1.1) | (1.4) | (1.2) | (1.5) | (1.3) |
| 15 Knowledge of survey procedures | 2.1 | 2.1 | 2.1 | 2.1 | 2.1 |
| | (.8) | (1.0) | (.9) | (1.1) | (1.0) |
| 16 Knowledge of data management | 2.7 | 2.6 | 2.7 | 2.5 | 2.6 |
| | (1.3) | (1.3) | (1.3) | (1.3) | (1.3) |
| 17 Knowledge of data analysis and statistical methods | 2.7 | 2.5 | 2.6 | 2.4 | 2.6 |
| | (1.1) | (1.2) | (1.1) | (1.3) | (1.2) |
| Knowledge of the uniform requirements (developed by the International | 2.1 | 1.9 | 2.1 | 1.8 | 2.0 |
| Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | (.8) | (1.0) | (.9) | (1.0) | (1.0) |
| 19 Knowledge of components of well written research abstracts, reports, and | 2.5 | 2.4 | 2.6 | 2.2 | 2.4 |
| monographs | (1.0) | (1.1) | (1.0) | (1.1) | (1.1) |

| | | CPS ication | Resid | dency | _ Total |
|---|-------|----------------|-------|-------|---------|
| | Yes | No | Yes | No | |
| 20 Knowledge of techniques for presentation of research findings | 2.3 | 2.2 | 2.4 | 2.0 | 2.2 |
| | (.9) | (1.1) | (1.0) | (1.1) | (1.0) |
| 21 Knowledge of the content of an effective research presentation | 2.3 | 2.2 | 2.4 | 2.1 | 2.2 |
| | (.8) | (1.1) | (.9) | (1.1) | (1.0) |
| 22 Knowledge of venues for presentation and publication (for example, | 2.4 | 2.4 | 2.5 | 2.3 | 2.4 |
| pharmacy organization conferences, journals) | (.8) | (1.1) | (.9) | (1.1) | (1.0) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse | 2.5 | 2.6 | 2.5 | 2.6 | 2.6 |
| ug/vaccine events and problems observed with drug/vaccine products to propriate governmental entities | (1.0) | (1.1) | (1.1) | (1.1) | (1.1) |
| 24 Knowledge of the role and benefits of professional organizations for | 2.8 | 2.8 | 2.9 | 2.7 | 2.8 |
| ambulatory care pharmacy practice | (1.0) | (1.1) | (1.0) | (1.2) | (1.1) |
| 25 Knowledge of staff development principles and avenues for providing | 2.6 | 2.8 | 2.8 | 2.7 | 2.7 |
| continuing education | (.9) | (1.1) | (1.0) | (1.1) | (1.0) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy | 2.7 | 2.6 | 2.8 | 2.5 | 2.6 |
| ecialist (for example, Certified Diabetes Educator, Board Certified armacotherapy Specialist, Certified Geriatric Pharmacist, Certified aticoagulation Pharmacy Specialist, Certified Asthma Educator). | (1.1) | (1.2) | (1.1) | (1.1) | (1.1) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines | 4.2 | 3.6 | 4.1 | 3.2 | 3.8 |
| and protocols in the ambulatory care environment | (1.1) | (1.4) | (1.2) | (1.4) | (1.3) |
| Patient Advocacy | | | | | |
| 1 Knowledge of assertive and persuasive communication techniques for | 3.9 | 3.8 | 3.9 | 3.6 | 3.8 |
| representing a patient's healthcare needs and interests | (1.1) | (1.3) | (1.2) | (1.3) | (1.2) |
| 2 Knowledge of patient-specific factors which may impact access to medications | 4.2 | 4.0 | 4.2 | 3.9 | 4.1 |
| (for example, socioeconomic) | (1.0) | (1.2) | (1.1) | (1.3) | (1.1) |
| 3 Knowledge of the structure, guidelines, and process of patient and/or | 2.9 | 3.1 | 3.0 | 3.1 | 3.0 |
| medication assistance programs | (1.2) | (1.3) | (1.3) | (1.3) | (1.3) |
| 4 Knowledge of the structure, including benefits and limitations, of prescription | 3.9 | 3.8 | 3.9 | 3.8 | 3.9 |
| drug plans/ formularies for patients in ambulatory care | (1.2) | (1.3) | (1.2) | (1.4) | (1.3) |
| 5 Knowledge of resources for medication reconciliation necessary to transition | 3.4 | 3.3 | 3.4 | 3.2 | 3.3 |
| patients to and from the ambulatory care setting | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.6 | 3.4 | 3.6 | 3.3 | 3.5 |
| | (1.3) | (1.4) | (1.3) | (1.4) | (1.4) |

| | | CPS Res | | · · · · · · · · · · · · · · · · · · · | |
|--|-------|---------|-------|---------------------------------------|-------|
| | Yes | No | Yes | No | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 |
| | (1.0) | (1.2) | (1.1) | (1.2) | (1.2) |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | 3.6 | 3.2 | 3.4 | 3.2 | 3.3 |
| | (1.2) | (1.4) | (1.3) | (1.4) | (1.3) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.9 | 3.5 | 3.8 | 3.4 | 3.6 |
| | (1.1) | (1.3) | (1.2) | (1.4) | (1.3) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 3.0 | 3.0 | 3.0 | 3.0 |
| | (1.1) | (1.2) | (1.2) | (1.2) | (1.2) |
| 11 Knowledge of conflict management and negotiation skills | 3.6 | 3.4 | 3.5 | 3.4 | 3.5 |
| | (1.2) | (1.3) | (1.2) | (1.3) | (1.3) |

| | | BCPS Certification | | | | | | lency | _ Total |
|---|------|-----------------------|------|------|------|--|--|-------|---------|
| | Yes | No | Yes | No | | | | | |
| Direct Patient Care | | | | | | | | | |
| 1 Knowledge of anatomy and physiology | 3.3 | 3.4 | 3.2 | 3.5 | 3.3 | | | | |
| | (.7) | (.7) | (.7) | (.6) | (.7) | | | | |
| 2 Knowledge of pathophysiology | 3.7 | 3.6 | 3.6 | 3.6 | 3.6 | | | | |
| | (.6) | (.6) | (.6) | (.7) | (.6) | | | | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their | 3.9 | 3.8 | 3.9 | 3.7 | 3.8 | | | | |
| interpretation as they relate to drug therapy | (.2) | (.5) | (.3) | (.5) | (.4) | | | | |
| 4 Knowledge of the clinical assessment process | 3.7 | 3.6 | 3.7 | 3.5 | 3.6 | | | | |
| | (.5) | (.7) | (.6) | (.7) | (.6) | | | | |
| 5 Knowledge of physical assessment techniques | 3.1 | 3.1 | 3.1 | 3.0 | 3.1 | | | | |
| | (.7) | (.8) | (.8) | (.8) | (.8) | | | | |
| 6 Knowledge of pharmacology | 3.7 | 3.8 | 3.8 | 3.8 | 3.8 | | | | |
| | (.5) | (.5) | (.5) | (.5) | (.5) | | | | |
| 7 Knowledge of pharmacotherapy | 4.0 | 3.9 | 4.0 | 3.9 | 3.9 | | | | |
| | (.1) | (.3) | (.2) | (.3) | (.3) | | | | |
| 8 Knowledge of the principles of both focused and integrated disease-state | 3.8 | 3.7 | 3.8 | 3.6 | 3.7 | | | | |
| management | (.5) | (.6) | (.5) | (.6) | (.5) | | | | |
| 9 Knowledge of the principles of and regulations governing collaborative drug | 3.4 | 3.3 | 3.3 | 3.3 | 3.3 | | | | |
| therapy management | (.7) | (.8) | (.8) | (.8) | (.8) | | | | |
| 10 Knowledge of OTC medications | 3.7 | 3.7 | 3.7 | 3.8 | 3.7 | | | | |
| | (.5) | (.5) | (.5) | (.5) | (.5) | | | | |
| 11 Knowledge of the principles of self-care | 3.6 | 3.6 | 3.6 | 3.6 | 3.6 | | | | |
| | (.6) | (.6) | (.6) | (.6) | (.6) | | | | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and | 3.5 | 3.4 | 3.4 | 3.4 | 3.4 | | | | |
| treatments used in complementary and alternative medicine | (.6) | (.7) | (.6) | (.7) | (.7) | | | | |
| 13 Knowledge of common immunizations | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 | | | | |
| | (.7) | (.8) | (.8) | (.8) | (.8) | | | | |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, | 3.9 | 3.5 | 3.8 | 3.4 | 3.6 | | | | |
| NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (.4) | (.7) | (.5) | (.8) | (.7) | | | | |
| 15 Knowledge of the principles and practice of evidence-based medicine | 3.8 | 3.5 | 3.8 | 3.4 | 3.6 | | | | |
| | (.4) | (.7) | (.5) | (.8) | (.6) | | | | |
| | | | | | | | | | |

| _ | | BCPS Certification | | lency | _ Total |
|--|------|-----------------------|------|-------|---------|
| | Yes | No | Yes | No | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory | 3.7 | 3.6 | 3.7 | 3.6 | 3.6 |
| practice | (.5) | (.7) | (.6) | (.7) | (.6) |
| 17 Knowledge of factors affecting medication and treatment adherence | 3.8 | 3.7 | 3.7 | 3.7 | 3.7 |
| | (.5) | (.5) | (.5) | (.5) | (.5) |
| 18 Knowledge of effective interventions to address medication and treatment | 3.7 | 3.6 | 3.7 | 3.6 | 3.7 |
| nonadherence | (.5) | (.6) | (.5) | (.6) | (.6) |
| 19 Knowledge of the techniques for use of point of care testing (for example, | 3.2 | 3.4 | 3.3 | 3.4 | 3.3 |
| blood glucose, cholesterol, INR) | (.7) | (.8) | (.8) | (.7) | (.8) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing | 2.6 | 2.8 | 2.7 | 2.8 | 2.7 |
| (for example, OSHA, CLIA) | (.7) | (.9) | (.8) | (.9) | (.8) |
| 21 Knowledge of patient interviewing skills | 3.9 | 3.8 | 3.9 | 3.7 | 3.8 |
| | (.3) | (.5) | (.3) | (.5) | (.4) |
| 22 Knowledge of motivational interviewing techniques | 3.3 | 3.3 | 3.4 | 3.2 | 3.3 |
| | (.7) | (.8) | (.7) | (.8) | (.7) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to | 3.4 | 3.5 | 3.5 | 3.4 | 3.5 |
| participate in their own care | (.6) | (.7) | (.7) | (.7) | (.7) |
| 24 Knowledge of how to develop effective collaborative partnerships with | 3.6 | 3.5 | 3.6 | 3.5 | 3.5 |
| individual patients in order to maximize trust, encourage patient self- management, and optimize treatment outcomes | (.6) | (.7) | (.6) | (.7) | (.7) |
| 25 Knowledge of barriers to patient education and interventions to overcome | 3.6 | 3.6 | 3.6 | 3.5 | 3.6 |
| them | (.6) | (.6) | (.6) | (.6) | (.6) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.1 | 3.2 | 3.2 | 3.1 | 3.1 |
| | (.6) | (.7) | (.7) | (.7) | (.7) |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how | 3.2 | 3.3 | 3.2 | 3.4 | 3.3 |
| they may impact the care of the patient | (.7) | (.7) | (.7) | (.7) | (.7) |
| 28 Knowledge of how to obtain a medication history | 3.9 | 3.7 | 3.8 | 3.6 | 3.8 |
| | (.4) | (.6) | (.4) | (.7) | (.5) |
| 29 Knowledge of the principles and process of medication reconciliation | 3.5 | 3.4 | 3.5 | 3.4 | 3.5 |
| | (.6) | (.8) | (.7) | (.8) | (.7) |
| 30 Knowledge of how to develop effective collaborative relationships with other | 3.8 | 3.7 | 3.8 | 3.7 | 3.7 |
| nealthcare professionals in order to access health-related patient information essential to the care of the patient | (.5) | (.6) | (.5) | (.6) | (.6) |
| 31 Knowledge of how to collaborate with other healthcare professionals to | 3.9 | 3.8 | 3.8 | 3.8 | 3.8 |
| optimize patient care outcomes | (.4) | (.5) | (.4) | (.5) | (.5) |

| - | | BCPS Certification | | lency | _ Total |
|--|------|-----------------------|------|-------|---------|
| | Yes | No | Yes | No | |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | 3.8 | 3.7 | 3.8 | 3.7 | 3.8 |
| | (.4) | (.5) | (.4) | (.6) | (.5) |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 |
| specialist | (.6) | (.8) | (.7) | (.8) | (.8) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a | 3.4 | 3.5 | 3.4 | 3.5 | 3.4 |
| treatment plan | (.7) | (.7) | (.7) | (.7) | (.7) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 3.9 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (.4) | (.6) | (.4) | (.7) | (.6) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 3.9 | 3.7 | 3.8 | 3.6 | 3.7 |
| | (.4) | (.6) | (.4) | (.7) | (.6) |
| 37 Knowledge of patient education principles and techniques (for example, | 3.6 | 3.5 | 3.5 | 3.4 | 3.5 |
| group classes, individual patient counseling). | (.6) | (.7) | (.6) | (.8) | (.7) |
| 38 Knowledge of the format for documentation of patient care activities, plans | 3.7 | 3.3 | 3.6 | 3.2 | 3.4 |
| and recommendations (for example, SOAP notes) | (.5) | (.9) | (.6) | (.9) | (.8) |
| 39 Knowledge of the types, indications, and uses of health-related screening | 2.9 | 3.1 | 3.0 | 3.2 | 3.1 |
| tests (for example, home pregnancy tests, hemoccult tests) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 40 Knowledge of the types, indications, and uses of self-care devices for | 3.5 | 3.6 | 3.5 | 3.5 | 3.5 |
| monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (.6) | (.6) | (.6) | (.7) | (.6) |
| 41 Knowledge of the process of determining appropriateness of over-the- | 3.5 | 3.7 | 3.6 | 3.7 | 3.6 |
| counter treatments for individualized patients | (.6) | (.6) | (.6) | (.6) | (.6) |
| 42 Knowledge of how to effectively communicate treatment recommendations | 3.8 | 3.8 | 3.8 | 3.8 | 3.8 |
| to the appropriate healthcare provider(s) | (.4) | (.5) | (.4) | (.5) | (.4) |
| 43 Knowledge of how to effectively communicate with the patient | 3.9 | 3.9 | 3.9 | 3.9 | 3.9 |
| | (.3) | (.3) | (.2) | (.4) | (.3) |
| 44 Knowledge of the principles and practices of wellness and prevention | 3.5 | 3.6 | 3.6 | 3.6 | 3.6 |
| | (.6) | (.6) | (.6) | (.6) | (.6) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, | 3.7 | 3.7 | 3.7 | 3.7 | 3.7 |
| dietary factors, exercise, tobacco use) and appropriate modifications | (.5) | (.6) | (.5) | (.6) | (.5) |
| 46 Knowledge of the proper administration techniques for various drugs and | 3.5 | 3.7 | 3.6 | 3.7 | 3.7 |
| immunizations (for example, eye drops, inhalers, injections) | (.6) | (.6) | (.6) | (.6) | (.6) |
| 47 Knowledge of State and Federal regulations regarding protection of patient | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 |
| information | (.6) | (.7) | (.7) | (.7) | (.7) |

| | | CPS Re ication | | dency | _ Total |
|---|------|-------------------|------|-------|---------|
| | Yes | No | Yes | No | |
| 48 Knowledge of the steps involved in continuity of care between healthcare | 3.2 | 3.2 | 3.2 | 3.2 | 3.2 |
| settings (i.e., transitioning) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 49 Knowledge of appropriate writing techniques for composing patient | 3.0 | 3.1 | 3.2 | 2.9 | 3.1 |
| education materials | (.7) | (.8) | (.8) | (.9) | (.8) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual | 3.2 | 3.1 | 3.2 | 3.0 | 3.1 |
| aids, handouts) for delivering educational programs | (.7) | (.9) | (.7) | (.9) | (.8) |
| Practice Management | | | | | |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of | 3.5 | 3.3 | 3.4 | 3.3 | 3.4 |
| the pharmacist's role in a successful ambulatory care practice | (.6) | (.8) | (.7) | (.8) | (.8) |
| 2 Knowledge of effective interdisciplinary communication strategies | 3.6 | 3.4 | 3.6 | 3.3 | 3.5 |
| | (.6) | (.8) | (.7) | (.8) | (.7) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy | 3.3 | 3.1 | 3.3 | 3.0 | 3.2 |
| agreements | (.6) | (.9) | (.7) | (.9) | (.8) |
| 4 Knowledge of the strategies and resources necessary for establishing a | 3.3 | 3.1 | 3.3 | 3.0 | 3.2 |
| collaborative care agreement and referral process | (.7) | (.9) | (.7) | (.9) | (.8) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care | 3.1 | 3.1 | 3.2 | 2.9 | 3.1 |
| pharmacy services | (.8) | (.8) | (.7) | (.9) | (.8) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy | 3.3 | 3.2 | 3.3 | 3.0 | 3.2 |
| services | (.7) | (.8) | (.7) | (.9) | (.8) |
| 7 Knowledge of the continuous quality improvement process | 3.3 | 3.3 | 3.3 | 3.2 | 3.3 |
| | (.7) | (.8) | (.7) | (.8) | (.8) |
| 8 Knowledge of business principles to effectively manage the practice (for | 2.7 | 3.1 | 2.8 | 3.2 | 3.0 |
| example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | (.8) | (.8) | (.8) | (.8) | (.8) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy | 3.1 | 3.2 | 3.1 | 3.2 | 3.2 |
| practice | (.8) | (.9) | (.8) | (.9) | (.9) |
| 10 Knowledge of tasks involved in managing the implementation of a new | 3.2 | 3.1 | 3.2 | 3.1 | 3.2 |
| service or program | (.7) | (.8) | (.7) | (.8) | (.8) |
| 11 Knowledge of effective marketing strategies for initiating or expanding | 3.0 | 3.0 | 3.0 | 3.0 | 3.0 |
| ambulatory pharmacy services | (.9) | (.9) | (.8) | (.9) | (.9) |
| 12 Knowledge of systems for patient referral and follow up | 3.2 | 3.1 | 3.2 | 3.1 | 3.1 |
| | (.8) | (.9) | (.8) | (1.0) | (.9) |

| | | CPS ication | Resid | dency | _ Total |
|--|------|----------------|-------|-------|---------|
| | Yes | No | Yes | No | |
| 13 Knowledge of special order drug systems (for example, patient assistant | 2.7 | 3.1 | 2.9 | 3.1 | 3.0 |
| programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | (.8) | (.9) | (.9) | (.9) | (.9) |
| 14 Knowledge of regulations with regard to point of care testing (for example, | 2.7 | 3.0 | 2.8 | 3.0 | 2.9 |
| OSHA, CLIA, state Board of Pharmacy, other state laws) | (.8) | (.9) | (.8) | (.9) | (.9) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 2.6 | 3.0 | 2.8 | 3.0 | 2.9 |
| | (.8) | (.8) | (.9) | (.8) | (.8) |
| 16 Knowledge of how to integrate patient care services within an ambulatory | 3.0 | 3.2 | 3.1 | 3.2 | 3.2 |
| dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 17 Knowledge of formulary management systems (for example, P&T committee | 3.2 | 3.2 | 3.1 | 3.2 | 3.2 |
| function, therapeutic interchange, prior authorization, nonformulary process) | (.7) | (.8) | (.8) | (.8) | (.8) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 |
| | (.7) | (.7) | (.7) | (.7) | (.7) |
| 19 Knowledge of State and Federal regulations regarding protection of patient | 3.4 | 3.4 | 3.4 | 3.4 | 3.4 |
| rmation | (.8) | (.8) | (.7) | (.8) | (.8) |
| 20 Knowledge of service development process (for example, needs assessment, | 2.6 | 2.6 | 2.6 | 2.7 | 2.6 |
| business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | (.8) | (.9) | (.9) | (.9) | (.9) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.3 | 3.3 | 3.3 | 3.2 | 3.3 |
| | (.7) | (.8) | (.7) | (.9) | (.8) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of | 3.2 | 3.1 | 3.2 | 3.0 | 3.1 |
| services | (.7) | (.9) | (.8) | (.9) | (.8) |
| 23 Knowledge of compensation strategies and funding sources | 3.1 | 3.1 | 3.1 | 3.0 | 3.1 |
| | (.8) | (.9) | (.8) | (.9) | (.9) |
| 24 Knowledge of the literature evaluating medication errors and patient safety | 3.2 | 3.2 | 3.3 | 3.2 | 3.2 |
| (for example, IOM report, Beers criteria) | (.7) | (.8) | (.7) | (.9) | (.8) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of | 3.2 | 3.3 | 3.2 | 3.3 | 3.2 |
| ambulatory care pharmacy | (.7) | (.8) | (.7) | (.8) | (.8) |
| Public Health | | | | | |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 2.9 | 3.0 | 2.9 | 3.0 | 3.0 |
| | (.8) | (.9) | (.8) | (.9) | (.8) |
| 2 Knowledge of resources available through relevant groups, organizations, and | 3.1 | 3.1 | 3.1 | 3.0 | 3.1 |
| agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | (.8) | (.8) | (.8) | (.9) | (.8) |
| | | | | | |

| | | CPS Res ication | | dency | _ Total |
|--|------|--------------------|------|-------|---------|
| | Yes | No | Yes | No | |
| 3 Knowledge of disease prevention strategies | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 |
| | (.6) | (.7) | (.6) | (.7) | (.7) |
| 4 Knowledge of disease screening guidelines | 3.4 | 3.3 | 3.4 | 3.3 | 3.3 |
| | (.7) | (.7) | (.7) | (.8) | (.7) |
| 5 Knowledge of complementary and alternative medicine treatments for the | 3.1 | 3.1 | 3.1 | 3.1 | 3.1 |
| prevention and treatment of diseases | (.7) | (.8) | (.7) | (.9) | (.8) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and | 2.7 | 2.9 | 2.8 | 2.9 | 2.8 |
| treatment of diseases | (.8) | (.9) | (.8) | (.9) | (.8) |
| 7 Knowledge of information that is accessible to the public regarding the | 3.0 | 3.1 | 3.1 | 3.1 | 3.1 |
| prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | (.8) | (.8) | (.8) | (.9) | (.8) |
| 8 Knowledge of surveillance methods and surveillance resources for public | 2.5 | 2.7 | 2.5 | 2.7 | 2.6 |
| health threats | (.8) | (.8) | (.8) | (.9) | (.8) |
| 9 Knowledge of prevention and treatment of public health threats | 2.6 | 2.8 | 2.7 | 2.9 | 2.8 |
| | (.8) | (.9) | (.8) | (.9) | (.9) |
| 10 Knowledge of processes for delivery and implementation strategies for public | 2.5 | 2.7 | 2.6 | 2.8 | 2.7 |
| health services | (.8) | (.8) | (.8) | (.8) | (.8) |
| Medical Informatics and Professional Development | | | | | |
| 1 Knowledge of principles of evidence-based medicine | 3.8 | 3.6 | 3.7 | 3.4 | 3.6 |
| | (.4) | (.7) | (.5) | (.8) | (.6) |
| 2 Knowledge of common resources of biomedical literature applicable to | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 |
| ambulatory pharmacy practice | (.7) | (.9) | (.8) | (.9) | (.8) |
| 3 Knowledge of primary (for example, original research reports), secondary (for | 3.7 | 3.4 | 3.6 | 3.2 | 3.5 |
| example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | (.6) | (.9) | (.7) | (.9) | (.8) |
| 4 Knowledge of how to formulate a search strategy to retrieve information from | 3.7 | 3.4 | 3.6 | 3.2 | 3.5 |
| the biomedical literature | (.6) | (.9) | (.7) | (.9) | (.8) |
| 5 Knowledge of process for identifying educational needs of healthcare | 3.1 | 3.0 | 3.1 | 3.0 | 3.1 |
| professionals in ambulatory care practice | (.8) | (.9) | (.8) | (1.0) | (.9) |
| 6 Knowledge of principles and methods of educating health care students, | 3.5 | 3.2 | 3.5 | 3.1 | 3.3 |
| sidents, and professionals | (.6) | (.9) | (.7) | (.9) | (.8) |
| 7 Knowledge of research methodology to interpret study validity (for example, | 3.6 | 3.2 | 3.5 | 3.0 | 3.3 |
| study design, population selection, blinding, statistical analysis) | (.6) | (.9) | (.7) | (1.0) | (.9) |

| | | CPS ication | Resid | lency | _ Total |
|---|------|----------------|-------|-------|---------|
| | Yes | No | Yes | No | |
| 8 Knowledge of strengths and limitations of various study methods | 3.5 | 3.2 | 3.4 | 3.0 | 3.3 |
| | (.6) | (.9) | (.7) | (.9) | (.8) |
| 9 Knowledge of clinical versus statistical significance in order to interpret | 3.7 | 3.3 | 3.6 | 3.1 | 3.4 |
| medical literature | (.5) | (.9) | (.6) | (1.0) | (.8) |
| 10 Knowledge of appropriate research methodology to design studies to assess | 3.3 | 3.0 | 3.2 | 2.8 | 3.1 |
| a research hypothesis | (.8) | (1.0) | (.8) | (1.0) | (.9) |
| 11 Knowledge of granting agencies and their application procedures | 2.4 | 2.5 | 2.5 | 2.4 | 2.5 |
| | (.8) | (.9) | (.9) | (1.0) | (.9) |
| 12 Knowledge of regulatory requirements for the coordination of research (for | 2.6 | 2.7 | 2.7 | 2.6 | 2.7 |
| example, HIPAA, IRB, OSHA) | (.8) | (1.0) | (.9) | (1.0) | (.9) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 2.9 | 2.8 | 3.0 | 2.7 | 2.8 |
| | (.9) | (1.0) | (.9) | (1.0) | (1.0) |
| 14 Knowledge of elements of informed consent | 2.9 | 2.9 | 3.0 | 2.8 | 2.9 |
| | (.9) | (1.0) | (1.0) | (1.0) | (1.0) |
| 15 Knowledge of survey procedures | 2.4 | 2.5 | 2.5 | 2.4 | 2.5 |
| | (.8) | (.9) | (.8) | (.8) | (.8) |
| 16 Knowledge of data management | 2.6 | 2.7 | 2.7 | 2.6 | 2.7 |
| | (.8) | (.9) | (.9) | (.9) | (.9) |
| 17 Knowledge of data analysis and statistical methods | 2.7 | 2.7 | 2.8 | 2.6 | 2.7 |
| | (.8) | (.9) | (.9) | (.9) | (.9) |
| 18 Knowledge of the uniform requirements (developed by the International | 2.4 | 2.4 | 2.5 | 2.3 | 2.4 |
| Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | (.7) | (1.0) | (.9) | (.9) | (.9) |
| 19 Knowledge of components of well written research abstracts, reports, and | 2.8 | 2.7 | 2.8 | 2.6 | 2.8 |
| monographs | (.8) | (.9) | (.9) | (.9) | (.9) |
| 20 Knowledge of techniques for presentation of research findings | 2.6 | 2.7 | 2.7 | 2.5 | 2.6 |
| | (.8) | (1.0) | (.9) | (.9) | (.9) |
| 21 Knowledge of the content of an effective research presentation | 2.7 | 2.7 | 2.8 | 2.6 | 2.7 |
| | (.8) | (1.0) | (.9) | (1.0) | (.9) |
| 22 Knowledge of venues for presentation and publication (for example, | 2.7 | 2.7 | 2.8 | 2.6 | 2.7 |
| pharmacy organization conferences, journals) | (.8) | (.9) | (.8) | (.9) | (.9) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse | 3.3 | 3.2 | 3.2 | 3.1 | 3.2 |
| drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | (.7) | (.9) | (.8) | (.9) | (.8) |

| | | CPS ication | Resid | lency | Total |
|--|------|----------------|-------|-------|---------|
| | Yes | No | Yes | No | - Fotal |
| 24 Knowledge of the role and benefits of professional organizations for | 3.0 | 3.0 | 3.0 | 2.9 | 3.0 |
| ambulatory care pharmacy practice | (.8) | (.9) | (.8) | (.9) | (.8) |
| 25 Knowledge of staff development principles and avenues for providing | 2.8 | 2.9 | 2.9 | 2.9 | 2.9 |
| continuing education | (.9) | (.8) | (.8) | (.9) | (.9) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy | 3.0 | 3.0 | 3.0 | 3.0 | 3.0 |
| specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certified Asthma Educator). | (.8) | (.9) | (.8) | (.9) | (.9) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines | 3.7 | 3.4 | 3.6 | 3.2 | 3.5 |
| and protocols in the ambulatory care environment | (.5) | (.8) | (.6) | (.9) | (.8) |
| Patient Advocacy | | | | | |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | 3.3 | 3.3 | 3.3 | 3.2 | 3.3 |
| representing a patient's healthcare needs and interests | (.7) | (.8) | (.7) | (.9) | (.8) |
| 2 Knowledge of patient-specific factors which may impact access to medications | 3.5 | 3.4 | 3.5 | 3.3 | 3.4 |
| (for example, socioeconomic) | (.6) | (.8) | (.6) | (.9) | (.7) |
| 3 Knowledge of the structure, guidelines, and process of patient and/or | 2.9 | 3.1 | 3.0 | 3.1 | 3.0 |
| medication assistance programs | (.8) | (.9) | (.8) | (.9) | (.8) |
| 4 Knowledge of the structure, including benefits and limitations, of prescription | 3.3 | 3.3 | 3.3 | 3.3 | 3.3 |
| drug plans/ formularies for patients in ambulatory care | (.7) | (.8) | (.7) | (.9) | (.8) |
| 5 Knowledge of resources for medication reconciliation necessary to transition | 3.2 | 3.2 | 3.3 | 3.1 | 3.2 |
| patients to and from the ambulatory care setting | (.7) | (.8) | (.7) | (.9) | (.8) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.3 | 3.2 | 3.3 | 3.1 | 3.3 |
| | (.7) | (.8) | (.7) | (.9) | (.8) |
| 7 Knowledge of the healthcare resources and services available to ambulatory | 3.1 | 3.2 | 3.2 | 3.2 | 3.2 |
| care patients (for example, disease specific websites, medication assistance programs social services). | (.7) | (.8) | (.7) | (.9) | (.8) |
| 8 Knowledge of collaborative relationships necessary to enable case | 3.2 | 3.0 | 3.1 | 3.1 | 3.1 |
| management of ambulatory care patients | (.7) | (.9) | (.8) | (.9) | (.8) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.2 | 3.2 | 3.3 | 3.2 | 3.2 |
| | (.8) | (.8) | (.8) | (.9) | (.8) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 2.9 | 2.9 | 2.9 | 2.9 |
| | (.8) | (.8) | (.8) | (.9) | (.8) |
| 11 Knowledge of conflict management and negotiation skills | 3.2 | 3.1 | 3.2 | 3.1 | 3.2 |
| | (.8) | (.8) | (.8) | (.9) | (.8) |

Appendix D-2

Follow-up Analysis on Report of the Role Delineation Study of Ambulatory Care Pharmacists

| | С | ert |
|---|-------|---------|
| | Cert | No Cert |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | 4.5 | 4.3 |
| | (1.0) | (1.2) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | 4.5 | 4.1 |
| | (1.0) | (1.2) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, | 4.4 | 4.2 |
| and previous adverse drug reactions. | (1.1) | (1.2) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical | 4.3 | 4.0 |
| records. | (1.1) | (1.2) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | 4.0 | 3.7 |
| | (1.3) | (1.4) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual | 3.4 | 2.7 |
| spection). | (1.5) | (1.6) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | 2.7 | 2.2 |
| | (1.6) | (1.5) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | 3.8 | 3.1 |
| | (1.3) | (1.5) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | 4.3 | 3.9 |
| | (1.1) | (1.3) |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | 4.6 | 4.3 |
| | (.9) | (1.1) |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong dose, side effects, drug interactions) and response to therapy. | 4.6 | 4.4 |
| | (.9) | (1.1) |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient putcomes (for example, tobacco, activity level, nutrition). | 4.2 | 3.8 |
| comes (for example, tobacco, activity level, nutrition). | | (1.3) |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.9 | 3.5 |

| | С | ert |
|---|-------|---------|
| | Cert | No Cert |
| ambulatory care pharmacy specialist. | (1.2) | (1.3) |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a | 4.0 | 3.9 |
| plan to overcome these (for example, home visits, interpreter, picture-based | (1.2) | (1.3) |
| Provide drug-related patient education/counseling (for example, purpose of cation, proper administration, directions for use, foods or drugs to avoid while taking nedication, potential side effects and when to report problems). | | 4.5 |
| the medication, potential side effects and when to report problems). | (.9) | (1.0) |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, | 3.4 | 3.5 |
| subcutaneous injections). | (1.3) | (1.3) |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | 4.3 | 4.0 |
| | (1.1) | (1.2) |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations). | 3.9 | 3.4 |
| | (1.2) | (1.4) |
| 19 Recommend appropriate immunizations to specific patients. | | 2.6 |
| | (1.3) | (1.3) |
| .20 Administer appropriate immunizations to specific patients. | 1.6 | 1.6 |
| | (1.1) | (1.1) |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | 4.0 | 4.1 |
| | (1.1) | (1.2) |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | 3.9 | 3.1 |
| | (1.6) | (1.8) |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | 3.3 | 2.6 |
| | (1.6) | (1.6) |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | 3.8 | 3.2 |
| | (1.4) | (1.7) |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | 2.5 | 2.2 |
| | (1.4) | (1.4) |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend treatment options. | 4.1 | 4.0 |
| · · · | (1.1) | (1.2) |

| | C | ert |
|---|-------|---------|
| | Cert | No Cert |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | 4.4 | 4.0 |
| | (1.0) | (1.2) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.8 | 3.5 |
| | (1.2) | (1.3) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.3 | 2.9 |
| | (1.2) | (1.4) |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 2.3 | 2.6 |
| | (1.2) | (1.3) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, nome pregnancy tests, hemoccult tests). | 1.9 | 2.2 |
| | (1.1) | (1.3) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | 4.1 | 3.3 |
| | (1.3) | (1.6) |
| .33 Determine patient's ability and willingness to pay for services (for example, insurance overage, out of pocket expenses). | | 3.4 |
| overage, out of pocket expenses). | (1.6) | (1.6) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | 4.2 | 4.0 |
| | (1.1) | (1.2) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 4.3 | 3.5 |
| and green and problems to improve patient outcomes. | (1.1) | (1.5) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 4.3 | 3.4 |
| | (1.1) | (1.5) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | 4.2 | 3.3 |
| | (1.2) | (1.6) |
| 1.38 Communicate patient-specific findings and treatment recommendations to other nealthcare professionals involved in the care of the patient. | 4.3 | 3.7 |
| | (1.1) | (1.4) |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal | 4.3 | 3.9 |
| communication). | (1.1) | (1.4) |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug | 3.9 | 3.0 |

| | С | ert |
|---|-------|---------|
| | Cert | No Cert |
| therapy and assure safety. | (1.3) | (1.6) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | 4.1 | 3.2 |
| | (1.3) | (1.6) |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 4.0 | 3.3 |
| | (1.3) | (1.7) |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | 4.1 | 3.4 |
| | | (1.5) |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed reatment recommendations and communications with patient and other healthcare | 4.3 | 3.5 |
| providers). | | (1.6) |

Comparisons of Column Means(a)

| | С | ert |
|--|------|----------------|
| | Cert | No Cert (B) |
| | (A) | |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | В | |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | В | |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | | |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | В | |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | В | |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | В | |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | В | |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | В | |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | В | |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | В | |

| | C | ert |
|---|------|--------|
| | Cert | No Cer |
| 1.11 Assess the available information to identify drug related problems (for example, no | (A) | (B) |
| drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | | |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition). | В | |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | В | |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based | | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | | |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | | |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | В | |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations). | В | |
| 1.19 Recommend appropriate immunizations to specific patients. | В | |
| 1.20 Administer appropriate immunizations to specific patients. | | |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | | |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | В | |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | В | |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | В | |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend treatment options. | | |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | В | |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | В | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | В | |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | Α |

| | C | ert | |
|---|------|--------|--|
| | Cert | No Cer | |
| | (A) | (B) | |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests). | | A | |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | В | | |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses). | | | |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | | | |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | | |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | | |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | В | | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | В | | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). | В | | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | В | | |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | В | | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | В | | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | В | | |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). | В | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean. a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Practice Management

| | cert | |
|--|-------|---------|
| | Cert | No Cert |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | 2.6 | 2.6 |
| | (1.3) | (1.4) |
| Establish new ambulatory clinical pharmacy services in response to patient care needs l/or business potential (for example, Medication Therapy Management, focused or | 2.1 | 2.1 |
| integrated disease-state management programs/clinics). | (1.1) | (1.2) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | 2.8 | 2.6 |
| | (1.3) | (1.5) |
| .4 Promote and market patient care services to patients and health care providers. | 2.7 | 2.4 |
| | (1.3) | (1.4) |
| .5 Establish and maintain a system for patient referral. | 3.0 | 2.5 |
| | (1.5) | (1.6) |
| 2.6 Establish and maintain a system for patient follow up. | 3.4 | 2.8 |
| | (1.5) | (1.7) |
| Develop systems for ongoing quality improvement, patient safety, and provision of t-effective care (for example, medication use evaluation, ADR reporting, incident report | 2.7 | 2.7 |
| evaluation). | (1.2) | (1.4) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 2.5 | 2.5 |
| | (1.2) | (1.4) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 4.2 | 3.7 |
| | (1.3) | (1.6) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | 3.1 | 2.9 |
| | (1.4) | (1.5) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary | 3.3 | 3.1 |
| ersonnel, group visits, disciplined appointment system, use of technology, coord | (1.4) | (1.6) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | 1.9 | 2.3 |
| | (1.3) | (1.6) |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 1.8 | 1.9 |

| | С | ert |
|---|-------|---------|
| | Cert | No Cert |
| | (1.1) | (1.3) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | 2.3 | 2.3 |
| | (1.2) | (1.4) |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | 2.5 | 2.6 |
| | (1.2) | (1.4) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | 2.1 | 2.2 |
| | (1.5) | (1.6) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | 1.8 | 2.2 |
| | (1.2) | (1.6) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 2.8 | 3.9 |
| | (1.7) | (1.5) |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop | 2.4 | 2.4 |
| stem for obtaining prior authorization and nonformulary drugs based on medical ne | (1.2) | (1.5) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible ntervention measures. | 2.7 | 3.0 |
| | (1.2) | (1.4) |

| | C | ert |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | | |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | | |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | | |
| 2.4 Promote and market patient care services to patients and health care providers. | | |
| 2.5 Establish and maintain a system for patient referral. | В | |

| | cert | |
|---|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 2.6 Establish and maintain a system for patient follow up. | В | |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | | |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | | |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | В | |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | | |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | | |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | | A |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | | |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | | |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | | |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | | |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | | A |
| 2.18 Ensure timely and accurate delivery of medication to patients. | | A |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | | |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | | A |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | С | ert |
|--|-------|---------|
| | Cert | No Cert |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | 2.6 | 2.8 |
| | (1.3) | (1.3) |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | 2.6 | 2.6 |
| | (1.3) | (1.4) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer | 2.2 | 2.6 |
| Society). | (1.1) | (1.2) |
| 3.4 Participate in community health screening programs. | 1.9 | 2.0 |
| | (.8) | (1.1) |
| 5 Serve as a public advocate regarding preventive health issues. | 2.1 | 2.2 |
| | (1.1) | (1.3) |
| 6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy actice. | 2.1 | 2.2 |
| | (1.2) | (1.3) |
| .7 Identify and report suspected public health threats (for example, disasters, infectious iseases). | 1.5 | 1.7 |
| | (.8) | (1.1) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 1.5 | 1.7 |
| | (.7) | (1.1) |
| 3.9 Participate in disaster response preparation and planning. | 1.5 | 1.7 |
| | (.7) | (.9) |

| | С | ert |
|---|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | | |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | | A |
| 3.4 Participate in community health screening programs. | | |
| 3.5 Serve as a public advocate regarding preventive health issues. | | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | | |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | | |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | | А |
| 3.9 Participate in disaster response preparation and planning. | | Α |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Medical Informatics and Professional Development

| | С | ert |
|--|-------|---------|
| | Cert | No Cert |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | 3.9 | 3.6 |
| | (1.0) | (1.1) |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | 3.7 | 3.6 |
| | (.8) | (.9) |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | 3.5 | 3.0 |
| | (1.0) | (1.3) |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 4.4 | 4.3 |

| | С | ert |
|--|-------|---------|
| | Cert | No Cert |
| | (.9) | (.9) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 3.7 | 3.5 |
| | (1.2) | (1.4) |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.8 | 3.5 |
| | (1.1) | (1.3) |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care obarmacy practice. | 3.7 | 3.2 |
| | (1.4) | (1.5) |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | 2.2 | 2.0 |
| | (1.2) | (1.4) |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, | 1.9 | 1.7 |
| and national audiences. | (.9) | (1.1) |
| .10 Document and report adverse drug-related events as appropriate (for example, dverse reactions, drug interactions, drug/device/assay defects) to add to the body of | 2.4 | 2.5 |
| knowledge. | (1.0) | (1.3) |
| 4.11 Participate in local, state, and/or national professional organizations. | 3.0 | 2.8 |
| | (1.1) | (1.2) |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | 2.6 | 2.7 |
| | (1.0) | (1.3) |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | В | |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | В | |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | | |

| | cert | |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | | |
| 4.6 Provide health and medication-related education to healthcare professionals. | | |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | В | |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | В | |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | | |
| 4.11 Participate in local, state, and/or national professional organizations. | | |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | C | ert |
|---|-------|---------|
| | Cert | No Cert |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 3.9 | 3.9 |
| | (1.1) | (1.3) |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 2.5 | 2.9 |
| | (1.3) | (1.4) |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | 2.7 | 3.0 |
| rescription drug coverage and racintate best outcomes. | (1.5) | (1.6) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.5 | 3.5 |
| | (1.4) | (1.5) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care | 2.9 | 3.0 |

Patient Advocacy

| | С | ert |
|--|-------|---------|
| | Cert | No Cert |
| (for example, transition from acute to ambulatory care setting). | (1.3) | (1.5) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all | 3.9 | 3.6 |
| healthcare providers. | (1.2) | (1.3) |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to | 3.9 | 3.6 |
| provide patient care. | (1.3) | (1.5) |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | 3.6 | 3.3 |
| | (1.3) | (1.5) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist. | 3.4 | 2.9 |
| | (1.3) | (1.5) |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 2.7 | 2.7 |
| | (1.3) | (1.4) |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | 3.1 | 2.8 |
| | (1.2) | (1.4) |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment | 4.0 | 3.9 |
| plan, use of herbal remedies or non-traditional treatments). | (1.1) | (1.2) |

| | cert | |
|--|-------------|----------------|
| | Cert (A) | No Cert (B) |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | | A |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | | |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | | |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | | |

| | C | ert |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | В | |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | В | |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist. | В | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | | |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | В | |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Direct Patient Care

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | 3.9 | 3.8 |
| | (.4) | (.4) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | 3.9 | 3.8 |
| | (.4) | (.5) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, | 3.9 | 3.8 |
| and previous adverse drug reactions. | (.3) | (.5) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical | 3.8 | 3.7 |
| records. | (.4) | (.6) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | 3.6 | 3.5 |
| | (.6) | (.7) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual | 3.3 | 3.0 |
| inspection). | (.7) | (.9) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | 3.1 | 2.9 |
| | (.9) | (1.0) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | 3.4 | 3.2 |
| | (.7) | (.8) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | 3.8 | 3.6 |
| | (.5) | (.7) |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | 3.9 | 3.8 |
| | (.3) | (.5) |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | 3.9 | 3.8 |
| | (.3) | (.5) |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition). | 3.6 | 3.5 |
| | (.6) | (.7) |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the | 3.6 | 3.4 |

| | cert | |
|--|------|--------|
| | Cert | No Cer |
| ambulatory care pharmacy specialist. | (.6) | (.8) |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a | 3.7 | 3.6 |
| plan to overcome these (for example, home visits, interpreter, picture-based | (.5) | (.7) |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of nedication, proper administration, directions for use, foods or drugs to avoid while taking | 3.9 | 3.9 |
| he medication, potential side effects and when to report problems). | (.4) | (.4) |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, | 3.6 | 3.7 |
| ubcutaneous injections). | (.6) | (.6) |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | 3.8 | 3.8 |
| | (.5) | (.5) |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle nodifications, immunizations). | 3.5 | 3.4 |
| | (.5) | (.7) |
| .19 Recommend appropriate immunizations to specific patients. | 3.3 | 3.1 |
| | (.6) | (.9) |
| .20 Administer appropriate immunizations to specific patients. | 2.8 | 2.7 |
| | (.9) | (1.1) |
| I.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | 3.7 | 3.6 |
| | (.5) | (.7) |
| .22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | 3.8 | 3.6 |
| | (.5) | (.8) |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | 3.6 | 3.3 |
| | (.6) | (.9) |
| .24 Provide focused disease-state management (for example, diabetes, hypertension, isthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | 3.8 | 3.5 |
| | (.5) | (.7) |
| .25 Provide wellness and preventive programs for individual patients (for example, veight management program, tobacco cessation program, immunization program). | 3.3 | 3.2 |
| vergine managemente program, tobacco cossation program, inimunization program. | (.7) | (.9) |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend | 3.6 | 3.6 |

| | C | ert |
|--|------|---------|
| | Cert | No Cert |
| treatment options. | (.5) | (.6) |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | 3.9 | 3.7 |
| | (.3) | (.6) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.6 | 3.5 |
| | (.6) | (.7) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.5 | 3.3 |
| | (.6) | (.9) |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 3.0 | 3.0 |
| | (.8) | (.9) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, nome pregnancy tests, hemoccult tests). | 2.8 | 3.0 |
| | (.8) | (.9) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | 3.7 | 3.4 |
| | (.5) | (.8) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses). | 3.3 | 3.2 |
| | (.8) | (.9) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | 3.7 | 3.6 |
| | (.6) | (.7) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 3.8 | 3.7 |
| | (.5) | (.6) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 3.8 | 3.6 |
| | (.4) | (.6) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | 3.8 | 3.5 |
| | (.5) | (.7) |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | 3.9 | 3.7 |
| | (.3) | (.6) |
| 1.39 Communicate patient-specific findings and treatment recommendations to the | 3.9 | 3.7 |

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| patient/caregiver in language they can understand (includes both written and verbal communication). | (.4) | (.6) |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | 3.7 | 3.4 |
| | (.5) | (.8) |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, | 3.8 | 3.5 |
| pulmonary function tests) to determine if and when adjustments to dru | (.5) | (.7) |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 3.8 | 3.5 |
| | (.5) | (.8) |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | 3.8 | 3.6 |
| | (.5) | (.6) |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare | 3.8 | 3.6 |
| providers). | (.5) | (.7) |

| | C | ert |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | В | |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | В | |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | В | |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | В | |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | | |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | В | |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | | |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | В | |

| | C | ert |
|---|-------------|----------------|
| | Cert (A) | No Cert (B) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | B | |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | В | |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | В | |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition). | В | |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | В | |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based | | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | | |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | | |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | | |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations). | | |
| 1.19 Recommend appropriate immunizations to specific patients. | В | |
| 1.20 Administer appropriate immunizations to specific patients. | | |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | | |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | В | |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | В | |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | В | |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend treatment options. | | |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | В | |

| | C | cert |
|---|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | В | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | В | |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests). | | |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | В | |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses). | | |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | | |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | В | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | В | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). | В | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | В | |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | В | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | В | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | В | |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). | В | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean. a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Practice Management

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused | 3.5 | 3.4 |
| or integrated disease-state management programs/clinics). | (.7) | (.8) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or | 3.5 | 3.4 |
| integrated disease-state management programs/clinics). | (.7) | (.8) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | 3.7 | 3.6 |
| | (.5) | (.7) |
| 2.4 Promote and market patient care services to patients and health care providers. | 3.4 | 3.3 |
| | (.7) | (.9) |
| 2.5 Establish and maintain a system for patient referral. | 3.5 | 3.2 |
| | (.7) | (.9) |
| 2.6 Establish and maintain a system for patient follow up. | 3.6 | 3.4 |
| | (.6) | (.8) |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report | 3.4 | 3.5 |
| evaluation). | (.6) | (.7) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 3.4 | 3.4 |
| | (.7) | (.8) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 3.8 | 3.7 |
| | (.5) | (.7) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, | 3.4 | 3.4 |
| ancillary personnel, staff). | (.7) | (.8) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary | 3.5 | 3.4 |
| personnel, group visits, disciplined appointment system, use of technology, coord | (.6) | (.8) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | 3.2 | 3.3 |
| payment systems, mounded contracting, accounting systems, priority, expense analysis). | (.8) | (.9) |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 3.4 | 3.4 |

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| - | (.8) | (.9) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | 3.5 | 3.5 |
| | (.7) | (.8) |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | 3.5 | 3.6 |
| g | (.7) | (.7) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | 3.1 | 3.2 |
| | (.9) | (1.0) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | 2.8 | 3.1 |
| | (.9) | (1.0) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 3.3 | 3.6 |
| | (.9) | (.7) |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop | 3.3 | 3.3 |
| ystem for obtaining prior authorization and nonformulary drugs based on medical ne | (.7) | (.9) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | 3.5 | 3.6 |
| | (.7) | (.7) |

| | CE | ert |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs. | | |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | | |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | В | |
| 2.4 Promote and market patient care services to patients and health care providers. | | |
| 2.5 Establish and maintain a system for patient referral. | В | |
| 2.6 Establish and maintain a system for patient follow up. | В | |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | | |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | | |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | В | |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | | |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | | |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | | |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | | |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | | |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | | |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | | |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | | A |
| 2.18 Ensure timely and accurate delivery of medication to patients. | | A |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | | |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | C | cert | |
|---|------|---------|--|
| | Cert | No Cert | |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | 3.3 | 3.3 | |
| | (.7) | (.7) | |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | 3.3 | 3.3 | |
| | (.7) | (.7) | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | 3.0 | 3.1 | |
| | (.7) | (.8) | |
| 3.4 Participate in community health screening programs. | 2.9 | 3.0 | |
| | (.8) | (.9) | |
| 3.5 Serve as a public advocate regarding preventive health issues. | 3.0 | 3.1 | |
| | (.8) | (.9) | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | 3.3 | 3.2 | |
| | (.7) | (.9) | |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | | 3.0 |
| | (.8) | (.9) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 2.9 | 3.1 |
| | (.9) | (.9) |
| 3.9 Participate in disaster response preparation and planning. | 2.9 | 3.1 |
| | (.8) | (.9) |

| | cert | |
|---|-------------|----------------|
| | Cert (A) | No Cert (B) |
| | | |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | | |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | | |
| 3.4 Participate in community health screening programs. | | |
| 3.5 Serve as a public advocate regarding preventive health issues. | | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | | |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | | A |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | | A |
| 3.9 Participate in disaster response preparation and planning. | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | C | cert |
|--|------|---------|
| | Cert | No Cert |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | 3.7 | 3.6 |
| | (.5) | (.7) |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | 3.8 | 3.8 |
| | (.4) | (.5) |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | 3.6 | 3.4 |
| | (.6) | (.8) |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 3.8 | 3.8 |
| | (.5) | (.5) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 3.7 | 3.6 |
| | (.5) | (.6) |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.7 | 3.6 |
| | (.5) | (.6) |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | 3.8 | 3.6 |
| | (.4) | (.7) |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | 3.1 | 3.0 |
| | (.8) | (.8) |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, | 3.1 | 2.9 |
| and national audiences. | (.8) | (.9) |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of | 3.4 | 3.4 |
| knowledge. | (.7) | (.8) |
| 4.11 Participate in local, state, and/or national professional organizations. | 3.4 | 3.3 |
| | (.7) | (.8) |
| 4.12 Provide ongoing staff training and development, and opportunities/support for | 3.4 | 3.3 |

Medical Informatics and Professional Development

| | CE | ert |
|---|------|---------|
| | Cert | No Cert |
| credentialing and continuing education. | (.7) | (.8) |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | | |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | В | |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | | |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | | |
| 4.6 Provide health and medication-related education to healthcare professionals. | В | |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | В | |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | | |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | | |
| 4.11 Participate in local, state, and/or national professional organizations. | | |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean. a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Patient Advocacy

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 3.6 | 3.6 |
| | (.5) | (.6) |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 3.1 | 3.1 |
| | (.7) | (.9) |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | 3.1 | 3.1 |
| | (.8) | (.9) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.3 | 3.3 |
| | (.6) | (.8) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care for example, transition from acute to ambulatory care setting). | 3.5 | 3.3 |
| | (.6) | (.8) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | 3.7 | 3.6 |
| | (.5) | (.6) |
| 5.7 Establish a system for two-way communication between the pharmacist and the batient's healthcare providers in order to exchange vital patient information necessary to | 3.7 | 3.6 |
| provide patient care. | (.5) | (.6) |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and | 3.5 | 3.5 |
| services required to meet the patient's health and human service needs). | (.6) | (.7) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care other barmacist. | 3.4 | 3.2 |
| | (.7) | (.8) |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 3.2 | 3.2 |
| | (.8) | (.9) |
| .11 Manage conflict and differences of opinions with other healthcare professionals to ptimize care for the patient | 3.3 | 3.2 |
| | (.7) | (.8) |
| 5.12 Encourage patients to openly communicate health and medication related concerns vith all healthcare providers (for example, patient disagreement with outlined treatment | 3.6 | 3.5 |
| plan, use of herbal remedies or non-traditional treatments). | (.6) | (.6) |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | | |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | | |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | | |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | | |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | В | |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | | |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist. | В | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | | |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | | |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| Direct | Patient | Care |
|--------|---------|------|
| | | |

| | C | cert | |
|--|-------|---------|--|
| | Cert | No Cert | |
| 1 Knowledge of anatomy and physiology | 4.1 | 4.1 | |
| | (1.0) | (1.0) | |
| 2 Knowledge of pathophysiology | 4.5 | 4.3 | |
| | (.8) | (.9) | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy | 4.8 | 4.4 | |
| incipietation as they relate to drug therapy | (.6) | (.9) | |
| 4 Knowledge of the clinical assessment process | 4.6 | 4.2 | |
| | (.7) | (1.1) | |
| 5 Knowledge of physical assessment techniques | 3.8 | 3.6 | |
| | (1.1) | (1.2) | |
| 6 Knowledge of pharmacology | 4.7 | 4.6 | |
| | (.7) | (.7) | |
| 7 Knowledge of pharmacotherapy | 4.9 | 4.8 | |
| | (.4) | (.4) | |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 4.7 | 4.3 | |
| | (.6) | (.9) | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy management | 3.8 | 3.6 | |
| management | (1.2) | (1.4) | |
| 10 Knowledge of OTC medications | 4.5 | 4.5 | |
| | (.7) | (.7) | |
| 11 Knowledge of the principles of self-care | 4.5 | 4.4 | |
| | (.8) | (.9) | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | 4.0 | 4.0 | |
| used in complementary and alternative medicine | (.9) | (.9) | |
| 13 Knowledge of common immunizations | 3.4 | 3.3 | |

| | C | ert |
|---|-------|---------|
| | Cert | No Cert |
| | (1.0) | (1.1) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III | 4.6 | 3.9 |
| guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (.8) | (1.3) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 4.6 | 4.2 |
| | (.8) | (1.1) |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 4.3 | 4.1 |
| | (.9) | (1.0) |
| 17 Knowledge of factors affecting medication and treatment adherence | 4.5 | 4.4 |
| | (.8) | (.8) |
| 18 Knowledge of effective interventions to address medication and treatment | 4.4 | 4.2 |
| nonadherence | (.8) | (.9) |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood | 3.7 | 3.7 |
| Jlucose, cholesterol, INR) | (1.4) | (1.2) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for | 2.6 | 2.7 |
| example, OSHA, CLIA) | (1.4) | (1.3) |
| 21 Knowledge of patient interviewing skills | 4.7 | 4.5 |
| | (.8) | (.9) |
| 22 Knowledge of motivational interviewing techniques | 4.1 | 3.8 |
| | (1.1) | (1.2) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in | 4.2 | 4.0 |
| their own care | (1.0) | (1.1) |
| 24 Knowledge of how to develop effective collaborative partnerships with individual | 4.3 | 3.9 |
| patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | (1.1) | (1.2) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 4.3 | 4.1 |
| | (.9) | (1.0) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.7 | 3.6 |
| | (1.1) | (1.1) |

| | C | ert |
|---|-------|---------|
| | Cert | No Cert |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may mpact the care of the patient | 3.9 | 4.0 |
| | (1.0) | (1.1) |
| 28 Knowledge of how to obtain a medication history | 4.6 | 4.2 |
| | (.8) | (1.1) |
| 29 Knowledge of the principles and process of medication reconciliation | 4.1 | 3.9 |
| | (1.1) | (1.3) |
| 80 Knowledge of how to develop effective collaborative relationships with other healthcare | 4.4 | 4.3 |
| professionals in order to access health-related patient information essential to the care of he patient | (.9) | (1.0) |
| 81 Knowledge of how to collaborate with other healthcare professionals to optimize | 4.7 | 4.5 |
| patient care outcomes | (.7) | (.9) |
| 2 Knowledge of how to prioritize patient needs and/or drug-related problems | 4.7 | 4.5 |
| | (.5) | (.8) |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 4.4 | 3.9 |
| | (.9) | (1.3) |
| Knowledge of how to apply pharmacoeconomic principles when designing a treatment | 4.1 | 3.8 |
| blan | (1.1) | (1.2) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 4.6 | 4.1 |
| | (.8) | (1.2) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 4.6 | 4.0 |
| | (.8) | (1.2) |
| 87 Knowledge of patient education principles and techniques (for example, group classes, | 4.2 | 3.8 |
| ndividual patient counseling). | (1.0) | (1.3) |
| 8 Knowledge of the format for documentation of patient care activities, plans and | 4.6 | 3.7 |
| ecommendations (for example, SOAP notes) | (.9) | (1.5) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for | 3.1 | 3.2 |
| example, home pregnancy tests, hemoccult tests) | | |
| | (1.2) | (1.2) |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring | 4.0 | 3.8 |

| | C | ert |
|---|-------|---------|
| | Cert | No Cert |
| chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (1.0) | (1.1) |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | 4.2 | 4.1 |
| | (.8) | (1.0) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | 4.7 | 4.5 |
| | (.6) | (.8) |
| 43 Knowledge of how to effectively communicate with the patient | 4.8 | 4.7 |
| | (.6) | (.7) |
| 44 Knowledge of the principles and practices of wellness and prevention | 4.3 | 4.1 |
| | (.9) | (1.0) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | 4.5 | 4.3 |
| | (.9) | (.9) |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | 3.9 | 4.2 |
| | (1.2) | (1.1) |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | 4.5 | 4.5 |
| | (.9) | (.9) |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., | 3.7 | 3.6 |
| transitioning) | (1.1) | (1.2) |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | 3.1 | 3.1 |
| | (1.1) | (1.3) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 3.3 | 3.1 |
| handouts) for delivering educational programs | (1.1) | (1.3) |

| | cert | |
|--|------|--------|
| | Cert | No Cer |
| 1. Knowledge of england newspland | (A) | (B) |
| 1 Knowledge of anatomy and physiology | | |
| 2 Knowledge of pathophysiology | В | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy | В | |
| 4 Knowledge of the clinical assessment process | В | |
| 5 Knowledge of physical assessment techniques | В | |
| 6 Knowledge of pharmacology | | |
| 7 Knowledge of pharmacotherapy | В | |
| 8 Knowledge of the principles of both focused and integrated disease-state management | В | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy management | | |
| 10 Knowledge of OTC medications | | |
| 11 Knowledge of the principles of self-care | | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine | | |
| 13 Knowledge of common immunizations | | |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | В | |
| 15 Knowledge of the principles and practice of evidence-based medicine | В | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | | |
| 17 Knowledge of factors affecting medication and treatment adherence | В | |
| 18 Knowledge of effective interventions to address medication and treatment nonadherence | В | |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR) | | |

| | cert | |
|---|------|--------|
| | Cert | No Cer |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | (A) | (B) |
| 21 Knowledge of patient interviewing skills | В | |
| 22 Knowledge of motivational interviewing techniques | В | |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care | В | |
| 24 Knowledge of how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | В | |
| 25 Knowledge of barriers to patient education and interventions to overcome them | В | |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | | |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient | | |
| 28 Knowledge of how to obtain a medication history | В | |
| 29 Knowledge of the principles and process of medication reconciliation | | |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient | | |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize patient care outcomes | В | |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | В | |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | В | |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment plan | В | |
| 35 Knowledge of how to develop an effective, individualized treatment plan | В | |
| 36 Knowledge of how to implement an effective, individualized treatment plan | В | |
| 37 Knowledge of patient education principles and techniques (for example, group classes, individual patient counseling). | В | |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | В | |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | |

| | cert | |
|--|-------------|---------------|
| | Cert (A) | No Cer (B) |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | | |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | | |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | В | |
| 43 Knowledge of how to effectively communicate with the patient | | |
| 44 Knowledge of the principles and practices of wellness and prevention | | |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | В | |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | | |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | | |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | | |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Practice Management

| | C | ert |
|--|-------|---------|
| | Cert | No Cert |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | 4.0 | 3.6 |
| | (1.1) | (1.3) |
| 2 Knowledge of effective interdisciplinary communication strategies | 4.3 | 4.0 |
| | (1.0) | (1.2) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 3.2 | 3.1 |
| | (1.3) | (1.4) |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative | 3.0 | 2.9 |
| care agreement and referral process | (1.3) | (1.3) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy | 2.8 | 2.7 |
| services | (1.2) | (1.3) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | 3.0 | 2.8 |
| | (1.2) | (1.3) |
| 7 Knowledge of the continuous quality improvement process | 3.4 | 3.4 |
| | (1.2) | (1.2) |
| 8 Knowledge of business principles to effectively manage the practice (for example, | 2.4 | 3.1 |
| knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | (1.3) | (1.5) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 3.1 | 3.1 |
| | (1.5) | (1.5) |
| 10 Knowledge of tasks involved in managing the implementation of a new service or | 2.9 | 2.8 |
| program | (1.2) | (1.3) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory | 2.6 | 2.4 |
| pharmacy services | (1.3) | (1.2) |
| 12 Knowledge of systems for patient referral and follow up | 3.6 | 3.1 |
| | (1.2) | (1.4) |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, | 2.4 | 3.1 |
| To knowledge of special order drug systems (for example, patient assistant programs, | 2.4 | J. I |

| | C | ert |
|--|-------|---------|
| | Cert | No Cert |
| Accutane [®] , Enbrel [®] , Clozaril [®] , thalidomide) | (1.2) | (1.4) |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | 2.5 | 2.7 |
| | (1.3) | (1.4) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 2.7 | 3.1 |
| | (1.3) | (1.4) |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy | 2.8 | 2.8 |
| Management services, and disease management clinics) | (1.5) | (1.4) |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | 3.4 | 3.6 |
| | (1.3) | (1.4) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 4.2 | 4.1 |
| | (1.1) | (1.1) |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | 4.0 | 4.2 |
| | (1.2) | (1.1) |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | 2.3 | 2.3 |
| | (1.2) | (1.2) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.9 | 3.6 |
| | (1.2) | (1.3) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 3.0 | 2.9 |
| | (1.3) | (1.3) |
| 23 Knowledge of compensation strategies and funding sources | 2.7 | 2.7 |
| | (1.4) | (1.4) |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | 3.2 | 3.3 |
| | (1.1) | (1.4) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | 2.9 | 3.1 |
| care phannacy | (1.2) | (1.4) |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | В | |
| 2 Knowledge of effective interdisciplinary communication strategies | В | |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | | |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | | |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | | |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | | |
| 7 Knowledge of the continuous quality improvement process | | |
| 8 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | | A |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | | |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | | |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory obarmacy services | | |
| 12 Knowledge of systems for patient referral and follow up | В | |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, Accutane [®] , Enbrel [®] , Clozaril [®] , thalidomide) | | A |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | | |
| 15 Knowledge of work flow efficiencies and process improvement analyses | | A |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | | |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | | |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | | |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | | |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | В | |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | | |
| 23 Knowledge of compensation strategies and funding sources | | |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | | |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | cert | |
|--|-------|---------|
| | Cert | No Cert |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 2.9 | 3.0 |
| | (1.3) | (1.4) |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | 3.5 | 3.2 |
| | (1.2) | (1.2) |
| 3 Knowledge of disease prevention strategies | 4.1 | 3.8 |
| | (1.0) | (1.1) |
| 4 Knowledge of disease screening guidelines | 3.9 | 3.6 |

| | С | ert |
|--|-------|---------|
| | Cert | No Cert |
| | (1.2) | (1.1) |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | 3.6 | 3.5 |
| | (1.1) | (1.1) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | 2.7 | 2.9 |
| | (1.2) | (1.3) |
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | 3.3 | 3.5 |
| | (1.1) | (1.2) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.0 | 2.4 |
| - | (1.0) | (1.2) |
| 9 Knowledge of prevention and treatment of public health threats | 2.2 | 2.5 |
| | (1.1) | (1.2) |
| 10 Knowledge of processes for delivery and implementation strategies for public health | 2.1 | 2.4 |
| services | (1.1) | (1.2) |

| | C | ert |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | | |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | В | |
| 3 Knowledge of disease prevention strategies | В | |
| 4 Knowledge of disease screening guidelines | В | |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | | |

| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | |
|--|---|
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | A |
| 9 Knowledge of prevention and treatment of public health threats | А |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean. a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | cert | |
|---|-------|---------|
| | Cert | No Cert |
| 1 Knowledge of principles of evidence-based medicine | 4.5 | 4.1 |
| | (.9) | (1.2) |
| Knowledge of common resources of biomedical literature applicable to ambulatory narmacy practice | 4.0 | 3.7 |
| | (1.1) | (1.3) |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) | 4.3 | 3.8 |
| references | (.9) | (1.2) |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | 4.0 | 3.8 |
| | (1.0) | (1.2) |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | 3.4 | 3.2 |
| | (1.2) | (1.3) |
| Knowledge of principles and methods of educating health care students, residents, and professionals | 4.2 | 3.6 |
| | (1.0) | (1.4) |
| Knowledge of research methodology to interpret study validity (for example, study esign, population selection, blinding, statistical analysis) | 3.7 | 3.2 |
| | (1.1) | (1.3) |
| 8 Knowledge of strengths and limitations of various study methods | 3.6 | 3.3 |

Medical Informatics and Professional Development

| | C | cert | |
|--|-------|---------|--|
| | Cert | No Cert | |
| | (1.0) | (1.2) | |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | 3.8 | 3.4 | |
| | (1.0) | (1.2) | |
| 10 Knowledge of appropriate research methodology to design studies to assess a research | 3.1 | 2.9 | |
| hypothesis | (1.1) | (1.4) | |
| 11 Knowledge of granting agencies and their application procedures | 2.0 | 2.0 | |
| | (1.0) | (1.1) | |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, | 2.4 | 2.4 | |
| HIPAA, IRB, OSHA) | (1.1) | (1.3) | |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 2.4 | 2.4 | |
| | (1.1) | (1.3) | |
| 14 Knowledge of elements of informed consent | 2.5 | 2.7 | |
| | (1.1) | (1.4) | |
| 15 Knowledge of survey procedures | 2.2 | 2.1 | |
| | (.9) | (1.0) | |
| 16 Knowledge of data management | 2.8 | 2.5 | |
| | (1.3) | (1.3) | |
| 17 Knowledge of data analysis and statistical methods | 2.7 | 2.5 | |
| | (1.2) | (1.2) | |
| 18 Knowledge of the uniform requirements (developed by the International Committee of | 2.1 | 2.0 | |
| Medical Journal Editors) for manuscripts submitted to biomedical journals | (.9) | (1.0) | |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | 2.6 | 2.4 | |
| | (1.0) | (1.2) | |
| 20 Knowledge of techniques for presentation of research findings | 2.3 | 2.2 | |
| | (.9) | (1.1) | |
| 21 Knowledge of the content of an effective research presentation | 2.3 | 2.2 | |
| | (.9) | (1.1) | |

| | cert | |
|--|-------|---------|
| | Cert | No Cert |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | 2.5 | 2.5 |
| | (.9) | (1.1) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | 2.5 | 2.6 |
| | (1.0) | (1.1) |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | 2.9 | 2.7 |
| | (1.1) | (1.1) |
| 25 Knowledge of staff development principles and avenues for providing continuing education | 2.7 | 2.8 |
| | (.9) | (1.1) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified | 2.8 | 2.5 |
| Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (1.1) | (1.2) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 4.2 | 3.4 |
| | (1.1) | (1.4) |

| | C | ert |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 1 Knowledge of principles of evidence-based medicine | В | |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | | |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | В | |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | В | |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | | |
| 6 Knowledge of principles and methods of educating health care students, residents, and professionals | В | |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | В | |
| 8 Knowledge of strengths and limitations of various study methods | В | |

| | Ce | ert |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | В | |
| 10 Knowledge of appropriate research methodology to design studies to assess a research hypothesis | | |
| 11 Knowledge of granting agencies and their application procedures | | |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | | |
| 13 Knowledge of the ethical principles surrounding research on human subjects | | |
| 14 Knowledge of elements of informed consent | | |
| 15 Knowledge of survey procedures | | |
| 16 Knowledge of data management | В | |
| 17 Knowledge of data analysis and statistical methods | | |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | | |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | | |
| 20 Knowledge of techniques for presentation of research findings | | |
| 21 Knowledge of the content of an effective research presentation | | |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | | |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | | |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | | |
| 25 Knowledge of staff development principles and avenues for providing continuing education | | |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | В | |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | В | |

Patient Advocacy

| | C | cert | |
|---|-------|---------|--|
| | Cert | No Cert | |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | 4.0 | 3.7 | |
| | (1.1) | (1.2) | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | 4.2 | 3.9 | |
| | (1.0) | (1.2) | |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | 2.9 | 3.1 | |
| | (1.3) | (1.3) | |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | 3.9 | 3.8 | |
| , . | (1.2) | (1.3) | |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | 3.4 | 3.3 | |
| | (1.3) | (1.4) | |
| 6 Knowledge of medication reconciliation skills and techniques | 3.6 | 3.4 | |
| | (1.3) | (1.4) | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social | 3.6 | 3.5 | |
| services). | (1.1) | (1.2) | |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | 3.6 | 3.2 | |
| | (1.3) | (1.4) | |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.9 | 3.4 | |
| | (1.2) | (1.3) | |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 3.0 | |
| | (1.1) | (1.2) | |
| 11 Knowledge of conflict management and negotiation skills | 3.6 | 3.3 | |
| | (1.2) | (1.3) | |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | В | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | В | |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | | |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | | |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | | |
| 6 Knowledge of medication reconciliation skills and techniques | | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | В | |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | В | |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | | |
| 11 Knowledge of conflict management and negotiation skills | В | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

| Direct I | Patient | Care |
|----------|---------|------|
|----------|---------|------|

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| 1 Knowledge of anatomy and physiology | 3.3 | 3.4 |
| | (.7) | (.7) |
| 2 Knowledge of pathophysiology | 3.6 | 3.6 |
| | (.6) | (.6) |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy | 3.9 | 3.8 |
| interpretation as they relate to drug therapy | (.4) | (.5) |
| 4 Knowledge of the clinical assessment process | 3.7 | 3.6 |
| | (.5) | (.6) |
| 5 Knowledge of physical assessment techniques | 3.1 | 3.1 |
| | (.8) | (.8) |
| 6 Knowledge of pharmacology | 3.7 | 3.8 |
| | (.5) | (.5) |
| 7 Knowledge of pharmacotherapy | 3.9 | 3.9 |
| | (.3) | (.3) |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 3.8 | 3.6 |
| | (.5) | (.6) |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy management | 3.4 | 3.3 |
| management | (.8) | (.8) |
| 10 Knowledge of OTC medications | 3.8 | 3.7 |
| | (.5) | (.6) |
| 11 Knowledge of the principles of self-care | 3.6 | 3.6 |
| | (.6) | (.7) |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine | 3.4 | 3.4 |
| asea in complementary and alternative medicine | (.6) | (.7) |
| 13 Knowledge of common immunizations | 3.1 | 3.1 |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (.7) | (.8) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | 3.8 | 3.5 |
| guidennes, futti Astrinia guidennes, GOLD guidennes, ACIF guidennes) | (.5) | (.8) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 3.7 | 3.5 |
| | (.5) | (.7) |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 3.7 | 3.6 |
| | (.5) | (.7) |
| 17 Knowledge of factors affecting medication and treatment adherence | 3.7 | 3.7 |
| | (.5) | (.6) |
| 18 Knowledge of effective interventions to address medication and treatment | 3.7 | 3.6 |
| nonadherence | (.5) | (.6) |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood | 3.3 | 3.3 |
| glucose, cholesterol, INR) | (.8) | (.8) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | 2.7 | 2.7 |
| | (.8) | (.9) |
| 21 Knowledge of patient interviewing skills | 3.9 | 3.8 |
| - | (.3) | (.5) |
| 22 Knowledge of motivational interviewing techniques | 3.4 | 3.3 |
| | (.7) | (.8) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in | 3.5 | 3.4 |
| their own care | (.6) | (.7) |
| 24 Knowledge of how to develop effective collaborative partnerships with individual | 3.6 | 3.4 |
| patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | (.6) | (.7) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 3.6 | 3.5 |
| | (.6) | (.7) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.2 | 3.2 |
| | (.7) | (.7) |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient | 3.3 | 3.4 |
| | (.7) | (.7) |
| 28 Knowledge of how to obtain a medication history | 3.9 | 3.7 |
| | (.4) | (.7) |
| 29 Knowledge of the principles and process of medication reconciliation | 3.6 | 3.4 |
| | (.6) | (.8) |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare | 3.7 | 3.7 |
| professionals in order to access health-related patient information essential to the care of the patient | (.5) | (.6) |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize | 3.8 | 3.8 |
| batient care outcomes | (.4) | (.5) |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | 3.8 | 3.7 |
| | (.4) | (.5) |
| 3 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 3.5 | 3.4 |
| | (.6) | (.9) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment | 3.5 | 3.4 |
| plan | (.7) | (.8) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | 3.9 | 3.6 |
| | (.4) | (.7) |
| 36 Knowledge of how to implement an effective, individualized treatment plan | 3.9 | 3.6 |
| | (.4) | (.7) |
| 37 Knowledge of patient education principles and techniques (for example, group classes, | 3.6 | 3.4 |
| individual patient counseling). | (.6) | (.8) |
| 38 Knowledge of the format for documentation of patient care activities, plans and | 3.7 | 3.2 |
| recommendations (for example, SOAP notes) | (.6) | (.9) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for | 3.0 | 3.1 |
| example, home pregnancy tests, hemoccult tests) | (.7) | (.8) |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring | 3.5 | 3.5 |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | (.6) | (.7) |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | 3.6 | 3.6 |
| | (.5) | (.6) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | 3.9 | 3.8 |
| | (.4) | (.5) |
| 43 Knowledge of how to effectively communicate with the patient | 3.9 | 3.9 |
| | (.3) | (.4) |
| 44 Knowledge of the principles and practices of wellness and prevention | 3.6 | 3.6 |
| | (.5) | (.6) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | 3.7 | 3.7 |
| | (.5) | (.6) |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | 3.6 | 3.7 |
| | (.6) | (.6) |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | 3.5 | 3.5 |
| | (.7) | (.7) |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | 3.2 | 3.3 |
| transitioning) | (.7) | (.8) |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | 3.1 | 3.1 |
| | (.7) | (.9) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 3.2 | 3.1 |
| handouts) for delivering educational programs | (.7) | (.9) |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| I Knowledge of anatomy and physiology | | |
| | | |
| 2 Knowledge of pathophysiology | | |
| | | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their | В | |
| nterpretation as they relate to drug therapy | | |
| 4 Knowledge of the clinical assessment process | В | |
| | | |
| 5 Knowledge of physical assessment techniques | | |
| | | |
| 6 Knowledge of pharmacology | | |
| | | |
| 7 Knowledge of pharmacotherapy | | |
| Riowiedge of pharmacotherapy | | |
| | | |
| 3 Knowledge of the principles of both focused and integrated disease-state management | В | |
| | | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy | | |
| management | | |
| 10 Knowledge of OTC medications | | |
| | | |
| 11 Knowledge of the principles of self-care | | |
| | | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | | |
| used in complementary and alternative medicine | | |
| 13 Knowledge of common immunizations | | |
| | | |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III | В | |
| guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | D | |
| 15 Knowledge of the principles and practice of evidence-based medicine | В | |
| To knowledge of the principles and practice of evidence-based medicine | D | |
| 14 Knowledge of recent advances related to phormeesthereny in ambulatory prestice | р | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | В | |
| | | |
| 17 Knowledge of factors affecting medication and treatment adherence | | |
| | | |
| 18 Knowledge of effective interventions to address medication and treatment nonadherence | | |
| | | |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood | | |
| glucose, cholesterol, INR) | | |

| | C | ert | |
|--|------|-----|--------|
| | Cert | | No Cer |
| 20. Knowledge of the regulatory requirements for the use of point of ears testing (for | (A) | (B) | |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | | | |
| 21 Knowledge of patient interviewing skills | В | | |
| 22 Knowledge of motivational interviewing techniques | | | |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care | | | |
| 24 Knowledge of how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes 25 Knowledge of barriers to patient education and interventions to overcome them | В | | |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | | | |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient | | | |
| 28 Knowledge of how to obtain a medication history | В | | |
| 29 Knowledge of the principles and process of medication reconciliation | В | | |
| 30 Knowledge of how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient | | | |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize patient care outcomes | | | |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | | | |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | В | | |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment plan | | | |
| 35 Knowledge of how to develop an effective, individualized treatment plan | В | | |
| 36 Knowledge of how to implement an effective, individualized treatment plan | В | | |
| 37 Knowledge of patient education principles and techniques (for example, group classes, individual patient counseling). | В | | |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | В | | |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | | |

| | C | ert |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | | |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | | |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | | |
| 43 Knowledge of how to effectively communicate with the patient | | |
| 44 Knowledge of the principles and practices of wellness and prevention | | |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | | |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | | |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | | |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | | |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs | | |

Practice Management

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the oharmacist's role in a successful ambulatory care practice | 3.5 | 3.3 |
| | (.7) | (.8) |
| 2 Knowledge of effective interdisciplinary communication strategies | 3.6 | 3.4 |
| | (.7) | (.8) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 3.3 | 3.1 |
| | (.6) | (.9) |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | 3.3 | 3.1 |
| | (.7) | (.9) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | 3.2 | 3.0 |
| | (.8) | (.9) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | 3.3 | 3.1 |
| | (.7) | (.9) |
| 7 Knowledge of the continuous quality improvement process | 3.3 | 3.2 |
| | (.7) | (.8) |
| 3 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | 2.8 | 3.1 |
| the weage of accounting, parenasing, resource atilization, work now, pront analysis) | (.8) | (.8) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 3.2 | 3.2 |
| | (.9) | (.9) |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | 3.2 | 3.1 |
| Jogram | (.7) | (.8) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory | 3.1 | 2.9 |
| pharmacy services | (.8) | (.9) |
| 12 Knowledge of systems for patient referral and follow up | 3.3 | 3.0 |
| | (.8) | (.9) |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, | 2.8 | 3.1 |

| | C | ert |
|--|------|---------|
| | Cert | No Cert |
| Accutane [®] , Enbrel [®] , Clozaril [®] , thalidomide) | (.9) | (.9) |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | 2.8 | 2.9 |
| | (.8) | (.9) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | 2.8 | 2.9 |
| | (.8) | (.8) |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy | 3.2 | 3.1 |
| Management services, and disease management clinics) | (.8) | (.9) |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | 3.2 | 3.2 |
| | (.8) | (.8) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | 3.5 | 3.5 |
| | (.7) | (.7) |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | 3.4 | 3.4 |
| | (.8) | (.8) |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | 2.6 | 2.6 |
| oran, swor [strengths, weaknesses, opportanties, and threats] analysis) | (.9) | (.9) |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.4 | 3.2 |
| | (.7) | (.9) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 3.2 | 3.0 |
| | (.7) | (.9) |
| 23 Knowledge of compensation strategies and funding sources | 3.2 | 3.0 |
| | (.7) | (.9) |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | 3.2 | 3.3 |
| | (.7) | (.8) |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory | 3.2 | 3.3 |
| care pharmacy | (.7) | (.8) |

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | В | |
| 2 Knowledge of effective interdisciplinary communication strategies | В | |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | В | |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | В | |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | В | |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | В | |
| 7 Knowledge of the continuous quality improvement process | | |
| 8 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | | A |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | | |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | | |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services | | |
| 12 Knowledge of systems for patient referral and follow up | В | |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | | A |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | | |
| 15 Knowledge of work flow efficiencies and process improvement analyses | | А |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | | |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | | |

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | | |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | | |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | | |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | В | |
| 23 Knowledge of compensation strategies and funding sources | В | |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | | |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | 2.9 | 3.0 |
| | (.8) | (.9) |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | 3.1 | 3.1 |
| | (.8) | (.8) |
| 3 Knowledge of disease prevention strategies | 3.5 | 3.5 |
| | (.6) | (.7) |
| 4 Knowledge of disease screening guidelines | 3.4 | 3.3 |

| | C | cert |
|---|------|---------|
| | Cert | No Cert |
| | (.7) | (.7) |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | 3.1 | 3.2 |
| | (.8) | (.8) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | 2.7 | 3.0 |
| | (.8) | (.8) |
| 7 Knowledge of information that is accessible to the public regarding the prevention and reatment of diseases (for example, reliable internet websites, toll-free information notlines) | 3.0 | 3.2 |
| | (.8) | (.8) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.5 | 2.8 |
| | (.8) | (.9) |
| 9 Knowledge of prevention and treatment of public health threats | 2.6 | 2.9 |
| | (.8) | (.9) |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | 2.5 | 2.8 |
| SELVICES | (.7) | (.8) |

| | C | ert |
|--|------|--------|
| | Cert | No Cer |
| | (A) | (B) |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | | |
| | | |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | | |
| 3 Knowledge of disease prevention strategies | | |
| 4 Knowledge of disease screening guidelines | | |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | | |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | | A |
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | | Α |

| | cert | |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | | A |
| 9 Knowledge of prevention and treatment of public health threats | | A |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | | A |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | C | cert | |
|---|------|---------|--|
| | Cert | No Cert | |
| 1 Knowledge of principles of evidence-based medicine | 3.7 | 3.6 | |
| | (.6) | (.7) | |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory oharmacy practice | 3.4 | 3.4 | |
| | (.8) | (.9) | |
| ³ Knowledge of primary (for example, original research reports), secondary (for example, ndexing and abstracting services), and tertiary (for example, textbook review articles) | 3.6 | 3.4 | |
| references | (.7) | (.9) | |
| Knowledge of how to formulate a search strategy to retrieve information from the piomedical literature | 3.6 | 3.4 | |
| | (.7) | (.9) | |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | 3.1 | 3.1 | |
| | (.8) | (.9) | |
| 5 Knowledge of principles and methods of educating health care students, residents, and professionals | 3.4 | 3.3 | |
| | (.7) | (.9) | |
| Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | 3.4 | 3.2 | |
| | (.7) | (1.0) | |
| 3 Knowledge of strengths and limitations of various study methods | 3.4 | 3.2 | |
| | (.7) | (.9) | |

Medical Informatics and Professional Development

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | 3.6 | 3.3 |
| | (.7) | (.9) |
| 10 Knowledge of appropriate research methodology to design studies to assess a research | 3.2 | 3.0 |
| nypothesis | (.8) | (1.0) |
| 11 Knowledge of granting agencies and their application procedures | 2.5 | 2.5 |
| | (.8) | (1.0) |
| 2 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | 2.6 | 2.8 |
| | (.8) | (1.0) |
| 3 Knowledge of the ethical principles surrounding research on human subjects | 2.9 | 2.9 |
| | (.9) | (1.0) |
| 4 Knowledge of elements of informed consent | 2.9 | 3.0 |
| | (.9) | (1.0) |
| 15 Knowledge of survey procedures | 2.4 | 2.5 |
| | (.8) | (.9) |
| 16 Knowledge of data management | 2.7 | 2.7 |
| | (.8) | (.9) |
| 17 Knowledge of data analysis and statistical methods | 2.7 | 2.8 |
| | (.8) | (.9) |
| 8 Knowledge of the uniform requirements (developed by the International Committee of Aedical Journal Editors) for manuscripts submitted to biomedical journals | 2.4 | 2.5 |
| | (.8) | (1.0) |
| 9 Knowledge of components of well written research abstracts, reports, and monographs | 2.8 | 2.7 |
| | (.8) | (1.0) |
| 20 Knowledge of techniques for presentation of research findings | 2.7 | 2.7 |
| | (.8) | (1.0) |
| 21 Knowledge of the content of an effective research presentation | 2.7 | 2.7 |
| | (.8) | (1.0) |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy | 2.7 | 2.8 |

| | C | cert |
|---|------|---------|
| | Cert | No Cert |
| organization conferences, journals) | (.8) | (.9) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental | 3.3 | 3.2 |
| entities | (.7) | (.9) |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | 3.0 | 3.0 |
| | (.8) | (.8) |
| 25 Knowledge of staff development principles and avenues for providing continuing education | 2.9 | 2.9 |
| | (.9) | (.8) |
| 6 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified | 3.1 | 3.0 |
| Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (.8) | (.9) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 3.7 | 3.3 |
| | (.6) | (.9) |

| | cert | |
|--|-------------|----------------|
| | Cert (A) | No Cert (B) |
| 1 Knowledge of principles of evidence-based medicine | | |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | | |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | В | |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | В | |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | | |
| 6 Knowledge of principles and methods of educating health care students, residents, and professionals | | |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | В | |
| 8 Knowledge of strengths and limitations of various study methods | В | |

| | CE | ert |
|---|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | В | |
| 10 Knowledge of appropriate research methodology to design studies to assess a research hypothesis | | |
| 11 Knowledge of granting agencies and their application procedures | | |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | | |
| 13 Knowledge of the ethical principles surrounding research on human subjects | | |
| 14 Knowledge of elements of informed consent | | |
| 15 Knowledge of survey procedures | | |
| 16 Knowledge of data management | | |
| 17 Knowledge of data analysis and statistical methods | | |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | | |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | | |
| 20 Knowledge of techniques for presentation of research findings | | |
| 21 Knowledge of the content of an effective research presentation | | |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | | |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | | |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | | |
| 25 Knowledge of staff development principles and avenues for providing continuing education | | |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | | |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | В | |

Patient Advocacy

| | C | ert |
|---|------|---------|
| | Cert | No Cert |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | 3.3 | 3.2 |
| | (.7) | (.8) |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | 3.5 | 3.4 |
| | (.7) | (.8) |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | 3.0 | 3.1 |
| | (.8) | (.9) |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | 3.3 | 3.3 |
| | (.7) | (.8) |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | 3.2 | 3.2 |
| | (.7) | (.8) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.3 | 3.3 |
| | (.8) | (.8) |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social | 3.2 | 3.2 |
| services). | (.8) | (.8) |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | 3.2 | 3.0 |
| | (.8) | (.8) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.3 | 3.2 |
| | (.8) | (.9) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 3.0 |
| | (.8) | (.8) |
| 11 Knowledge of conflict management and negotiation skills | 3.2 | 3.1 |
| | (.8) | (.8) |

| | cert | |
|--|------|---------|
| | Cert | No Cert |
| | (A) | (B) |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | | |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | | |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | | |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | | |
| 6 Knowledge of medication reconciliation skills and techniques | | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | | |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | | |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | | |
| 11 Knowledge of conflict management and negotiation skills | | |

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | 4.5 | 4.3 |
| | (1.1) | (1.1) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | 4.4 | 4.1 |
| | (1.1) | (1.2) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, | 4.3 | 4.1 |
| and previous adverse drug reactions. | (1.1) | (1.2) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver nterview, patient's healthcare provider(s), patient's documented medication profiles, and | 4.3 | 3.8 |
| medical records. | (1.1) | (1.4) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | 4.1 | 3.3 |
| | (1.2) | (1.5) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual | 3.5 | 2.5 |
| inspection). | (1.5) | (1.6) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | 2.7 | 2.1 |
| | (1.6) | (1.4) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | 3.8 | 2.8 |
| | (1.3) | (1.5) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | 4.3 | 3.7 |
| | (1.2) | (1.4) |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | 4.6 | 4.1 |
| | (.9) | (1.2) |
| I.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | 4.5 | 4.3 |
| | (1.0) | (1.1) |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient butcomes (for example, tobacco, activity level, nutrition). | 4.3 | 3.6 |
| | (1.1) | (1.3) |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | 3.8 | 3.4 |
| | (1.2) | (1.4) |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a | 4.1 | 3.6 |
| olan to overcome these (for example, home visits, interpreter, picture-based | (1.1) | (1.4) |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking | 4.5 | 4.5 |
| the medication, potential side effects and when to report problems). | (1.0) | (.9) |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, | 3.3 | 3.5 |
| subcutaneous injections). | (1.3) | (1.3) |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | 4.3 | 3.8 |
| | (1.1) | (1.3) |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle nodifications, immunizations). | 3.8 | 3.3 |
| | (1.3) | (1.4) |
| 1.19 Recommend appropriate immunizations to specific patients. | 3.0 | 2.5 |
| | (1.3) | (1.3) |
| 1.20 Administer appropriate immunizations to specific patients. | 1.6 | 1.6 |
| | (1.1) | (1.1) |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | 3.9 | 4.1 |
| | (1.2) | (1.1) |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | 4.0 | 2.6 |
| | (1.5) | (1.7) |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | 3.5 | 2.1 |
| · · · · · · · · · · · · · · · · · · · | (1.5) | (1.5) |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | 4.0 | 2.7 |
| | (1.3) | (1.6) |
| 1.25 Provide wellness and preventive programs for individual patients (for example, | 2.5 | 2.1 |

| | Residence | etion of y Training gram |
|--|-----------|--------------------------------|
| | Yes | No |
| weight management program, tobacco cessation program, immunization program). | (1.4) | (1.3) |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend reatment options. | 3.9 | 4.2 |
| | (1.2) | (1.1) |
| 1.27 Make recommendations to manage drug therapy which may include initiation, nodification, or discontinuation of medication therapy as appropriate. | 4.4 | 3.8 |
| ······································ | (1.0) | (1.2) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.6 | 3.6 |
| | (1.3) | (1.3) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.1 | 3.1 |
| | (1.3) | (1.3) |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 2.2 | 2.6 |
| | (1.2) | (1.2) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, nome pregnancy tests, hemoccult tests). | 1.9 | 2.3 |
| | (1.1) | (1.3) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | 4.2 | 2.9 |
| | (1.2) | (1.6) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, nsurance coverage, out of pocket expenses). | 3.3 | 3.3 |
| | (1.6) | (1.7) |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | 4.2 | 3.9 |
| | (1.1) | (1.3) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 4.3 | 3.2 |
| | (1.1) | (1.5) |
| .36 Implement a patient-specific plan to address prioritized patient needs and identified lrug-related problems to improve patient outcomes. | 4.2 | 3.1 |
| | (1.1) | (1.5) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | 4.2 | 2.9 |
| o both and and hon and thorapy and assure safety. | (1.2) | (1.6) |

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | 4.4 | 3.4 | |
| | (1.1) | (1.5) | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal | 4.3 | 3.6 | |
| communication). | (1.1) | (1.4) | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | 3.9 | 2.7 | |
| | (1.4) | (1.6) | |
| .41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver unction tests, cholesterol results) and other diagnostic results (for example, ECHO results, | 4.2 | 2.7 | |
| pulmonary function tests) to determine if and when adjustments to dru | (1.3) | (1.6) | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 4.2 | 2.7 | |
| | (1.2) | (1.6) | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | 4.1 | 3.1 | |
| | (1.2) | (1.5) | |
| .44 Document all patient care activities (for example, patient-specific findings, detailed reatment recommendations and communications with patient and other healthcare | 4.3 | 3.0 | |
| providers). | (1.2) | (1.6) | |

| | - | etion of y Training jram |
|--|-----|--------------------------------|
| | Yes | No |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | (A) | (B) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | В | |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | В | |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | В | |
| Ambulatory Care Pharmacy Analysis 4 | | 8/11/0 |

| | Residency | etion of y Trainin <u>c</u> jram |
|---|------------|--|
| | Yes (A) | No (B) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | B | (0) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | В | |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | В | |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | В | |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | В | |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | В | |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | В | |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition). | В | |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | В | |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based | В | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | | |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | | |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | В | |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations). | В | |
| 1.19 Recommend appropriate immunizations to specific patients. | В | |

| | Residency | etion of y Trainin <u>c</u> gram |
|---|-----------|--|
| | Yes | No |
| | (A) | (B) |
| I.20 Administer appropriate immunizations to specific patients. | | |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | | A |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | В | |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | В | |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | В | |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | В | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend reatment options. | | А |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | В | |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | | |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | A |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, nome pregnancy tests, hemoccult tests). | | A |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | В | |
| 1.33 Determine patient's ability and willingness to pay for services (for example, nsurance coverage, out of pocket expenses). | | |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | В | |

| | | etion of |
|---|-----|------------|
| | | y Training |
| | - | gram |
| | Yes | No |
| | (A) | (B) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | В | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | В | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). | В | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | В | |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | В | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | В | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | В | |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). | В | |

Practice Management

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, | 2.7 | 2.5 |
| focused or integrated disease-state management programs/clinics). | (1.4) | (1.4) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or | 2.2 | 2.0 |
| integrated disease-state management programs/clinics). | (1.1) | (1.2) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | 2.8 | 2.5 |
| | (1.4) | (1.5) |
| 2.4 Promote and market patient care services to patients and health care providers. | 2.6 | 2.4 |
| | (1.3) | (1.4) |
| 2.5 Establish and maintain a system for patient referral. | 3.1 | 2.2 |
| | (1.5) | (1.5) |
| 2.6 Establish and maintain a system for patient follow up. | 3.5 | 2.6 |
| | (1.5) | (1.6) |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report | 2.7 | 2.7 |
| evaluation). | (1.2) | (1.5) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 2.5 | 2.4 |
| | (1.2) | (1.5) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 4.3 | 3.3 |
| | (1.2) | (1.7) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, | 3.1 | 2.9 |
| ancillary personnel, staff). | (1.4) | (1.5) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary | 3.3 | 2.9 |
| personnel, group visits, disciplined appointment system, use of technology, coord | (1.4) | (1.6) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | 1.8 | 2.6 |
| payment systems, insurance contracting, accounting systems, pricing, expense dildiysis). | (1.3) | (1.7) |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 1.8 | 1.9 |
| | (1.1) | (1.3) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | 2.4 | 2.3 |
| | (1.2) | (1.4) |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | 2.6 | 2.5 |
| | (1.2) | (1.4) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | 2.0 | 2.3 |
| | (1.4) | (1.6) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | 1.7 | 2.5 |
| | (1.2) | (1.6) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 2.8 | 4.1 |
| | (1.7) | (1.5) |
| 2.19 Participate in formulary management (for example, participate on P&T committee, levelop criteria for use protocols, design cost-effective treatment protocols, develop | 2.5 | 2.2 |
| system for obtaining prior authorization and nonformulary drugs based on medical ne | (1.2) | (1.4) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | 2.7 | 3.1 |
| | (1.3) | (1.4) |

| | Residency | etion of y Training gram |
|--|-----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | | |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | | |

Ambulatory Care Pharmacy Analysis

| | Residence | etion of y Training gram |
|--|-----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | В | |
| 2.4 Promote and market patient care services to patients and health care providers. | | |
| 2.5 Establish and maintain a system for patient referral. | В | |
| 2.6 Establish and maintain a system for patient follow up. | В | |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | | |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | | |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | В | |
| | | |
| example, patient education materials, immunization supplies, office equipment and space, | | |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | В | |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff).2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary | В | A |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord 2.12 Manage a financially viable practice (for example, cash flow management, cash | В | A |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | B | A |
| example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the | B | A |

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | | A |
| 2.18 Ensure timely and accurate delivery of medication to patients. | | A |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | В | |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | | А |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | 2.5 | 2.9 |
| | (1.2) | (1.3) |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | 2.7 | 2.5 |
| | (1.3) | (1.4) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer | 2.2 | 2.6 |
| Society). | (1.1) | (1.3) |
| 3.4 Participate in community health screening programs. | 1.9 | 2.0 |
| | (.8) | (1.0) |
| 3.5 Serve as a public advocate regarding preventive health issues. | 2.0 | 2.3 |
| | (1.2) | (1.3) |

| | Completion of Residency Trainii Program | |
|--|---|-------|
| | Yes | No |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | 2.1 | 2.2 |
| | (1.2) | (1.3) |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | 1.5 | 1.7 |
| | (.8) | (1.1) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 1.4 | 1.7 |
| | (.8) | (1.0) |
| 3.9 Participate in disaster response preparation and planning. | 1.5 | 1.7 |
| | (.7) | (.9) |

| | Residence | etion of y Training gram |
|---|-----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | | A |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | | A |
| 3.4 Participate in community health screening programs. | | |
| 3.5 Serve as a public advocate regarding preventive health issues. | | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | | |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | | A |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | | A |
| 3.9 Participate in disaster response preparation and planning. | | A |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy | 3.8 | 3.4 |
| practice. | (1.0) | (1.2) |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | 3.6 | 3.5 |
| | (.9) | (.9) |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | 3.5 | 2.7 |
| | (1.0) | (1.3) |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | 4.2 | 4.3 |
| | (1.0) | (.9) |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 3.8 | 3.1 |
| | (1.2) | (1.4) |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.8 | 3.4 |
| | (1.1) | (1.3) |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | 3.7 | 3.0 |
| | (1.4) | (1.5) |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | 2.3 | 1.7 |
| | (1.2) | (1.3) |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, | 1.9 | 1.6 |
| and national audiences. | (.9) | (1.0) |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of | 2.4 | 2.4 |
| knowledge. | (1.1) | (1.2) |
| 4.11 Participate in local, state, and/or national professional organizations. | 2.9 | 2.8 |
| | (1.1) | (1.2) |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | 2.6 | 2.7 |
| | (1.1) | (1.2) |

Medical Informatics and Professional Development

| | Residence | letion of cy Training gram |
|--|-----------|----------------------------------|
| | Yes | No |
| | (A) | (B) |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | В | |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | В | |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | | |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | В | |
| 4.6 Provide health and medication-related education to healthcare professionals. | В | |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | В | |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | В | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | В | |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | | |
| 4.11 Participate in local, state, and/or national professional organizations. | | |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of *the smaller category appears under the category with larger mean.* a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 4.0 | 3.7 |
| | (1.2) | (1.3) |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 2.6 | 2.8 |
| | (1.3) | (1.4) |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | 2.6 | 3.3 |
| | (1.5) | (1.5) |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.3 | 3.7 |
| | (1.4) | (1.4) |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | 2.9 | 3.0 |
| | (1.4) | (1.4) |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all | 3.8 | 3.6 |
| healthcare providers. | (1.2) | (1.4) |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to | 3.8 | 3.5 |
| provide patient care. | (1.4) | (1.5) |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and | 3.7 | 3.0 |
| services required to meet the patient's health and human service needs). | (1.3) | (1.5) |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care obarmacist. | 3.3 | 2.7 |
| | (1.3) | (1.4) |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 2.7 | 2.6 |
| | (1.3) | (1.4) |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | 3.1 | 2.6 |
| | (1.2) | (1.4) |
| 5.12 Encourage patients to openly communicate health and medication related concerns | 3.9 | 3.8 |

Patient Advocacy

| | Residence | etion of y Training gram |
|---|-----------|--------------------------------|
| | Yes | No |
| with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | (1.2) | (1.3) |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | В | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | | |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | | A |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | | А |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | | |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | | |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | В | |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | В | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist. | В | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | | |

Frequency Ratings of Task Statements by Residency or Not

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | В | |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Direct Patient Care

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | 3.9 | 3.8 |
| | (.3) | (.5) |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | 3.9 | 3.7 |
| | (.3) | (.6) |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, | 3.9 | 3.8 |
| and previous adverse drug reactions. | (.3) | (.5) |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and | 3.8 | 3.6 |
| medical records. | (.4) | (.7) |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | 3.6 | 3.4 |
| substances of abuse, diagnostic test results). | (.5) | (.7) |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual | 3.3 | 2.9 |
| ispection). | (.7) | (.9) |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | 3.1 | 2.9 |
| | (.9) | (.9) |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | 3.5 | 3.1 |
| | (.7) | (.9) |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | 3.8 | 3.5 |
| | (.4) | (.8) |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | 3.9 | 3.6 |
| · · · · · · · · · · · · · · · · · · · | (.3) | (.7) |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | 3.9 | 3.7 |
| 5. 5 5. 5 5. 5 5. 5 5. 5 5. 5 5. 5 5. | (.2) | (.6) |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient | 3.6 | 3.4 |

| | Residency | etion of y Trainin <u>g</u> jram |
|--|---------------------|--|
| | Yes | No |
| outcomes (for example, tobacco, activity level, nutrition). | (.5) | (.7) |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | 3.6 | 3.4 |
| | (.6) | (.8) |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a | 3.7 | 3.5 |
| blan to overcome these (for example, home visits, interpreter, picture-based | (.6) | (.7) |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of nedication, proper administration, directions for use, foods or drugs to avoid while taking | 3.9 | 3.8 |
| he medication, potential side effects and when to report problems). | (.4) | (.5) |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, | 3.7 | 3.6 |
| subcutaneous injections). | (.6) | (.6) |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | 3.8 | 3.6 |
| | (.4) | (.6) |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle nodifications, immunizations). | 3.6 | 3.4 |
| | (.6) | (.7) |
| 1.19 Recommend appropriate immunizations to specific patients. | 3.2 | 3.1 |
| | (.7) | (.9) |
| 1.20 Administer appropriate immunizations to specific patients. | 2.7 | 2.7 |
| | (1.0) | (1.0) |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | 3.7 | 3.6 |
| | (.6) | (.7) |
| I.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | 3.8 | 3.4 |
| | (.5) | (.9) |
| .23 Provide integrated disease-state management (for example, pharmacotherapy | 3.7 | 3.2 |
| linics primary care clinics where more than one disease may be addressed in a visit) | (.6) | (.9) |
| linics, primary care clinics where more than one disease may be addressed in a visit). | x = <i>y</i> | |
| clinics, primary care clinics where more than one disease may be addressed in a visit). 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | 3.8 | 3.4 |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | 3.3 | 3.2 |
| | (.8) | (.8) |
| I.26 Identify situations in which OTC treatment may be appropriate, and recommend reatment options. | 3.6 | 3.6 |
| | (.6) | (.6) |
| 1.27 Make recommendations to manage drug therapy which may include initiation, nodification, or discontinuation of medication therapy as appropriate. | 3.9 | 3.6 |
| | (.3) | (.6) |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.5 | 3.4 |
| | (.6) | (.7) |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | 3.4 | 3.4 |
| | (.7) | (.7) |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 2.9 | 3.1 |
| | (.8) | (.8) |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, nome pregnancy tests, hemoccult tests). | 2.8 | 3.0 |
| | (.8) | (.9) |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | 3.8 | 3.3 |
| | (.5) | (.9) |
| 1.33 Determine patient's ability and willingness to pay for services (for example, nsurance coverage, out of pocket expenses). | 3.3 | 3.2 |
| | (.9) | (.9) |
| .34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | 3.7 | 3.5 |
| | (.6) | (.7) |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 3.8 | 3.6 |
| | (.4) | (.7) |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | 3.8 | 3.5 |
| | (.5) | (.7) |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response | 3.8 | 3.4 |

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| to both drug and non-drug therapy and assure safety. | (.5) | (.8) | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other nealthcare professionals involved in the care of the patient. | 3.9 | 3.5 | |
| | (.3) | (.7) | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal | 3.9 | 3.5 | |
| communication). | (.4) | (.7) | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug herapy and assure safety. | 3.7 | 3.2 | |
| | (.5) | (.9) | |
| I.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, | 3.8 | 3.3 | |
| pulmonary function tests) to determine if and when adjustments to dru | (.4) | (.8) | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | 3.8 | 3.3 | |
| | (.4) | (.8) | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | 3.8 | 3.4 | |
| | (.4) | (.8) | |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed reatment recommendations and communications with patient and other healthcare | 3.9 | 3.4 | |
| providers). | (.4) | (.8) | |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management. | В | |
| 1.2 Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness). | В | |
| 1.3 Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions. | В | |
| 1.4 Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records. | В | |
| 1.5 Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results). | В | |
| 1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection). | В | |
| 1.7 Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow). | В | |
| 1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues. | В | |
| 1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care. | В | |
| 1.10 Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors. | В | |
| 1.11 Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy. | В | |
| 1.12 Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition). | В | |
| 1.13 Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist. | В | |

| | Residence | Completion of Residency Training Program | |
|---|-----------|--|--|
| | Yes | No | |
| | (A) | (B) | |
| 1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based | В | | |
| 1.15 Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems). | | | |
| 1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections). | | | |
| 1.17 Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia). | В | | |
| 1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations). | В | | |
| 1.19 Recommend appropriate immunizations to specific patients. | В | | |
| 1.20 Administer appropriate immunizations to specific patients. | | | |
| 1.21 Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs). | | | |
| 1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers. | В | | |
| 1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit). | В | | |
| 1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain). | В | | |
| 1.25 Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program). | | | |
| 1.26 Identify situations in which OTC treatment may be appropriate, and recommend treatment options. | | | |
| 1.27 Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate. | В | | |

| | Residence | Completion of Residency Training Program | |
|---|-----------|--|--|
| | Yes | No | |
| | (A) | (B) | |
| 1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | | | |
| 1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors). | | | |
| 1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | A | |
| 1.31 Teach patients how to use appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests). | | A | |
| 1.32 Define treatment goals in collaboration with the patient and other healthcare providers. | В | | |
| 1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses). | | | |
| 1.34 Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan. | В | | |
| 1.35 Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | | |
| 1.36 Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes. | В | | |
| 1.37 Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety. | В | | |
| 1.38 Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient. | В | | |
| 1.39 Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication). | В | | |
| 1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety. | В | | |
| 1.41 Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to dru | В | | |

| | Completion of Residency Training Program | |
|--|--|-----------|
| | Yes | No (B) |
| | (A) | |
| 1.42 Modify patient-specific treatment plan based on follow up assessment. | В | |
| 1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy. | В | |
| 1.44 Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers). | В | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Practice Management

| | Completion of Residency Training Program | |
|--|--|-------|
| | Yes | No |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, | 3.5 | 3.3 |
| focused or integrated disease-state management programs/clinics). | (.7) | (.8) |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | 3.5 | 3.2 |
| | (.7) | (.9) |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | 3.7 | 3.4 |
| | (.5) | (.7) |
| 2.4 Promote and market patient care services to patients and health care providers. | 3.4 | 3.2 |
| | (.7) | (.9) |
| 2.5 Establish and maintain a system for patient referral. | 3.5 | 3.1 |
| | (.7) | (1.0) |
| 2.6 Establish and maintain a system for patient follow up. | 3.6 | 3.3 |
| | (.6) | (.8) |

| | Completion of Residency Training Program | |
|---|--|-------|
| | Yes | No |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report | 3.5 | 3.4 |
| evaluation). | (.6) | (.8) |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | 3.5 | 3.3 |
| | (.7) | (.8) |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | 3.9 | 3.5 |
| | (.4) | (.8) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, | 3.5 | 3.3 |
| ancillary personnel, staff). | (.7) | (.8) |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary | 3.5 | 3.3 |
| personnel, group visits, disciplined appointment system, use of technology, coord | (.6) | (.8) |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash bayment systems, insurance contracting, accounting systems, pricing, expense analysis). | 3.2 | 3.4 |
| | (.9) | (.8) |
| 13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | 3.4 | 3.3 |
| | (.8) | (.9) |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | 3.6 | 3.3 |
| | (.6) | (.8) |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | 3.6 | 3.4 |
| | (.6) | (.8) |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | 3.1 | 3.2 |
| | (.9) | (1.0) |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | 2.9 | 3.1 |
| | (.9) | (.9) |
| 2.18 Ensure timely and accurate delivery of medication to patients. | 3.3 | 3.7 |
| | (.9) | (.6) |
| 2.19 Participate in formulary management (for example, participate on P&T committee, | 3.3 | 3.2 |

| | Completion of Residency Training Program | |
|--|--|------|
| | Yes | No |
| develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | (.7) | (.9) |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | 3.5 | 3.6 |
| | (.7) | (.7) |

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | В | |
| 2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics). | В | |
| 2.3 Establish relationships and/or collaborative practice agreements with other health care providers. | В | |
| 2.4 Promote and market patient care services to patients and health care providers. | В | |
| 2.5 Establish and maintain a system for patient referral. | В | |
| 2.6 Establish and maintain a system for patient follow up. | В | |
| 2.7 Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation). | | |
| 2.8 Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services. | В | |
| 2.9 Participate as an integral member of an interdisciplinary health care team. | В | |

| | Completion of Residency Training Program | |
|---|--|-----|
| | Yes | No |
| | (A) | (B) |
| 2.10 Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff). | | |
| 2.11 Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coord | | |
| 2.12 Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis). | | A |
| 2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services. | | |
| 2.14 Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements. | В | |
| 2.15 Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice. | В | |
| 2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA). | | |
| 2.17 Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs). | | A |
| 2.18 Ensure timely and accurate delivery of medication to patients. | | A |
| 2.19 Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical ne | | |
| 2.20 Report medication errors and develop systems to track and analyze these for possible intervention measures. | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | Completion of Residency Training Program | |
|---|--|------|
| | Yes | No |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | 3.3 | 3.3 |
| | (.7) | (.7) |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | 3.3 | 3.2 |
| | (.7) | (.8) |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer | 3.0 | 3.1 |
| Society). | (.8) | (.8) |
| 3.4 Participate in community health screening programs. | 3.0 | 3.0 |
| | (.8) | (.9) |
| 3.5 Serve as a public advocate regarding preventive health issues. | 3.0 | 3.1 |
| | (.8) | (.9) |
| 8.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | 3.3 | 3.2 |
| | (.8) | (.9) |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | 2.9 | 3.0 |
| | (.9) | (.9) |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | 2.9 | 3.1 |
| | (.9) | (.9) |
| 8.9 Participate in disaster response preparation and planning. | 2.9 | 3.1 |
| | (.9) | (.9) |

| | Completion of Residency Training Program | |
|---|--|-----|
| | Yes | No |
| | (A) | (B) |
| 3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations). | | |
| 3.2 Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues. | | |
| 3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society). | | |
| 3.4 Participate in community health screening programs. | | |
| 3.5 Serve as a public advocate regarding preventive health issues. | | |
| 3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice. | | |
| 3.7 Identify and report suspected public health threats (for example, disasters, infectious diseases). | | A |
| 3.8 Facilitate appropriate care for patients affected by public health threats and disasters. | | A |
| 3.9 Participate in disaster response preparation and planning. | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Residenc | Completion of Residency Training Program | |
|--|----------|--|--|
| | Yes | No | |
| 1.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy | 3.8 | 3.5 | |
| practice. | (.5) | (.7) | |
| 1.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | 3.8 | 3.6 | |
| | (.4) | (.6) | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | 3.6 | 3.1 | |
| | (.6) | (.9) | |
| 1.4 Respond to drug information requests from patients and healthcare professionals. | 3.8 | 3.7 | |
| | (.5) | (.5) | |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | 3.7 | 3.4 | |
| | (.5) | (.7) | |
| 4.6 Provide health and medication-related education to healthcare professionals. | 3.7 | 3.5 | |
| | (.5) | (.7) | |
| 7 Provide experiential training to pharmacy students and residents in ambulatory care armacy practice. | 3.8 | 3.4 | |
| | (.5) | (.7) | |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | 3.2 | 2.8 | |
| | (.7) | (.9) | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, | 3.2 | 2.7 | |
| and national audiences. | (.7) | (.9) | |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of | 3.4 | 3.3 | |
| knowledge. | (.7) | (.8) | |
| 4.11 Participate in local, state, and/or national professional organizations. | 3.4 | 3.3 | |
| | (.7) | (.8) | |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | 3.4 | 3.3 | |
| | (.7) | (.8) | |

Medical Informatics and Professional Development

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 4.1 Stay current with the biomedical literature applicable to ambulatory care pharmacy practice. | В | |
| 4.2 Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs). | В | |
| 4.3 Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions. | В | |
| 4.4 Respond to drug information requests from patients and healthcare professionals. | | |
| 4.5 Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine. | В | |
| 4.6 Provide health and medication-related education to healthcare professionals. | В | |
| 4.7 Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice. | В | |
| 4.8 Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice | В | |
| 4.9 Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences. | В | |
| 4.10 Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge. | | |
| 4.11 Participate in local, state, and/or national professional organizations. | В | |
| 4.12 Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education. | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Patient Advocacy

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | 3.6 | 3.6 | |
| | (.6) | (.6) | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | 3.1 | 3.1 | |
| | (.8) | (.8) | |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | 3.1 | 3.1 | |
| | (.8) | (.9) | |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | 3.3 | 3.3 | |
| | (.7) | (.8) | |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care for example, transition from acute to ambulatory care setting). | 3.4 | 3.3 | |
| tor example, transition normaleate to ambulatory care setting). | (.7) | (.8) | |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all | 3.7 | 3.6 | |
| healthcare providers. | (.6) | (.6) | |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to | 3.7 | 3.6 | |
| provide patient care. | (.5) | (.6) | |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and | 3.5 | 3.4 | |
| services required to meet the patient's health and human service needs). | (.7) | (.7) | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care obarmacist. | 3.4 | 3.2 | |
| | (.7) | (.9) | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | 3.2 | 3.2 | |
| | (.8) | (.9) | |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | 3.3 | 3.1 | |
| | (.7) | (.9) | |
| 5.12 Encourage patients to openly communicate health and medication related concerns vith all healthcare providers (for example, patient disagreement with outlined treatment | 3.6 | 3.4 | |
| blan, use of herbal remedies or non-traditional treatments). | (.6) | (.7) | |

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 5.1 Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes. | | |
| 5.2 Facilitate access to Patient and/or Medication Assistance Programs. | | |
| 5.3 Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes. | | |
| 5.4 Resolve formulary issues to ensure access to cost-effective drug therapy. | | |
| 5.5 Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting). | | |
| 5.6 Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers. | | |
| 5.7 Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care. | | |
| 5.8 Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs). | | |
| 5.9 Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist. | В | |
| 5.10 Advocate to ensure appropriate healthcare policy for optimal patient outcomes. | | |
| 5.11 Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient | В | |
| 5.12 Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments). | В | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Completion of Residency Trainin Program | |
|---|---|-------|
| | Yes | No |
| 1 Knowledge of anatomy and physiology | 4.0 | 4.2 |
| | (1.0) | (.9) |
| 2 Knowledge of pathophysiology | 4.5 | 4.2 |
| | (.8) | (1.0) |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their nterpretation as they relate to drug therapy | 4.8 | 4.2 |
| The pretation as they relate to drug therapy | (.6) | (1.0) |
| Knowledge of the clinical assessment process | 4.6 | 4.1 |
| | (.8) | (1.1) |
| 5 Knowledge of physical assessment techniques | 3.8 | 3.6 |
| | (1.1) | (1.2) |
| 6 Knowledge of pharmacology | 4.7 | 4.7 |
| | (.7) | (.6) |
| 7 Knowledge of pharmacotherapy | 4.9 | 4.8 |
| | (.5) | (.5) |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 4.7 | 4.3 |
| | (.6) | (1.0) |
| O Knowledge of the principles of and regulations governing collaborative drug therapy nanagement | 3.7 | 3.6 |
| hanagement | (1.3) | (1.4) |
| 10 Knowledge of OTC medications | 4.4 | 4.7 |
| | (.8) | (.6) |
| 11 Knowledge of the principles of self-care | 4.4 | 4.5 |
| | (.9) | (.9) |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | 4.0 | 4.1 |
| used in complementary and alternative medicine | (.9) | (1.0) |

Direct Patient Care

| | Completion of Residency Training Program | |
|---|--|-------|
| | Yes | No |
| 13 Knowledge of common immunizations | 3.4 | 3.3 |
| | (1.1) | (1.1) |
| Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III uidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | 4.6 | 3.6 |
| | (.9) | (1.2) |
| 5 Knowledge of the principles and practice of evidence-based medicine | 4.6 | 3.9 |
| | (.7) | (1.2) |
| 6 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 4.3 | 4.1 |
| | (.9) | (1.0) |
| 7 Knowledge of factors affecting medication and treatment adherence | 4.5 | 4.4 |
| | (.8) | (.8) |
| 8 Knowledge of effective interventions to address medication and treatment | 4.3 | 4.2 |
| onadherence | (.9) | (.9) |
| 9 Knowledge of the techniques for use of point of care testing (for example, blood | 3.5 | 3.8 |
| lucose, cholesterol, INR) | (1.4) | (1.1) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | 2.6 | 2.8 |
| | (1.4) | (1.3) |
| 1 Knowledge of patient interviewing skills | 4.6 | 4.4 |
| | (.8) | (1.0) |
| 2 Knowledge of motivational interviewing techniques | 4.0 | 3.8 |
| | (1.2) | (1.2) |
| 3 Knowledge of how to assess the patient's readiness and/or willingness to participate in heir own care | 4.2 | 4.0 |
| | (1.1) | (1.1) |
| 4 Knowledge of how to develop effective collaborative partnerships with individual batients in order to maximize trust, encourage patient self-management, and optimize | 4.1 | 3.9 |
| reatment outcomes | (1.2) | (1.2) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 4.2 | 4.1 |

| | Residenc | etion of y Trainin <u>g</u> gram |
|--|----------|--|
| | Yes | No |
| | (1.0) | (1.0) |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | 3.6 | 3.6 |
| | (1.1) | (1.2) |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may mpact the care of the patient | 3.9 | 4.0 |
| | (1.0) | (1.0) |
| 28 Knowledge of how to obtain a medication history | 4.6 | 4.1 |
| | (.9) | (1.1) |
| 89 Knowledge of the principles and process of medication reconciliation | 4.1 | 3.8 |
| | (1.2) | (1.3) |
| 80 Knowledge of how to develop effective collaborative relationships with other nealthcare professionals in order to access health-related patient information essential to | 4.4 | 4.2 |
| he care of the patient | (1.0) | (1.0) |
| 81 Knowledge of how to collaborate with other healthcare professionals to optimize batient care outcomes | 4.6 | 4.4 |
| | (.8) | (.9) |
| 82 Knowledge of how to prioritize patient needs and/or drug-related problems | 4.6 | 4.4 |
| | (.7) | (.8) |
| Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 4.3 | 3.8 |
| | (1.1) | (1.2) |
| Knowledge of how to apply pharmacoeconomic principles when designing a treatment blan | 4.1 | 3.8 |
| | (1.1) | (1.2) |
| Knowledge of how to develop an effective, individualized treatment plan | 4.6 | 3.8 |
| | (.8) | (1.3) |
| Knowledge of how to implement an effective, individualized treatment plan | 4.6 | 3.8 |
| | (.9) | (1.3) |
| 87 Knowledge of patient education principles and techniques (for example, group classes, ndividual patient counseling). | 4.1 | 3.8 |
| | (1.1) | (1.3) |

| | Completion of Residency Training Program | |
|--|--|-------|
| | Yes | No |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | 4.5 | 3.3 |
| | (1.0) | (1.5) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 3.1 | 3.3 |
| | (1.2) | (1.2) |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure | 3.9 | 3.9 |
| monitors) | (1.1) | (1.1) |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | 4.1 | 4.4 |
| | (1.0) | (.9) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | 4.7 | 4.5 |
| | (.7) | (.8) |
| 43 Knowledge of how to effectively communicate with the patient | 4.7 | 4.7 |
| | (.7) | (.7) |
| 44 Knowledge of the principles and practices of wellness and prevention | 4.2 | 4.2 |
| | (1.0) | (1.0) |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | 4.4 | 4.4 |
| | (1.0) | (.8) |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | 3.9 | 4.4 |
| | (1.2) | (1.0) |
| 47 Knowledge of State and Federal regulations regarding protection of patient nformation | 4.4 | 4.6 |
| | (1.0) | (.8) |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | 3.7 | 3.6 |
| | (1.2) | (1.2) |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | 3.2 | 2.9 |
| | (1.2) | (1.3) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 3.4 | 2.9 |

| | Completion of Residency Training Program | |
|---|--|-------|
| | Yes | No |
| handouts) for delivering educational programs | (1.1) | (1.2) |

| | Completion of Residency Trainin Program | |
|--|---|-----|
| | Yes | No |
| 1 Knowledge of anatomy and physiology | (A) | (B) |
| | | |
| 2 Knowledge of pathophysiology | В | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy | В | |
| 4 Knowledge of the clinical assessment process | В | |
| 5 Knowledge of physical assessment techniques | | |
| 6 Knowledge of pharmacology | | |
| 7 Knowledge of pharmacotherapy | | |
| 3 Knowledge of the principles of both focused and integrated disease-state management | В | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy management | | |
| 10 Knowledge of OTC medications | | A |
| 11 Knowledge of the principles of self-care | | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine | | |
| 13 Knowledge of common immunizations | | |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | В | |

| | Residenc | Completion of Residency Training Program | |
|---|------------|--|--|
| | Yes (A) | No (B) | |
| 15 Knowledge of the principles and practice of evidence-based medicine | B | | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | | | |
| 17 Knowledge of factors affecting medication and treatment adherence | | | |
| 18 Knowledge of effective interventions to address medication and treatment nonadherence | | | |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR) | | A | |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | | | |
| 21 Knowledge of patient interviewing skills | В | | |
| 22 Knowledge of motivational interviewing techniques | | | |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care | | | |
| 24 Knowledge of how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | | | |
| 25 Knowledge of barriers to patient education and interventions to overcome them | | | |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | | | |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient | | | |
| 28 Knowledge of how to obtain a medication history | В | | |
| 29 Knowledge of the principles and process of medication reconciliation | В | | |
| Knowledge of how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient Knowledge of how to collaborate with other healthcare professionals to optimize | | | |
| patient care outcomes | | | |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | В | | |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | В | | |

| | Completion of Residency Training Program | |
|--|--|------------------|
| | Yes (A) | <u>No</u> (B) |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment plan | | (0) |
| 35 Knowledge of how to develop an effective, individualized treatment plan | В | |
| 36 Knowledge of how to implement an effective, individualized treatment plan | В | |
| 37 Knowledge of patient education principles and techniques (for example, group classes, individual patient counseling). | В | |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | В | |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | | |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | | А |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | В | |
| 43 Knowledge of how to effectively communicate with the patient | | |
| 44 Knowledge of the principles and practices of wellness and prevention | | |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | | |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | | А |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | | |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | | |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs | В | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | 3.9 | 3.5 |
| | (1.2) | (1.4) |
| 2 Knowledge of effective interdisciplinary communication strategies | 4.4 | 3.8 |
| | (.9) | (1.3) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 3.3 | 2.9 |
| | (1.3) | (1.4) |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | 3.1 | 2.8 |
| care agreement and referral process | (1.3) | (1.3) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy | 2.9 | 2.7 |
| services | (1.3) | (1.3) |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | 3.0 | 2.7 |
| | (1.3) | (1.3) |
| 7 Knowledge of the continuous quality improvement process | 3.4 | 3.4 |
| | (1.2) | (1.3) |
| 8 Knowledge of business principles to effectively manage the practice (for example, | 2.4 | 3.4 |
| nowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | (1.3) | (1.5) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 2.8 | 3.4 |
| | (1.5) | (1.6) |
| 10 Knowledge of tasks involved in managing the implementation of a new service or | 2.8 | 3.0 |
| program | (1.3) | (1.3) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory | 2.5 | 2.6 |
| pharmacy services | (1.3) | (1.3) |
| 12 Knowledge of systems for patient referral and follow up | 3.4 | 3.1 |

| | Residenc | etion of y Trainin <u>g</u> gram |
|---|----------|--|
| | Yes | No |
| | (1.3) | (1.4) |
| 3 Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | 2.4 | 3.2 |
| | (1.3) | (1.4) |
| 4 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | 2.5 | 2.9 |
| | (1.3) | (1.4) |
| 5 Knowledge of work flow efficiencies and process improvement analyses | 2.7 | 3.3 |
| | (1.3) | (1.3) |
| 6 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy | 2.7 | 2.9 |
| Management services, and disease management clinics) | (1.5) | (1.5) |
| 7 Knowledge of formulary management systems (for example, P&T committee function, herapeutic interchange, prior authorization, nonformulary process) | 3.4 | 3.5 |
| nerapeutie interenange, pror autionzation, noniormulary process) | (1.3) | (1.4) |
| 8 Knowledge of cost-effective alternative and therapeutic interchange options | 4.2 | 4.1 |
| | (1.1) | (1.2) |
| 9 Knowledge of State and Federal regulations regarding protection of patient nformation | 4.0 | 4.3 |
| | (1.2) | (1.1) |
| 20 Knowledge of service development process (for example, needs assessment, business blan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | 2.2 | 2.4 |
| | (1.2) | (1.2) |
| 1 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.9 | 3.5 |
| | (1.3) | (1.4) |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 3.0 | 2.9 |
| | (1.3) | (1.3) |
| 23 Knowledge of compensation strategies and funding sources | 2.6 | 2.8 |
| | (1.4) | (1.4) |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for | 3.3 | 3.2 |
| example, IOM report, Beers criteria) | (1.2) | (1.3) |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | 2.9 | 3.2 |
| · · · | (1.2) | (1.3) |

| | Comple Residenc Proc | Training | |
|--|----------------------------|----------|--|
| | Yes | No | |
| | (A) | (B) | |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | В | | |
| 2 Knowledge of effective interdisciplinary communication strategies | В | | |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | В | | |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | В | | |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | | | |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | | | |
| 7 Knowledge of the continuous quality improvement process | | | |
| 8 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | | A | |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | | A | |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | | | |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services | | | |
| 12 Knowledge of systems for patient referral and follow up | В | | |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | | A | |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | | A | |

| | | etion of y Training jram |
|---|------------|--------------------------------|
| | Yes (A) | No (B) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | | A |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | | |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | | |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | | |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | | А |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | | |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | В | |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | | |
| 23 Knowledge of compensation strategies and funding sources | | |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | | |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | | |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| Knowledge of the role of ambulatory care pharmacists in public health | Yes 2.8 | No 3.1 |
|--|---------|-----------|
| Knowledge of the role of ambulatory care pharmacists in public health | 2.8 | 3.1 |
| | | |
| | (1.3) | (1.4) |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | 3.4 | 3.2 |
| | (1.3) | (1.2) |

| | Residenc | etion of y Training gram |
|--|----------|--------------------------------|
| | Yes | No |
| 3 Knowledge of disease prevention strategies | 4.0 | 3.8 |
| | (1.1) | (1.1) |
| 4 Knowledge of disease screening guidelines | 3.8 | 3.5 |
| | (1.2) | (1.2) |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | 3.5 | 3.5 |
| | (1.1) | (1.2) |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | 2.8 | 2.9 |
| | (1.2) | (1.3) |
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information | 3.3 | 3.5 |
| hotlines) | (1.1) | (1.2) |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.1 | 2.3 |
| | (1.1) | (1.2) |
| 9 Knowledge of prevention and treatment of public health threats | 2.2 | 2.5 |
| | (1.1) | (1.3) |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | 2.1 | 2.5 |
| | (1.1) | (1.3) |

| | Completion of Residency Trainir Program | |
|--|---|-----|
| | Yes | No |
| | (A) | (B) |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | | A |
| 2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI) | | |
| 3 Knowledge of disease prevention strategies | В | |

| | Residenc | etion of y Training jram |
|--|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 4 Knowledge of disease screening guidelines | В | |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | | |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | | |
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | | |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | | A |
| 9 Knowledge of prevention and treatment of public health threats | | А |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | | A |

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| 1 Knowledge of principles of evidence-based medicine | 4.5 | 3.9 |
| | (.9) | (1.2) |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | 4.0 | 3.5 |
| | (1.1) | (1.4) |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) | 4.3 | 3.5 |
| references | (.9) | (1.3) |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | 4.0 | 3.4 |
| | (1.0) | (1.3) |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in | 3.4 | 3.1 |
| Ambulatory Care Pharmacy Analysis 48 | ļ | 8/11 |

Medical Informatics and Professional Development

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| ambulatory care practice | (1.2) | (1.4) |
| 6 Knowledge of principles and methods of educating health care students, residents, and professionals | 4.2 | 3.3 |
| | (1.1) | (1.4) |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | 3.7 | 2.9 |
| acsign, population selection, binning, statistical analysis) | (1.0) | (1.4) |
| 3 Knowledge of strengths and limitations of various study methods | 3.7 | 3.0 |
| | (1.0) | (1.3) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical iterature | 3.8 | 3.1 |
| | (.9) | (1.3) |
| 10 Knowledge of appropriate research methodology to design studies to assess a | 3.2 | 2.6 |
| esearch hypothesis | (1.2) | (1.3) |
| 11 Knowledge of granting agencies and their application procedures | 2.1 | 1.9 |
| | (1.0) | (1.1) |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, | 2.4 | 2.3 |
| HIPAA, IRB, OSHA) | (1.0) | (1.4) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 2.5 | 2.2 |
| | (1.1) | (1.3) |
| 14 Knowledge of elements of informed consent | 2.6 | 2.6 |
| | (1.2) | (1.5) |
| 15 Knowledge of survey procedures | 2.1 | 2.1 |
| | (.9) | (1.1) |
| 16 Knowledge of data management | 2.7 | 2.5 |
| | (1.3) | (1.3) |
| 17 Knowledge of data analysis and statistical methods | 2.6 | 2.4 |
| | (1.1) | (1.3) |

| | Completion of Residency Trainin Program | |
|--|---|-------|
| | Yes | No |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | 2.1 | 1.8 |
| | (.9) | (1.0) |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | 2.6 | 2.2 |
| | (1.0) | (1.1) |
| 20 Knowledge of techniques for presentation of research findings | 2.4 | 2.0 |
| | (1.0) | (1.1) |
| 21 Knowledge of the content of an effective research presentation | 2.4 | 2.1 |
| - | (.9) | (1.1) |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | 2.5 | 2.3 |
| Siganization conterences, journals/ | (.9) | (1.1) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | 2.5 | 2.6 |
| | (1.1) | (1.1) |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | 2.9 | 2.7 |
| | (1.0) | (1.2) |
| 25 Knowledge of staff development principles and avenues for providing continuing education | 2.8 | 2.7 |
| | (1.0) | (1.1) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified | 2.8 | 2.5 |
| Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (1.1) | (1.1) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 4.1 | 3.2 |
| | (1.2) | (1.4) |

| | Completion of Residency Trainir Program | |
|--|---|-----|
| | Yes | No |
| 1 Knowledge of principles of evidence-based medicine | (A) B | (B) |
| | | |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | В | |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | В | |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | В | |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | В | |
| 6 Knowledge of principles and methods of educating health care students, residents, and professionals | В | |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | В | |
| 8 Knowledge of strengths and limitations of various study methods | В | |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | В | |
| 10 Knowledge of appropriate research methodology to design studies to assess a research hypothesis | В | |
| 11 Knowledge of granting agencies and their application procedures | | |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | | |
| 13 Knowledge of the ethical principles surrounding research on human subjects | В | |
| 14 Knowledge of elements of informed consent | | |
| 15 Knowledge of survey procedures | | |
| 16 Knowledge of data management | | |
| 17 Knowledge of data analysis and statistical methods | | |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | В | |

| | Residenc | etion of y Training gram |
|---|----------|--------------------------------|
| | Yes | No |
| | (A) | (B) |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | s B | |
| 20 Knowledge of techniques for presentation of research findings | В | |
| 21 Knowledge of the content of an effective research presentation | В | |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | | |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | | |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | | |
| 25 Knowledge of staff development principles and avenues for providing continuing education | | |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | В | |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | В | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Patient Advocacy

| | Completion of Residency Trainin Program | |
|--|---|-------|
| | Yes | No |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | 3.9 | 3.6 |
| | (1.2) | (1.3) |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | 4.2 | 3.9 |
| | (1.1) | (1.3) |
| Knowledge of the structure, guidelines, and process of patient and/or medication ssistance programs | 3.0 | 3.1 |
| F 9, | (1.3) | (1.3) |

| | Completion of Residency Training Program | |
|--|--|-------|
| | Yes | No |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | 3.9 | 3.8 |
| | (1.2) | (1.4) |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | 3.4 | 3.2 |
| | (1.3) | (1.4) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.6 | 3.3 |
| | (1.3) | (1.4) |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | 3.5 | 3.5 |
| | (1.1) | (1.2) |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | 3.4 | 3.2 |
| | (1.3) | (1.4) |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.8 | 3.4 |
| | (1.2) | (1.4) |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | 3.0 | 3.0 |
| | (1.2) | (1.2) |
| 11 Knowledge of conflict management and negotiation skills | 3.5 | 3.4 |
| | (1.2) | (1.3) |

| | Completion of Residency Trainir Program | |
|--|---|-----|
| | Yes | No |
| | (A) | (B) |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | В | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | В | |

Frequency Ratings of Knowledge Statements by Residency or Not

| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting 6 Knowledge of medication reconciliation skills and techniques 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). 8 Knowledge of collaborative relationships necessary to enable case management of | Yes (A) | gram No (B) |
|---|------------|-------------------|
| assistance programs 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting 6 Knowledge of medication reconciliation skills and techniques 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | (A) | (B) |
| assistance programs 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting 6 Knowledge of medication reconciliation skills and techniques 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| plans/ formularies for patients in ambulatory care 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting 6 Knowledge of medication reconciliation skills and techniques 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| and from the ambulatory care setting 6 Knowledge of medication reconciliation skills and techniques 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| patients (for example, disease specific websites, medication assistance programs social services). | В | |
| 9. Knowledge of collaborative relationships percent to enable case management of | | |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | В | |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | В | |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | | |
| 11 Knowledge of conflict management and negotiation skills | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| 1 Knowledge of anatomy and physiology | 3.2 | 3.5 | |
| | (.7) | (.6) | |
| 2 Knowledge of pathophysiology | 3.6 | 3.6 | |
| | (.6) | (.7) | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their | 3.9 | 3.7 | |
| interpretation as they relate to drug therapy | (.3) | (.5) | |
| 4 Knowledge of the clinical assessment process | 3.7 | 3.5 | |
| | (.6) | (.7) | |
| 5 Knowledge of physical assessment techniques | 3.1 | 3.0 | |
| | (.8) | (.8) | |
| 6 Knowledge of pharmacology | 3.8 | 3.8 | |
| | (.5) | (.5) | |
| 7 Knowledge of pharmacotherapy | 4.0 | 3.9 | |
| | (.2) | (.3) | |
| 8 Knowledge of the principles of both focused and integrated disease-state management | 3.8 | 3.6 | |
| | (.5) | (.6) | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy | 3.3 | 3.3 | |
| management | (.8) | (.8) | |
| 10 Knowledge of OTC medications | 3.7 | 3.8 | |
| | (.5) | (.5) | |
| 11 Knowledge of the principles of self-care | 3.6 | 3.6 | |
| | (.6) | (.6) | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments | 3.4 | 3.4 | |
| used in complementary and alternative medicine | (.6) | (.7) | |
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Direct Patient Care

| | Completion of Residency Training Program | |
|---|--|------|
| | Yes | No |
| 13 Knowledge of common immunizations | 3.1 | 3.1 |
| | (.8) | (.8) |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III | 3.8 | 3.4 |
| guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | (.5) | (.8) |
| 15 Knowledge of the principles and practice of evidence-based medicine | 3.8 | 3.4 |
| | (.5) | (.8) |
| 6 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | 3.7 | 3.6 |
| | (.6) | (.7) |
| 7 Knowledge of factors affecting medication and treatment adherence | 3.7 | 3.7 |
| | (.5) | (.5) |
| 8 Knowledge of effective interventions to address medication and treatment nonadherence | 3.7 | 3.6 |
| | (.5) | (.6) |
| • Knowledge of the techniques for use of point of care testing (for example, blood ucose, cholesterol, INR) | 3.3 | 3.4 |
| | (.8) | (.7) |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | 2.7 | 2.8 |
| | (.8) | (.9) |
| 21 Knowledge of patient interviewing skills | 3.9 | 3.7 |
| | (.3) | (.5) |
| 22 Knowledge of motivational interviewing techniques | 3.4 | 3.2 |
| | (.7) | (.8) |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in | 3.5 | 3.4 |
| heir own care | (.7) | (.7) |
| 24 Knowledge of how to develop effective collaborative partnerships with individual | 3.6 | 3.5 |
| patients in order to maximize trust, encourage patient self-management, and optimize reatment outcomes | (.6) | (.7) |
| 25 Knowledge of barriers to patient education and interventions to overcome them | 3.6 | 3.5 |

| | Residenc | etion of y Trainin <u>c</u> gram |
|---|----------|--|
| | Yes | No |
| | (.6) | (.6) |
| 6 Knowledge of cultural diversity and how it may impact the care of the patient | 3.2 | 3.1 |
| | (.7) | (.7) |
| 7 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may | 3.2 | 3.4 |
| mpact the care of the patient | (.7) | (.7) |
| 8 Knowledge of how to obtain a medication history | 3.8 | 3.6 |
| | (.4) | (.7) |
| 9 Knowledge of the principles and process of medication reconciliation | 3.5 | 3.4 |
| | (.7) | (.8) |
| 0 Knowledge of how to develop effective collaborative relationships with other | 3.8 | 3.7 |
| ealthcare professionals in order to access health-related patient information essential to he care of the patient | (.5) | (.6) |
| Knowledge of how to collaborate with other healthcare professionals to optimize | 3.8 | 3.8 |
| batient care outcomes | (.4) | (.5) |
| 2 Knowledge of how to prioritize patient needs and/or drug-related problems | 3.8 | 3.7 |
| | (.4) | (.6) |
| Knowledge of the scope of practice of the ambulatory care pharmacy specialist | 3.5 | 3.3 |
| | (.7) | (.8) |
| 4 Knowledge of how to apply pharmacoeconomic principles when designing a treatment | 3.4 | 3.5 |
| lan | (.7) | (.7) |
| 5 Knowledge of how to develop an effective, individualized treatment plan | 3.8 | 3.6 |
| | (.4) | (.7) |
| 6 Knowledge of how to implement an effective, individualized treatment plan | 3.8 | 3.6 |
| | (.4) | (.7) |
| 7 Knowledge of patient education principles and techniques (for example, group classes, | 3.5 | 3.4 |
| ndividual patient counseling). | (.6) | (.8) |

| | Completion of Residency Training Program | |
|--|--|------|
| | Yes | No |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | 3.6 | 3.2 |
| | (.6) | (.9) |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | 3.0 | 3.2 |
| | (.8) | (.8) |
| 10 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure | 3.5 | 3.5 |
| nonitors) | (.6) | (.7) |
| 1 Knowledge of the process of determining appropriateness of over-the-counter reatments for individualized patients | 3.6 | 3.7 |
| | (.6) | (.6) |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | 3.8 | 3.8 |
| | (.4) | (.5) |
| 13 Knowledge of how to effectively communicate with the patient | 3.9 | 3.9 |
| | (.2) | (.4) |
| Knowledge of the principles and practices of wellness and prevention | 3.6 | 3.6 |
| | (.6) | (.6) |
| 5 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | 3.7 | 3.7 |
| | (.5) | (.6) |
| 16 Knowledge of the proper administration techniques for various drugs and mmunizations (for example, eye drops, inhalers, injections) | 3.6 | 3.7 |
| | (.6) | (.6) |
| 17 Knowledge of State and Federal regulations regarding protection of patient nformation | 3.5 | 3.5 |
| | (.7) | (.7) |
| 8 Knowledge of the steps involved in continuity of care between healthcare settings i.e., transitioning) | 3.2 | 3.2 |
| -, | (.8) | (.9) |
| 9 Knowledge of appropriate writing techniques for composing patient education naterials | 3.2 | 2.9 |
| | (.8) | (.9) |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, | 3.2 | 3.0 |

| | Completion of Residency Training Program | |
|---|--|------|
| | Yes | No |
| handouts) for delivering educational programs | (.7) | (.9) |

| | Completion of Residency Trainin Program | |
|--|---|----------|
| | Yes | No |
| 1 Knowledge of anatomy and physiology | (A) | (B) A |
| | | |
| 2 Knowledge of pathophysiology | | |
| 3 Knowledge of laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy | В | |
| 4 Knowledge of the clinical assessment process | В | |
| 5 Knowledge of physical assessment techniques | | |
| 6 Knowledge of pharmacology | | |
| 7 Knowledge of pharmacotherapy | В | |
| 8 Knowledge of the principles of both focused and integrated disease-state management | В | |
| 9 Knowledge of the principles of and regulations governing collaborative drug therapy management | | |
| 10 Knowledge of OTC medications | | |
| 11 Knowledge of the principles of self-care | | |
| 12 Knowledge of herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine | | |
| 13 Knowledge of common immunizations | | |
| 14 Knowledge of clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines) | В | |

| | Residence | Completion of Residency Training Program | |
|---|------------|--|--|
| | Yes (A) | No (B) | |
| 15 Knowledge of the principles and practice of evidence-based medicine | B | | |
| 16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice | | | |
| 7 Knowledge of factors affecting medication and treatment adherence | | | |
| 8 Knowledge of effective interventions to address medication and treatment nonadherence | | | |
| 19 Knowledge of the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR) | | | |
| 20 Knowledge of the regulatory requirements for the use of point of care testing (for example, OSHA, CLIA) | | | |
| 21 Knowledge of patient interviewing skills | В | | |
| 22 Knowledge of motivational interviewing techniques | | | |
| 23 Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care | | | |
| 24 Knowledge of how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes | | | |
| 25 Knowledge of barriers to patient education and interventions to overcome them | | | |
| 26 Knowledge of cultural diversity and how it may impact the care of the patient | | | |
| 27 Knowledge of humanistic factors (e.g., quality of life, end of life), and how they may mpact the care of the patient | | | |
| 28 Knowledge of how to obtain a medication history | В | | |
| 29 Knowledge of the principles and process of medication reconciliation | | | |
| 30 Knowledge of how to develop effective collaborative relationships with other nealthcare professionals in order to access health-related patient information essential to the care of the patient | | | |
| 31 Knowledge of how to collaborate with other healthcare professionals to optimize batient care outcomes | | | |
| 32 Knowledge of how to prioritize patient needs and/or drug-related problems | В | | |
| 33 Knowledge of the scope of practice of the ambulatory care pharmacy specialist | В | | |

| | Completion of Residency Training Program | | |
|--|--|-----------|--|
| | Yes (A) | No (B) | |
| 34 Knowledge of how to apply pharmacoeconomic principles when designing a treatment plan | (٢) | (b) | |
| 35 Knowledge of how to develop an effective, individualized treatment plan | В | | |
| 36 Knowledge of how to implement an effective, individualized treatment plan | В | | |
| 37 Knowledge of patient education principles and techniques (for example, group classes, individual patient counseling). | | | |
| 38 Knowledge of the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes) | В | | |
| 39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests) | | | |
| 40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors) | | | |
| 41 Knowledge of the process of determining appropriateness of over-the-counter treatments for individualized patients | | | |
| 42 Knowledge of how to effectively communicate treatment recommendations to the appropriate healthcare provider(s) | | | |
| 43 Knowledge of how to effectively communicate with the patient | | | |
| 44 Knowledge of the principles and practices of wellness and prevention | | | |
| 45 Knowledge of lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications | | | |
| 46 Knowledge of the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections) | | | |
| 47 Knowledge of State and Federal regulations regarding protection of patient information | | | |
| 48 Knowledge of the steps involved in continuity of care between healthcare settings (i.e., transitioning) | | | |
| 49 Knowledge of appropriate writing techniques for composing patient education materials | В | | |
| 50 Knowledge of appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs | В | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Ambulatory Care Pharmacy Analysis

Practice Management

| | Completion of Residency Training Program | |
|--|--|-------|
| | Yes | No |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the | 3.4 | 3.3 |
| pharmacist's role in a successful ambulatory care practice | (.7) | (.8) |
| 2 Knowledge of effective interdisciplinary communication strategies | 3.6 | 3.3 |
| | (.7) | (.8) |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | 3.3 | 3.0 |
| | (.7) | (.9) |
| Knowledge of the strategies and resources necessary for establishing a collaborative are agreement and referral process | 3.3 | 3.0 |
| | (.7) | (.9) |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | 3.2 | 2.9 |
| | (.7) | (.9) |
| Knowledge of implementation strategies for ambulatory care pharmacy services | 3.3 | 3.0 |
| | (.7) | (.9) |
| 7 Knowledge of the continuous quality improvement process | 3.3 | 3.2 |
| | (.7) | (.8) |
| 8 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | 2.8 | 3.2 |
| | (.8) | (.8) |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | 3.1 | 3.2 |
| | (.8) | (.9) |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | 3.2 | 3.1 |
| | (.7) | (.8) |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services | 3.0 | 3.0 |
| | (.8) | (.9) |
| 12 Knowledge of systems for patient referral and follow up | 3.2 | 3.1 |
| | (.8) | (1.0) |

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | 2.9 | 3.1 | |
| | (.9) | (.9) | |
| 4 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | 2.8 | 3.0 | |
| | (.8) | (.9) | |
| 5 Knowledge of work flow efficiencies and process improvement analyses | 2.8 | 3.0 | |
| | (.9) | (.8) | |
| 6 Knowledge of how to integrate patient care services within an ambulatory dispensing obarmacy practice (for example, medication adherence programs, Medication Therapy | 3.1 | 3.2 | |
| anagement services, and disease management clinics) | (.8) | (.9) | |
| 17 Knowledge of formulary management systems (for example, P&T committee function, herapeutic interchange, prior authorization, nonformulary process) | 3.1 | 3.2 | |
| is apeal to interest ange, pror authorization, noniormalary process) | (.8) | (.8) | |
| 8 Knowledge of cost-effective alternative and therapeutic interchange options | 3.5 | 3.5 | |
| | (.7) | (.7) | |
| 9 Knowledge of State and Federal regulations regarding protection of patient formation | 3.4 | 3.4 | |
| | (.7) | (.8) | |
| 20 Knowledge of service development process (for example, needs assessment, business blan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | 2.6 | 2.7 | |
| | (.9) | (.9) | |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | 3.3 | 3.2 | |
| | (.7) | (.9) | |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | 3.2 | 3.0 | |
| | (.8) | (.9) | |
| 23 Knowledge of compensation strategies and funding sources | 3.1 | 3.0 | |
| | (.8) | (.9) | |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | 3.3 | 3.2 | |
| | (.7) | (.9) | |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory | 3.2 | 3.3 | |

| | Residenc | etion of y Training gram |
|---------------|----------|--------------------------------|
| | Yes | No |
| care pharmacy | (.7) | (.8) |

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| 1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice | (A) B | (B) |
| 2 Knowledge of effective interdisciplinary communication strategies | В | |
| 3 Knowledge of the regulations surrounding collaborative drug therapy agreements | В | |
| 4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process | В | |
| 5 Knowledge of needs assessment techniques for prospective ambulatory care pharmacy services | В | |
| 6 Knowledge of implementation strategies for ambulatory care pharmacy services | В | |
| 7 Knowledge of the continuous quality improvement process | | |
| 8 Knowledge of business principles to effectively manage the practice (for example, knowledge of accounting, purchasing, resource utilization, work flow, profit analysis) | | A |
| 9 Knowledge of procedures for coding and billing as relevant to pharmacy practice | | |
| 10 Knowledge of tasks involved in managing the implementation of a new service or program | | |
| 11 Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services | | |
| 12 Knowledge of systems for patient referral and follow up | | |
| 13 Knowledge of special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide) | | A |
| 14 Knowledge of regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws) | | |

| | Completion of Residency Training Program | |
|---|--|-----------|
| | Yes (A) | No (B) |
| 15 Knowledge of work flow efficiencies and process improvement analyses | | A |
| 16 Knowledge of how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics) | | |
| 17 Knowledge of formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process) | | |
| 18 Knowledge of cost-effective alternative and therapeutic interchange options | | |
| 19 Knowledge of State and Federal regulations regarding protection of patient information | | |
| 20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [Strengths, Weaknesses, Opportunities, and Threats] analysis) | | |
| 21 Knowledge of scope of practice for ambulatory care pharmacy practice | | |
| 22 Knowledge of process necessary for evaluation, analysis, and justification of services | В | |
| 23 Knowledge of compensation strategies and funding sources | | |
| 24 Knowledge of the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria) | | |
| 25 Knowledge of legislative and regulatory issues that impact the practice of ambulatory care pharmacy | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Public Health

| | | Completion of Residency Training Program | |
|---|---|--|------|
| | | Yes | No |
| 1 Knowledge of the role of ambulatory care pharma | Knowledge of the role of ambulatory care pharmacists in public health | 2.9 | 3.0 |
| | | (.8) | (.9) |
| | 2 Knowledge of resources available through relevant groups, organizations, and agencies for example, ADA, AHA, NIH, CDC, AAAAI) | 3.1 | 3.0 |
| | | (.8) | (.9) |

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| 3 Knowledge of disease prevention strategies | 3.5 | 3.5 | |
| | (.6) | (.7) | |
| 4 Knowledge of disease screening guidelines | 3.4 | 3.3 | |
| | (.7) | (.8) | |
| Knowledge of complementary and alternative medicine treatments for the prevention nd treatment of diseases | 3.1 | 3.1 | |
| | (.7) | (.9) | |
| Knowledge of legislative and regulatory issues that impact the prevention and reatment of diseases | 2.8 | 2.9 | |
| | (.8) | (.9) | |
| Knowledge of information that is accessible to the public regarding the prevention and reatment of diseases (for example, reliable internet websites, toll-free information | 3.1 | 3.1 | |
| reatment of diseases (for example, reliable internet websites, toll-free information otlines) | | (.9) | |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | 2.5 | 2.7 | |
| | (.8) | (.9) | |
| 9 Knowledge of prevention and treatment of public health threats | 2.7 | 2.9 | |
| | (.8) | (.9) | |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | 2.6 | 2.8 | |
| | (.8) | (.8) | |

| | Residence | etion of cy Training gram |
|--|------------|---------------------------------|
| | Yes (A) | No (B) |
| 1 Knowledge of the role of ambulatory care pharmacists in public health | | |
| 2 Knowledge of resources available through relevant groups, organizations, and agence (for example, ADA, AHA, NIH, CDC, AAAAI) | cies | |
| 3 Knowledge of disease prevention strategies | | |

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 4 Knowledge of disease screening guidelines | | |
| 5 Knowledge of complementary and alternative medicine treatments for the prevention and treatment of diseases | | |
| 6 Knowledge of legislative and regulatory issues that impact the prevention and treatment of diseases | | |
| 7 Knowledge of information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines) | | |
| 8 Knowledge of surveillance methods and surveillance resources for public health threats | | |
| 9 Knowledge of prevention and treatment of public health threats | | А |
| 10 Knowledge of processes for delivery and implementation strategies for public health services | | A |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

| | Completion of Residency Training Program | |
|--|--|------|
| | Yes | No |
| 1 Knowledge of principles of evidence-based medicine | 3.7 | 3.4 |
| | (.5) | (.8) |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | 3.5 | 3.3 |
| | (.8) | (.9) |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | 3.6 | 3.2 |
| | (.7) | (.9) |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | 3.6 | 3.2 |
| | (.7) | (.9) |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in | 3.1 | 3.0 |
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Medical Informatics and Professional Development

| | Completion of Residency Training Program | |
|---|--|-------|
| | Yes | No |
| ambulatory care practice | (.8) | (1.0) |
| 6 Knowledge of principles and methods of educating health care students, residents, and | 3.5 | 3.1 |
| professionals | (.7) | (.9) |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | 3.5 | 3.0 |
| acsign, population selection, binning, statistical analysis) | (.7) | (1.0) |
| 3 Knowledge of strengths and limitations of various study methods | 3.4 | 3.0 |
| | (.7) | (.9) |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical iterature | 3.6 | 3.1 |
| | (.6) | (1.0) |
| 10 Knowledge of appropriate research methodology to design studies to assess a research hypothesis | 3.2 | 2.8 |
| | (.8) | (1.0) |
| 1 Knowledge of granting agencies and their application procedures | 2.5 | 2.4 |
| | (.9) | (1.0) |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | 2.7 | 2.6 |
| | (.9) | (1.0) |
| 13 Knowledge of the ethical principles surrounding research on human subjects | 3.0 | 2.7 |
| | (.9) | (1.0) |
| 14 Knowledge of elements of informed consent | 3.0 | 2.8 |
| | (1.0) | (1.0) |
| 15 Knowledge of survey procedures | 2.5 | 2.4 |
| | (.8) | (.8) |
| 6 Knowledge of data management | 2.7 | 2.6 |
| | (.9) | (.9) |
| 17 Knowledge of data analysis and statistical methods | 2.8 | 2.6 |
| | (.9) | (.9) |

| | Completion of Residency Training Program | |
|--|--|-------|
| | Yes | No |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | 2.5 | 2.3 |
| | (.9) | (.9) |
| 19 Knowledge of components of well written research abstracts, reports, and monographs | 2.8 | 2.6 |
| | (.9) | (.9) |
| 20 Knowledge of techniques for presentation of research findings | 2.7 | 2.5 |
| | (.9) | (.9) |
| 21 Knowledge of the content of an effective research presentation | 2.8 | 2.6 |
| | (.9) | (1.0) |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | 2.8 | 2.6 |
| | (.8) | (.9) |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine | 3.2 | 3.1 |
| events and problems observed with drug/vaccine products to appropriate governmental entities | | (.9) |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | 3.0 | 2.9 |
| | (.8) | (.9) |
| 25 Knowledge of staff development principles and avenues for providing continuing education | 2.9 | 2.9 |
| | (.8) | (.9) |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified | 3.0 | 3.0 |
| Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | (.8) | (.9) |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | 3.6 | 3.2 |
| | (.6) | (.9) |

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 1 Knowledge of principles of evidence-based medicine | В | |
| 2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice | В | |
| 3 Knowledge of primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references | В | |
| 4 Knowledge of how to formulate a search strategy to retrieve information from the biomedical literature | В | |
| 5 Knowledge of process for identifying educational needs of healthcare professionals in ambulatory care practice | | |
| 6 Knowledge of principles and methods of educating health care students, residents, and professionals | В | |
| 7 Knowledge of research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis) | В | |
| 8 Knowledge of strengths and limitations of various study methods | В | |
| 9 Knowledge of clinical versus statistical significance in order to interpret medical literature | В | |
| 10 Knowledge of appropriate research methodology to design studies to assess a research hypothesis | В | |
| 11 Knowledge of granting agencies and their application procedures | В | |
| 12 Knowledge of regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA) | | |
| 13 Knowledge of the ethical principles surrounding research on human subjects | В | |
| 14 Knowledge of elements of informed consent | | |
| 15 Knowledge of survey procedures | | |
| 16 Knowledge of data management | | |
| 17 Knowledge of data analysis and statistical methods | В | |
| 18 Knowledge of the uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals | В | |

| | Residenc | Completion of Residency Training Program | |
|---|----------|--|--|
| | Yes | No | |
| | (A) | (B) | |
| 19 Knowledge of components of well written research abstracts, reports, and monograph | is B | | |
| 20 Knowledge of techniques for presentation of research findings | В | | |
| 21 Knowledge of the content of an effective research presentation | В | | |
| 22 Knowledge of venues for presentation and publication (for example, pharmacy organization conferences, journals) | | | |
| 23 Knowledge of the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities | | | |
| 24 Knowledge of the role and benefits of professional organizations for ambulatory care pharmacy practice | | | |
| 25 Knowledge of staff development principles and avenues for providing continuing education | | | |
| 26 Knowledge of certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certi | d | | |
| 27 Knowledge of the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment | В | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Patient Advocacy

| | Completion of Residency Training Program | |
|--|--|------|
| | Yes | No |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | 3.3 | 3.2 |
| | (.7) | (.9) |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | 3.5 | 3.3 |
| | (.6) | (.9) |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | 3.0 | 3.1 |
| | (.8) | (.9) |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug | 3.3 | 3.3 |
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| | Completion of Residency Training Program | |
|--|--|------|
| | Yes | No |
| plans/ formularies for patients in ambulatory care | (.7) | (.9) |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | 3.3 | 3.1 |
| | (.7) | (.9) |
| 6 Knowledge of medication reconciliation skills and techniques | 3.3 | 3.1 |
| | (.7) | (.9) |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | 3.2 | 3.2 |
| | (.7) | (.9) |
| Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | 3.1 | 3.1 |
| | (.8) | (.9) |
| 7 Knowledge of the scope and limitations of ambulatory care pharmacy practice | 3.3 | 3.2 |
| | (.8) | (.9) |
| 0 Knowledge of legislative and regulatory issues that impact patient outcomes | 2.9 | 2.9 |
| | (.8) | (.9) |
| 11 Knowledge of conflict management and negotiation skills | 3.2 | 3.1 |
| | (.8) | (.9) |

| | Completion of Residency Training Program | |
|---|--|-----------|
| | Yes (A) | No (B) |
| 1 Knowledge of assertive and persuasive communication techniques for representing a patient's healthcare needs and interests | | |
| 2 Knowledge of patient-specific factors which may impact access to medications (for example, socioeconomic) | В | |
| 3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs | | |
| 4 Knowledge of the structure, including benefits and limitations, of prescription drug plans/ formularies for patients in ambulatory care | | |

Importance Ratings of Knowledge Statements by Residency or Not

| | Completion of Residency Training Program | |
|--|--|-----|
| | Yes | No |
| | (A) | (B) |
| 5 Knowledge of resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting | В | |
| 6 Knowledge of medication reconciliation skills and techniques | В | |
| 7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services). | | |
| 8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients | | |
| 9 Knowledge of the scope and limitations of ambulatory care pharmacy practice | | |
| 10 Knowledge of legislative and regulatory issues that impact patient outcomes | | |
| 11 Knowledge of conflict management and negotiation skills | | |

Results are based on two-sided tests assuming equal variances with significance level 0.05. For each significant pair, the key of the smaller category appears under the category with larger mean.

a Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Appendix D-3 NABPLEX Blueprint

NAPLEX Blueprint

The NAPLEX Competency Statements

The NAPLEX Competency Statements provide a blueprint of the topics covered on the examination. They offer important information about the knowledge, judgment, and skills you are expected to demonstrate as an entry-level pharmacist. A strong understanding of the Competency Statements will aid in your preparation to take the examination.

Area 1 Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes (Approximately 54% of Test)

- 1.1.0 Obtain, interpret and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management.
 - 1.1.1 Identify and assess patient information including medication, laboratory and disease state histories.
 - 1.1.2 Identify and/or use instruments and techniques related to patient assessment and diagnosis.
 - 1.1.3 Identify and define the terminology, signs, and symptoms associated with diseases and medical conditions.
 - 1.1.4 Identify and evaluate patient factors, genetic factors, biosocial factors, and concurrent drug therapy that are relevant to the maintenance of wellness and the prevention or treatment of a disease or medical condition.

1.2.0 Identify, evaluate, and communicate to the patient or health-care provider, the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems.

- 1.2.1 Identify specific uses and indications for drug products.
- 1.2.2 Identify the known or postulated sites and mechanisms of action of pharmacotherapeutic agents.
- 1.2.3 Evaluate drug therapy for the presence of pharmacotherapeutic duplications and interactions with other drugs, food, diagnostic tests, and monitoring procedures.
- 1.2.4 Identify contraindications, warnings and precautions associated with a drug product's active and inactive ingredients.
- 1.2.5 Identify physicochemical properties of drug substances that affect their solubility, pharmacodynamic and pharmacokinetic properties, pharmacologic actions, and stability.
- 1.2.6 Interpret and apply pharmacodynamic and pharmacokinetic principles to calculate and determine appropriate drug dosing regimens.
- 1.2.7 Interpret and apply biopharmaceutic principles and the pharmaceutical characteristics of drug dosage forms and delivery systems, to assure bioavailability and enhance patient compliance.
- 1.3.0 Manage the drug regimen by monitoring and assessing the patient and/or patient information, collaborating with other health care professionals, and providing patient education.
 - 1.3.1 Identify pharmacotherapeutic outcomes and endpoints.
 - 1.3.2 Evaluate patient signs and symptoms, and the results of monitoring tests and procedures to determine the safety and effectiveness of pharmacotherapy.
 - 1.3.3 Identify, describe the mechanism of, and remedy adverse reactions, allergies, side effects and iatrogenic or drug-induced illness.
 - 1.3.4 Prevent, recognize, and remedy medication non-adherence, misuse or abuse.
 - 1.3.5 Recommend pharmacotherapeutic alternatives.

Area 2 Assure Safe and Accurate Preparation and Dispensing of Medications (Approximately 35% of Test)

- 2.1.0 Perform calculations required to compound, dispense, and administer medication.
 - 2.1.1 Calculate the quantity of medication to be compounded or dispensed; reduce and enlarge formulation quantities and calculate the quantity of ingredients needed to compound the proper amount of the preparation.
 - 2.1.2 Calculate nutritional needs and the caloric content of nutrient sources.
 - 2.1.3 Calculate the rate of drug administration.
 - 2.1.4 Calculate or convert drug concentrations, ratio strengths, and/or extent of ionization.
- 2.2.0 Select and dispense medications in a manner that promotes safe and effective use.
 - 2.2.1 Identify drug products by their generic, brand, and/or common names.
 - 2.2.2 Determine whether a particular drug dosage strength or dosage form is commercially available, and whether it is available on a nonprescription basis.
 - 2.2.3 Identify commercially available drug products by their characteristic physical attributes.
 - 2.2.4 Interpret and apply pharmacokinetic parameters and quality assurance data to determine equivalence among manufactured drug products, and identify products for which documented evidence of inequivalence exists.
 - 2.2.5 Identify and communicate appropriate information regarding packaging, storage, handling, administration, and disposal of medications.
 - 2.2.6 Identify and describe the use of equipment and apparatus required to administer medications.
- 2.3.0 Prepare and compound extemporaneous preparations and sterile products.
 - 2.3.1 Identify and describe techniques and procedures related to drug preparation, compounding, and quality assurance.
 - 2.3.2 Identify and use equipment necessary to prepare and extemporaneously compound medications.
 - 2.3.3 Identify the important physicochemical properties of a preparation's active and inactive ingredients; describe the mechanism of, and the characteristic evidence of incompatibility or degradation; and identify methods for achieving stabilization of the preparation.

Area 3 Provide Health Care Information and Promote Public Health (Approximately 11% of Test)

- 3.1.0 Access, evaluate, and apply information to promote optimal health care.
 - 3.1.1 Identify the typical content and organization of specific sources of drug and health information for both health-care providers and consumers.
 - 3.1.2 Evaluate the suitability, accuracy, and reliability of information from reference sources by explaining and evaluating the adequacy of experimental design and by applying and evaluating statistical tests and parameters.
- 3.2.0 Educate the public and health-care professionals regarding medical conditions, wellness, dietary supplements, and medical devices.
 - 3.2.1 Provide health care information regarding the prevention and treatment of diseases and medical conditions, including emergency patient care.
 - 3.2.2 Provide health care information regarding nutrition, lifestyle, and other non-drug measures that are effective in promoting health or preventing or minimizing the progression of a disease or medical condition.
 - 3.2.3 Provide information regarding the documented uses, adverse effects and toxicities of dietary supplements.
 - 3.2.4 Provide information regarding the selection, use and care of medical/surgical appliances and devices, self-care products, and durable medical equipment, as well as products and techniques for self-monitoring of health status and medical conditions.

Appendix F-1

Educational Outcomes, Goals, and Objectives for PGY2 Ambulatory Care Pharmacy Residency Programs



Educational Outcomes, Goals, and Objectives for Postgraduate Year Two (PGY2) Ambulatory Care Pharmacy Residency Programs

Overview of PGY2 Ambulatory Care Pharmacy Residencies

The PGY2 residency in ambulatory pharmacy is designed to transition PGY1 residency graduates from generalist practice that includes the ambulatory environment to specialized practice specific to the needs of ambulatory patients. PGY2 residency graduates exit with the ability to secure the agreements necessary for the establishment of a collaborative interdisciplinary ambulatory practice. They will have the capability to design and implement the services made possible by these approvals or agreements and to take full responsibility for the ongoing management of and planning for those services, including skills to assess their success via outcomes analyses. This residency's graduates are empowered to treat and appropriately triage the most complex chronic and acute illnesses presented by ambulatory patients, including those with multiple disease states and serious complications. This care is delivered within the context of a long-term health care partnership with the patient that emphasizes health improvement, wellness, and disease prevention.

PGY2 residency graduates are primed for ambulatory practice leadership. This includes the ability to perceive the need for and deliver a wide range of programs that contribute to the public's health, active participation in professional organizations, mentoring skills, and advanced capability to provide insightful education or training for students, pharmacy residents, pharmacy colleagues, nurses, physicians, and medical residents. The leadership skills of these graduates equips them to serve the ambulatory practice as the expert on medication prescribing, including dealing with drug shortages, and managing the prescribing and procurement of special order medications.

Explanation of the Contents of This Document:

The educational outcomes, goals, and objectives below are to be used in conjunction with the PGY2 accreditation standard for second year specialized residencies conducted in a variety of ambulatory pharmacy practice environments, including primary care and family medicine. Users of this document will want to refer to the accompanying glossary to assure a shared understanding of terms.

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Each of the document's objectives has been classified according to educational taxonomy (cognitive, affective, or psychomotor) and level of learning. An explanation of the taxonomies is available elsewhere.¹

The educational outcomes, goals, and objectives are divided into those that are required and those that are elective. The required outcomes, including all of the goals and objectives falling under them, must be included in the design of all programs. The elective outcomes are provided for those programs that wish to add to the required outcomes. Programs selecting an elective outcome are not required to include all of the goals and objectives falling under that outcome. In addition to the potential elective outcomes contained in this document, programs are free to create their own elective outcomes with associated goals and objectives. Each of the goals falling under the program's selection of program outcomes (required and elective) must be evaluated at least once during the resident's year.

Educational Outcomes (*Outcome***):** Educational outcomes are statements of broad categories of the residency graduates' capabilities.

Educational Goals (Goal): Educational goals listed under each educational outcome are broad sweeping statements of abilities.

Educational Objectives (OBJ): Resident achievement of educational goals is determined by assessment of the resident's ability to perform the associated educational objectives below each educational goal.

Instructional Objectives (*IO*): Instructional objectives are the result of a learning analysis of each of the educational objectives. They are offered as a resource for preceptors encountering difficulty in helping residents achieve a particular educational objective. The instructional objectives falling below the educational objectives suggest knowledge and skills required for successful performance of the educational objective that the resident may not possess upon entering the residency year. Instructional objectives are teaching tools only. They are not required in any way nor are they meant to be evaluated.

¹ Nimmo, CM. Developing training materials and programs: creating educational objectives and assessing their attainment. In: Nimmo CM, Guerrero R, Greene SA, Taylor JT, eds. Staff development for pharmacy practice. Bethesda, MD: ASHP; 2000.

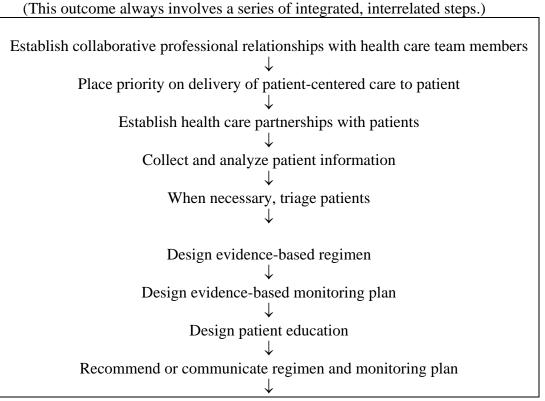
Required Educational Outcomes, Goals, and Objectives for Postgraduate Year Two (PGY2) Ambulatory Care Pharmacy Residencies

Outcome R1: Establish a collaborative interdisciplinary practice.

- Goal R1.1 Participate in the development and implementation of collaborative interdisciplinary practice agreements.
 - OBJ R1.1.1 (Comprehension) Explain the process by which collaborative interdisciplinary practice agreements are developed and implemented.
 - *IO* State the practice area settings in which specialized ambulatory care pharmacists practice.
 - *IO Explain the role of collaborative practice agreements in defining the scope of an individual ambulatory care pharmacy specialist's practice.*
 - *IO Explain the legal environment in which collaborative practice agreements are possible.*
 - *IO* For a given situation, identify the stakeholders in the formation of a collaborative practice agreement.
 - *IO Explain strategies for establishing a collaborative practice agreement.*
 - *IO Explain the collaborative relationships that are necessary to successful fulfillment of the pharmacist's role in a collaborative practice.*
 - OBJ R1.1.2 (Synthesis) Develop a proposal (may be hypothetical) for a collaborative interdisciplinary practice agreement that could be used in a specific area of the ambulatory practice.
 - *IO* State the categories of information provided in a typical proposal to establish a collaborative practice.
- Goal R1.2 Contribute to the development of a new ambulatory pharmacy service or to the enhancement of an existing service.
 - OBJ R1.2.1 (Evaluation) Assess a current ambulatory pharmacy service or program to determine if it meets the stated goals.
 - OBJ R1.2.2 (Synthesis) Participate in the writing of a proposal (may be hypothetical) for a marketable, new or enhanced ambulatory pharmacy service.
 - *IO* Accurately identify unmet customer (i.e., patient, physicians, and other health care providers) needs.
 - *IO Explain the organization's desired format for a proposal for a new or enhanced pharmacy service.*
 - *IO Explain the components of a new service.*
 - *IO Explain the role of other health care providers in meeting the needs of patients involved in a new service.*
 - *IO Explain the process by which pharmacy databases are used to develop a new service.*
 - *IO* Use modeling to predict the financial outcome(s) of implementing a proposed new or enhanced service on meeting unmet customer needs.
 - *IO* Accurately predict system and human resource needs for developing and implementing a new or enhanced service.

- *IO* Accurately predict the outcome(s) for patients of implementing a new or enhanced service.
- *IO* Accurately predict financial benefit to the organization of implementing a new or enhanced service.
- OBJ R1.2.3 (Synthesis) Formulate an effective strategy for promoting a proposal (may be hypothetical) for a new or enhanced ambulatory pharmacy service.
 IO Explain how to identify the stakeholders for a specific proposal.
- OBJ R1.2.4 (Synthesis) Devise effective plans (may be hypothetical) for marketing a new or enhanced service, including the recruitment of patients.
 - *IO Explain the components of a marketing plan.*
 - *Explain why and how potential shifts in market share should be factored into decisions on the marketability of a service.*
- OBJ R1.2.5 (Synthesis) Formulate a plan (may be hypothetical) for full implementation of a new or enhanced ambulatory pharmacy service or program.
 - *IO Explain the components of an implementation plan for implementing a new or an improved service or program.*
- OBJ R1.2.6 (Synthesis) When applicable, manage the implementation of a new or enhanced ambulatory pharmacy service or program.
 - *IO Explain the kinds of tasks involved in managing the implementation of a new service or program.*

Outcome R2: In a collaborative interdisciplinary ambulatory practice provide efficient, effective, evidence-based, patient-centered treatment for chronic and/or acute illnesses in all degrees of complexity.



| | Implement regimen, monitoring plan, and patient education |
|-------------|--|
| | \checkmark |
| | Evaluate patient progress and redesign as necessary |
| | \checkmark |
| | Communicate ongoing patient information |
| | \checkmark |
| | Document direct patient care activity |
| | |
| | stablish collaborative professional relationships with members of the ambulatory |
| | ealth care team. |
| OBJ R2.1 | |
| | collaborative, and communicative working relationships with members of |
| T | interdisciplinary ambulatory health care teams. |
| IC | |
| | <i>"earn" credibility with the health care team.</i> |
| | lace priority on the delivery of patient-centered care to ambulatory patients. |
| OBJ R2.2 | |
| | priority on the delivery of appropriate patient-centered care to each |
| Goal R2.3 E | ambulatory patient. stablish health care partnerships with ambulatory patients. |
| OBJ R2.3 | |
| ODJ K2. | partnership with a particular ambulatory patient. |
| IC | |
| | focus on health promotion, and focus on health care maintenance can |
| | have on the establishment of health care partnerships with ambulatory |
| | patients. |
| IC | • |
| | care partnership with ambulatory patients both in gathering information |
| | and achieving patient adherence to prescribed therapy and/or prevention |
| | and health promotion strategies. |
| IC | |
| | an ambulatory patient must change as the age category of the patient (i.e., |
| | adolescent, adult, geriatric) changes. |
| IC | |
| | the pharmacist and patient in the ambulatory environment. |
| IC | <i>Explain the importance of adjusting one's communications according to</i> |
| | the level of health literacy of the patient. |
| IC | <i>D</i> Explain common situations in the practice of pharmacy which can |
| | produce a difficult communications encounter. |
| IC | 1 00 0 |
| | difficult encounter including the use of active listening. |
| IC | |
| IC | |
| _ | are non-English speakers or who are impaired. |
| IC | 1 7 8 |
| | accommodate the individual's personal characteristics. |
| | |

Goal R2.4 Collect and analyze information specific to an ambulatory patient.

- OBJ R2.4.1 (Application) Exercise proficiency in the application of physical assessment skills commonly employed by ambulatory care pharmacists to secure needed patient-specific information.
 - *IO Identify a core physical assessment reference library.*
 - *IO List the pertinent physical assessments necessary to appropriately evaluate one's practice's typical patient population.*
 - *IO Explain the technique for executing each physical assessment required for one's own practice.*
- OBJ R2.4.2 (Analysis) Collect and organize all patient-specific information needed by the pharmacist to prevent, detect, and resolve medication-related problems and to make appropriate evidence-based, patient-centered medication, non-medication, health improvement, wellness, and/or disease prevention recommendations.
 - *IO* Identify the types of patient-specific information the ambulatory care pharmacist requires to prevent, detect, and resolve medication-related problems and to make appropriate evidence-based, patient-centered medication, non-medication, health improvement, wellness, and/or disease prevention recommendations.
 - *IO* Explain the increased importance in the ambulatory environment of collecting information regarding the patient's culture, emotional needs, preferences, values, caregivers, and life issues in formulating evidence-based, patient-centered care decisions.
 - *IO Explain circumstances in which there is increased importance for the ambulatory care pharmacist to collect pharmacogenomic and/or pharmacogenetic information.*
 - *IO* Explain unique ambulatory care environment issues surrounding confidentiality of patient information and the impact of HIPPA regulations on the collection and safeguarding of patient-specific information.
 - *IO Explain how physical assessment data fits within the subjective and objective database to support the patient therapeutic plan.*
 - *IO Explain prevention, signs and symptoms, epidemiology, risk factors, pathogenesis, natural history, pathophysiology, clinical course, etiology, biopsychosocial factors, socioeconomic factors, and treatment of diseases commonly encountered in the ambulatory environment.*
 - *IO* Explain the mechanism of action, pharmacokinetics, pharmacodynamics, pharmacoeconomics, usual regimen (dose, schedule, form, route, and method of administration), indications, contraindications, interactions, adverse reactions, and therapeutics of medications used in the treatment of diseases commonly encountered in the ambulatory environment.
 - *IO* Where known, explain the mechanism of action, pharmacokinetics, pharmacodynamics, usual regimen, indications, contraindications, interactions, adverse reactions, and therapeutics of nontraditional medications used in the treatment of ambulatory patients.

IO Explain the importance of securing information from the previous health care provider(s) of patients transitioning to the ambulatory environment.

- OBJ R2.4.3 (Analysis) Determine the presence of any of the following medication, non-medication, or adherence problems in a patient's current therapy:
 - 1. Medication used with no medical indication
 - 2. Patient has medical conditions for which there is no medication or nonmedication therapy prescribed
 - 3. Medication or non-medication therapy prescribed inappropriately for a particular medical condition
 - 4. Immunization regimen is incomplete
 - 5. Current medication therapy regimen contains something inappropriate (dose, dosage form, duration, schedule, route of administration, method of administration)
 - 6. There is therapeutic duplication
 - 7. Medication to which the patient is allergic has been prescribed
 - 8. There are adverse drug or device-related events or potential for such events
 - 9. There are clinically significant drug-drug, drug-disease, drug-nutrient, or drug-laboratory test interactions or potential for such interactions
 - 10. Medication or non-medication therapy has been interfered with by social, recreational, nonprescription, or nontraditional drug use by the patient or others
 - 11. Patient not receiving full benefit of prescribed medication or nonmedication therapy
 - 12. There are problems arising from the financial impact of medication or non-medication therapy on the patient
 - 13. Patient lacks understanding of medication or non-medication therapy
 - 14. Patient not adhering to medication or non-medication regimen
 - 15. Patient not adhering to prescribed monitoring plan
 - *IO Explain the increased impact of psychological, cultural, and economic factors on ambulatory patients' adherence to prescribed medication or non-medication therapy.*
 - *IO Explain how the patient's failure to sense importance or urgency of complying with therapy may affect adherence.*
 - *IO Explain varying methods of payment for medication therapy for ambulatory patients and their affect on adherence.*
 - *IO* Explain how the perspective of long-term management influences the prioritization of ambulatory patients' medication and non-medication therapy problems.
 - *IO Explain how the ambulatory care organization's priorities for patient care influence management of patients' medical problems.*
- OBJ R2.4.4 (Analysis) Using an organized collection of patient-specific information, prioritize ambulatory patients' health care needs.
 - *IO Explain how new symptoms or changes in the acuity of chronic disease may affect the prioritization of ambulatory patients' health care needs.*

IO Explain how an ambulatory patient's health beliefs, personal health goals, and socioeconomic status may affect the prioritization of the patient's health care needs.

Goal R2.5 Appropriately triage patients.

- OBJ R2.5.1 (Evaluation) When presented with a patient with health care needs that cannot be met by the ambulatory care pharmacist, make a referral to the appropriate health care provider based on the patient's presenting problem and acuity.
- OBJ R2.5.2 (Evaluation) Assure a plan for follow-up for a referred ambulatory patient.
- Goal R2.6 Design evidence-based medication, non-medication, health improvement, wellness, and/or disease prevention regimens for ambulatory patients presenting with a wide range of disease states or conditions.
 - OBJ R2.6.1 (Synthesis) Specify therapeutic goals, compatible with long-term management of the ambulatory patient, incorporating the principles of evidence-based medicine that integrate patient-specific data, disease and medication-specific information, ethics, quality-of-life, and end-of-life considerations.
 - *IO Explain the role of advance directives in the specification of therapeutic goals.*
 - *IO* Explain the use in the ambulatory environment of evidence-based consensus statements and guidelines in the setting of patient-specific therapeutic goals.
 - *IO Explain the roles of disease prevention, health maintenance, and adherence to prescribed therapy in the specification of therapeutic goals.*
 - *IO Explain the increased influence in the ambulatory environment of culture on patients' perceptions of desirable outcomes.*
 - *IO Explain the realistic limits of treatment outcomes in the ambulatory setting.*
 - *Explain how the ambulatory environment's emphasis on long-term planning and patient continuity affects the setting of therapeutic goals.*
 - *IO Explain unique aspects of the patient's role in the ambulatory environment in determining his/her therapeutic goals.*
 - OBJ R2.6.2 (Synthesis) Design a patient-centered regimen, compatible with long-term management of an ambulatory patient, that meets the evidence-based therapeutic goals established for a patient; integrates patient-specific information, disease and drug information, ethical issues and quality-of-life issues; and considers pharmacoeconomic principles.
 - *IO Explain the role of advance directives in the design of therapeutic goals.*
 - *IO Explain the use in the ambulatory environment of evidence-based consensus statements and guidelines in the design of patient-specific therapeutic regimens.*
 - *IO Explain how culture influences ambulatory patients' perception of disease and how this affects responses to various symptoms, diseases, and treatments.*
 - *IO Explain how patient-specific pharmacogenomics and pharmacogenetics may influence the design of ambulatory patients' medication regimens.*

- *IO Explain how the ambulatory environment's emphasis on long-term planning and patient continuity affects the design of therapeutic regimens.*
- *IO Explain procedures for acquiring medications for patients who lack adequate medical insurance coverage.*
- *IO Explain how to incorporate disease prevention and wellness promotion into ambulatory patients' therapeutic regimens.*
- *IO Explain the contents of the organization's formulary and those drugs available for restricted use.*

Goal R2.7 Design evidence-based monitoring plans for ambulatory patients.

- OBJ R2.7.1 (Synthesis) Design a patient-centered, evidenced-based monitoring plan for an ambulatory patient's medication, non-medication, health improvement, wellness, and/or disease prevention regimen that effectively evaluates achievement of the patient-specific goals.
 - *IO Explain the role of advance directives in the specification of therapeutic goals.*
 - *IO Explain the use in the ambulatory environment of evidence-based consensus statements and guidelines in the design of patient-specific monitoring plans.*
 - *IO Explain cultural and social issues that should be considered when designing a monitoring plan for a ambulatory patient.*
 - *IO Explain the importance of considering what is feasible and useful when designing a monitoring plan for an ambulatory patient.*
 - *IO Explain effective approaches to assuring patient return for follow-up visits in the ambulatory environment.*
 - *IO Explain effective strategies for measuring adherence to prescribed medication and non-medication therapies for the ambulatory patient.*

Goal R2.8 Design education for a specific ambulatory patient's regimen and monitoring plan.

- OBJ R2.8.1 (Analysis) Accurately identify what education will be essential to the patient's or caregiver's understanding of the medication, non-medication, health improvement, wellness, and/or disease prevention regimen and monitoring plan; how to adhere to it; and the importance of adherence.
- OBJ R2.8.2 (Synthesis) Design an effective and efficient plan for meeting the educational needs of a specific ambulatory patient, including information on medication therapy, adverse effects, adherence, appropriate use, handling, and medication administration.
- Goal R2.9 Recommend or communicate regimens and monitoring plans for ambulatory patients.
 - OBJ R2.9.1 (Application) Recommend or communicate a patient-centered, evidencebased medication, non-medication, health improvement, wellness, and/or disease prevention regimen and corresponding monitoring plan to other members of the interdisciplinary team, patients, and/or caregiver in a way that is systematic, logical, accurate, timely, and secures consensus.
- Goal R2.10 Implement medication, non-medication, health improvement, wellness, and/or disease prevention regimens; monitoring plans; and education for ambulatory patients.

- OBJ R2.10.1 (Application) When appropriate, prescribe and administer medications under collaborative practice agreements.
- OBJ R2.10.2 (Complex Overt Response) When appropriate, use skills to administer immunizations.
- OBJ R2.10.3 (Application) When appropriate, order tests according to the ambulatory environment's policies and procedures.
- OBJ R2.10.4 (Application) Use effective patient education techniques to provide and evaluate the effectiveness of the regimen's patient education.
- OBJ R2.10.5 (Application) Use a working knowledge of the organization's referral process to make any necessary patient referrals.
- OBJ R2.10.6 (Application) Make follow-up appointments as specified in the monitoring plan.
- Goal R2.11 Evaluate ambulatory patients' progress and redesign medication, non-medication, health improvement, wellness, and/or disease prevention regimens and monitoring plans.
 - OBJ R2.11.1 (Evaluation) Accurately assess the patient's progress toward the specified goal(s).
 - *IO* Explain the potential for decreased reliability of the monitoring data reported or collected by ambulatory patients or their caregivers when compared to inpatient settings.
 - *IO Explain the importance of the analysis of trends over time in monitoring parameter measurements for ambulatory patients.*
 - OBJ R2.11.2 (Synthesis) If necessary, redesign a patient-centered, evidence-based medication, non-medication, health improvement, wellness, and/or disease prevention regimen as necessary based on evaluation of monitoring data and outcomes.
 - *IO Explain the role of advance directives in the interpretation of success in meeting therapeutic goals.*
- Goal R2.12: Communicate ongoing patient information.
 - OBJ R2.12.1 (Application) When given an ambulatory patient who is transitioning to a different health care setting, communicate pertinent medication, non-medication, health improvement, wellness, and/or disease prevention information to the receiving health care professional(s).
 - OBJ R2.12.2 (Application) Ensure that accurate and timely medication-specific information regarding a specific ambulatory patient reaches those who need it at the appropriate time.
 - *IO* Determine instances in which there is urgency in communicating the results of monitoring to the ambulatory care interdisciplinary team.

Goal R2.13 Document direct patient care activities appropriately.

- OBJ R2.13.1 (Analysis) Appropriately select direct patient-care activities for documentation.
 - *IO Explain the increased need for documenting patient care activities in the medical record in the ambulatory environment.*
- OBJ R2.13.2 (Application) Use effective communication practices when documenting a direct patient-care activity.

- OBJ R2.13.3 (Comprehension) Explain the characteristics of exemplary documentation systems that may be used in the ambulatory environment.
- OBJ R2.13.4 (Application) Record patient outcomes according to the ambulatory organization's policies and procedures.

Outcome R3: Demonstrate leadership and practice management skills.

Goal R3.1 Exhibit essential personal skills of a practice leader.

- OBJ R.3.1.1 (Characterization) Practice self-managed continuing professional development with the goal of improving the quality of one's own performance through self-assessment and personal change.
 - *IO* State the criteria for judging one's performance of tasks that are critical in one's own practice.
- OBJ R3.1.2 (Characterization) Demonstrate commitment to the profession through active participation in local, state, and/or national professional organizations.
- OBJ R3.1.3 (Characterization) Demonstrate a commitment to advocacy for the optimal care of patients through the assertive and persuasive presentation of patient care issues to members of the health care team, the patient, and/or the patient's caregivers.
- OBJ R3.1.4 (Application) Use effective negotiation skills to resolve conflicts.
- OBJ R3.1.5 (Comprehension) Explain the nature of mentoring in pharmacy, its potential connection with achievement, and the importance of willingness to serve as mentor to appropriate individuals.
- OBJ R3.1.6 (Application) Use group participation skills when leading or working as a member of a committee or informal work group.
- Goal R3.2 Manage the operation of an ambulatory care pharmacy service.
 - OBJ R3.2.1 (Synthesis) Participate in the management of the service's manpower needs and scheduling of staff including backup plans for when assigned staff are not available.
 - *IO Explain the components of an effective and efficient plan for the orientation of new ambulatory care staff.*
 - *IO Explain the effect of competition among professions on manpower needs in the ambulatory setting.*
 - *IO Explain the common areas of ongoing training needs of ambulatory care staff.*
 - OBJ R3.2.2 (Synthesis) Assure that the service operates in accord with legal and regulatory requirements.
 - OBJ R3.2.3 (Comprehension) Explain those things to consider when setting up an efficient and effective structure for scheduling patients.
 - OBJ R3.2.4 (Synthesis) Manage the day-to-day space needs required to serve patients appropriately.
 - OBJ R3.2.5 (Application) Maintain coding and billing activities according to the design of the service.
 - OBJ R3.2.6 (Application) Maintain the established system for securing service supplies (e.g., patient education materials, clinic supplies).

- OBJ R3.2.7 (Synthesis) Implement effective plans for the ongoing marketing of the service including the recruitment of patients.
- OBJ R3.2.8 (Synthesis) Identify and implement changes in the service based on changes in standards of practice.
 - *IO* Explain the particular relevance of the existence and use of evidencebased treatment guidelines/protocols in the ambulatory environment.
 - *IO Explain effective strategies for the ambulatory environment for gaining necessary commitment and approval for use of a treatment guideline/protocol.*
- OBJ R3.2.9 (Analysis) Apply the principles of performance improvement to the ongoing functions of the service.
- OBJ R3.2.10 (Synthesis) Exercise skill in the systematic resolution of problems arising in the operation of the service.
 - *IO Explain strategies that can be employed when demand exceeds staffing.*
 - *IO Explain strategies that can be employed when clinic resources are not sufficient.*
 - *IO Explain strategies for managing overbooks.*
 - *IO Explain the potential effectiveness of establishing minimum return to clinic policies.*
 - *IO Explain strategies for managing "no shows" to clinic.*
 - *IO Explain the functions of a group session clinic.*
- OBJ R3.2.11 (Evaluation) Contribute to strategic planning for the service and/or practice.
- Goal R3.3 Conduct a clinical, humanistic or economic outcomes analysis of an ambulatory service.
 - OBJ R3.3.1 (Analysis) Identify a clinical, humanistic, or economic service issue that would be useful to study and can be completed in one year.
 - *IO Explain the principles and methodology of basic pharmacoeconomic analyses.*
 - *IO Explain the purpose of a clinical, humanistic or economic outcomes analysis.*
 - OBJ R3.3.2 (Application) Use a systematic procedure for performing a comprehensive literature search.
 - OBJ R3.3.3 (Analysis) Draw appropriate conclusions based on a summary of a comprehensive literature search.
 - OBJ R3.3.4 (Synthesis) Generate a research question(s) to be answered by the outcomes investigation.
 - OBJ R3.3.5 (Synthesis) Develop specific aims and design study methods that will answer the question(s) identified.
 - *IO Explain the ethics of human research on human subjects and the role of the IRB.*
 - *IO* Explain patient privacy issues as defined by HIPPA.
 - *IO Explain study designs appropriate for a clinical, humanistic and economic outcomes analysis.*
 - *IO Explain the technique and application of modeling.*

- *IO Explain the types of data that must be collected in a clinical, humanistic and economic outcomes analysis.*
- *IO Explain possible reliable sources of data for a clinical, humanistic and economic outcomes analysis.*
- OBJ R3.3.6 (Synthesis) Use a systematic procedure to collect and analyze data. *IO* Explain methods for analyzing data in a clinical, humanistic and economic outcomes analysis.
- OBJ R3.3.7 (Evaluation) Draw valid conclusions through evaluation of the data.
- OBJ R3.3.8 (Synthesis) Use effective communication skills to report orally the study results and recommendations.
- OBJ R3.3.9 (Synthesis) Prepare, using accepted manuscript style, the results of the outcomes study.

Outcome R4: Promote health improvement, wellness, and disease prevention.

Goal R4.1 Design and deliver programs that contribute to public health efforts.

- OBJ R4.1.1 (Comprehension) Explain the pharmacist's role in public health, including specific contributions to public health efforts.
- OBJ R4.1.2 (Synthesis) Design and deliver programs for health care consumers that center on health improvement, wellness, and disease prevention.
 - *IO Explain the prevalent health improvement educational needs of consumers.*
 - *IO Explain the prevalent wellness educational needs of consumers.*
 - *IO Explain the prevalent disease prevention educational needs of consumers.*
- OBJ R4.1.3 (Synthesis) Participate in the development of organizational plans for emergency preparedness.

Outcome R5: Demonstrate excellence in the provision of training or educational activities for health care professionals and health care professionals in training.

- Goal R5.1 Provide effective education or training to health care professionals and health care professionals in training.
 - OBJ R5.1.1 (Comprehension) Explain the differences in effective educational strategies when teaching colleagues versus residents versus students versus health professionals in other disciplines.
 - OBJ R5.1.2 (Application) Use effective educational techniques in the design of all educational activities.
 - IO Design instruction that meets the individual learner's needs.
 IO Explain the concept of learning styles and its influence on the design of instruction
 - *IO* Write appropriately worded educational objectives.
 - *IO* Design instruction to reflect the specified objectives for education or training.
 - *IO* Explain the match between instructional delivery systems (e.g., demonstration, written materials, videotapes) and the specific types of learning each facilitates.
 - *IO* Design instruction that employs strategies, methods, and techniques congruent with the objectives for education or training.

- *IO* Explain effective teaching approaches for the various types of learning (e.g., imparting information, teaching psychomotor skills, inculcation of new attitudes).
- OBJ R5.1.3 (Synthesis) Design an assessment strategy that appropriately measures the specified objectives for education or training and fits the learning situation.
 - *IO Explain appropriate assessment techniques for assessing the learning outcomes of educational or training programs.*
- OBJ R5.1.4 (Application) Use skill in the four preceptor roles employed in practicebased teaching (direct instruction, modeling, coaching, and facilitation).
 - *IO Explain the stages of learning that are associated with each of the preceptor roles.*
- OBJ R5.1.5 (Application) Use skill in case-based teaching.
 - *IO Explain the importance of identifying the key teaching points for a case before attempting to construct it.*
 - *IO Explain factors to consider when deciding the patient data to present in a case.*
- OBJ R5.1.6 (Application) Use public speaking skills to speak effectively in large and small group situations.
 - *IO Explain techniques that can be used to enhance audience interest.*
 - *IO Explain techniques that can be used to enhance audience understanding of one's topic.*
 - *IO* Explain speaker habits that distract the audience.
- OBJ R5.1.7 (Application) Use knowledge of audio-visual aids and handouts to enhance the effectiveness of communications.
 - *IO* Use a systematic and educationally sound method for determining when it is appropriate to use handouts or visual aids and for selecting the appropriate aid.
 - *IO Explain accepted conventions for the design of visual aids and handouts.*
 - *IO Exercise skill in the operation of audio-visual equipment.*

Outcome R6: Serve as an authoritative resource on the optimal use of medications.

- Goal R6.1 Participate in the maintenance of the organization's formulary or prescribing process.
 - OBJ R6.1.1 (Synthesis) When the organization uses a formulary, formulate effective strategies for communicating formulary restrictions and options to providers.
 - *IO Explain conventional routes of communication of formulary information in the ambulatory setting.*
 - *IO Explain the routes of communication within one's own ambulatory setting.*
 - *IO Explain circumstances in which formulary information should be conveyed on a one-to-one basis as opposed to organization-wide.*
 - OBJ R6.1.2 (Synthesis) Make or recommend pharmacoeconomically sound medication choices.
 - *IO* Explain how price differences influence medication choices.

- *IO Explain how insurance coverage structure affects patient access to medication.*
- *IO Explain the importance of considering the patient's economic status in making medication choices.*
- *IO Explain the role of pharmaceutical industry billing structures in making medication choices.*
- *IO Explain situations in which a pharmacoeconomic analysis is warranted.*
- OBJ R6.1.3 (Analysis) When presented with a real or hypothetical drug shortage, identify appropriate alternative medications.
 - *IO* State resources for identifying medications in short supply.
 - *IO* Explain the ambulatory environment's system for communicating information regarding drug shortages.

Goal R6.2 Strategize approaches to the use of special order medications (e.g., non-formulary, patient assistance, high risk, medications through specialty pharmacies).

- OBJ R6.2.1 (Evaluation) When presented with a request for a special order medication, evaluate the appropriateness of the medication for the requested use.
 - *IO Explain how to evaluate a request for a special order medication.*
- OBJ R6.2.2 (Synthesis) When a request for a special order medication is not appropriate, suggest an appropriate formulary alternative.
- OBJ R6.2.3 (Analysis) Identify sources for a requested special order medication.
 - *IO* State common resources for various types of medications that end up special order.
- OBJ R6.2.4 (Synthesis) Facilitate procurement of the requested special order medication.
 - *IO Explain the range of approaches that might be involved in procuring special order medications.*
 - *IO* Assess the need for prescriber education related to the procurement of the special order medication.
- Goal R6.3 Demonstrate ownership of and responsibility for the welfare of the patient by performing all necessary aspects of the medication-use system.
 - OBJ R6.3.1 (Characterization) Display initiative in preventing, identifying, and resolving pharmacy-related patient-care problems.

Goal R6.4 Assure an effective relationship with regard to the pharmaceutical industry

OBJ R6.4.1 (Synthesis) Formulate effective academic detailing strategies that give providers accurate information upon which to base decisions.

- *IO Explain the organization's policy governing the presence of representatives from the pharmaceutical industry.*
- *IO Explain the principles of counter-detailing.*
- OBJ R6.4.2 (Application) If appropriate, manage the use and storage of medication samples.

Elective Educational Outcomes, Goals, and Objectives for Postgraduate Year Two (PGY2) Ambulatory Care Pharmacy Residencies

Outcome E1: Where the ambulatory pharmacy practice is within a setting that allows pharmacist credentialing, successfully apply for credentialing.

- Goal E1.1 Successfully petition for credentialing as an ambulatory care pharmacy practitioner.
 - OBJ E1.1.1 (Application) Follow established procedures to successfully apply (may be a hypothetical application if not permitted at the site) for credentialing as an ambulatory care pharmacy practitioner.
 - *IO* Explain the importance of credentialing and how that influences practice.
 - IO State the practice setting's policy for applying to be credentialed as an ambulatory care pharmacy practitioner.

Outcome E2: Understand the role of the ambulatory care pharmacy leader in the development of public health policy.

- Goal E2.1 Understand the role of ambulatory care pharmacists in the development of public health policy.
 - OBJ E2.1.1 (Comprehension) Explain contributions to the development of public health policy that can be made by ambulatory pharmacists.

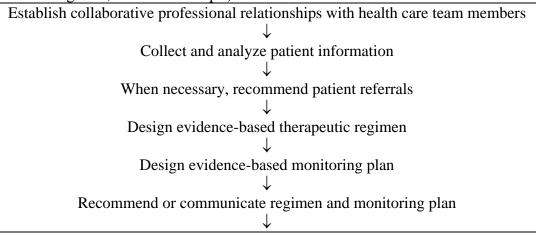
Outcome E3: Participate in the management of medical emergencies.

Goal E3.1 Participate in the management of medical emergencies.

OBJ E3.1.1 (Evaluation) Exercise skill as a team member in the management of medical emergencies according to the organization's policies and procedures.

Outcome E4: Where the practice includes integrated care such as in family medicine, provide efficient, effective, evidence-based, patient-centered treatment for chronic and/or acute illnesses in all degrees of complexity to hospitalized patients.

(When provided as part of the practice of direct patient care, this outcome always involves a series of integrated, interrelated steps.)



When applicable, provide patient education ↓ Evaluate patient progress and recommend redesign as necessary ↓ Transition patient to the ambulatory environment

- Goal E4.1 As appropriate, establish collaborative professional relationships with members of the health care team.
 - OBJ E4.1.1 (Synthesis) Implement a strategy that effectively establishes cooperative, collaborative, and communicative working relationships with members of interdisciplinary health care teams.
 - *Explain the role and responsibilities on the interdisciplinary team of the ambulatory care pharmacist when a patient from the ambulatory care practice is hospitalized and when the ambulatory care pharmacist is acting as a consultant to the health system team caring for the patient.*
- Goal E4.2 Collect and analyze patient information.
 - OBJ E4.2.1 (Analysis) Collect and organize all patient-specific information needed by the ambulatory pharmacist to prevent, detect, and resolve medication-related problems and to make appropriate evidence-based, patient-centered medication therapy recommendations as part of the interdisciplinary team.
 - OBJ E4.2.2 (Analysis) Determine the presence of any of the following medication therapy problems in a patient's current medication therapy:
 - 1. Medication used with no medical indication
 - 2. Patient has medical conditions for which there is no medication prescribed
 - 3. Medication prescribed inappropriately for a particular medical condition
 - 4. Immunization regimen is incomplete
 - 5. Current medication therapy regimen contains something inappropriate (dose, dosage form, duration, schedule, route of administration, method of administration)
 - 6. There is therapeutic duplication
 - 7. Medication to which the patient is allergic has been prescribed
 - 8. There are adverse drug or device-related events or potential for such events
 - 9. There are clinically significant drug-drug, drug-disease, drug-nutrient, or drug-laboratory test interactions or potential for such interactions
 - 10. Medical therapy has been interfered with by social, recreational, nonprescription, or nontraditional drug use by the patient or others
 - 11. Patient not receiving full benefit of prescribed medication therapy
 - 12. There are problems arising from the financial impact of medication therapy on the patient
 - 13. Patient lacks understanding of medication therapy
 - 14. Patient not adhering to medication regimen
 - OBJ E4.2.3 (Analysis) Using an organized collection of patient-specific information, summarize patients' health care needs.
- Goal E4.3 When necessary, recommend patient referrals.

- OBJ E4.3.1 (Evaluation) When presented with a patient with health care needs that cannot be met by the pharmacist, recommend to the interdisciplinary team that a referral be made to the appropriate health care provider based on the patient's acuity and the presenting problem.
- Goal E4.4 Design evidence-based therapeutic regimens.
 - OBJ E4.4.1 (Synthesis) Specify therapeutic goals for a patient incorporating the principles of evidence-based medicine that integrate patient-specific data, disease and medication-specific information, ethics, and quality-of-life considerations.
 - OBJ E4.4.2 (Synthesis) Design a patient-centered regimen that meets the evidencebased therapeutic goals established for a patient; integrates patient-specific information, disease and drug information, ethical issues and quality-of-life issues; and considers pharmacoeconomic principles.
- Goal E4.5 Design evidence-based monitoring plans.
 - OBJ E4.5.1 (Synthesis) Design a patient-centered, evidenced-based monitoring plan for a therapeutic regimen that effectively evaluates achievement of the patientspecific goals.
- Goal E4.6 Recommend or communicate regimens and monitoring plans.
 - OBJ E4.6.1 (Application) Recommend or communicate a patient-centered, evidencebased therapeutic regimen and corresponding monitoring plan to other members of the interdisciplinary team and/or patients in a way that is systematic, logical, accurate, timely, and secures consensus from the team and patient.
- Goal E4.7 When applicable, provide patient education.
 - OBJ E4.7.1 (Application) When applicable, use effective patient education techniques to provide counseling to patients and caregivers, including information on medication therapy, adverse effects, compliance, appropriate use, handling, and medication administration.
- Goal E4.8 Evaluate patients' progress and recommend redesign of regimens and monitoring plans.
 - OBJ E4.8.1 (Evaluation) Accurately assess the patient's progress toward the therapeutic goal(s).
 - OBJ E4.8.2 (Synthesis) Recommend redesign of a patient-centered, evidence-based therapeutic plan as necessary based on evaluation of monitoring data and therapeutic outcomes.
- Goal E4.9 Transition hospitalized patients to the ambulatory environment.
 - OBJ E4.9.1 (Synthesis) Design a plan for patient pharmacotherapeutic follow-up post hospitalization.
 - *IO Explain the categories of information that should be in a complete pharmacotherapeutic follow-up plan post discharge.*
 - *IO Explain issues, including ability to pay, that may arise regarding access to medications that may occur as the patient transitions from the hospital to the ambulatory environment.*
 - *IO Explain the importance of updating the outpatient medication record post hospitalization.*
 - OBJ E4.9.2 (Synthesis) Communicate or recommend to the patient, health-system interdisciplinary team, ambulatory health care team, and /or the patient's caregiver the plan for pharmacotherapeutic follow-up.

Outcome E5: Demonstrate skills required to function in an academic setting.

Goal E5.1 Understand faculty roles and responsibilities.

- OBJ E5.1.1 (Comprehension) Explain variations in the expectations of different colleges/schools of pharmacy for teaching, practice, research, and service.
 - *IO* Discuss how the different missions of public versus private colleges/schools of pharmacy can impact the role of faculty members.
 - *IO* Discuss maintaining a balance between teaching, practice, research and service.
 - *IO* Discuss the relationships between scholarly activity and teaching, practice, research and service.
 - OBJ E5.1.2 (Analysis) Explain the role and influence of faculty in the academic environment.
 - *IO Explain the responsibilities of faculty in governance structure (e.g. the faculty senate, committee service).*
 - IO Describe the responsibilities of faculty (e.g. curriculum development and committee service) related to teaching, practice, research, and service roles.
- OBJ E5.1.3 (Comprehension) Describe the academic environment.
 - *IO* Describe how the decisions by university and college administration impact the faculty.
 - *IO* Discuss outside forces (e.g. change in the profession, funding source, accreditation requirements) that impact administrator and faculty roles.
- OBJ E5.1.4(Comprehension) Describe the types and ranks of faculty appointments.IOExplain the various types of appointments (e.g. non-tenure, tenure-track,
 - and tenured faculty).IO Differentiate among the various ranks of faculty (e.g. instructor, assistant)
 - professor, associate professor, full professor).
 - *IO* Discuss the role and implications of part-time and adjunct faculty as schools continue to expand and faculty shortages occur.
- OBJ E5.1.5 (Comprehension) Discuss the promotion and/or tenure process for each type of appointment.
 - *IO Identify the types of activities that are considered in the promotion process.*
 - *IO Identify the types of activities that are considered for tenure.*
- OBJ E5.1.6 (Application) Identify resources available to help develop academic skills.
 - *IO Explain the role of academic-related professional organizations (e.g. AACP) in faculty professional development.*
 - *IO Identify resources to help develop teaching skills and a teaching philosophy.*
- OBJ E5.1.7 (Comprehension) Explain the characteristics of a typical affiliation agreement between a college of pharmacy and a practice site (e.g., health system, hospital, clinic, retail pharmacy).
 - *IO Explain how the political environments of either a college or a practice site may affect the other.*

Goal E5.2 Exercise teaching skills essential to pharmacy faculty.

- OBJ E5.2.1 (Synthesis) Develop an instructional design for a class session, module, or course.
 - *IO Construct a student-centered syllabus.*
 - *IO* Construct educational objectives for a class session, module, or course that is appropriate to the audience.
 - *IO Identify appropriate instructional strategies for the class session, module, or course to achieve the objectives.*
 - *IO Consider assessment tools that measure student achievement of the educational objectives.*
- OBJ E5.2.2 (Synthesis) Prepare and deliver didactic instruction on a topic relevant to the specialized area of pharmacy residency training.
 - *IO Identify educational technology that could be used for a class session, module, or course (e.g., streaming media, course management software, audience response systems).*
 - *IO Create instructional materials appropriate for the topic and audience.*
 - *IO Identify strategies to deal with difficult learners.*
 - *IO* Given feedback from teaching evaluations (e.g. student and or peer), devise a plan to incorporate improvements in future instruction.
- OBJ E5.2.3 (Application) Develop and deliver cases for workshops and/or exercises for laboratory experiences.
 - *IO Identify the appropriate level of case-based teachings for small group instruction.*
 - *IO Identify appropriate exercises for laboratory experiences.*
 - *IO Provide appropriate and timely feedback to improve performance.*
- OBJ E5.2.4 (Application) Serve as a preceptor or co-preceptor utilizing the four roles employed in practice-based teaching (direct instruction, modeling, coaching and facilitation).
 - *IO* Assess the learner's skill level to determine the appropriate preceptor strategy for providing practice-based teaching.
 - *IO Given performance-based criteria, identify ways to provide constructive feedback to learners.*
 - *IO* Develop strategies to promote professional behavior.
 - *IO Identify strategies to deal with difficult learners in the practice setting.*
 - *IO Given a diverse learner population, identify strategies to interact with all groups with equity and respect.*

OBJ E5.2.5 (Analysis) Develop a teaching experience for a practice setting (e.g., introductory or advanced pharmacy experience).

- *IO Create educational goals and objectives to be achieved.*
- *IO* Develop activities that will allow achievement of identified educational goals and objectives.
- *IO Identify how and when feedback should be provided.*
- *IO Identify other preceptors for the experience, if appropriate.*
- *IO* Determine training that might be needed for the preceptors to deliver student education.

- *IO Identify potential challenges of precepting and providing patient care services simultaneously.*
- OBJ E5.2.6 (Synthesis) Design an assessment strategy that appropriately measures the specified educational objectives for the class session, module, course, or rotation.
 - *IO* Identify appropriate techniques for assessing learning outcomes in various educational settings [e.g., written examinations, oral examinations, practical examinations, Objective Structured Clinical Examination (OSCE)].
 - *IO* Develop examination questions to assess the knowledge, skills, attitudes and behaviors that are appropriate to the learner's level and topic.
 - *IO* Discuss the various methods for administering examination questions (e.g., computerized testing, paper testing).
- OBJ E5.2.7 (Evaluation) Create a teaching portfolio.
 - *IO* Define the concept of a teaching portfolio and describe its primary purpose
 - *IO Outline the steps in building a teaching portfolio.*
 - *IO* Develop a personal teaching philosophy to guide one's teaching efforts and facilitate student learning.
- OBJ E5.2.8 (Evaluation) Compare and contrast methods to prevent and respond to academic and profession dishonesty.
 - *IO* Evaluate physical and attitudinal methods to prevent academic dishonesty.
 - *IO* Discuss methods of responding to incidents of academic dishonesty.
 - *IO* Discuss the role of academic honor committees in cases of academic dishonesty.
 - *IO Identify examples and methods to address unprofessional behavior in learners.*
- OBJ E5.2.9 (Comprehension) Explain the relevance of copyright laws to developing teaching materials.
 - *IO* Discuss copyright regulations as related to reproducing materials for teaching purposes.
 - *IO* Discuss copyright regulations as related to linking and citing on-line materials.

Approved by the Commission on Credentialing of the American Society of Health-System Pharmacists on August 21, 2006. Endorsed by the ASHP Board of Directors on September 22, 2006. Developed by an ASHP working group of the following specialized pharmacy practitioners and ASHP staff: Jeffrey M. Brewer, Pharm.D., Director, Primary Care Pharmacy Practice Residency Program, The Johns Hopkins Hospital; Douglas F. Covey, Pharm.D., M.H.A., Director, Primary Care Pharmacy Practice Residency Program. James A. Haley Veterans Affairs Medical Center; Laura B. Hansen, Pharm.D., FCCP, BCPS, Assistant Professor, Clinical Pharmacy and Family Medicine, University of Colorado at Denver Health Sciences Center; Kelly R. Ragucci, Pharm.D., FCCP, BCPS, CDE, Director, Primary Care Pharmacy Practice Residency Program, Medical University of South Carolina; Joseph Saseen, Pharm.D., FCCP, BCPS, Associate Professor, Departments of Clinical Pharmacy and Family Medicine, University of Colorado at Denver Health Sciences Center; Arthur A. Schuna, M.S., FASHP, Director, Primary Care Pharmacy Practice Residency Program, William S. Middleton Memorial Veterans Affairs Hospital; Bruce A. Nelson, R.Ph., M.S., Director, Operations, Accreditation Services Division, ASHP; and Christine M. Nimmo, Ph.D., Manager, Standards Development and Training, Accreditation Services Division, ASHP. This document replaces a set of goals and objectives approved by the ASHP Board of Directors April 22, 1998 for use in primary care pharmacy residencies. The contribution of reviewers is gratefully acknowledged. These included directors of ASHP-accredited primary care pharmacy practice residencies and primary care pharmacy practitioners recommended by the working group's specialized pharmacy practitioners.

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The effective date for implementation of these educational outcomes, goals and objectives is commencing with the entering resident class of 2007.

Glossary

Adherence – the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider. (Sabadé E.,ed. Adherence to long-term therapies: evidence for action. World Health Organization, Geneva, Switzerland. 2003. ISBN 92 4 154599 2.

Ambulatory practice – the services of the pharmacist are provided to patients who are not hospitalized. Ambulatory practice may take place in a variety of settings that include:

- Acute care hospitals
- Health system-based or freestanding clinics
- Physician offices
- Independent pharmacist practices
- Critical care centers
- Home care practices
- Community health centers
- Hospices
- Long-term care facilities

Collaborative practice agreements – In collaborative drug therapy management, pharmacists enter agreements with physicians and other prescribers that may authorize pharmacists, for patients who have a confirmed diagnosis, to select appropriate medication therapies and regimens and adjust them on the basis of patients' responses. (American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in primary care. *Am J Health-Syst Pharm.* 1999; 56:1665-7.)

Culture -- an integrated system of learned behavior patterns that are characteristic of the members of any particular group. It is more than race or ethnicity. Culture includes race or customs, rituals, food, religion, and music; and, in addition, it includes health beliefs and practices, death and birth rituals, structure, and dynamics, social practices and beliefs that define personal space, eye contact, time orientation, and nonverbal communication behaviors. (Randall-David E. Culturally competent HIV counseling and education. Material & Child Health Clearinghouse: McLean, VA: 1994)

Evidence-based medicine -- the integration of best research evidence, clinical expertise, and patient values in making decisions about the care of individual patients (Institute of medicine, 2001; Straus and Sackett, 1998). *Best research evidence* includes evidence that can be quantified, such as that from randomized controlled trials, laboratory experiments, clinical trials, epidemiological research, and outcomes research and evidence derived from the practice knowledge of experts, including inductive reasoning (Guyatt et al., Higgs et al., 2001). *Clinical expertise* is derived from the knowledge and experience developed over time from practice, including inductive reasoning. *Patient values and circumstances* are the unique preferences, concerns, expectations, financial resources, and social supports that are brought by each patient to a clinical encounter. (Institute of Medicine. Health professions education: a bridge to quality. Washington, DC: The National Acadamies Press; 2001.)

Interdisciplinary team -- a team composed of members from different professions and occupations with varied and specialized knowledge, skills, and methods. The team members integrate their observations, bodies of expertise, and spheres of decision making to coordinate, collaborate, and communicate with one another in order to optimize care for a patient or group of patients. (Institute of Medicine. Health professions education: a bridge to quality. Washington, DC: The National Acadamies Press; 2001.)

Leadership -- leadership practices include scanning, focusing, aligning/mobilizing, and inspiring. Scanning:

- \checkmark Identify client and stakeholder needs and priorities.
- \checkmark Recognize trends, opportunities, and risks.
- ✓ Look for best practices.
- ✓ Identify staff capacities and constraints.
- ✓ Know yourself, your staff, and your organization values, strengths, and weaknesses.

Focusing:

- \checkmark Articulate the organizations' mission and strategy.
- ✓ Identify critical challenges.
- \checkmark Link goals with the overall organizational strategy.
- \checkmark Determine key priorities for action
- ✓ Create a common picture of desired results.

Aligning/Mobilizing:

- ✓ Ensure congruence of values, mission, strategy, structure, systems and daily actions.
- \checkmark Facilitate teamwork.
- ✓ Unite key stakeholders around an inspiring vision.
- ✓ Link goals with rewards and recognition.
- ✓ Enlist stakeholders to commit resources.

Inspiring:

- \checkmark Match deeds to words.
- ✓ Demonstrate honest in interactions.
- ✓ Show trust and confidence in staff, acknowledge the contributions of others.
- ✓ Provide staff with challenges, feedback and support.
- \checkmark Be a model of creativity, innovation, and learning

(Management and Leadership Program. Leading and managing framework. Management Sciences for Health, Ballston, VA. 2004.)

Management -- management practices include planning, organizing, implementing, and monitoring and evaluating.

Planning:

- ✓ Set short-term organizational goals and performance objectives.
- ✓ Develop multi-year and annual plans
- ✓ Allocate adequate resources (money, people, and materials).
- ✓ Anticipate and reduce risks.

Organizing:

- ✓ Ensure a structure that provides accountability and delineates authority.
- ✓ Ensure that systems for human resource management, finance, logistics, quality assurance, operations, information, and marketing effectively support the plan.
- \checkmark Strengthen work processes to implement the plan.

 \checkmark Align staff capacities with planned activities.

Implementing:

- \checkmark Integrate systems and coordinate work flow.
- ✓ Balance competing demands.
- ✓ Routinely use data for decision making.
- \checkmark Coordinate activities with programs and sectors.
- ✓ Adjust plans and resources as circumstances change.

Monitoring and Evaluating:

- ✓ Monitor and reflect on progress against plans.
- ✓ Provide feedback.
- \checkmark Identify needed changes
- ✓ Improve work processes, procedures, and tools.

(Management and Leadership Program. Leading and managing framework. Management Sciences for Health, Ballston, VA. 2004.)

Medication-use system - Medication use is a complex process that comprises the sub-processes of medication prescribing, order processing, dispensing, administration, and effects monitoring. The key elements that most often affect the medication use process...are...., patient information; drug information, communication of drug information; drug labeling, packaging and nomenclature; drug storage, stock and standardization; drug device acquisition, use and monitoring; environmental factors; competency and staff education; patient education; and quality processes and risk management. (Institute of Safe Medication Practices web site accessed May 31, 2005 http://www.ismp.org/Pages/ismp_faq.html#Question%207.)

Patient-centered care -- identify, respect, and care about patients' differences, values, preferences, and expressed needs; relieve pain and suffering; coordinate continuous care; listen to, clearly inform, communicate with, and educate patients; share decision making and management; and continuously advocate disease prevention, wellness, and promotion of healthy lifestyles, including a focus on population health. (Institute of Medicine. Health professions education: a bridge to quality. Washington, DC: The National Acadamies Press; 2001.)

Pharmacy practice research – includes all forms of scholarly scientific inquiry that may be performed by pharmacy residents. Broad in scope, it may include prospective or retrospective clinical studies, pharmacokinetic or pharmacodynamic studies, outcome studies, or evaluation of some aspect of pharmacy practice (e.g., impact of a new program or service). Typically, research projects should be applied in nature, using human data, but exceptions may occur.

Professional -- the active demonstration of the 10 traits of a professional.

- 1. Knowledge and skills of a profession.
- 2. Commitment to self-improvement of skills and knowledge.
- 3. Service orientation.
- 4. Pride in the profession.

- 5. Covenantal relationship with the client.
- 6. Creativity and innovation.
- 7. Conscience and trustworthiness.
- 8. Accountability for his/her work.
- 9. Ethically sound decision making.
- 10. Leadership.

(Ten marks of a professional working smart. New York, NY: National Institute of Business Management, March 11, 1991;17[5].).

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Appendix G-2

Copies of Select Peer Reviewed Articles in Ambulatory Care Pharmacy Practice Care Pharmacy

Appendix G-2. Copies of Select Peer Reviewed Articles in Ambulatory Care Pharmacy Practice

Knapp D. Professionally determined need for pharmacy services in 2020. *Am J Pharm Educ* Winter 2002;66:421-429.

Nkansah NT, Brewer JM, Connors R, Shermock KM. Clinical outcomes of patients with diabetes mellitus receiving medication management by pharmacists in an urban private physician practice. Am J Health Syst Pharm. 2008 Jan 15;65(2):145-9.

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Clinical outcomes of patients with diabetes mellitus receiving medication management by pharmacists in an urban private physician practice

NANCY T. NKANSAH, JEFFREY M. BREWER, ROBERT CONNORS, AND KENNETH M. SHERMOCK

oday's primary care providers are increasingly inundated with administrative and clinical responsibilities that place great demand on their schedules, leaving them less time to devote to direct patient care. A study of young physicians practicing in California found that the percentage of physicians who felt that they were able to spend sufficient time with their patients fell from 80% in 1991 to 56% in 1996.¹ Advances in medical care, changing disease patterns, greater demand for clinical accountability, and evolving professional norms, among other factors, have created heightened expectations for performance in primary care practice.² With the 25% increase in medication use over the past decade, primary care providers are spending more time perusing the growing body of literature on medication efficacy and maintaining pa-

Purpose. The clinical outcomes of patients with diabetes mellitus in an urban environment receiving pharmacist medication management in collaboration with private-practice physicians were assessed.

Methods. Patients older than 18 years with type 1 or 2 diabetes mellitus who were receiving oral and insulin therapy and who were referred to a pharmacy clinic within a private physician practice for medication management between March 1, 2002, and August 31, 2003, were eligible for study inclusion. Data were collected at three junctures: six months before the first visit with the pharmacist (preperiod measure), on the date of clinic entry (index measure), and six months after the first clinic visit (postperiod measure). Primary outcomes analyzed were glycosylated hemoglobin (HbA1,), weight, and blood pressure (goal, <130/80 mm Hg). Secondary outcomes analyzed were smoking cessation and initiation of aspirin, angiotensin-converting-enzyme

inhibitor, or angiotensin receptor blocker therapy.

Results. A significant reduction in HbA_{1c} from the index measure to the postperiod measure was observed (p < 0.001). No significant change was noted in weight or number of patients at goal blood pressure among the preperiod, index, and postperiod measures. No change was observed in the secondary outcomes during the study time intervals.

Conclusion. Integrating a pharmacist into a private physician practice significantly improved patient glycemic control and maintained patients' weight and the number of patients at blood pressure goal. Clinic adherence with the American Diabetes Association recommendations was sustained.

Index terms: Ambulatory care; American Diabetes Association; Clinical pharmacists; Diabetes mellitus; Outcomes; Pharmaceutical services; Primary care; Protocols; Team Am J Health-Syst Pharm. 2008; 65:145-9

The contribution of the Johns Hopkins Community Physicians at Wyman Park providers and Medical Record Department for their assistance in conducting this study is acknowledged. Leena Choi, Ph.D., is acknowledged for her expertise in biostatistics. The Johns Hopkins Department of Pharmacy Primary Care team is acknowledged for providing clinical services at this site.

Presented at the ASHP Summer Meeting, Las Vegas, NV, June 21, 2004; at the American College of Clinical Pharmacy Annual Meeting, Dallas, TX, October 2004; and at the 28th Annual Meeting of the Society of General Internal Medicine, New Orleans, LA, May 2005.

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tients' medication profiles.³ In a typical 18-minute office visit, primary care providers are expected to relieve symptoms, cure disease, diagnose potentially serious conditions, and provide chronic illness management and preventive care.^{4,5}

The American Diabetes Association (ADA)⁶ and the American Association of Clinical Endocrinologists7 have published evidence-based recommendations on the standard of care for patients with diabetes mellitus. A study using the National Health and Nutrition Examination Survey's 1999-2000 data found deficiencies in diabetes care.8 Of the patients included in the study, 37% achieved a glycosylated hemoglobin (HbA_{1c}) concentration of <7%, 36% had a blood pressure of <130/80 mm Hg, 48% had a total cholesterol level of <200 mg/dL, and only 7.3% achieved all three treatment goals. The benefits of maintaining optimal glycemic, blood pressure, and lipidemic control are well documented.6 Providing diabetes self-management education and preventive care and reinforcing lifestyle modifications help patients optimize metabolic control, prevent and manage complications, and maximize their quality of life.

The 2003 Institute of Medicine (IOM) report on racial and ethnic health disparities stated that African Americans and Hispanics with diabetes receive lower quality of health care than do other ethnicities.9 As type 2 diabetes mellitus predominates in these ethnic groups, innovative public health initiatives have been instituted to eliminate such health disparities. Studies demonstrating the effectiveness of collaborative pharmacist-physician diabetes models have been conducted primarily in patient populations with few minorities and rarely in the privatepractice setting.

As the medical community looks for ways to improve the delivery of long-term care, pharmacists are collaborating successfully with other health care practitioners to improve the outcomes of patients with diabetes.10-14 Studies conducted in community pharmacies, managed care settings, and Veterans Affairs (VA) medical centers have found reduced HbA_{1c} values overall and an increase in the number of pharmacist-assisted patients suffering from diabetes with an optimal HbA₁. Pharmacists can augment diabetes care by providing medication management from drug therapy initiation to, if necessary, medication modification or education. The manner in which this collaboration is structured depends significantly on the state laws and regulations under which the pharmacist practices.

Before this study, clinical outcomes associated with this pharmacy collaborative model had rarely been evaluated in a private physician practice serving a predominately African-American population. The purpose of this study was to evaluate whether pharmacists working in collaboration with primary care providers in an urban, private physician practice could help improve clinical outcomes in patients with type 1 or 2 diabetes.

Methods

A retrospective, time-series, single-group design was chosen for this study. All patients over 18 years of age who had a documented diagnosis of type 1 or 2 diabetes mellitus for at least six months and were referred to the pharmacy clinic for medication management between March 1, 2002, and August 31, 2003, were eligible for study inclusion. Patients receiving oral or insulin therapy (or both) for diabetes were included in this study. Women who were pregnant or became pregnant during the study period were excluded. Institutional review board approval was obtained through the Johns Hopkins Hospital before study initiation.

Clinic format and intervention. New patients were scheduled for 45-minute time slots with the pharmacist; follow-up visits lasted 30 minutes. Follow-up visits were scheduled with the pharmacist as needed for medication management; patients generally alternated between the pharmacist and the primary care provider depending on patient needs.

The pharmacy clinic, located within the physician's practice, allowed pharmacists and other primary care providers to interact daily. The clinic scheduled patient visits on Tuesdays and Thursdays, half day each, and Wednesdays for a full day. The daily number of patient visits scheduled ranged from five to seven, depending on the number of new patient visits. Clinic hours were occasionally extended for walk-ins or same-day consultations with primary care providers.

The pharmacy clinic was managed by two pharmacists, both of whom had a doctor of pharmacy degree and two years of pharmacy residency training. One was a board-certified pharmacotherapy specialist. They each evaluated patients, oversaw the operation of the pharmacy clinic, and provided a clinical training site for regional schools of pharmacy. All of the primary care pharmacists working with the Johns Hopkins Community Physicians operated under a leased-employee agreement with a renewable two-year lease.

The practice focused on internal medicine issues, with the majority of patients having multiple risk factors for cardiovascular disease. Services provided in the pharmacy clinic—part of a course of treatment established by the primary care provider—included evidence-based medication management and adherence counseling, lifestyle modification, device and disease-state education, and helping patients enroll in medication assistance programs.

All patients with diabetes referred to the pharmacy clinic had their vital signs checked and medication regimens evaluated by the pharmacist. Patients typically returned every two to six weeks as determined by the severity of their illness or level of educational need. Once the initial goals were met, a patient would be discharged from the clinic or asked to return in three to six months for a follow-up appointment. When recommending a medication change, the pharmacist discussed the patient's needs with his or her primary care provider or designee. Almost all of the pharmacist's recommendations were accepted. If the patient was experiencing an acute clinical problem (e.g., unstable angina, symptomatic hyperglycemia or hypoglycemia, hypertensive urgency), he or she was triaged according to protocol. After the patient's appointment, the pharmacist wrote a progress note and billed for services according to "incident to" regulations. The note was then reviewed and signed by the primary care provider. If a patient with an acute symptom or change in health status was seen by the physician or designee, the physician evaluated the patient, documented the visit, and billed for services. In this instance, a separate bill for pharmacy services was not prepared.

Outcomes. The primary objective of this study was to evaluate whether a pharmacist working in collaboration with other health care providers could improve HbA_{1c} levels, help patients maintain a healthy weight, and increase the number of patients with a target blood pressure of <130/80 mm Hg. The secondary objectives were to evaluate compliance with select ADA guidelines, such as smoking cessation, initiation of aspirin therapy, and initiation of angiotensinconverting-enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy.

Data were collected for the six months before (preperiod measure), the day of (index measure), and six months after (postperiod measure) the first visit with the pharmacist. HbA_{1c} levels were checked less frequently than were other values. An algorithm was developed to provide a clinical basis by which the preperiod, index, and postperiod data were collected and evaluated. The exact date of the first and third data collection periods were calculated based on the index date. The HbA_{1c} was the first outcome collected for each patient. Per study protocol, the HbA_{1c} value closest to the preperiod, index, and postperiod measurement dates were recorded. At that point, data for the other endpoints (e.g., blood pressure, weight, secondary measures) were collected from the progress note dated closest to the HbA_{1c} measurement. To minimize investigator bias and inconsistencies in data collection, a pharmacist not involved in patient care at the clinic was responsible for chart review.

Statistical analyses. The change in HbA_{1c} values from before the point of referral to the patient's pharmacybased clinic entry (i.e., preperiod measure to index measure) and the change in values from clinic entry to the end of study period (i.e., index measure to postperiod measure) were compared using a multiple regression approach and generalized estimating equations with robust variance estimation.15 Potential covariates evaluated for inclusion in the final multivariate model were age, race, sex, body mass index, height, and weight. All secondary outcomes were assessed using chi-square analysis or Fisher's exact test, as appropriate. The a priori level of significance was 0.05. Statistical analyses were performed using Stata software, version 9.0 (Stata Corporation, College Station, TX).

Results

Baseline characteristics. Of the 222 patients seen during the study period, 77 met inclusion criteria. Most (103) of the patients who did not meet study criteria either did not have diabetes, were newly diagnosed with diabetes, or had gestational dia-

betes. Of the remaining 42 patients excluded, 2 transferred to another clinic before seeing the pharmacist, 14 were never seen by the pharmacist, and 26 were missing one of the study's three measurements. Baseline demographics are outlined in Table 1. Sixty-four patients (83%) were African American.

Changes in primary and secondary outcomes. Values for the primary and secondary outcomes for each study period are presented in Table 2. The HbA_{1c} value was not significantly reduced from the preperiod measure to the index measure (mean change, -0.1%) (p = 0.79; 95% confidence interval [CI], -0.3% to 0.2%). However, there was a significant reduction in HbA_{1c} from the index measure to the postperiod measure (mean change, -0.9%) (p < 0.0001; 95% CI, -1.2% to -0.4%). The difference among these changes over study periods was significant (p < 0.0001). No significant change was noted in weight or number of patients at goal blood pressure among the three time periods studied. No difference was detected in the secondary study measures (the number of patients treated with an ACE inhibitor, ARB, or aspirin and who smoked) among the study periods.

Discussion

In a primary health care system with overextended practitioners, diminishing resources, and a rising prevalence of chronic disease, it is essential for health care practitioners to find innovative ways to ameliorate the current primary care model. According to a 2001 IOM report, health care systems are required to continuously monitor the results of the care they provide and use that information for quality improvement and assurance.¹⁶ The purpose of this study was to provide data on the clinical outcomes of a multidisciplinary model incorporating a clinical pharmacist into the medical care model of a private-practice

NOTES Medication management

physician serving primarily African Americans. This study found a significant change of HbA_{1c} values—by -0.9%—after the first pharmacist visit. The clinical pharmacists were able to optimize standard medical care by providing medication dosage adjustments as needed and patient education. Continual patient reinforcement that focused on healthy lifestyles and medication issues may have led to improved medication adherence, which would be reflected in improved glycemic control.

Given the preliminary nature of this study, it was conducted using a time-series (pre-post) study design. In future studies, a prospective, cohort study design should be used to improve the ability to draw causal inferences from the study results. The study was conducted retrospectively and involved the review of patients' charts. Inconsistencies, typical with

| Tabl | le 1 | | |
|------|------|--|--|
|------|------|--|--|

| Patient Demographics at Clinic Entry (n = 77 |
|--|
|--|

| Variable | Value |
|---|--------------|
| Mean \pm S.D. age (yr) | 64±10.9 |
| No. (%) male | 42 (55) |
| Race, no. (%) | |
| African American | 64 (83) |
| Caucasian | 12 (16) |
| Hispanic | 1 (1) |
| Mean \pm S.D. difference from first pharmacist visit (wk) | |
| Preperiod measure | -33 ± 16 |
| Index measure | -3 ± 4 |
| Postperiod measure | 23 ± 10 |
| Measurements at index visit ^a | |
| Mean \pm S.D. HbA _{1c} concentration (%) | 8.7 ± 1.9 |
| No. (%) pts with goal BP (<130/80 mm Hg) | 22 (29) |
| Mean \pm S.D. BMI (kg/m ²) | 33.5 ± 7.5 |
| Mean \pm S.D. weight (lb) | 211 ± 48 |
| No. (%) pts smoking tobacco | 9 (12) |
| No. (%) pts taking aspirin | 46 (60) |
| No. (%) pts taking ACE inhibitor or ARB | 62 (81) |

^aHbA_{1c} = glycosylated hemoglobin, BP = blood pressure, BMI = body mass index, ACE = angiotensinconverting-enzyme, ARB = angiotensin receptor blocker. retrospective chart reviews, were noted in the documentation of patient information as was the frequency with which laboratory test values were measured. As a result, it became necessary to exclude patients whose data, based on a clinically based algorithm, could not be exclusively categorized as occurring in the preperiod measure, index measure, or postperiod measure (collaborative model) time period. In addition, referral bias may have affected the results, since physicians chose to refer patients based upon clinical judgment. This factor would limit the generalizability of these findings.

A number of factors might explain the lack of significant improvement in blood pressure, weight, and secondary outcomes. Blood pressure data could have been affected by measurement bias, as multiple health care practitioners take patients' blood pressures in the clinic. In an attempt to control for this variation, blood pressure was not analyzed as a continuous variable but rather as nominal data (i.e., at goal or not). The apparent negligible change in the weight category may be because weight gain tends to be associated with intensive glucose control. Although patients are encouraged about and advised on weight loss in pharmacy clinic visits, it is common practice to initiate insulin, sulfonylurea, or a thiazolidinedioneagents that typically result in weight

| Variable | Preperiod | Index | Postperiod | $p^{ m b}$ |
|---|-------------------------------|------------|---------------------------------|------------|
| Primary endpoints | | | | |
| Mean \pm S.D. HbA _{1c} concentration (%) | $\textbf{8.8}\pm\textbf{2.1}$ | 8.7 ± 1.9 | $\textbf{7.9} \pm \textbf{1.5}$ | <0.0001 |
| Mean \pm S.D. weight (lb) | 211 ± 46 | 211 ± 48 | 210 ± 47 | 0.67 |
| No. (%) pts at goal BP | 25 (32) | 22 (29) | 30 (39) | 0.36 |
| Secondary endpoints | | | | |
| No. (%) pts smoking tobacco | 7 (9) | 7 (9) | 6 (8) | 0.96 |
| No. (%) pts taking aspirin | 41 (53) | 49 (63) | 46 (59) | 0.42 |
| No. (%) pts taking ACE inhibitor or ARB | 55 (71) | 64 (83) | 64 (83) | 0.13 |

 $^{\text{a}}$ HbA_{1c} = glycosylated hemoglobin, BP = blood pressure, ACE = angiotensin-converting-enzyme, ARB = angiotensin receptor blocker.

^bp values for primary outcomes derived from multiple regression with generalized estimating equations; p values for secondary outcomes derived from chi-square analysis or Fisher's exact test, as appropriate.

gain.¹⁷ It is possible that the pharmacists' frequent positive reinforcement on weight loss during diabetic therapy enabled the patients to maintain their weight instead of realizing the usual weight gain associated with such therapy.

In terms of the secondary outcomes, a large percentage (88%) of patients were not smoking tobacco at baseline, which may account for the negligible improvement seen in this measure. A similar argument could be made for the ACE inhibitor and ARB therapy measures as well; 81% of patients were taking an ACE inhibitor or an ARB at baseline, and those who were not may have had conditions (e.g., cough, bilateral renal artery stenosis, hyperkalemia, angioedema) to preclude use. In the case of aspirin, only 60% of patients were receiving such therapy at baseline, and no improvement was noted over the study period. This may be indicative of a need for further intervention and better documentation of aspirin use by all health care practitioners to ensure adherence to those recommendations.

Similar multidisciplinary models of pharmacists working in community pharmacies, VA medical centers, and managed care settings have been previously described in the literature. Cranor and Christensen¹⁰ assessed the outcomes of community-based pharmaceutical care services using a cohort of patients from the Asheville Project, an innovative program offering disease-state management services in collaboration with physicians in North Carolina. This study found a significant reduction in mean \pm S.D. HbA_{1c}, from 7.5% \pm 1.5% at baseline to $7.0\% \pm 1.3\%$ over 7–9 months (p < 0.01). A significant increase in the percentage of patients with optimal HbA_{1c} values (p = 0.04) was demonstrated as well.¹⁰ These results are corroborated by another study conducted in a VA setting, in which pharmacists were shown to demonstrate a significant

improvement in mean ± S.D. HbA_{1c}, from 10.3% ± 2.2% to 6.9% ± 1.1% over 9–12 months (p < 0.001).¹¹ A recently published study showed a 1.6% reduction in HbA_{1c} (p < 0.001) and demonstrated an improvement in the frequency of the clinic's adherence to ADA's preventive care recommendations.¹⁴ These clinic-based models provided services similar to those offered in the pharmacy clinic described in this article.

Multiple explanations have been proposed for the existence of health care disparities, including patient mistrust and refusal to follow recommendations.9 Anecdotally, the patients in this study expressed satisfaction with the services they received and time spent in the pharmacy clinic, which was likely due to their perceptions of the provider's attentiveness to their medical concerns. The majority of patients served in this pharmacy clinic are African American. Given the paucity of literature evaluating pharmacy clinic effectiveness in controlling diabetes mellitus in African Americans, this study can serve as a pilot for future research in this patient population.

The fundamental goal of the pharmacy medication management clinic is to improve patient health outcomes. This study described a successful partnership between pharmacists and other health care practitioners to provide comprehensive, multidisciplinary chronic care. With the ever-increasing pressure on primary care providers, the health care community will need to continue to evaluate innovative practice models that provide quality care to patients.

Conclusion

Integrating a pharmacist into a private physician practice significantly improved patient glycemic control and maintained patients' weight and the number of patients at blood pressure goal. Clinic adherence with ADA recommendations was sustained.

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Pharmacist's role in managing anemia in patients with chronic kidney disease: Potential clinical and economic benefits

CHERYL GILMARTIN

Purpose. Barriers to the treatment of anemia in patients with chronic kidney disease (CKD), the role of pharmacists in screening patients for anemia and developing guidelines for the use of anemia therapies in patients with CKD, the goals of and considerations in developing pharmacistmanaged anemia management clinics, and the potential benefits of these clinics are described.

Summary. The complexity of patients with CKD, patient nonadherence to the treatment regimen, a shortage of nephrologists, and a lack of familiarity with clinical practice guidelines and recommendations for treating anemia in these patients are possible barriers to the treatment of anemia. Pharmacists can play a role in improving the treatment of anemia in patients with CKD by screening for anemia, developing guidelines for the use of anemia therapies, and providing patient education to promote adherence to the

treatment regimen. The optimal upper limit for hemoglobin concentration during treatment with erythropoietin-stimulating agents (ESA) in patients with CKD remains to be determined, but it should not routinely exceed 13.0 g/dL. Extended dosing of darbepoetin alfa and the new agent continuous erythropoiesis receptor activator appears effective. Iron status often is not assessed in patients with CKD because of difficulty interpreting iron laboratory values and identifying iron deficiency. The usefulness of iron supplementation is not limited to patients with iron deficiency. The intravenous (i.v.) or oral route of administration may be used for iron supplementation in predialysis patients and peritoneal dialysis patients, but the i.v. route is recommended for hemodialysis patients. Adverse effects and drug interactions limit the use of oral iron supplements. Administration of parenteral iron is time consuming and accompanied by concerns

about iron accumulation and uncertainty about the optimal maximum serum ferritin concentration. Improved access to care and clinical outcomes and reduced costs have been documented in pharmacist-managed anemia management clinics.

Conclusion. Pharmacists can help overcome barriers to treating anemia in patients with CKD. Clinical and economic benefits are associated with pharmacist-managed anemia management clinics.

Index terms: Anemia; Compliance; Continuous erythropoiesis receptor activator; Darbepoetin alfa; Diagnosis; Dialysis; Dosage schedules; Drug administration routes; Drug interactions; Economics; Hematopoietic agents; Iron; Iron preparations; Kidney diseases; Patient information; Patients; Pharmaceutical services; Pharmacists; Protocols; Toxicity

Am J Health-Syst Pharm. 2007; 64 (Suppl 8):S15–22

Screening for and detection and treatment of anemia in patients with chronic kidney disease (CKD) are inadequate (see the overview article by Dowling in this supplement) for several reasons.¹

Patients with CKD are complex, often presenting with hypertension, diabetes mellitus, or other comorbid conditions (e.g., secondary hyperparathyroidism).² Many primary care physicians are overwhelmed by the complexity of patients with CKD and the practice guidelines for management of CKD. Obtaining reimbursement from the Centers for Medicare and Medicaid Services (CMS) for anemia therapies also has become

symposium and for the preparation of this article. Dr. Gilmartin reports that she serves on the speakers bureau for Watson Pharma, Inc.

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Based on the proceedings of a symposium held December 4 and 5, 2006, during the ASHP Midyear Clinical Meeting in Anaheim, CA, and supported by an educational grant from Roche Pharmaceuticals. Dr. Gilmartin received an honorarium for her participation in the

complex because of changes in CMS rules and regulations. Physician time constraints, inefficient coordination and inconsistent delivery of patient care, and knowledge deficits present barriers to the management of anemia in patients with CKD.

Patient nonadherence to complex treatment regimens also interferes with the management of anemia. Patients with CKD often receive numerous medications. Advice about proper medication use from various healthcare professionals sometimes differs, resulting in patient confusion.

Failure to properly manage anemia in patients with CKD may be explained in part by a shortage of nephrologists and the delayed referral of patients by primary care physicians to nephrologists until the late stages of CKD when patients have complex problems that are difficult to manage.³ The prevalence of patients with end-stage renal disease (ESRD) is increasing (see the overview article by Dowling in this supplement).⁴ Each 10% increase in patients with CKD requires the services of 33 nephrologists.³

A lack of familiarity with clinical practice guidelines for the treatment of anemia in patients with CKD is another possible barrier to the treatment of anemia in these patients. In a survey of 388 ambulatory care pharmacists who routinely provide care to predialysis patients or patients with risk factors for CKD (e.g., diabetes, hypertension, decreased creatinine clearance), only 24% of pharmacists routinely monitored hemoglobin or hematocrit levels in these patients.5 Only 7% of pharmacists were very familiar and 45% were somewhat familiar with the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative clinical practice guidelines and recommendations for treating anemia in CKD.6 Another 34% were not very familiar and 13% were not at all familiar with the NKF guidelines and recommendations.

Pharmacist involvement

Pharmacist participation in the management of anemia in patients with CKD who do not yet require dialysis (i.e., stages 2, 3, and 4) is a logical extension of pharmacist involvement in the management of hypertension and diabetes because of the prominent role that these diseases play in CKD (see the overview article by Dowling in this supplement). A favorable impact on clinical and economic outcomes has been demonstrated in pharmacistmanaged hypertension and diabetes clinics.7-11 Predialysis (i.e., stage 2-4) CKD can be thought of as a separate disease state from ESRD requiring dialysis (i.e., stage 5 CKD). The impact of pharmacy services as part of multidisciplinary efforts to improve outcomes in dialysis patients has been described, and these multidisciplinary approaches could be applied to predialysis patients.12-15

Screening for and detecting anemia in patients at risk for CKD (i.e., patients with diabetes, hypertension, or a glomerular filtration rate < 90 mL/min), generating interest among key institutional opinion leaders in clinical and economic outcomes in patients with anemia and CKD, and spearheading or assisting in the development of guidelines for the use of anemia therapies in predialysis patients with CKD are among the roles that pharmacists can play in treating anemia in patients with CKD. Pharmacists also can promote patient adherence to the anemia treatment regimen by providing patient education about the proper use of therapy.

Erythropoietin-stimulating agents (ESAs) are among the most costly drug therapies in the pharmacy budget at healthcare institutions. Efforts by pharmacists to develop and implement institutional protocols or guidelines for ESA use can have economic benefits as well as improve clinical outcomes.¹³

ESA use

Hemoglobin levels should be monitored at least monthly after the initiation of an ESA.⁶ The target hemoglobin concentration should be 11.0 g/dL or greater, but there is insufficient evidence to recommend routinely maintaining hemoglobin levels of 13.0 g/dL or greater in ESAtreated patients.6 At the University of Illinois Medical Center, hemoglobin levels are monitored quarterly after the therapeutic goal (11-12 g/dL) is reached in predialysis patients. There is evidence of harm from higher hemoglobin concentrations.16-19 The Correction of Hemoglobin and Outcomes in Renal Insufficiency trial, an open-label study known as CHOIR, compared a target hemoglobin of 13.5 g/dL with a lower target of 11.3 g/dL using epoetin alfa therapy in 1432 patients with CKD.19 The study was terminated early because a significantly higher risk of a composite of death, myocardial infarction, hospitalization for congestive heart failure, and stroke was associated with the higher hemoglobin target compared with the lower target.19 However, in a three-year study of subcutaneous (s.c.) epoetin beta therapy (a formulation not available in the United States) in 603 patients with CKD, there was no significant difference in cardiovascular events between patients treated to a target hemoglobin concentration of 11.0-12.5 g/dL and patients treated to a target hemoglobin of 13.0-15.0 g/dL.20 In light of the boxed warnings, several studies are under way to clarify the optimal upper limit for hemoglobin concentration during ESA therapy in patients with CKD.21

Reimbursement rules and regulations of CMS provide incentive to limit hemoglobin concentrations during ESA therapy. Medicare requires a 25% reduction in ESA dosage for reimbursement if the hemoglobin concentration reaches or exceeds 13 g/dL. The reimbursement rate for ESA is only 75% of the previous month's dose used to attain a hemoglobin of 13 g/dL or greater if the hemoglobin is 13 g/dL or higher.

Extended ESA dosing

In a retrospective review of the charts of 243 predialysis patients who received subcutaneous (s.c.) epoetin alfa for a mean of 10.3 months to treat anemia associated with CKD, 185 patients used extended dosing intervals of two or more weeks.22 Most (79%) of the 124 patients who used a two-week dosing interval maintained the target hemoglobin of at least 11 g/dL for at least three months. The number of patients using a three-week, four-week, or longer dosing interval was 22, 30, and 9, respectively, and the percentage of these patients who maintained the target hemoglobin of at least 11 g/dL for at least three months was 96%, 90%, and 100%, respectively.

In a prospective, open-label study, 519 predialysis patients with CKD and stable hemoglobin values of at least 11 g/dL who had been receiving epoetin alfa were randomly assigned to receive s.c. epoetin alfa 10,000 units once weekly, 20,000 units every two weeks, 30,000 units every three weeks, or 40,000 units every four weeks for 16 weeks.²³ Dosage reductions were permitted, but dosage increases were not allowed. The target hemoglobin ($\geq 11 \text{ g/dL}$) was maintained throughout the study in 94%, 90%, 77%, and 76% of patients receiving epoetin alfa once weekly, every two weeks, every three weeks, and every four weeks, respectively. Thus, biweekly dosing of epoetin alfa appears feasible, but longer dosing intervals may be less effective. Extended dosing of epoetin alfa was similarly tolerated for all dosing intervals. Prior to the initiation of epoetin alfa, 37.6% of patients were hypertensive (i.e., blood pressure > 140/90), while hypertension occurred in 41.6% of the patients maintaining a mean hemoglobin of 11.6 \pm 0.9 g/dL. However no statistically significant differences occurred among patients for each of the dosing regimens in either mean systolic or diastolic pressure. Likewise, the occurrence of hospitalizations was similar between groups.

Studies have demonstrated the efficacy of extended dosing of darbepoetin alfa for up to 78 weeks in predialysis patients with CKD.²⁴⁻ ²⁷ These studies included CKD patients who were being treated for anemia of CKD successfully and unsuccessfully who had been switched to extended dosing (i.e., they were not naïve to ESAs). In a 29-week study, the target hemoglobin (10–12 g/dL) was achieved and maintained when the biweekly dose of darbepoetin alfa was doubled and administered once monthly in 73 (85%) of 86 patients.24 Adverse events were similar between each of the four treatment groups (n = 513). Thrombotic events and death occurred in 2.5% and 1.4% of the patients, respectively. Another study evaluated the effectiveness and safety of extended darbepoetin dosing in patients with CKD who did not require dialysis.²⁵ Patients who were already stable on biweekly dosing were switched to monthly dosing. Patients in the study had stage 3–4 CKD and Hb > 11 g/dL (i.e., adequate iron stores). The goal Hb was 11-13 g/dL. The group attained a mean final Hb of 11 g/dL. Additionally quality of life scores were maintained or improved within each dosing regimen.

Two studies of once-monthly administration of darbepoetin alfa for 20 weeks with eight weeks of follow up were conducted in a total of 319 predialysis patients with CKD who had received at least eight weeks of epoetin alfa treatment once weekly or every two weeks.²⁶ The target hemoglobin concentration (10–12 g/dL) was maintained throughout the study by monthly darbepoetin alfa therapy, and 305 (96%) of the 319 patients preferred monthly darbepoetin alfa treatment over more frequent epoetin alfa treatment.

In a 52-week study of monthly darbepoetin alfa, 70% (n = 48) of 108 predialysis patients with CKD achieved the target hemoglobin (11-12 g/dL).²⁷ The other 30% (*n* = 21) of patients who did not achieve this target had significantly lower serum albumin concentrations and transferrin saturation values, reflecting malnutrition and iron deficiency. Malnutrition is associated with ESA resistance, and iron is required for erythropoiesis and a hematopoietic response to ESA.²⁸ These factors should be considered in patients who fail to exhibit a response to an ESA before attributing therapeutic failure to an extended dosing regimen.

Continuous erythropoiesis receptor activator

Continuous erythropoiesis receptor activator (CERA), a new agent with a long elimination half-life created by integrating polyethylene glycol into recombinant human erythropoietin, has been used once monthly in dialysis patients with CKD (see the preceding article by Grabe in this supplement).²⁹⁻³¹ Data from clinical studies in predialysis patients recently became available.

In a phase II study, 65 ESA-naïve predialysis patients with CKD were randomly assigned to receive CERA at various s.c. doses $(0.15-0.60 \mu g/kg/week)$ and dosing intervals (once every one to three weeks).³² The mean increase from baseline in hemoglobin concentration after six weeks of therapy ranged from 0.30 g/dL at lower doses to 1.76 g/dL at higher doses. In 51 patients who entered an extension trial, the mean hemoglobin concentration was maintained at the target (>11 g/dL) for more than 54 weeks.

The efficacy of extended dosing of CERA was compared with that of darbepoetin alfa in a Phase 3 openlabel, randomized, multicenter, par-

allel group study of 324 predialysis patients who were ESA naïve.33 The mean baseline hemoglobin in both treatment groups was 10.2 g/dL. In the initial phase of the study, patients received either CERA 0.6 µg/kg/week s.c. biweekly or darbepoetin alfa 0.45 µg/kg/week with dose adjustments to achieve an increase from baseline in hemoglobin of at least 1 g/dL and a target hemoglobin of 11-13 g/dL. Patients with a hemoglobin response after 28 weeks of CERA treatment were randomized to receive an additional 24 weeks of CERA treatment once every two weeks or once every four weeks during an extension phase of the trial. The hemoglobin response rates after 28 weeks of treatment were high in both treatment groups (98% with CERA and 96% with darbepoetin alfa). Patients in both groups had a significant change in Hb from baseline to end of study at week 28 (12.3 g/dL in the CERA group and 12.2 g/dL in the darbepoetin group). The mean change in baseline Hb was 0.16 g/dL (-0.05-0.35, p < 0.001). The hemoglobin was maintained in the target range with CERA administration every two weeks and every four weeks during the 24-week extension phase of the study. Adverse events were similar in both groups and included hypertension, nasopharyngitis, diarrhea, and peripheral edema. At weeks 1-28, 67.7% of CERA patients and 80.6% of darbepoetin patients had Hb > 13 g/dL (p < 0.0082). Thus, extended dosing of CERA appears effective in predialysis patients with CKD as well as in dialysis patients.

Iron therapy

The assessment of iron status in patients with CKD usually involves measurement of the serum iron concentration (which reflects iron available for hemoglobin synthesis), the serum ferritin concentration (an indirect measure of total body iron stores), and the total iron binding capacity (TIBC). The transferrin saturation (TSAT) is calculated by dividing the serum iron concentration by the TIBC and multiplying the result by 100. It is a measure of the iron that is immediately available for hemoglobin synthesis. The content of hemoglobin in reticulocytes is a new measure that also reflects the adequacy of iron for erythropoiesis.⁶

Interpreting iron laboratory values and identifying iron deficiency in patients with CKD can present a challenge. In a study conducted at the Nephrology Clinics at the University of North Carolina (UNC) at Chapel Hill, iron status was not evaluated in 43% of patients with CKD, and 22% of those patients had a serum ferritin value <100 ng/mL and 55% of the patients had a TSAT < 20% (i.e., laboratory values suggesting the presence of iron deficiency).³⁴ Sixty percent of patients did not receive iron therapy.

In a retrospective study of a cohort of 602 patients with CKD (serum creatinine ≥ 2.0 mg/dL in men and ≥ 1.5 mg/dL in women) and a mean predicted glomerular filtration rate of 22 mL/min, screening laboratory iron tests were performed in 18% of patients.³⁵ A hematocrit less than 30% (i.e., anemia) was present in 38% of patients. Thus, failure to assess iron status is not uncommon in patients with CKD. This failure can have consequences if iron deficiency goes undetected.

Iron status should be measured in conjunction with hemoglobin in patients with CKD and anemia to ensure that patients have adequate iron stores when initiating ESA therapy. Iron supplementation should be initiated simultaneously with ESA treatment. Parenteral iron therapy may be needed to replenish diminished iron stores (i.e., serum ferritin <100 ng/mL or TSAT <20%), but the usefulness of iron supplementation is not limited to patients with iron deficiency.6 Iron supplementation can help prevent depletion of iron stores during erythropoiesis and achieve and maintain target hemoglobin levels.6 Iron status should be monitored monthly in patients with iron deficiency until stores are replenished. Quarterly monitoring of iron status suffices in patients with adequate iron stores.

The intravenous (i.v.) or oral route of administration may be used for iron supplementation in predialysis patients and peritoneal dialysis patients, but the i.v. route is specifically recommended by NKF for hemodialysis patients.6 Oral iron supplements include ferrous sulfate, ferrous gluconate, and ferrous fumarate, and the elemental calcium content of these products is 300 mg/g, 120 mg/g, and 330 mg/g, respectively.³⁶ A daily dosage of at least 200 mg of elemental iron (i.e., three 325-mg ferrous sulfate tablets or two 325-mg ferrous fumarate tablets) is recommended for patients with CKD who receive an ESA because of the increased iron demands associated with erythropoiesis.37 However, oral iron absorption may be impaired in patients with CKD, and the recommended amount of oral iron usually is inadequate in dialysis patients because of blood losses.36,38 Parenteral iron circumvents problems with low oral bioavailability. Adverse effects from oral iron (e.g., constipation, abdominal pain, gastrointestinal [GI] upset) often limit patient adherence.36 The supplements are preferably taken on an empty stomach two hours before or one hour after a meal, but tolerability may be a problem. Taking iron at bedtime or in divided doses may ameliorate adverse effects. Combination products that contain the stool softener docusate sodium may be used to minimize constipation. Extended-release and enteric-coated iron products have been purported to reduce adverse GI effects, but iron absorption from these products is diminished compared with immediate-release products.36 Oral iron supplements may interact with aluminum-containing phosphate binders and certain other drugs.³⁶ Doses of iron supplements and drugs that interact with them should be taken as far apart as possible to minimize the risk of interaction.

Parenteral iron supplements include iron sucrose and sodium ferric gluconate. The recommended dosage of iron sucrose, which contains 20 mg/mL elemental iron, in hemodialysis patients with iron deficiency is 100 mg one to three times weekly.³⁹ Doses may be administered by slow i.v. injection (preferably at a rate not to exceed 20 mg/min) or by i.v. infusion (100 mg diluted in 100 mL of 0.9% sodium chloride over at least 15 min).³⁹ Total cumulative doses of 1000 mg in divided doses have been used for predialysis and peritoneal dialysis patients with iron deficiency.40 Five 200-mg doses over 2–5 minutes were used over a 14-day period in predialysis patients.⁴⁰ Two 300-mg infusions over 1.5 hours 14 days apart followed 14 days later by 400 mg over 2.5 hours were used in peritoneal dialysis patients.40

Sodium ferric gluconate contains 12.5 mg/mL elemental iron. Most hemodialysis patients with iron deficiency require a cumulative dose of 1000 mg of elemental iron in eight divided doses.⁴¹ Each 125-mg dose may be given undiluted by slow i.v. injection at a rate of 12.5 mg/min or the dose may be diluted in 100 mL 0.9% sodium chloride and given by i.v. infusion over one hour.⁴²

The safe serum ferritin concentration in hemodialysis patients receiving i.v. iron is controversial because of concerns about accumulation of iron in the liver and other organs (see the preceding article in this supplement by Grabe). The Dialysis Patients' Response to Intravenous Iron With Elevated Ferritin (DRIVE) trial was conducted to explore the safety and efficacy of i.v. iron therapy in anemic hemodialysis patients treated with epoetin alfa who had high serum ferritin levels and low or normal iron saturation values.43 These results were recently published.

Anemia management clinics

The goals of anemia management clinics for patients with CKD include increasing awareness of the problem of anemia in patients with CKD and providing proactive screening for anemia in all patients with or at risk for CKD. Monitoring anemia therapy to improve the continuity and consistency of care provided to patients, and ensuring that care is consistent with NKF guidelines and recommendations and that billing is adequate to obtain reimbursement from CMS and other insurers also are goals. Therapy should be streamlined and patients and healthcare providers should be educated to promote the use of treatment plans consistent with NKF guidelines and patient adherence to the treatment plan.

Considerations in developing an anemia management clinic include current use of anemia therapies and clinical and financial outcomes in patients with CKD who develop anemia. Potential clinical and economic benefits from proposed changes in the use of anemia therapies and patient monitoring associated with an anemia management clinic should be quantified to the extent possible. Such an analysis requires an assessment of current prescribing and monitoring practices and the potential impact of an anemia management clinic on these practices. A plan for implementing an anemia management clinic that establishes an organizational structure for the clinic and takes into consideration the institutional organization can then be developed based on these analyses. Failure to consider institutional organizational relationships could compromise the success of the clinic.

In 2002, a pharmacist-managed clinic for the management of anemia in patients with CKD was established at the Nephrology Clinics at UNC after conducting a retrospective analysis of the clinical and financial management of anemia in this patient population at the institution.³⁴

A multidisciplinary approach, including staff from the billing department as well as physicians (the chief of nephrology and several fellows), pharmacists (a nephrology clinical pharmacist and pharmacy fellow), and nurses (clinic and clinical research nursing staff), was used to ensure that reimbursement for services and pharmaceuticals was obtained.

Clinicians at UNC were educated about the findings of the retrospective clinical and financial analysis, which included a loss of substantial revenue due to improper billing. Failure to achieve NKF goals (i.e., hematocrit values below the target range, failure to provide iron therapy despite iron laboratory values suggesting iron deficiency) also was documented. The goals of the clinic and an action plan for its operation were presented to and feedback was elicited from the UNC clinical staff.

One day each week was designated for patient clinic visits. The nephrology clinical pharmacist obtained clinical privileges to manage anemia (i.e., prescribe drug therapies and order laboratory tests) under a protocol approved by the medical staff. A billing code was established for the clinic, and a template was developed for scheduling clinic visits and billing for clinic services provided to patients with CKD.

Patients with CKD were screened for anemia at the clinic, and it soon became apparent that two days per week would be required to meet patient needs. To forestall and resolve billing and reimbursement issues, health insurance status was verified and documented for all patients, and prior approval was obtained for the use of ESAs and other drug therapies as necessary. Patients lacking health insurance were enrolled in manufacturer patient assistance programs.

Analysis of ESA and iron use in patients with CKD and anemia led to the decision to convert patients receiving epoetin alfa once weekly to darbepoetin alfa every other week and then once monthly. Patients initiating ESA treatment received darbepoetin alfa $0.75 \,\mu$ g/kg s.c. once every two weeks initially, with eventual lengthening of the dosing interval.

Initially, iron therapy was administered orally to most clinic patients, with titration of the dosage to 200 mg/day of elemental iron over several weeks. However, the need for an i.v. iron protocol soon became apparent because of problems with tolerability and a low response rate to oral iron therapy (20%).

The target hemoglobin was achieved and maintained with a darbepoetin alfa dosing interval of four to six weeks in approximately 40% of clinic patients and an interval of two or three weeks in 58% of patients (total of 98% receiving extended dosing). In the first three months of clinic operations, a cost savings was realized that was equivalent to the financial losses experienced in the preceding year. Benefits of the clinic for established patients included reduced transportation time and costs due to a reduced frequency of visits. Access to care was improved for new patients, who experienced shorter waits to be seen by a nephrologist after referral from a primary care provider.

Clinical and financial outcomes in patients receiving epoetin alfa at another pharmacist-managed protocoldriven outpatient clinic were compared with outcomes in patients receiving conventional care provided by primary care physicians.44 The baseline hemoglobin concentrations in the two groups were similar, but the time to achieve the target hemoglobin (11.0-12.9 g/dL) was substantially shorter in clinic patients (56 days) than in conventional care patients (103 days). The percentage of time with the hemoglobin concentration in the target range was higher in the clinic group (70%) than in the conventional care group (44%). The amount of epoetin alfa used in the clinic group (8449 units/week) was lower than that in the conventional care group (20,148 units/week), resulting in considerable cost savings.

At the University of Illinois Medical Center, where a clinic for the management of anemia in patients with CKD was established not long ago, a retrospective analysis of the management of anemia in CKD patients revealed that no particular ESA was used consistently, and ESA administration was performed weekly or biweekly for most patients (i.e., extended dosing was seldom used). Scheduling of patient visits for ESA injections was not coordinated with physician visits. Laboratory tests for hemoglobin concentration and iron status were ordered haphazardly. Iron therapy often was improperly prescribed, if it was ordered at all, and ESA doses were not routinely adjusted based on hemoglobin values.

The clinic had four nephrology attending physicians, four to six physician fellows, a pharmacist, and a nurse. Prescribing and laboratory monitoring practices were inconsistent among the attending physicians and physician fellows. A patient might be seen by any of the 10 physicians at any one visit, resulting in a lack of continuity of care. The nurse monitored blood pressure before ESA injections, but she did not order laboratory tests or modify ESA doses because of inexperience and time doing so.

Problems were identified with improper billing and failure to obtain reimbursement from CMS and private insurers for clinic services and medications. Failure to obtain patient referrals at an early stage when treatment could prevent disease progression also was a source of concern.

The clinic staff convened and decided to designate one individual, the pharmacist, to coordinate clinic operations and improve the consistency and continuity of care. The staff networked with personnel at clinics regarding patients at high risk for CKD and anemia (e.g., a diabetes clinic), and patient referrals to the anemia clinic were solicited for proactive screening for anemia. Certain days were set aside at the anemia clinic for visits by newly referred patients.

A computer-based anemia management system was developed for use in the clinic. This computer system addresses billing and reimbursement problems (e.g., patient eligibility for coverage by Medicare Part B, Medicaid, or another health insurer is verified and documented). It also facilitates coordination of patient visits for evaluation by a physician or pharmacist, ESA injections by the nurse, and laboratory monitoring.

The decision was made to use monthly darbepoetin alfa therapy for all clinic patients. In patients who had been receiving epoetin alfa, the dosage was titrated until the target hemoglobin was achieved before switching to biweekly darbepoetin alfa administration and then monthly darbepoetin alfa therapy. In most cases, the target hemoglobin was maintained by increasing the biweekly darbepoetin alfa dose by 25% to 50% and giving it monthly. Assessment of iron status and the use of oral or i.v. iron therapy as appropriate became routine when the computer system was implemented.

The pharmacist evaluates the most recent laboratory hemoglobin and iron values and makes ESA and iron dosing recommendations to the physician before each patient visit, and the nurse is informed about these recommendations. The pharmacist also orders follow-up laboratory tests. The use of computer templates (i.e., standardized screens) for laboratory tests and drug therapy ensures the continuity and consistency of care.

Reimbursement for anemia therapies

Obtaining reimbursement for ESAs and iron therapy requires a knowledge of the requirements of CMS and private insurers. Medicaid requirements may vary locally.

Two International Classification of Diseases, 9th revision (ICD-9) codes (one for the anemia of CKD and the other for the CKD stage) are required to obtain Medicare reimbursement for ESAs. Medicare Part B covers ESA injections administered in the clinic setting. In Illinois, Medicaid covers ESA administration on an outpatient basis, which allows self administration. Medicare Part D and some private insurance plans cover outpatient ESA prescriptions with prior approval. Letters requesting approval must include information about the ESA dose, CKD stage, and laboratory values for hemoglobin, iron, TIBC, TSAT, and ferritin. Coverage for ESAs by private insurers varies and is consistent with coverage under Medicare or Medicaid in some but not all private insurance plans.

Medicare Part B provides coverage for i.v. iron therapy administered in a clinic setting. Two ICD-9 codes are required (one for iron deficiency anemia and the other for the CKD stage). In Illinois, reimbursement is provided by Medicaid for i.v. but not oral iron therapy if prior approval is obtained. The iron product and dosage, ESA dosage, CKD stage, and laboratory values for hemoglobin, iron, TIBC, TSAT, and ferritin are required in the request for approval. Private insurers may follow Medicare or Medicaid reimbursement policies for iron therapy.

Conclusion

Pharmacists can use various strategies to overcome barriers to the management of anemia in patients with CKD, including spearheading a multidisciplinary approach to improve patient screening and the continuity and consistency of care for anemic patients. The use of extended dosing regimens for anemia therapies has the potential to simplify therapy, promote adherence to the treatment regimen, and improve clinical and financial outcomes.

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NOTES

Effects of pharmacists' interventions on patient outcomes in an HIV primary care clinic

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n the early 1990s, advances in combination therapy for the treatment of human immunodeficiency virus (HIV) infection, including the introduction of highly active antiretroviral therapy (HAART), transformed the prognosis from a terminal to a chronic condition that can be managed using multidrug therapy in the outpatient setting.1-9 Studies found that patients who adhered to their HAART regimen had improved viral loads and a better immunologic response.^{10,11} One study found that patients receiving protease inhibitor (PI)-based HAART who had an adherence rate of at least 95% had less risk for viral resistance and immunologic failure, which corresponded to fewer days spent in the hospital.¹⁰

In 1994, a pharmacist-managed HIV drug optimization clinic (DOC) was implemented in a federally funded, county-based HIV clinic in Los Angeles to evaluate drug interactions and monitor the use and safety of investigational drugs. In 1999, the DOC received funding from the AIDS Education and Training Center, enabling pharmacists to develop **Purpose.** The effects of pharmacists' interventions on patient outcomes in an HIV primary care clinic were studied.

Methods. All study participants were referred to a pharmacist-managed drug optimization clinic (DOC) in a county-based HIV primary care clinic between November 1, 2003, and September 30, 2004. Patients were eligible for study participation if they were 18 years of age or older and gave informed consent to participate. Pharmacists' interventions were categorized as follows: patient education, addition of a medication, dosage adjustment, discontinuation of a medication, and interpretation of viralresistance tests. Changes in baseline CD4+ T-lymphocyte counts and viral load were also measured over the study period. Toxicities related to highly active antiretroviral therapy were recorded and graded from 0 to 4, with 0 indicating no toxicity and 4 indicating severe toxicity. Study participants used a standardized survey to measure their own health-related quality of life. Changes in CD4+ lymphocyte counts and viral load were analyzed using Student's

t test and analysis of variance. Toxicity grades were analyzed using the Wilcoxon signed-rank test.

Results. A total of 34 patients completed the study. Pharmacists made a total of 253 interventions, most of which were categorized as patient education. The mean CD4+ lymphocyte count increased from baseline levels by 54 \pm 78 cells/mm³ over the study period (p < 0.0002). The mean \pm S.D. reduction in circulating viral load over the study period was 1.02 log₁₀ copies/mL (p < 0.004).

Conclusion. HIV-infected patients who were managed by pharmacists in a DOC demonstrated significant improvement from baseline in their CD4+ lymphocyte counts, viral loads, and drug-related toxicities.

Index terms: Ambulatory care; Antiretroviral agents; Dosage; HIV infections; Interventions; Patient information; Pharmaceutical services; Pharmacists; Quality of life; Toxicity

Am J Health-Syst Pharm. 2007; 64:2574-8

new models to enhance medication adherence and educational tools for the patients and health care providers. To this end, the pharmacistbased clinic was transformed into a medication adherence clinic with the

Dr. March was a recipient of the ASHP Research and Education Foundation Residency Award for the proposal and additional funding of this study.

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Funded by the Pacific AIDS Educational Training Center from the

Health Resources and Services Administration, Rockville, MD.

goal of optimizing HAART and associated therapy.

Providers in this outpatient clinic, including physicians, physician assistants, nurses, psychiatrists, pharmacists, and social workers, work as a multidisciplinary team to provide optimal care to patients with HIV infection. Primary care providers may refer patients whom they suspect are nonadherent to their HAART regimen, have drug-related adverse effects, have issues regarding potential drug-drug interactions, or are infected with multidrug-resistant viruses with minimal clinical treatment options. Upon patient referral, the DOC pharmacist reviews the patient's medical history and evaluates and manages his or her therapy through a collaborative practice agreement with the patient's primary care provider. Two clinical pharmacists, pharmacy residents, pharmacy students, a supervising physician, and a nurse staff the DOC.

Numerous published reports have shown that patient-specific HAART regimens may minimize drug toxicity and increase medication adherence, thereby maximizing virological and immunologic responses.¹²⁻¹⁶ The objectives of this study were to evaluate the impact of DOC pharmacists' interventions on patients' virological and immunologic responses, the rate of adverse events, and patients' perception of their own health status.

Methods

All study participants were referred to the DOC between November 1, 2003, and September 30, 2004. Patients were eligible for study participation if they were 18 years of age or older and gave informed consent to participate in the study. Patients were excluded if they were participating in another study that limited pharmacist interventions at the DOC. All patients seen at the DOC were treated according to the most current HIV treatment guidelines available at the study time.¹⁷

Patients' medical records were reviewed at their initial visit to the DOC and for 12 weeks beyond the date of enrollment or until the patient was discharged from the DOC, whichever occurred first. Data recorded for study participants included demographic characteristics, medication regimens, comorbidities, drug-related adverse effects, and laboratory test values. Pharmacists' interventions were categorized as follows: patient education, addition of a medication, dosage adjustment, discontinuation of a medication, and interpretation of viral-resistance tests. Changes in baseline CD4+ lymphocyte counts and viral loads were also measured over the study period. HAART-related toxicities were recorded and graded on a scale of 0 to 4, where 0 indicated no toxicity and 4 indicated severe toxicity, based on criteria from the Radiation Therapy Oncology Group (RTOG) common toxicity scale.18

Study participants were also asked to rate their perception of their own health status using the eight-item Short-Form (SF-8) health survey at the end of the study.¹⁹ The SF-8 survey contained various questions about patients' quality of life and required patients to answer excellent, very good, good, fair, poor, or very poor. These responses were compiled and analyzed by SF-8 software.

Changes in CD4+ T-lymphocyte counts and viral loads before and after the pharmacists' interventions were analyzed using Student's t test and analysis of variance. Toxicity grades were analyzed using the Wilcoxon signed-rank test. The a priori level of significance was set at 0.05.

This study was reviewed and approved by the institutional review board at the Health Science Campus of Los Angeles County Hospital and the University of Southern California.

Results

A total of 34 patients completed

the study. Baseline patient demographics, viral load, CD4+ lymphocyte count, HIV status, and reasons for referral are summarized in Table 1. The majority of patients were male and were Hispanic or Black. Patients' mean \pm S.D. age was 47 \pm 10 years. Patients had been previously treated with a mean \pm S.D. of 3 \pm 2 HAART regimens, suggesting that patients referred to this clinic had a high level of treatment resistance. Most patients were referred to the clinic because of poor adherence, viral resistance, and drug-related toxicity.

At the initial visit, pharmacists found that 23 patients (68%) had more than one problem that required additional therapeutic recommendations. The most common comorbidities were psychiatric related (n = 12). Other comorbidities included hypertension (n = 7), hepatitis B (n = 4), diabetes mellitus (n =3), hepatitis C (n = 2), chronic renal insufficiency (n = 2), and basal cell carcinoma (n = 1).

The DOC pharmacists devised best-fit regimens that allowed minimal insult to other diseases while offering the best possible suppression of HIV. One-hundred percent of the pharmacists' recommendations were approved and adopted by the patients' primary care providers. Pharmacists made a total of 253 interventions, of which 135 were associated with HIV therapy (n = 135) and 118 were associated with primary-carerelated issues. Most interventions were categorized as patient education (n = 115). Other interventions included the addition of a medication (n = 50), dosage adjustment (n = 51), discontinuation of a medication (n =26), and interpretation of resistance tests (n = 11). Dosage adjustments were made in response to altered renal functioning, drug-related toxicities, and drug-drug interactions.

The mean CD4+ T-lymphocyte count increased from baseline levels by 54 ± 78 cells/mm³ (p < 0.0002) over the study period (mean \pm S.D.,

Table 1.

Characteristics of Patients Managed by Pharmacists in an HIV Primary Care Clinic (n = 34)

| Characteristic | Value |
|---|-------------------|
| Mean ± S.D. age (range), yr | 47 ± 10 (24–67) |
| Male, no. (%) | 28 (82) |
| Ethnicity, no. (%) | |
| Hispanic | 19 (55) |
| Black | 9 (26) |
| White | 5 (15) |
| Asian | 1 (0.02) |
| Baseline mean \pm S.D. CD4+ lymphocyte count | |
| (cells/mm³) | 229 ± 183 |
| Baseline mean \pm S.D. viral load (copies/mL) | 103,681 ± 195,400 |
| Diagnosed with AIDS, no. (%) | 30 (88) |
| Reason for referral, no. (%)ª | |
| Drug-related toxicity | 14 (41) |
| Viral resistance | 13 (38) |
| Nonadherence to HAART ^a | 16 (47) |
| Primary care management ^b | 5 (15) |

^aSome patients were referred for more than one reason. HAART = highly active antiretroviral therapy. ^bManagement of dyslipidemia, hypertension, or diabetes mellitus.

 4 ± 2 months). This rate of CD4+ lymphocyte recovery is lower than typically seen in treatment-naive patients, where the number of cells recovered can range from 100 to 200 cells/mm³; however, the patients seen in this clinic had an extensive history of treatment. The mean \pm S.D. circulating viral loads were 5.02 \pm 5.29 log₁₀ copies/mL at baseline and $3.99 \pm 4.48 \log_{10}$ copies/mL after the study, representing a mean reduction of 1.02 \log_{10} copies/mL (p <0.004). Similar to CD4+ lymphocyte recovery, the reduction in viral load was not as dramatic as that seen in treatment-naive patients.

The clinical outcomes for patients referred to the DOC for the management of viral resistance (n = 11) were evaluated separately. The mean ± S.D. CD4+ lymphocyte recovery in these patients (79 ± 58 cells/mm³) was significant compared with baseline levels (p < 0.004). The mean reduction in viral load in these patients was 1.17 log₁₀ (from a mean ± S.D. of 5.35 ± 5.34 log₁₀ copies/mL at baseline to 4.14 ± 4.47 log₁₀ copies/mL at study end) (p < 0.004). Six of these patients achieved an undetectable viral load during the study, with a viral load of <50 copies/mL (n = 2) and <400 copies/mL (n = 4).

The 16 patients referred to the clinic for poor adherence to HAART had a mean \pm S.D. increase in CD4+ lymphocyte count of 88 \pm 60 cells/mm³, with a mean viral load reduction of 1.02 log₁₀ copies/mL (from 5.34 \pm 5.43 log₁₀ copies/mL at baseline to 4.32 \pm 4.66 log₁₀ copies/ mL at study end) (p < 0.01 for both comparisons).

Twenty-five patients had drugrelated toxicities during the study period, 13 of whom had experienced more than one toxicity. A total of 42 toxicity events were recorded, the most common of which were gastrointestinal-tract related (n = 9). The mean baseline toxicity grade was 1.9, and the overall toxicity score decreased by a mean \pm S.D. of 1 ± 0.8 on the RTOG scale (p < 0.001).

The mean \pm S.D. physical component summary (PCS) score and the mean \pm S.D. mental component

summary (MCS) scores on the SF-8 were 48.2 \pm 9.96 and 47.9 \pm 11.5, respectively. Compared with patients having at least one chronic physical condition, the mean \pm S.D. PCS score was similar (49.0 \pm 9.1 in other conditions) and the mean \pm S.D. MCS score was slightly lower (51.7 \pm 7.7 in other conditions).

Discussion

The DOC's objective is to maximize long-term and durable suppression of HIV replication through minimizing HAART-associated toxicity, improving HAART adherence, and providing options for an optimal HAART regimen. The study participants included patients who were underserved and uninsured with limited access to health care. In addition, study participants were highly treatment experienced, having already unsuccessfully used a mean \pm S.D. of 3 \pm 2 HAART regimens. These patients are considered the most difficult to treat and least likely to achieve positive CD4+ T-cell and viral-load outcomes. Despite the challenges posed by this study population, the levels of CD4+ lymphocyte recovery and viral-load suppression were significant, even with a short follow-up time. Viral-load reduction, which is considered the strongest predictor of long-term clinical success,⁷ was achieved in this study. A total of 21 patients (62%) attained or maintained an undetectable viral load during the study. Of the remaining 13 patients, 9 demonstrated some minor improvement in their viral loads by the end of the study, and the viral loads of 4 patients increased over the study period.

Improvements in overall CD4+ lymphocyte counts were also significant, as 22 patients (63%) had a CD4+ cell count of \geq 200 cells/mm³ by the final study visit. Attainment of this goal was the HIV treatment guideline recommendation at the time for partial immunologic restoration and the greatest chance for long-term survival.¹⁷ As previously mentioned, many of the study participants had comorbidities. Studies have shown that patients with psychiatric issues are less likely to adhere to medication regimens and achieve treatment goals.^{10,20-24} Furthermore, coinfections with hepatitis B or C may affect the immune response and suppress CD4+ T-cell count.25-28 In this study, the CD4+ lymphocyte count decreased in five patients, three of whom had at least one comorbidity, including hepatitis B and C (n =1), depression and dementia (n = 1), and type 2 diabetes mellitus (n = 1).

Nonadherence and viral resistance are established obstacles in the management of HIV.^{10,12-15,26,29,30} Although this study did not specifically track adherence, it is reasonable to infer from the improvement in viral loads that the study participants were more adherent at study end, possibly due to fewer adverse events. Previous studies have found that high rates of compliance (>90%) are required to achieve undetectable plasma viral loads in patients taking PI-based HAART, while lower degrees of adherence to HAART have been linked to treatment failure.^{10,17} Reducing the occurrence of toxicity improves the quality of life in HIV-infected patients, which aids in their adherence to medical regimens and achievement of treatment goals.15,16

In this study, dosage adjustments for renal function or body weight or to optimize efficacy accounted for 20% of interventions. Interestingly, renal insufficiency has recently become a more common reason for referral to the DOC. Because HIV acute nephropathy and druginduced nephrotoxicity are on the rise in HIV-infected patients, proactive monitoring of kidney function and HAART dosage adjustments are of the utmost importance in preventing renal dysfunction and the subsequent limiting of tolerable HAART.

Patients with HIV infection now commonly live beyond 60 years of

age, the age where the ability to eliminate drugs may be decreased. This may be a consequence of reduced renal and hepatic clearance. The ability to stage hepatic function, which may be measured using Child-Pugh scores,³¹ may be important, since HIV-infected patients are often coinfected with hepatitis. In this study, two of four patients coinfected with hepatitis B had Child-Pugh scores of ≥ 8 . One patient was switched from a regimen of lopinavir-ritonavir, tenofovir, and didanosine to a regimen of fosamprenavir, lamivudine, and tenofovir. Another patient was restarted on a HAART regimen including fosamprenavir with a reduced dosage of 700 mg twice daily (from 1400 mg twice daily). Dosage adjustments of fosamprenavir maintained viral suppression in these two patients, suggesting that dosage adjustment reduced the occurrence of drug-related adverse events without compromising antiviral activity.

Although the pharmacists in this clinic are highly trained in HIV pharmacotherapy, 47% of the interventions were associated with primary care issues. This is a reflection of the prolonged survival of HIV-infected patients and the subsequent development of chronic metabolic diseases, such as diabetes mellitus, hypertension, and hyperlipidemia. The management of these diseases requires additional medications, thereby increasing the risk of drug–drug interactions.

Limitations of this study include the small sample size and the short follow-up period. While the HIV clinic has an average of 2000 patient visits per month, the DOC has approximately 25 patient visits per month. At the time of the study, the DOC had approximately 40 active patients, and 34 met the inclusion criteria and gave informed consent for enrollment. The DOC operated a total of six clinic hours per week (three hours each on two separate mornings), which was a major factor in limiting the number of patients available. In addition, because the clinic operates only two mornings per week, access to providers was limited. Based on a study duration of approximately five months, with two clinics each week, there were approximately 6.3 interventions (253) interventions/40 clinics) achieved in each clinic held, which only lasted three hours each time. The limitations of the short-term follow-up period include inadequate assessment of long-term outcomes, and these findings should be reaffirmed in a subsequent time period.

Another shortcoming of the study is the administration of the SF-8 survey one time only at the end of the study. Although the results showed the HIV study population to have similar perceptions of health and quality of life with a chronic disease population, they do not allow for the assessment of the impact that DOC pharmacists may have made, since there was no before and after comparison.

Conclusion

HIV-infected patients who were managed by pharmacists in a DOC demonstrated significant improvement from baseline in their CD4+ lymphocyte counts, viral loads, and drug-related toxicities.

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PRACTICE INSIGHTS

Pharmacist-Managed Vaccination Program Increased Influenza Vaccination Rates in Cardiovascular Patients Enrolled in a Secondary Prevention Lipid Clinic

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Study Objectives. To determine whether a vaccination program in a pharmacist-managed secondary prevention lipid clinic increased influenza immunization rates in a high-risk population, and whether age or gender disparity existed among those vaccinated.

Design. Retrospective chart review.

Setting. Large, multispecialty, group practice.

- Patients. A total of 476 and 266 patients seen at clinic visits during the 2003-2004 and 2004-2005 influenza seasons, respectively.
- Measurements and Main Results. Immunization rates were compared before (2003-2004 influenza season) and after (2004-2005 influenza season) the implementation of the influenza vaccination program; χ^2 analysis was used for all statistical inferences. Vaccination rates increased significantly from 39% to 76% (p<0.0001) after program implementation. No before-after difference in rates was noted based on gender. Before implementation, patients younger than 65 years were less likely versus those aged 65 years or older to receive the influenza vaccine (29% vs 58%, p<0.0001). Age disparity in vaccination rates was eliminated after initiation of the program.
- **Conclusion**. The pharmacist-managed program increased influenza vaccination rates in high-risk patients with cardiovascular disease in advance of the newly published secondary prevention guidelines. Agerelated differences in the vaccination rates were eliminated after program implementation.

Key Words: prevention, risk factors, influenza vaccine, lipids, gender. (Pharmacotherapy 2007;27(5):729–733)

Influenza is responsible for approximately 36,000 deaths/year in the United States due to either the disease itself or secondary complications such as pneumonia, myositis, myocarditis, or exacerbation of chronic illness.¹ Influenza vaccination has reduced the frequency of

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way to reduce influenza-related hospitalizations and death, especially in the elderly. A series of studies over 10 consecutive influenza seasons showed that vaccinations in the elderly resulted in a 20-57% reduction in pneumonia and influenza-related hospitalizations and a 39-69% reduction in all-cause mortality.² The Advisory Committee on Immunization

Practices identified persons aged 65 years or older, residents of nursing homes, and patients of

infection, secondary complications, hospital-

izations, and exacerbations of underlying chronic

disease. In addition, it is the single most effective

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any age with chronic pulmonary or cardiovascular disorders as high-risk populations and recommended yearly influenza vaccination for these populations.¹ In addition, the American Heart Association and the American College of Cardiology recently released new guidelines advocating influenza vaccination for all patients with coronary and other atherosclerotic vascular disease.³

Healthy People 2010 advocates that health care providers achieve a 90% immunization rate for all high-risk individuals older than 65 years and a 60% immunization rate for high-risk individuals aged 18–64 years.¹ Unfortunately, national immunization rates for high-risk individuals are appropriately 65%, 46%, and 26% for those older than 65 years, those aged 50–64 years, and those aged 18–49 years, respectively. These data clearly identify the need for higher influenza immunization rates in high-risk populations.

Pharmacists in the role of immunization provider are supported by the American College of Physicians–American Society of Internal Medicine.⁴ Furthermore, state and national pharmacy organizations advocate pharmacist participation in the role of immunization provider.⁵ Pharmacists have the legal authority to administer vaccinations in 44 states (including Texas, where our study was conducted), and states allowing pharmacists to directly administer vaccines achieve higher statewide immunization rates than other states.⁶ In addition, pharmacistmanaged immunization programs have increased influenza vaccination rates in hospitals and rural primary care clinics.^{7, 8}

Efforts are needed to increase influenza vaccination awareness and rates among high-risk individuals. Clinical pharmacists employed in institutions and ambulatory health care clinics are strategically located to provide vaccinations as part of their usual standard of care. The primary objectives of our study were to determine whether a vaccination program in a pharmacistmanaged secondary prevention lipid clinic increased influenza immunization rates in a high-risk population, and whether gender and age disparity existed among those vaccinated.

Methods

Clinical Setting

Kelsey-Seybold Clinic is a large, multispecialty, group practice in Houston, Texas. The secondary prevention lipid clinic is a collaborative effort between the Kelsey-Seybold Clinic Department of

Cardiology, the Kelsey Research Foundation, and the University of Houston College of Pharmacy. The lipid clinic staff includes three cardiologists, a clinical pharmacist, pharmacy students, and postgraduate pharmacy residents. The clinical pharmacist or cardiologists screen patient charts from the Kelsey-Seybold clinic and identify those patients who should be seen at the lipid clinic. Patients who visit the clinic have a documented diagnosis of cardiovascular disease, peripheral vascular disease, or cerebrovascular disease and thus qualify for routine influenza vaccinations regardless of age. The clinical pharmacist collaborates with the cardiologists to optimize the pharmacologic and nonpharmacologic therapy for approximately 1000 patients/year.

Study Patients

The institutional review board at the University of Houston approved this project as a retrospective study. Eligible patients had a scheduled routine lipid clinic visit during the 2003-2004 influenza season (October 1, 2003-February 28, 2004) and the 2004-2005 influenza season (October 1, 2004–February 28, 2005). Immunization dates, clinic visit dates, age, and gender were routinely recorded for patients seen at the lipid clinic during both influenza seasons and stored in the patient's medical record. Data from the medical record were extracted to an administrative clinical tracking database. Immunizations received at other Kelsey-Seybold clinics were identified using the clinical tracking database for any patient from the lipid clinic with the International Classification of Diseases, Ninth Revision code for influenza immunization (V04.81).

Influenza Vaccine

During the 2003–2004 influenza season, no formal immunization program existed at Kelsey-Seybold. Clinics independently screened patients for influenza vaccination. During the 2004–2005 influenza season, the clinical pharmacist, residents, and students certified in immunization delivery screened patients and offered the influenza vaccination, under a standing-order protocol, to all patients treated at the lipid clinic as part of their usual activities. After appropriate screening, each patient requesting the vaccine received 0.5 ml intramuscularly. Vaccine delivery was documented in the medical record along with the vaccination date, vaccine lot number, manufacturer, expiration date, volume injected,

| | No. (%) o | No. (%) of Patients | | |
|-----------|-----------|---------------------|---------|--|
| | Influenza | Influenza | | |
| | Season | Season | | |
| | 2003-2004 | 2004-2005 | | |
| Variable | (n=476) | (n=266) | p Value | |
| Gender | | | 0.47 | |
| Male | 369 (78) | 200 (75) | | |
| Female | 107 (22) | 66 (25) | | |
| Age (yrs) | | | 0.0035 | |
| < 65 | 318 (67) | 149 (56) | | |
| ≥65 | 158 (33) | 117 (44) | | |

| Table 1. | Demographics | of the Study | Patients |
|----------|--------------|--------------|----------|
|----------|--------------|--------------|----------|

injection site, and signatures of both the patient and the vaccine administrator. Coding for vaccination and administration was added to the office visit billing form.

Statistical Analysis

Information collected for all study patients included identification number, date of clinic visit, receipt of influenza vaccine, gender, and age. From these data, the rate of influenza immunization was determined by dividing the number of patients receiving the influenza vaccine by the total number of patients seen in the lipid clinic during the specified 2003–2004 and 2004–2005 periods. Differences in immunization rates between the two periods were compared using χ^2 analysis. The SAS statistical program, version 9.1 (SAS Institute Inc., Cary, NC) was used for all analyses. A p value less than 0.05 was considered to indicate a statistically significant difference.

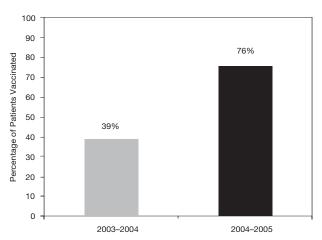


Figure 1. Vaccination rates in high-risk patients with cardiovascular disease before (gray bar) and after (black bar) implementation of a pharmacist-managed vaccination program (p<0.0001).

Results

A total of 476 and 266 patients were seen at lipid clinic visits during the 2003–2004 and 2004–2005 influenza seasons, respectively. During both seasons, the patients were mostly men (78% and 75%, respectively, p=0.47; Table 1). Fewer patients aged 65 years or older were seen during the 2003–2004 than the 2004–2005 season (33% and 44%, respectively, p=0.0035).

During the 2003–2004 influenza season, the overall vaccination rate was 39% in patients scheduled for lipid clinic visits (Figure 1). Rates increased significantly to 76% after vaccination was incorporated as part of the usual standard of care during the 2004–2005 season (p<0.0001). Of those receiving the vaccine during the 2004–2005 season, 133 (66%) were vaccinated during their routine lipid clinic visit.

No significant difference based on gender was noted in vaccination rates before and after implementation of the vaccination program (Figure 2). Before program implementation, patients younger than 65 years seen in the clinic were less likely to receive the influenza vaccine than those 65 years or older (29% and 58%, respectively, p<0.0001). Age disparity in vaccination rates was eliminated in this patient population after program implementation (Figure 3).

All opportunities for vaccination were provided during the originally scheduled 30-minute clinic appointment; screening, administration, and documentation required approximately 5 minutes. Follow-up for adverse effects was not planned; however, no adverse events were noted in the patients' medical records.

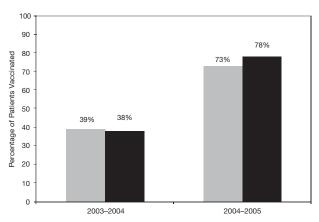


Figure 2. Distribution of vaccination rates in high-risk patients with cardiovascular disease by gender for the two influenza seasons (gray bars represent women, black bars represent men; p>0.4).

Discussion

The results of our study indicate that incorporating an influenza vaccination program into an established secondary prevention lipid clinic increased vaccination rates in high-risk patients with cardiovascular disease within a multispecialty group practice. The increase in vaccination rates at our clinic was approximately 2-fold, consistent with that seen in another pharmacist-managed vaccination program, in which vaccination rates increased from 24% to 54%.⁸ Our program was especially effective at increasing influenza vaccination rates in patients younger than 65 years. Vaccination rates were 76% after program implementation, exceeding the goal of 60% set by the Healthy People 2010 initiative for this age group.1 The 77% vaccination rate in those aged 65 years or older fell short of attaining the 2010 goal of 90%; however, improvements over the previous year's rate were observed.

Accessibility of the pharmacist with direct responsibility for patient evaluation and vaccine delivery in our lipid clinic likely contributed to the increased vaccination rates. Furthermore, availability of the vaccine at routine cardiology office visits allowed patients to be immunized with no additional visit to their primary care physician or vaccination clinic. Offering the influenza vaccine to patients in our clinic is now part of the standard of care. This follows the guidelines issued by the American Heart Association and the American College of

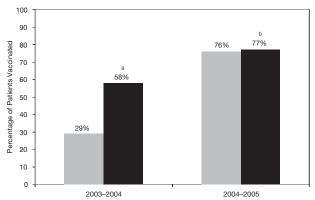


Figure 3. Distribution of vaccination rates in high-risk patients with cardiovascular disease by age for the two influenza seasons (gray bars represent age < 65 yrs, black bars represent age \geq 65 yrs). ^ap<0.0001 for the difference between age groups for the 2003–2004 season; ^bp>0.8 for the difference between age groups for the 2004–2005 season.

Cardiology advocating influenza vaccination for secondary prevention in patients with cardio-vascular disease.³

In our study, implementation of an influenza vaccination program in a cardiology clinic that employed a clinical pharmacist required minimal effort. The benefits of vaccinating patients with cardiovascular disease have been demonstrated. One study showed that influenza vaccination reduced hospitalizations for cardiac disease and stroke in those aged 65 years or older.9 A casecontrol study demonstrated that influenza vaccination reduced hospitalizations for acute respiratory and cardiovascular disease in highrisk adults aged 18-64 years.¹⁰ Moreover, additional studies have demonstrated that influenza vaccination was associated with reduced risk of stroke11 and of myocardial infarction in patients who had experienced one previously.12

Despite these findings, national immunization rates are below the goals set by the Healthy People 2010 initiative.¹ Published data from the Behavior Risk Factor Surveillance System survey indicated that 70% of those receiving the influenza vaccine did so in traditional health care settings, such as a physician's office.¹³ Therefore, our program provided the opportunity to target high-risk patients with cardiovascular disease and avoid missed opportunities for vaccination that may have contributed to low rates in this population during the previous year.

High-risk patients younger than 65 years have reported that the main reasons for not receiving vaccination against influenza were not knowing the vaccine was needed and not routinely being offered the vaccine.¹⁴ Furthermore, results of a nationwide survey suggested that practitioners may miss opportunities to vaccinate their highrisk patients because vaccination strategies were not built into their practice setting.¹⁵

Expanding the role of pharmacists as vaccination providers in our clinic has been valuable. Plans are in place to continue our program, with hopes of attaining the vaccination goals set by the Healthy People 2010 initiative. Our clinic also plans on offering the pneumococcal vaccine in addition to a yearly influenza vaccine.

Thus, pharmacists working in any clinic throughout ambulatory care centers are in a unique position to provide services due to their patient access, the minimal time required to immunize, and their ability to educate patients about the benefits of immunization. This premise is further strengthened by our study results, which demonstrated increased vaccination rates after implementation of an immunization program within a pharmacist-managed secondary prevention lipid clinic.

This study has several limitations. First, the influenza vaccination data were collected from the clinical tracking database, so vaccinations received outside the Kelsey-Seybold clinic would not have been recorded. Second, vaccination coding errors could have occurred, causing a misrepresentation of the vaccination rates. Third, the study design focused on providing comprehensive medical care, including influenza vaccination for high-risk patients, thus precluding evaluation of the vaccination's effectiveness in preventing influenza or its complications. Finally, because the clinical pharmacist responsible for scheduling patients had obligations with the college of pharmacy, fewer appointment slots were available during the second year of the program.

A potential limitation was posed by the unexpected shortage of vaccine during the 2004–2005 influenza season. However, all of our patients were in the high-risk category, and enough vaccine was provided to the clinic to ensure adequate immunization for this population.

Conclusion

To our knowledge, this study is the first to report an influenza vaccination program in an established secondary prevention lipid clinic. Our results proved conclusively that the pharmacist-managed immunization program improved vaccination rates. These rates increased significantly after implementation of the program, which targeted high-risk patients with cardiovascular disease. The significance and success of this program are further supported by the recently published secondary prevention guidelines advocating influenza immunization for this population. Based on the results of this study and on the recently published guidelines, as part of risk factor management, pharmacists should focus on preventive measures such as vaccinations.

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Stepwise approach to implementing ambulatory clinical pharmacy services

KELLY EPPLEN, MICHELLE DUSING-WIEST, JOANNA FREEDLUND, NICOLE HARGER, SUSAN KATHMAN, AND MARIANNE F. IVEY

harmaceutical care, defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life, has been adopted by much of the pharmacy profession.¹ Pharmacists in numerous settings have sought to reduce drug-related morbidity and mortality by providing service according to this model of care. The addition of clinical pharmacy services to health care teams has demonstrated significant cost savings to the health care system while improving patient satisfaction and therapy outcomes.²⁻⁴ Pharmacy services designed to improve patients' access to care, provide disease management, and focus on quality-related outcomes which contribute to optimizing drug costs.5

Multidisciplinary care models are now accepted and promoted by the medical community. A position statement released by the American College of Physicians and the American Society of Internal Medicine supports the development of pharmacist–physician collaborative care agreements.^{6,7} Many states have amended their pharmacy practice **Purpose.** A methodological approach was developed to facilitate expansion of clinical pharmacist-managed anticoagulation services across an integrated health care delivery network.

Methods. A stepwise approach to the development and implementation of ambulatory care clinical pharmacy services was used to facilitate expansion of pharmacistmanaged anticoagulation clinics in a university hospital setting and a community hospital within the same health network.

Results. The Health Alliance of Greater Cincinnati successfully created a care delivery model using clinical pharmacists to provide comprehensive anticoagulation management services at a university hospital and a community hospital. The incidence of thromboembolic events was significantly lower in the pharmacy anticoagulation service patients versus the patients in the usual care setting (p = 0.005). A statistically significant decrease in minor bleeding events was observed in the pharmacist-managed group (p = 0.038). Although a decrease in

major bleeding events was observed, it was not statistically significant (p = 0.075). International Normalized Ratio values of the patients managed by the pharmacy anticoagulation clinics were within the therapeutic range approximately 75% of the time.

Conclusion. A stepwise approach to the development and implementation of ambulatory care clinical pharmacy services has facilitated the expansion of pharmacistmanaged anticoagulation clinics across an integrated health system. This may serve as a valuable template for other systems as they strive to develop medication therapy management services.

Index terms: Ambulatory care; Anticoagulants; Clinical pharmacists; Clinical pharmacy; International Normalized Ratio; Interventions; Methodology; Models; Pharmaceutical services; Thromboembolism; Toxicity

Am J Health-Syst Pharm. 2007; 64:945-51

acts to allow for expansion of pharmacists' scope of practice.

In addition to state and professional organizations' support for the development of collaborative care agreements between pharmacists and physicians, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that medication therapy

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management services (MTMS) be offered by prescription drug plans to Medicare beneficiaries at high risk for adverse drug events. Neither the legislation nor the final ruling by the Centers for Medicare and Medicaid Services (CMS) provides guidance for designing or reimbursing MTMS programs. However, CMS has stated that programs should be "patient focused services aimed at improving therapeutic outcomes that are developed in conjunction with practicing pharmacists."⁸

There are numerous benefits resulting from the addition of clinical pharmacy services in the ambulatory care setting in disease areas such as anticoagulation, heart failure, lipids, diabetes, asthma, and vaccination.9 Recognizing the need to offer these services to distinctly different patient populations serviced by large health networks, a commitment was made to improve continuity of care and medication therapy outcomes of patients receiving care in the ambulatory care clinic systems of the Health Alliance of Greater Cincinnati. A methodological approach to implementing ambulatory clinical pharmacy services was developed to facilitate the implementation of several disease-management clinics including anticoagulation management, pharmacotherapy, and heart failure clinics across this integrated health care delivery network. The goal was to ensure seamless transition of patients from inpatient care to the outpatient clinic system.

As an integrated health care delivery network, the Health Alliance of Greater Cincinnati is composed of a university hospital and several community sites. With locations in multiple geographic regions, each of the hospitals within this network provides services to highly diverse patient populations.

Methods

Development of pharmacy anticoagulation services. A stepwise approach to the development and implementation of ambulatory clinical pharmacy services was used to help meet the needs of the distinct patient populations serviced by hospitals within the network. Using the following approach to facilitate the implementation of pharmacistdriven care delivery models in the ambulatory care setting, the Health Alliance was able to successfully implement numerous pharmacist clinics. The model was used to develop anticoagulation clinics at several Health Alliance institutions.

Needs assessment. Administrators and clinicians within the department of pharmacy identified patients at high risk for poor medication-related outcomes and patients in need of improved continuity of care. Patients most at risk included those with a high frequency of hospitalizations and emergency room visits, high morbidity and mortality related to diagnosis, the need for multiple medications, or the need for complicated drug therapy regimens.

Justification of services. The effect of clinical pharmacist interventions on clinical, economic, and humanistic outcomes was estimated using existing literature and institutionspecific statistics. Information regarding diagnostic-related grouping (DRG) volumes, patient payer mix (commercial third party, Medicare, Medicaid, other payment resources), medication costs, and resource use was collected on specific populations at most risk for poor medicationrelated outcomes.

Determination of scope of services to be provided. An evaluation of current state pharmacy practice acts was performed. A policy for the establishment of collaborative practice agreements was developed in conjunction with the drug policy and development committee for each of the participating hospitals.

Allocation of resources. A business plan was developed and presented to the corporate director of pharmacy services and hospital administration at each site. Costs related to required full-time equivalents (FTEs) including pharmacists and supportive personnel, space, and supplies (e.g., point-of-care devices, alcohol swabs, gloves) were estimated.

Projected patient volumes and revenue were estimated based on existing DRG information. Unfilled positions at each of the hospitals were identified as potential opportunities for hiring ambulatory care practitioners.

Identification of key stakeholders. Financial administration representatives were identified and contacted so that clear mechanisms for billing and revenue generation could be created. Presentations were made to the office of Medicare compliance to ensure compliance with CMS requirements. Registration and scheduling personnel were contacted to facilitate patient flow through the outpatient clinic systems.

Physicians willing to support the implementation of clinical pharmacy services in the ambulatory care setting were identified. Four physicians with interest and expertise in the areas of service to be implemented were asked to serve as medical directors for the pharmacist-managed clinics. Key laboratory personnel were contacted and collaboration occurred regarding point-of-care testing for anticoagulation monitoring.

Identification of quality standards. Practice standards were identified in the areas of service to be provided. Clinical practice guidelines were researched and used as education tools for involved clinical pharmacists.

Protocol development. Policies and procedures were developed for each clinical pharmacy service. Criteria for patient referral, collaborative practice documents, clinical evaluation models, methods for documentation, and channels for communication with responsible physicians were created. Point-of-care technology (CoaguChek, Roche Diagnostics and Hemachron Signature Plus, International Techidyne Corporation, Edison, NJ) and computer software (CoagClinic, Standing Stone, Inc., Westport, CT) were purchased.

Development of competency programs. Competency modules were developed for several areas of practice. Board certification programs, when offered in a specific area of practice, or continuing-education certification programs were completed by the pharmacists serving as directors of each clinic. A model for ongoing evaluation of staff competency was developed to ensure that participating staff members remain current in the selected areas of patient care.

Measurement of outcomes. The outcome measurements that were identified and collected included event rates, hospitalizations, emergency room visits, physician satisfaction, patient satisfaction, census growth, and revenue generation.

Development of mechanisms for reimbursement. A major barrier to the development and implementation of ambulatory clinical pharmacy services is the lack of clear-cut billing procedures to ensure reimbursement. A successful, standardized billing model was established for all pharmacist-managed clinics across the health system, allowing for justification and further development of ambulatory clinical pharmacy services. Codes specific to clinical pharmacy services within the ambulatory care clinic systems were created and applied to multiple institutions across the health system. A method for tracking charges and actual reimbursement was created.

Implementation of pharmacy anticoagulation services. Using this approach to the development and implementation of ambulatory clinical pharmacy services, two hospitals within Health Alliance successfully created a care delivery model using clinical pharmacists to provide comprehensive anticoagulation management services.

A university hospital experience. The University Hospital, Health Alliance, established the pharmacy anticoagulation service in the fall of 1997 as an extension of an outpatient treatment protocol for patients with uncomplicated deep-venous thrombosis (DVT). The objectives of the ambulatory pharmacy anticoagulation service were (a) to prevent thromboembolic events in patients on anticoagulant therapy, (b) to prevent hemorrhagic complications in patients on anticoagulant therapy, (c) to improve continuity of care for those patients requiring anticoagulation during transition from the inpatient setting to the ambulatory environment, and (d) to provide information and education on anticoagulation therapy to patients and health care providers.

The protocol allowed for early discharge (according to strict inclusion and exclusion criteria) for patients with DVT using subcutaneous administration of low-molecularweight heparin. This model of care allowed for the early and safe transition of patients from the inpatient to the outpatient setting. This innovative approach to the management of venous thromboembolic disease rapidly became the standard of care at the university hospital, with subsequent demand by physicians for an organized method for anticoagulation monitoring.

As the volume of referrals to the pharmacy anticoagulation service rapidly increased, additional support and resource allocation became necessary to maintain the intense level of patient care. As a result of the increased demand for clinical pharmacy anticoagulation services, on June 24, 1999, the pharmacy anticoagulation service ceased the acceptance of new patients for acute monitoring (for patients receiving low-molecular-weight heparin products) until medical directorship (oversight by medical staff with expertise in the area of anticoagulation), additional FTE allocation, office space, and reimbursement mechanisms were addressed.

On July 10, 2000, with support from the department of internal medicine and hospital administration, the pharmacy anticoagulation service became fully operational, accepting patients for acute monitoring and chronic monitoring (for patients receiving only oral anticoagulation). Collaborative practice agreements specify the desired length of anticoagulation therapy as determined by referring physicians. Point-ofcare technology is used to measure the intensity of anticoagulation for improving patient satisfaction. A Web-based, disease-management software program (CoagClinic) was purchased to facilitate data collection and analysis, documentation, and reporting.

A retrospective chart review was performed from July 2003 to January 2004 to compare the incidence rate of thromboembolic events (DVT and pulmonary embolism), major bleeding, and minor bleeding among patients referred to the pharmacy anticoagulation service versus patients whose anticoagulation was managed by methods employed in usual care settings. Major bleeding was defined as bleeding requiring treatment or that is life-threatening or fatal (e.g., overt gastrointestinal bleeding, gross hematuria requiring intervention, any bleeding requiring transfusion). Minor bleeding was defined as bleeding requiring no extra testing, referrals, or outpatient visits but remarkable enough to report to the provider (e.g., nosebleeds, bruising, hemorrhoidal bleeding, microscopic hematuria).

A community hospital experience. Recognizing that a successful model of care delivery utilizing clinical pharmacists for patients requiring anticoagulation therapy had been established at the university hospital, the Health Alliance department of pharmacy administration decided to pursue expansion of these services to its outlying community hospitals.

The St. Luke Hospitals, Health Alliance consists of two separate units (east and west) servicing two distinct geographic regions. The pharmacy anticoagulation clinic was established as an initiative to improve continuity of care by providing comprehensive anticoagulation management in the community hospital environment. The department of decision support provided information that illustrated that patients receiving anticoagulation therapy within the community hospital sites differ greatly from those in the university hospital setting with respect to indication for anticoagulation, average age, and demographic statistics (Table 1). The goals and objectives set forth by the department of pharmacy in establishing this service duplicate those of the university hospital service as clinical pharmacists strive to ensure the safe provision of anticoagulation management in a cost-effective manner.

The pharmacy anticoagulation clinics of the St. Luke Hospitals were established in May 2002 at the west unit and in November 2004 at the east unit. Consultative agreements with primary care physicians in the community setting were established whereby clinical pharmacists trained in anticoagulation monitored and adjusted anticoagulation therapy. Point-of-care technology was used to facilitate shorter turnaround time for laboratory results and improve patient and provider satisfaction.

The concept of clinical pharmacists managing anticoagulation therapy has rapidly gained popularity with area office-based cardiologists and primary care physicians. To accommodate the large influx of patients referred to the clinic, the pharmacy anticoagulation clinics of the St. Luke Hospitals implemented the

| Table 1. |
|--|
| Comparative Demographics of Pharmacy Outpatient |
| Anticoagulation Clinics |

| Demographic | University Hospital (n = 300) | Community Hospital East (n = 285) | Community Hospital West (n = 700) |
|--|-------------------------------------|---|---|
| Average age (yr) | 55.9 | 69.4 | 64.5 |
| Female sex (%) | 42.6 | 45 | 47.3 |
| Payer source (%) | | | |
| Medicare | 31 | 62 | 56 |
| Medicaid | 22 | 2 | 3 |
| Self-pay/tax levy | 37 | 1 | 1 |
| Private insurance | 10 | 35 | 40 |
| Indication for referral (%) ^a | | | |
| Afib | 22 | 65 | 48 |
| DVT | 21 | 7 | 13 |
| PE | 18 | 3 | 5 |
| CVA/TIA | 16 | 4 | 5 |
| MVR | 7 | 7 | 7 |
| AVR | 0 | 6 | 8 |
| Hypercoagulable state | 10 | 2 | 7 |
| PVD | 4 | 0 | 1 |
| CAD | 0 | 3 | 4 |
| Other ^b | 2 | 3 | 2 |

 a Afib = atrial fibrillation, AVR = aortic valve replacement, CAD = coronary artery disease, CVA = cerebrovascular accident, DVT = deep-vein thrombosis, MVR = mitral valve replacement, PE = pulmonary embolism, PVD = peripheral vascular disease, TIA = transient ischemic attack.

^bOther = chronic use of anticoagulants.

role of a clinical pharmacy technician. Responsibilities of this position included organization and management of patient flow, telephone triage and patient scheduling. In addition, the clinical pharmacy technicians were trained by clinical pharmacists and laboratory representatives to obtain blood pressure, pulse, and capillary whole blood samples for International Normalized Ratio (INR) determination. An examination was administered and competency established prior to allowing the clinical technician to obtain blood samples.

A strong relationship between time-within-therapeutic range (TTR) and bleeding or thromboembolic rates has been observed across a large number of studies.¹⁰ TTR has been calculated at each of the Health Alliance sites using the cross section of files methodology, in which a given date is selected and the proportion of INRs within target range, using the most recent INR value, is calculated for each patient.¹⁰

Results

In the University Hospital, Health Alliance, the anticoagulation service was instrumental in facilitating the transition of approximately 1000 patients (200 patients per year) requiring acute monitoring to the outpatient setting. Currently, the pharmacy anticoagulation service monitors 300 outpatients. The use of a Web-based software program has improved reporting capabilities for data such as TTR, patient census and volume fluctuation, indication for referral, and physician referral volumes.

Although the establishment of the service was not intended to generate revenue for the institution, increasing patient volume created a revenue stream due to capture of facility charges. In addition, cost avoidance secondary to decreased length of stay, demonstration in the literature of minimized adverse events subsequent to comprehensive anticoagulation management, and physician and patient satisfaction have helped to justify the service (Figure 1).^{10,11}

A retrospective chart review for outcomes of patients referred to the pharmacy anticoagulation service of the university hospital, Health Alliance (n = 61), versus patients whose anticoagulation was managed by methods employed in usual care settings (n = 61) revealed positive results in favor of clinical pharmacy services. The incidence of thromboembolic events was significantly lower in the pharmacy anticoagulation service patients versus the patients in the usual care setting (n = 0 versus n = 7, respectively; p = 0.005). In addition, a statistically significant decrease in minor bleeding events was observed in the pharmacist-managed group (n = 4 versus n = 10, respectively; p =0.038). A decrease in major bleeding events was observed, although it was not statistically significant (n = 0 versus n = 3, respectively; p = 0.075).

To date, the pharmacy anticoagulation clinics of the St. Luke Hospitals (east and west) are responsible for the anticoagulation management of approximately 1000 patients, experiencing a sharp increase from 175 in December 2003 (Figure 1). Patients managed by the pharmacy anticoagulation clinics of the St. Luke Hospitals have INR values within the therapeutic range approximately 75% of the time (Table 2). This is consistent with TTR values for anticoagulation management services reported in the literature.¹⁰ Patient satisfaction with the care provided by clinical pharmacists in the anticoagulation clinic is extremely high, as indicated by a recently administered internal survey (Table 3).

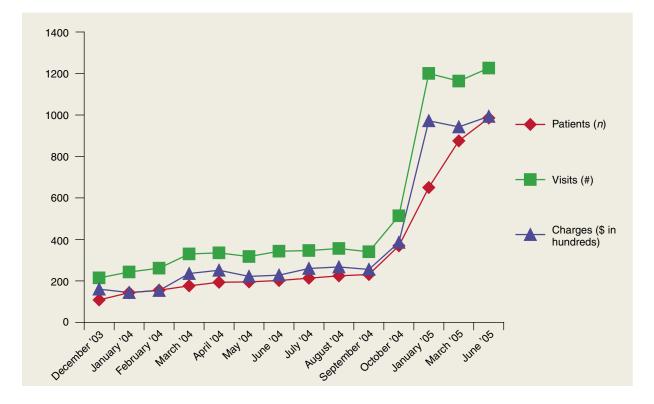
Discussion

The effect of clinical pharmacy services in the ambulatory clinic systems of this health system has been dramatic. The development of a stepwise approach to the implementation of these services has greatly facilitated expansion of services across an integrated health care delivery network. With multiple institutions representing vastly different patient populations, the Health Alliance of Greater Cincinnati recognized the need to expand clinical services in the ambulatory environment at each site. Using this template for ambulatory program development, a successful model for clinical pharmacist anticoagulation management services has been created.

Several distinct components of this program make it unique:

- 1. A successful model of care was created in a university hospital setting and subsequently adapted to meet the needs of a community hospital.
- A standardized billing model (using facility charge codes created specifically for pharmacist-managed clinics) was created, facilitating appropriate channeling of revenue to pharmacy cost centers across the health system.
- 3. An overwhelming response has been voiced by community physi-

Figure 1. Growth of the pharmacy outpatient anticoagulation clinic in the community hospital.



cians in favor of implementing collaborative agreements with clinical pharmacists to improve medication therapy outcomes. Many state boards of pharmacy have implemented similar collaborative practice agreements, facilitating the development and implementation of ambulatory clinical pharmacy services across state boundaries.

- 4. The role of a clinical pharmacy technician has been created to accommodate increasing patient referrals, allowing for increased clinic organization and decreased pharmacist overtime.
- 5. Improved continuity of care and patient outcomes, including statistically

significant decreases in thromboembolic events and minor hemorrhagic events, increased TTR, and increased patient satisfaction, have been established in the pharmacy anticoagulation clinics across the Health Alliance.

The development and implementation of ambulatory clinical pharmacy services is often met with several barriers including the lack of clear-cut billing mechanisms and processes for reimbursement, the lack of support from hospital administration, staff shortages, and resistance from physicians. CMS has stated that MTMS must "evolve and

Table 2.Patients from the Community Hospital Clinics with INR Valueswithin Therapeutic Range^a

| Clinic | Patients | Total | | No. (%) Patier | nts |
|----------|----------|------------|----------|----------------|--------------------|
| Location | (n) | Visits (n) | In Range | Out of Range | In Range \pm 0.2 |
| West | 498 | 588 | 365 (62) | 223 (38) | 450 (77) |
| East | 258 | 355 | 232 (65) | 123 (35) | 266 (75) |

^aINR = International Normalized Ratio.

Table 3.

Patient Satisfaction Survey Results

| | Mean \pm S.D. Score ^a | |
|--|------------------------------------|---------------------------------|
| Survey Items | University Hospital | Community Hospitals |
| I have a better understanding of my anticoagulation medications (blood thinners) | | |
| since I have been coming to the pharmacy anticoagulation clinic. | $\textbf{4.9}\pm\textbf{0.4}$ | 4.5 ± 0.8 |
| The pharmacists have been available to me when I have needed help. | $\textbf{4.9}\pm\textbf{0.4}$ | 4.8 ± 0.6 |
| The appointments with the pharmacists have not been kept on time. | 1.8 ± 1.5 | 2.0 ± 1.7 |
| The pharmacists have provided care in a friendly and considerate manner. | 4.9 ± 1.9 | 5 ± 0 |
| I feel comfortable knowing that the pharmacists are monitoring my Coumadin | | |
| therapy. | $\textbf{5.0} \pm \textbf{0.2}$ | 4.8 ± 0.5 |
| The pharmacists have helped me feel at ease about my medical condition. | 4.9 ± 0.4 | 4.6 ± 0.8 |
| I am satisfied with the monitoring of my anticoagulation therapy by the | | |
| pharmacy anticoagulation clinic. | $\textbf{4.9}\pm\textbf{0.4}$ | $\textbf{4.7}\pm\textbf{0.7}$ |
| Thirty minutes is not enough time for the pharmacist to address all of my | | |
| questions. | 1.9 ± 1.3 | $\textbf{2.0} \pm \textbf{1.4}$ |
| I feel there is good communication between the pharmacists and my primary | | |
| care doctor or cardiologist. | 4.6 ± 0.8 | $\textbf{4.6} \pm \textbf{0.8}$ |
| I prefer to have my blood tested by using a fingerstick machine instead of the | | |
| usual blood draw (using a needle and tube). | $\textbf{4.8}\pm\textbf{0.6}$ | 4.7 ± 0.6 |

^aStrongly disagree = 1, disagree somewhat = 2, neither disagree nor agree = 3, agree somewhat = 4, strongly agree = 5.

become a cornerstone of the Medicare Prescription Drug Benefit."¹² The creation of this methodological approach to the development of ambulatory clinical services can be used as a template to help other integrated health care delivery networks overcome these barriers and improve continuity of care for patients as they develop MTMS programs.

Conclusion

A stepwise approach to the development and implementation of ambulatory care clinical pharmacy services has facilitated the expansion of pharmacist-managed anticoagulation clinics across an integrated health system. This may serve as a valuable template for other systems as they strive to develop MTMS.

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Evaluation of a pharmacist-managed hepatitis C care clinic

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n 2000, hepatitis C virus (HCV) infection was first termed the silent epidemic because of the growing population of infected Americans with advanced liver disease seeking hospital treatment.¹ With greater than 3 million Americans infected with HCV, liver disease due to hepatitis C infection is the leading indication for liver transplantation. The U.S. Department of Veterans Affairs (VA) reports that 5.4% of U.S. veterans tested are infected, and the prevalence of an infected Vietnamera veteran is as high as 11%.

Acute HCV infection produces vague constitutional symptoms in only 25% to 30% of patients and is entirely asymptomatic in the remaining patients, although the conversion rate from acute to chronic hepatitis is as high as 85%.² Chronic HCV infection leads to cirrhosis in about 20% of patients within 20 years and conveys a 1% to 4% risk of hepatocellular carcinoma per year after the development of cirrhosis.3 Compared with the 1970s and 1980s, the number of patients with decompensated liver disease continues to rise due to the naturally long disease course.³

The key to preventing the development of complications arising **Purpose.** A description of an effort to create a more time, labor, and cost-efficient method for the management of patients with hepatitis C virus (HCV) infection in Department of Veterans Affairs (VA) hospitals is provided; this pilot study also revealed the outcomes of a pharmacist-managed clinic for these patients in comparison to established standards of care.

Methods. A retrospective analysis was performed on data obtained from patients who were referred to the clinic between October 2002 and March 2004 and who had a clinical pharmacist as their primary treatment provider. The patients' medical records were searched for demographic information, disease characteristics, treatment information, treatment and safety information, and virological response.

Results. Thirty-one patients were evaluated, and 27 were offered antiviral therapy in the hepatitis C care clinic between October 2002 and March 2004. Of the 27 patients who had sufficient data for analysis, there was a sustained response rate of 63% (17 of 27) overall after treatment with peginterferon and ribavirin combination therapy. Only 3 patients (11%) stopped therapy early secondary to adverse effects, whereas 8 (30%) were managed with growth factors.

Conclusion. VA patients managed by a clinical pharmacist for the treatment of chronic HCV infection demonstrated similar treatment outcomes compared with the results from earlier studies with VA patients managed with traditional care. Further studies are warranted to investigate the role of the pharmacist in the management of patients with HCV infection.

Index terms: Ambulatory care; Antivirals; Clinical pharmacists; Combined therapy; Economics; Hematopoietic agents; Hepatitis C; Peginterferon alfa 2-a; Peginterferon alfa 2-b; Ribavirin; Toxicity

Am J Health-Syst Pharm. 2007; 64:632-6

from end-stage liver disease lies in the early detection and treatment of these patients. Most veterans with HCV were identified during a VAwide screening initiative.⁴ Nevertheless, the treatment of chronic HCV infection is labor, time, and cost intensive. The total cost of HCV infection in the United States in 1997 was estimated at \$5.46 billion, about 67% of which was attributed to indirect costs.⁵ The high cost of treatment is not only due to the cost of the medications, but also due to the need for extensive patient selection and careful monitoring for the development of treatment-related adverse effects, which may range from nonspecific

Supported by the Department of Veterans Affairs.

DOI 10.2146/ajhp060153

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Hal Yee, Jr., M.D., Ph.D., Steven Han, M.D., Peggy Keyes, PA-C, Sarla Duller, N.P., Jeffrey Sayers, Pharm.D., and the department of pharmacy are acknowledged.

flu-like symptoms in the majority of patients to life-threatening depression and neutropenia experienced in 10% to 14% of patients.⁶

The accepted standard for a durable response to HCV treatment is termed the sustained virological response or SVR, defined as having undetectable virus measured by the most sensitive available test six months after treatment cessation. The SVR correlates well with sustained remission and thus has been universally adopted as the most important surrogate outcome.7 Recent clinical trials have documented the overall SVR for patients treated with pegylated interferon and ribavirin combination therapy to be between 50% and 60%.8,9 If greater than 80% of the prescribed medications were administered, SVR rates approached 75%.10 Mechanisms to improve adherence to therapy include pharmacologic management of treatmentrelated adverse effects and careful selection, monitoring, and education of patients.

As attention began to focus on hepatitis C among veterans, the General Accounting Office (GAO) launched a study to monitor the efficiency of VA in responding to referrals to specialty clinics responsible for evaluating hepatitis C-positive veterans. The report stated that in 30 out of the 101 facilities surveyed, there was greater than a 30-day delay to notify patients of positive HCV results, with 52 of 123 facilities having delays greater than 60 days for patients to see a physician specialist.11 Another study reported that only 13.8% of VA patients with HCV were suitable candidates for therapy, and of those treated with antiviral combination therapy, approximately 14% achieved an SVR compared with 47% achieving a sustained response in non-VA patients treated with the same regimen.8 Since VA is a capitated system, a clear need was established for cost-effective care of veterans infected with hepatitis C. Recommendations from the GAO

study included using midlevel practitioners as providers of care for veterans with HCV infection.¹¹

VA has recognized that clinical pharmacists can act as physician enhancers, applying their specific drug therapy knowledge to improve patient outcomes. Hepatitis C therapy offers a particular set of challenges to patients and providers alike that necessitate a midlevel provider to bridge the gap. Pharmacists offer a skill set ideal for improving treatment outcomes of hepatitis C-infected individuals.12 A test was conducted of the hypothesis that a pharmacist, in the context of a comprehensive hepatitis C care clinic, can safely achieve outcomes for hepatitis C therapy comparable to those achieved in traditional settings.

Retrospectively, this pilot study reveals the outcomes of the clinic in comparison to established standards of care, as derived from major clinical trials. The goal of this retrospective analysis is to report the response rates to therapy and the incidence and management of treatmentrelated adverse effects.

Methods

This pilot study was approved by the VA investigational review board. An agreement between the medical service, division of gastroenterology, and department of pharmacy was made to enable a clinical pharmacist to collaborate with a supervising physician under a scope of practice. A pharmacy fellow was accordingly employed and trained by existing gastroenterology staff to implement and maintain a pharmacist-managed hepatitis C therapy clinic.

All patients who were referred to the hepatitis C clinic between October 2002 and March 2004 were potential candidates for this analysis. Participants were selected from this pool if they received their follow-up care from the clinical pharmacy fellow. Patients were randomly referred by primary care physicians using existing hospital guidelines for management of hepatitis C-positive patients. These criteria minimally require a detectable hepatitis C antibody and an alanine aminotransferase (ALT) elevation twice the upper limit of normal (45 units/L).

Patients were evaluated by a staff gastroenterologist and determined to be appropriate for combination therapy by using inclusion and exclusion criteria published in VA treatment guidelines¹³ and National Institutes of Health Consensus Development Conference recommendations.¹⁴ Based on these criteria, patients eligible for combination therapy should have virological, clinical, or laboratory evidence of HCV infection as determined by the presence of positive HCV antibodies, detectable HCV ribonucleic acid (RNA), or evidence of HCV-related disease. Patients eligible for therapy should be free from alcohol and substance abuse for greater than six months; have stable psychiatric conditions; have well-compensated liver disease; have an absence of unstable, life-limiting, or life-threatening medical conditions; be willing to show adherence with treatment; and be willing to use adequate birth control. Pretreatment liver biopsies were performed at the discretion of the evaluating physician.

All patients that fit these criteria and agreed to initiate combination therapy were included in the final analysis. A clinical pharmacy fellow was employed to conduct the monitoring and act as the primary provider of medical care related to the patient's combination therapy. The clinical pharmacy fellow received his training from the department of pharmacy and the division of gastroenterology at the local institution.

Eligible patients with HCV genotype 1 or 4 were treated for 48 weeks with peginterferon alfa-2b (Peg-Intron, Schering-Plough Corp., Kenilworth, NJ) 1.5 μ g/kg/week or peginterferon alfa-2a (Pegasys, Roche, Basel, Switzerland) 180 μ g/ week in combination with ribavirin 1000–1200 mg/day. Patients with HCV genotype 2 or 3 were started on 24 weeks of the same interferon regimen and ribavirin 800 mg/day.

Once a patient was determined to be suitable for treatment, the clinical pharmacist scheduled an initial appointment to discuss treatment strategies, review medication administration, and provide education and support regarding chronic hepatitis C infection. At the initial visit, the clinical pharmacist recorded the patient's medical history as it pertained to the management of hepatitis C antiviral therapy. The clinical pharmacist followed patients with monthly visits and laboratory tests to monitor for treatment response and adverse reactions, particularly hemolytic anemia, neutropenia, thrombocytopenia, depression (followed with the Beck Depression Inventory), insomnia, and thyroid abnormalities. At 12 weeks, the end of treatment, and at six months posttreatment, the viral load and qualitative HCV polymerase chain reaction (PCR) assay were obtained to assess the virological response.

Patients who failed to achieve an early virological response (defined as either undetectable or greater than 2 log decrease in viral load at treatment week 12) or who relapsed (defined as undetectable HCV by PCR assay obtained during or at the end of treatment, followed by a detectable HCV by PCR value obtained at a later date) were discontinued from treatment. End of treatment response was defined as the absence of detectable HCV RNA by PCR at the end of the treatment course. SVR was defined as having undetectable virus measured by the most sensitive available test six months after treatment cessation. The primary treatment and followup of these patients were performed by the clinical pharmacy fellow, under the supervision of an attending gastroenterologist, with referrals to psychiatry, psychology, and specialty services as needed.

An investigator not directly involved in the care of the study population retrospectively searched the participants' medical records for demographic information (age, sex, race, prior psychiatric history), disease characteristics (HCV genotype, viral load, ALT levels, liver biopsy results, abdominal ultrasound results, results of prior treatment for HCV infection), treatment information (treatment regimen, dosage, duration), safety information (requirements for medication dosage reductions, requirements for growth factors, adverse reactions), and virological response (viral loads; qualitative HCV RNA detection by PCR; ALT levels at 12 weeks, at the end of treatment, and at six months posttreatment). Histological results were classified by pathologists according to the METAVIR scale, which reports fibrosis stage on a 5-point scale (no fibrosis, stage 0, to cirrhosis, stage 5).¹⁵

Results

Tabla 1

Demographics. Of the 31 patients who were referred to the hepatitis C clinic between October 2002 and March 2004 for combination therapy, 27 patients received the therapy under the guidance of the clinical pharmacy fellow. Four patients were deemed not suitable for treatment according to the gastroenterologist's interpretation of VA treatment guidelines and were not included in the analysis. Follow-up data are available for the treated patients up to 24 weeks after the end of treatment. The patient population studied was too small to extrapolate to the typical composition of veterans seeking care in the VA health care system (Table 1).

Nevertheless, a psychiatric diagnosis before initiation of treatment did approach reported rates seen in veterans. The majority of psychiatric diagnoses in this study population were depression or posttraumatic stress disorder (Table 2). In addition, two patients had prior treatment for HCV infection: one had received interferon monotherapy while the other had received combination therapy with interferon and ribavirin.

Treatment data and virological response. In total, 24 of 27 patients successfully completed their pre-

| atient Characteristics | |
|--|---------------------------|
| Characteristic | Patients (<i>n</i> = 27) |
| No. male | 26 |
| Mean \pm S.D. age (range), yr | 51.9±3.6 (44–58) |
| Ethnicity, no. (%) | |
| Caucasian | 13 (48) |
| African-American | 4 (14.8) |
| Hispanic | 1 (3.7) |
| Mixed | 1 (3.7) |
| Unspecified | 8 (29.6) |
| Mean \pm S.D. ALT ^a (units/L) | 114±53.8 |
| HCV genotype, no. (%) | |
| 1 | 15 (55.6) |
| 2 | 5 (18.5) |
| 3 | 7 (25.9) |
| Fibrosis ($n = 10$), no. | |
| Stage 0–2 | 5 |
| Stage 3–4 | 5 |
| Ultrasound results ($n = 24$), no. (%) | |
| Normal | 8 (33.3) |
| Hepatomegaly, fatty change | 15 (62.5) |
| Possible cirrhosis | 1 (4.2) |

^aHCV = hepatitis C virus, ALT = alanine aminotransferase.

scribed therapeutic regimens. After six months of follow-up using intent-to-treat analysis, stratified by genotype, 17 of 27 (63%) were able to achieve an SVR, 8 (30%) relapsed, and 2 (7%) were nonresponders.

Patients with genotype 2 or 3 were more likely to achieve an SVR than those with genotype 1. Of the 15 HCV genotype 1 patients, an SVR was achieved in 9 (60%), 4 relapsed (27%), and 2 (13%) did not respond. Among the 12 genotype 2 or 3 patients, 8 (67%) patients achieved an SVR, and 4 patients (33%) relapsed. Among the group of 21 patients who received peginterferon alfa-2a therapy with ribavirin, 12 patients (57%) achieved an SVR, 8 (38%) relapsed, and 1 (5%) did not respond to therapy. Among the 6 patients who received peginterferon alfa-2b therapy with ribavirin, 5 (83%) achieved an SVR and 1 (17%) relapsed.

Safety. During the period where patients were being monitored, a peer-reviewed protocol designed to guide adjunctive therapies for HCV, including the use of growth factors, did not exist. However, the available data supported the importance of maintaining baseline ribavirin dosages during a patient's course of therapy. Accordingly, growth factors were used to treat appropriate symptoms and continue therapeutic dos-

| Table 2. |
|----------------------------------|
| Psychiatric History before |
| Initiation of Treatment (n = 27) |

| Diagnosis | No. (%) Patients |
|---|---------------------|
| Depression | 8 (30) |
| PTSD ^a | 6 (22) |
| Anxiety | 2 (7) |
| Bipolar disorder | 2 (7) |
| Other ^b | 3 (11) |
| More than 1 diagnosis | 5 (19) |
| Overall ^c | 16 (59) |
| ^a PTSD – posttraumatic stress di | sorder |

^aPTSD = posttraumatic stress disorder. ^bIntermittent explosive disorder, obsessivecompulsive personality disorder, and schizophrenia. ^cSome patients had more than one concurrent diagnosis.

use of other medications required for treatment-related adverse effects. No patients developed any life-threatening complications.
biscussion
a-2a The majority of patients evalu-

administration.

The majority of patients evaluated (87%) started on treatment with either peginterferon alfa-2a or alfa-2b and ribavirin. Such a high percentage of treatment-eligible patients may indicate a self-selecting group and give reason to doubt that they are representative of all veterans. Of those who were eligible and initiated treatment, 63% overall were able to achieve an SVR, comparable to results of prior studies of nonveterans treated with the same regimen (55%).¹⁶ A concurrent safety analysis indicated that only 11% of patients discontinued treatment secondary to adverse effects. In comparison, pivotal clinical trials reached 42-46% SVR for genotype 1 patients and 76-82% SVR for genotype 2 and 3 patients, and up to 42% of patients required dosage reductions, temporary or permanent, for either type of peginterferon.16

ages of ribavirin and peginterferon

alfa. In total, dosage reductions and

use of growth factors due to cyto-

penias were necessary in 12 (57.1%)

patients (Table 3). Two patients were

discontinued from treatment because

of cytopenias that were refractory to

dose reductions and growth factor

In addition, Table 3 reports the

Antiviral therapy for hepatitis C infection is associated with a high incidence of adverse effects. In the veteran population especially, nearly 75% of veterans infected with HCV carry a psychiatric diagnosis. The well-known psychiatric adverse effects of interferons complicate treatment of this population.¹⁷ In addition to psychiatric adverse effects, hematologic adverse effects complicate treatment.^{6,18} We managed hematologic adverse effects effectively, with 88.9% of patients initiated on therapy completing the treatment course. Only 11% were discontinued from treatment because of adverse reactions whereas 41% of patients were managed with peginterferon or ribavirin dose reductions, consistent with data obtained from registration trials.^{8,9,19}

The patients treated through our HCV care clinic are representative of the veteran population at large²⁰ in terms of overwhelming male predominance (26 versus 1), an older age at initiation of treatment (mean of 52 years), and a high proportion of patients with prior psychiatric histories (59%). Being male is predictive of more severe disease, whereas age over 40 years and previous nonresponse to treatment are some of the predictors of poor response to treatment.²¹ Unstable psychiatric issues and ongoing substance abuse are the most common reasons for treatment ineligibility among veterans.¹⁷

Nonadherence is also a major issue at many veterans hospitals. In a study conducted at a VA medical center, for example, the HCV clinic attendance rate was only 44%.22 In our clinic, no patients were lost to follow-up. Adherence significantly affects treatment outcome, as shown in a study of genotype 1 patients, where 51% of patients who took more than 80% of the prescribed doses of peginterferon alfa-2b and ribavirin were able to attain an SVR versus only 42% of patients who were adherent to less than 80% of the combination regimen.¹⁰ The rate of adherence was not reported in this study because no formal adherence measure was used. However, there were no patients who self-reported missing any doses of study medication.

A specialized, dedicated hepatitis C care clinic is the ideal way to manage HCV-infected patients in a time-efficient manner. The effect on resource usage by the addition of a clinical pharmacist into the treatment team was not formally measured in this study. Nevertheless, we did note that the rate of response and responsible management of adverse effects warranted further quantita-

Table 3.

Protocol Modifications and Interventions Given during the Course of Therapy (n = 27)

| Intervention | No. (%) Patients |
|--|------------------|
| Required dosage reduction ^a | |
| Peginterferon alfa-2a or alfa-2b | 7 (26) |
| Ribavirin | 4 (15) |
| Required growth factors | |
| Epoetin alfa | 8 (30) |
| Filgrastim | 0 |
| Discontinuation of HCV ^b treatment due to adverse treatment | |
| effects | 2 (7) |
| New psychiatric medications started ^c | |
| Sedative-hypnotics ^d | 8 (30) |
| Antidepressants ^e | 5 (19) |
| Exogenous thyroxine replacement ^f | 2 (7) |

^aOne patient required dose reductions of peginterferon alfa-2a and ribavirin.

^bHCV = hepatitis C virus.

Three patients required a hypnotic and an antidepressant.

^dDiphenhydramine, lorazepam, temazepam, trazodone, and mirtazapine.

^eCitalopram, sertraline, and doxepin.

^fDue to treatment-induced hypothyroidism.

tive evaluation of the pharmacist's clinical services. In addition, having a dedicated clinic ensured adequate patient education and support and provided a standardized protocol.

Since the treatment of chronic hepatitis C revolves around medication and adverse effect management, it is sensible for a clinical pharmacist or other physician extenders, who are specially trained to deal with these issues, to be the primary care provider for HCV patients requiring antiviral treatment.23 Through this analysis, we have shown that our clinic can achieve SVR rates comparable to traditional physician-managed clinics or to therapy managed by individual subspecialists. The 63% SVR rate may reflect the small sample size, a relative enrichment of non-1 genotype subjects (44% as compared with 25% in nonveteran populations²), or preselection of patients for adherence and motivation. Nevertheless, the comprehensive care provided to our patients was likely to enhance adherence and increase the number of patients able to tolerate therapy and complete treatment. In addition, we have shown that having a clinical pharmacist manage HCV patients did not increase the incidence of adverse events.

Conclusion

VA patients managed by a clinical pharmacist for the treatment of chronic HCV infection demonstrated similar treatment outcomes compared with the results from earlier studies with VA patients managed with traditional care. Further studies are warranted to investigate the role of the pharmacist in the management of patients with HCV infection.

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ORIGINAL ARTICLE

The impact of pharmacist-managed oral anticoagulation therapy in older veterans

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SUMMARY

Background: Older adults frequently have conditions requiring oral anticoagulation. Although clearly benefiting from oral anticoagulation, they are at increased risk for bleeding complications. Regular monitoring to optimize anticoagulation and to reduce the chance of major bleeding complications is required. The impact of oral anticoagulation monitoring by pharmacists in patients older than 75 years of age has not been described well.

Objective: To compare warfarin therapy prescribed and monitored by physicians to a pharmacist-monitored anticoagulation service in a cohort of older veterans.

Methods: Retrospective chart review utilizing the Houston VA Medical Center's pharmacy database. Among all outpatients aged 75 years or older filling warfarin prescriptions between 1 March 2003 to 1 March 2005, and who were either monitored in a pharmacist's clinic or not, 103 patients per group were randomly selected. Information on demographics, indication for and length of warfarin therapy, INR values, and thromboembolic and bleeding events were abstracted. Differences were analysed using chisquared test, Fisher's Exact test, and unpaired Student *t*-test.

Received 7 August 2006, Accepted 11 October 2006

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Results: A total of 1521 patients (440 in the pharmacist-monitored group, 1081 in the traditionally monitored group) met our inclusion criteria. One hundred and three patients per group were randomly selected for chart review. Although no significant difference in percentage of therapeutic INR values (48.1% pharmacist group, 46.4% conventional group) or in the incidence of major bleeding events was found, thromboembolic events occurred significantly less frequently in the pharmacist-monitored group (2 events vs. 12 events, P = 0.01). Minor bleeding events were more frequent in the pharmacist-monitored group (50 vs. 17, P < 0.01). However, time to follow-up after a sub- or supra-therapeutic INR was significantly shorter in the pharmacist monitored group (22 days vs. 68 days, and 14 days vs. 32 days, respectively).

Conclusion: Pharmacist-monitored anticoagulation was associated with reduced thromboembolic events, an increase in minor bleeding events, and no difference in major bleeding events. Overall such monitoring by pharmacists should be recommended for older adults.

Keywords: anticoagulation, elderly, pharmacist, warfarin

INTRODUCTION

The clinical effectiveness of warfarin has been established by well-designed clinical trials for both primary and secondary prevention of thromboembolic events (1, 2). Guidelines developed by the American College of Chest Physicians (ACCP) and adapted by the American Geriatrics Society

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recommend warfarin use in elderly patients with chronic atrial fibrillation, prosthetic heart valves replacement, and recent thromboembolism (3). A prospective cohort study found that 30% of 2745 patients starting oral anticoagulation therapy were older than 70 years (4). Atrial fibrillation alone affects approximately 10% of individuals 80 years of age or older, and with the exponential increase of the 'oldest old' population, the prevalence of older adults receiving warfarin therapy is rising (5, 6).

Despite known benefits, warfarin is reportedly underused in the elderly due to concerns about an increased risk of warfarin-related bleeding (7–9), drug interactions and polypharmacy (10, 11), multiple comorbidities, insufficient social support, and reduced functional status (12, 13). The changes in pharmacokinetics and pharmacodynamics associated with aging add challenges in maintaining warfarin within therapeutic range (14). Among 12 202 patients older than 70 years of age, an initiation dose of 5 mg/day was found to be excessive for 82% of women and 65% of men (15). Similarly, a retrospective study (n = 253 patients, mean age 80.6 years) found that the required warfarin dosage for maintenance therapy was inversely related to age (14). Thus, close monitoring of older adults receiving warfarin is required to maintain the drug at a therapeutic range and to minimize the risk of adverse drug events (16).

Pharmacist-monitored anticoagulation services have been documented to be beneficial in improving access to anticoagulation (17) and reducing warfarin-related complications. (18–20) However, little is known regarding the use of pharmacist clinics to optimize management of anticoagulation therapy in patients older than 75 years of age. Therefore, the purpose of this study was to compare warfarin therapy prescribed and monitored by a physician (traditional monitoring) with a pharmacist-monitored anticoagulation service by measuring International Normalization Ratios (INRs), thromboembolic events, and bleeding complications in a cohort of veterans older than 75 years.

We hypothesized that the pharmacist-monitored group would have a higher percentage of therapeutic INRs, have a faster follow-up after supra or subtherapeutic INRs (thus achieving quicker optimal anticoagulation), and experience fewer thrombotic or bleeding events than the traditionally monitored group.

METHODS

Settings

The Michael E. DeBakey Veteran Affairs Medical Center (MEDVAMC), located in Houston Texas, is a teaching facility with 352 hospital beds and serves as the primary health care provider for more than 103 000 veterans in south-east Texas. Clinical pharmacists receive referrals for anticoagulation services by individual patients' primary care physicians and manage warfarin therapy in accordance with the ACCP guidelines (1, 2). During each pharmacist encounter for anticoagulation services, the pharmacist documents findings in a standardized electronic template providing a patient's demographic information, the indication for anticoagulation therapy, the target INR range, past medical history, social history, medication history, diet history, laboratory data, assessment and plan. Pharmacists verify patients' warfarin dosages and assess patients for changes in medications, dietary changes, haemorrhagic and thromboembolic signs and symptoms, missed doses, and illnesses. Once enrolled, patients are seen for 15- to 30-min appointments. Prothrombin time and the INR are collected by the facility's laboratory an hour before each scheduled appointment. Pharmacists discuss the results with the patient, adjust the warfarin dosage as necessary, and schedule the follow-up visit.

Traditional monitoring refers to monitoring by physicians during routine visits that not only address anticoagulation management but also all of the patient's other medical problems. Although physicians write an electronic progress note that usually follows a template, they do not use a special template to document anticoagulation monitoring.

Study design

After the institutional review boards of Baylor College of Medicine and the MEDVAMC approved the study protocol, a retrospective chart review was conducted for a random sample among all patients aged 75 years or older receiving warfarin

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at the MEDVAMC during the period of 1 March 2003 to 1 March 2005. The percentage of therapeutic, sub-, and supra-therapeutic INRs, and the incidence of thromboembolic and bleeding events were abstracted from patients' electronic charts.

Subject selection

From the MEDVAMC pharmacy database two lists of outpatients aged 75 years or older who filled warfarin prescriptions in the study period were generated. The first listed all patients who attended pharmacists' clinics, and the second listed all patients who were seen by their primary care provider, and not by a pharmacist. From each list two cohorts of 103 patients per group were selected using a random number generator. The sample size of 103 patients per group was based on an alpha of 0.05, 80% power, and an estimated effect size of a 20% decrease in thromboembolic events in patients monitored by pharmacists.

All patients included in this study received outpatient maintenance warfarin therapy for at least three consecutive months. Patients with only one or no INR laboratory values obtained as outpatients were excluded because it was not practical to calculate a percentage of therapeutic INRs. INR values obtained during a patient's hospitalization were excluded as we were interested only in outpatient monitoring.

Data collection

The electronic record of each patient meeting our inclusion criteria was reviewed using the electronic Clinical Patient Record System (CPRS) database at the MEDVAMC. During the chart abstraction process, data were recorded into a standardized data collection form, which included demographic information such as age, gender, race and ethnicity of each patient, indications for warfarin use, dates and results of INRs obtained, period between consecutive INR values, incidence of thromboembolic events, and incidence of minor and major bleeding events during the study period. Thromboembolic events included new onset of stroke, transient ischaemic attack, arterial thrombosis, pulmonary embolism, deep venous thrombosis and myocardial infarction while receiving oral anticoagulation therapy. Major bleeding events were defined as bleeding that caused hospitalization, retinal bleeding, or required blood transfusions. Minor bleeding events included bruising, nosebleeds, gum bleeding, haematuria, or rectal bleeding not requiring further action. All INR values recorded under the laboratory results tab in the electronic chart were reviewed. Additionally, all progress notes in the study period were read searching for documentation of INR values that had been obtained outside of the VAMC. Some patients who come to the VA for prescriptions only, often will show the warfarin-prescribing VA physician laboratory values obtained elsewhere, e.g. at a private physician's office. Thus, all progress notes were reviewed for documentation of INR values from outside the MEDVAMC.

Some patients were monitored successively by both physicians and pharmacists. For example, a patient's warfarin therapy could have been initially managed by a physician and subsequently a referral for pharmacy management was made. We placed such patients in the pharmacist-monitored group and included only INR values that were obtained after their first visit with a pharmacist, i.e. INR laboratory data collected prior to or after the pharmacist-monitored period (in case a patient was discharged from a pharmacist clinic) were excluded.

Statistical analysis

Indications for warfarin therapy were described by group. From the overall time period of warfarin therapy, the percentage of therapeutic INRs was calculated as number of therapeutic INRs divided by the total number of INRs obtained, again separately for each group. The percentages of sub- or supra-therapeutic INR values were calculated in three categories: INR ≤ 1.5 , INR 4–9, INR > 9. The mean number of INR measurements and the mean number of days on warfarin therapy were calculated by group. The ratio of the number of days on warfarin and the number of INRs per patient was analysed by unpaired t-test to estimate the frequency of INR monitoring. The number and percentage of patients with minor or major bleeding events and thromboembolic events was described by group. We used the chi-squared test with Yates correction to analyse nominal variables to detect differences in race, INR goals, minor bleedings,

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supra- (INR 4–9 and ≥9) or sub- (INR ≤ 1.5) therapeutic INRs among the groups. Fisher's exact test was utilized to analyse all other nominal variables (when *n* was <5) such as gender, race, reason for exclusion, major bleeding events and thromboembolic events. Unpaired *t*-test was utilized to detect differences in continuous variables including mean age, INR measurements, and day interval to next measured INR. Statistical significance was set at P < 0.05.

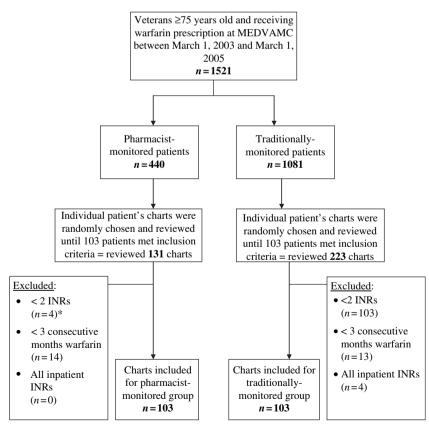
RESULTS

A total of 1521 patients met our inclusion criteria. Of these, 1081 patients were monitored traditionally and 440 patients were monitored by pharmacists. We randomly reviewed as many individual patients' charts from both groups until 103 patients were found in each group. In the traditionally monitored group a significant number of patients (103 vs. only four patients in the pharmacist-monitored group; P < 0.001) had to be excluded because less than two INR values were docu-

mented in their charts (Fig. 1). Demographic characteristics of patients are shown in Table 1. The mean age of subjects in both groups was 80 years. As expected in a VA setting, almost all subjects were male. There were significantly more Caucasian patients in the traditionally monitored group (P = 0.03).

The most common indication for warfarin use in both groups was atrial fibrillation or flutter (Table 2). Nineteen patients in the pharmacistmonitored group and 29 patients in the traditionally monitored group had more than one indication for warfarin therapy. There was a non-significant trend towards more patients in the pharmacistmonitored group than in the traditionally monitored group who required a higher target INR range of 2·5–3·5 (n = 14 vs. n = 5, P = 0.054) because of prosthetic valve replacement.

The mean number of days on warfarin therapy and the percentage of therapeutic INR values were not statistically different between the two groups (Table 3). Patients in the pharmacist-monitored group had more INR values documented in the



* significant, P<0.01

Fig. 1. Study sample.

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Table 1. Demographics of studysample

Table 2. Indications and Interna-tional Normalization Ratio (INR)target range for anticoagulation asdocumented in patients' charts

| Characteristics | Pharmacist-monitored group | Traditionally monitored group | <i>P</i> -value |
|------------------------------|-------------------------------|-------------------------------------|-----------------|
| Gender, male, n (%) | 103 (100) | 102 (99) | NS |
| Mean age in years (SD) | 80.4 (3.7) | 80.9 (3.4) | NS |
| Race | | | |
| Caucasian, n (%) | 77 (74.8) | 90 (89.2) | 0.03 |
| African American, n (%) | 21 (20.4) | 11 (10.8) | NS |
| Hispanic, n (%) | 3 (2.9) | 2 (2.0) | NS |
| Other ^a , n (%) | 2 (1.9) | 0 | NS |

^aOthers include Pacific Islanders (n = 1) and Asian (n = 1).

| | Pharmacist-monitored group | Traditionally monitored group | <i>P</i> -value |
|-------------------------------|----------------------------|-------------------------------------|-----------------|
| Indication(s): | | | |
| Atrial fibrillation/flutter | 68 | 64 | 0.92 |
| Stroke | 19 | 17 | 0.90 |
| Mechanical valve replacement | 19 | 12 | 0.34 |
| Bioprosthetic | 5 | 7 | |
| Prosthetic | 14 | 5 | |
| Myocardial infarction | 20 | 26 | 0.28 |
| Deep vein thrombosis | 7 | 8 | 0.88 |
| Pulmonary embolism | 5 | 1 | 0.22 |
| Arterial thrombosis | 1 | 2 | 0.61 |
| INR target range ^a | | | |
| 2–3 | 89 (86.4%) | 98 (95·1%) | 0.54 |
| 2·5–3·5 | 14 (13.6%) | 5 (4.9%) | 0.54 |

^aFor individuals with prosthetic valve replacement the target range was between 2.5 and 3.5; with bioprosthetic valve replacement the target range was between 2.0 and 3.0.

observation period than the traditionally monitored group (P < 0.01). Patients followed by pharmacists had INR values checked on average every 37.6 days vs. every 114.6 days for those followed by physicians (P < 0.01).

Patients in the traditionally monitored group had significantly more frequent subtherapeutic INR values (17.4% vs. 10%), whereas patients in the pharmacist-monitored group had significantly more supra-therapeutic INR values (4.8% vs. 2.8%). Patients with both sub- or supra-therapeutic INR values received quicker follow-up by pharmacists than by physicians.

The incidence of thromboembolic events was significantly less in the pharmacist-monitored group compared with the traditionally monitored group (2 vs. 12; P < 0.01) (Table 4). No difference in major bleeding events was noted between the two groups, however, there were significantly more documented minor bleeding events in the pharmacist-monitored group (50 vs. 17, P < 0.01).

DISCUSSION

Pharmacist-monitored anticoagulation therapy reduced thromboembolic events significantly compared with the traditionally monitored group in our sample of older veterans. A likely explanation is that a significantly higher number of patients in the traditionally monitored group had sub-therapeutic INR measurements ≤1.5, and that such patients did not return as quickly for adjustment of

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| Variables | Pharmacist-monitored group | Traditionally monitoring group | <i>P</i> -value |
|--|-------------------------------|--------------------------------------|-----------------|
| Mean number of days on warfarin therapy per patient (SD) | 556.8 (192.3) | 517.6 (188.8) | 0.14 |
| Mean number of INR per patient during study period (SD) | 17.7 (8.2) | 8.7 (7.7) | <0.01 |
| Number of days on therapy/number of INRs per patient in average (SD) | 37.6 (23.6) | 114.6 (98.8) | <0.01 |
| Therapeutic INRs in % (SD) | 48.1 (18.4) | 46.4 (26.8) | 0.59 |
| $INRs \le 1.5$ in % | 10 | 17.4 | <0.01 |
| INRs 4–9 in % | 4.8 | 2.8 | 0.02 |
| INRs > 9 in % | 0.1 | 0.2 | 0.30 |
| Mean interval after a sub-therapeutic INR ≤ 1.5 to next INR, in days (SD) | 22 (17) | 68 (92) | <0.01 |
| Mean interval after a supra-therapeutic INR ≥ 4 to next INR, in days (SD) | 14 (11) | 32 (57) | 0.05 |

Table 3. Comparison of laboratory data between the pharmacist-monitored and the traditionally monitored groups

INR, International Normalization Ratio.

| Adverse effects | Pharmacist-monitored group | Traditionally monitored group | <i>P</i> -value |
|-----------------------------|-------------------------------|-------------------------------------|-----------------|
| Total minor bleeding | 50 | 17 | <0.01 |
| Bruising | 17 | 3 | <0.01 |
| Nosebleed | 12 | 2 | 0.01 |
| Cuts/wound bleed | 6 | 1 | NS |
| Gum bleed | 4 | 0 | NS |
| Haematuria | 3 | 4 | NS |
| Bright red blood in stool | 6 | 4 | NS |
| Haemoptysis (minimal) | 2 | 3 | NS |
| Major bleeding | 3 ^a | 2 ^b | NS |
| Total thromboembolic events | 2 | 12 | 0.01 |
| Stroke | 0 | 5 | 0.06 |
| Transient ischaemic attacks | 0 | 2 | NS |
| Myocardial infarction | 0 | 3 | NS |
| Deep vein thrombosis | 2 | 0 | NS |
| Arterial thrombosis | 0 | 2 | NS |

 Table 4. Warfarin related adverse events

^aOne retinal bleeding, two gastrointestinal bleedings.

^bOne haematuria required hospitalization, one gastrointestinal bleeding.

their warfarin dose in order to bring the INR to a therapeutic level as patients in the pharmacistmonitored group. It is thus not surprising that patients in the pharmacist-monitored group had significantly more supra-therapeutic INR levels in the 4–9 range, and more episodes of minor bleeding (although this was statistically significant mainly for the most minor events, i.e. bruising and nosebleeds). All pharmacists use a standardized electronic template that specifically lists each minor bleeding symptom, and they review and document symptoms with the patient during each anticoagulation service encounter. During the chart reviews, information about the indication for

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warfarin or bleeding events was much more easily retrievable in the pharmacist-monitored group compared with the traditionally monitored group because of the use of this standardized anticoagulation monitoring template. In the traditionally monitored group, physicians document bleeding events in the progress notes as just one part of their routine visit documentation that includes a discussion of the patient's other medical problems. While managing anticoagulation is part of the visit, it is rarely the only focus of the visit. Unless the patient specifically mentions minor bleeding events, such symptoms are less likely to be documented in physicians' progress notes. Therefore, it is possible that the difference in minor bleeding events between the two groups was overestimated because of the different documentation styles, resulting in information and recall basis. On the other hand, it is possible that minor bleeding events truly did occur more frequently in the pharmacistmonitored group as pharmacist seemed to be more proactive in trying to achieve therapeutic INR values by adjusting doses faster than physicians did.

We found no significant differences in major bleeding events between the groups. The percentage of therapeutic INR values was not significantly different between the two groups, but did not even reach 50% in either group. In other studies, the percentage of therapeutic INR values achieved was similar for older adults over 65 years and varied between 32% and 70% (21, 22). To further investigate the effect of pharmacist-monitored anticoagulation outcomes, we reviewed the number of INR values ≤ 1.5 , 4–9, >9 and calculated mean elapsed time between INR values ≤1.5, between 4 and 9, and >9 and the next INR value in days to assess the timeliness of response to non-therapeutic INR values (19, 23). Pharmacist-monitored anticoagulation reduced the percentage of subtherapeutic INR values (P < 0.01) and reduced the interval from an INR value ≤ 1.5 or ≥ 4 to the subsequent INR check compared with traditional monitoring. On the other hand, pharmacist-monitored anticoagulation increased slightly, but significantly, the percentage of INR values between 4 and 9 (P = 0.02), while no difference in percentage of INR values >9 (P = 0.30) was found between groups. A meta-analysis of four randomized controlled trial demonstrated that low-dose warfarin (INR ≤ 1.6) in patients with atrial fibrillation led to more thromboembolic events without reducing major bleeding events when compared with adjusteddose warfarin (INR 2–3) (24). This is similar to our findings that the pharmacist-monitored group experienced less thromboembolic events than the traditionally monitored group which had a higher percentage of patients with INR values ≤ 1.5 .

Time to response to non-therapeutic INR values is crucial for optimizing warfarin therapy. A study involving 6645 patients (mean age 68 years) reported that the mean interval to re-check an INR after INR values of ≤ 1.5 and ≥ 4 was between 12.0 and 13.5 days (19). The time to response after supra-therapeutic and sub-therapeutic INR values in our study was similar in the pharmacistmonitored group (14 and 22 days), but much longer (32 and 68 days) in the traditionally monitored group.

Although the mean duration of warfarin therapy was not statistically significant between the two groups, the mean number of INR values collected per patient was almost half in the traditionally monitored group. As pointed out before, this was explained by the lengthier time interval, i.e. followup between obtaining INR values. Of note is that we had to exclude 103 patients in the traditionally monitored group because only one INR value was available throughout the 2-year study period, compared with excluding only four patients for the same reason in the pharmacist-monitored group. These results show a tendency towards inadequate INR monitoring (or possibly INR documentation if values were indeed obtained outside the VA) in the traditionally monitored group. In the VA setting, patients have prescription benefits. It is not uncommon that patients see providers outside of the VA but receive medication through the VA pharmacy and see a provider only for the purpose of obtaining medications. The patient is then encouraged to bring all physician orders, notes, and laboratory data generated elsewhere to the VA clinic. However, if the patient forgot to bring the lab result, or if the physician did not record the lab result into the note, then the information is missed. To remain under pharmacist monitoring, a patient has to commit to have INR values drawn at the VA laboratory, explaining partially why so few patients in the pharmacist-monitored group had only one INR value.

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There were several limitations to this study. First, the patients in this study were mostly male (99%) and thus the data obtained may not be generalizable to women. The Framingham Study found that the lifetime risk of stroke in men and women at 75 years of age was 14.3% and 19.7%, respectively (25). The authors further explained that the higher risk in women compared with men was largely due to their greater life expectancy, increasing their period at risk (25). Therefore, if our population had included more women, differences in thromboembolic events between the two groups might have been even more pronounced. Secondly, INR values obtained outside the MEDVAMC and recorded in progress notes may have been inaccurate. Thirdly, the absence of a standardized anticoagulation progress note in the traditionally monitored group might have underestimated the incidence of warfarin-related adverse events. Patients who experienced minor bleeding events, e.g. a resolved nosebleed or bruising might not have been mentioned to the doctor unless specifically asked, because of the mild nature of the problem. Even when mentioned, physicians might not have documented such symptoms because they did not require intervention. On the other hand, the presence of a standardized template for documentation prompted pharmacists to ask about and document every, even minor, adverse events.

A strength of this study was our ability to review completely all INR values obtained by the laboratory or noted in progress notes using the electronic charting system (CPRS) at MEDVAMC. The ease of use of CPRS facilitated the retrieval of *all* INR values collected by the laboratory within the study period. CPRS also provided a comprehensive dispensing history of warfarin on each pharmacy transaction including starting date, quantity dispensed, days supplied and date discontinued to give accurate information on the duration of warfarin therapy. The ability to use an electronic charting system for chart reviews helped reduce data loss or error because of illegible writing or missing medication records.

CONCLUSION

The use of a pharmacist-monitored anticoagulation service for older veterans was associated with a reduction of thromboembolic events without any difference in major bleeding events, compared with traditionally monitored anticoagulation therapy. Patients in the pharmacist-monitored group also received quicker follow-up after both sub- or supra-therapeutic INR values. However, the pharmacist-monitored group had more minor bleeding events. Monitoring of anticoagulation therapy by pharmacists improved outcomes and should be recommended.

ACKNOWLEDGEMENTS

The authors thank Dr Yvonne Martinez for her help with the project. Study results were presented in part at the poster session at the American Society of Health-System Pharmacists (ASHP) mid-year meeting in Las Vegas in December 2005. Dr Braun was supported by a VA HSR&D research career development award, RCD 02-029. Dr Poon was supported by a Center of Excellence in Health Disparity Research (CEDHR) faculty fellowship award.

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NOTE

Treatment and control of blood pressure in patients with diabetes mellitus

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he prevalence of diabetes mellitus in U.S. adults ≥ 20 years old is estimated at 5.9%.1 This represents approximately 11.8 million people, with the majority having type 2 diabetes mellitus.1 Various reports suggest the prevalence of concurrent hypertension in these patients is high at 60% to 71%.2-5 A majority of the affected individuals are hypertensive at the time their diabetes is diagnosed, suggesting that both diseases may have a common cause or that a hormonal or metabolic disturbance may exist in essential hypertension before the onset of diabetes.⁶ Reported rates of treatment and control of elevated blood pressure (as defined by <140/90 mm Hg) in patients with diabetes range from 45% to 66%, suggesting that considerable opportunity for improvement exists.^{2,7}

The risk of major cardiovascular morbidities such as coronary artery disease, stroke, peripheral vascular disease, lower-extremity amputations, nephropathy, end-stage renal disease, retinopathy, and blindness **Purpose.** A study was conducted to characterize the prevalence of hypertension in patients with diabetes mellitus and the percentage of patients with diabetes and hypertension who achieved a targeted blood pressure goal (<135/80 mm Hg).

Methods. A retrospective, cross-sectional study was conducted in an ambulatory care clinic. Eligible patients were those individuals being managed for type 2 diabetes mellitus at least once each year for two consecutive years. Blood pressure measurements that were recorded in the medical chart or written diagnoses of hypertension were used to determine the presence of comorbid hypertension. Data were collected from the chart and electronic record using a standardized form. Clinic visits over the previous 12 months were reviewed to evaluate hypertension criteria. A blood pressure of ≥135/80 mm Hg was used to define hypertension.

Results. A final sample of 362 patients with type 2 diabetes mellitus was included in the study. Of these, 79% had concomitant

diabetes and hypertension. Blood pressure was controlled in 175 of 270 (65%) patients. Patients who met the blood pressure goal tended to be older and weigh less than those who did not. The adjusted odds of achieving the blood pressure goal were 1.9 times higher in those patients who also achieved their low-density-lipoprotein cholesterol goal. Most patients were on at least one antihypertensive agent; approximately 39% of the 89 patients treated with monotherapy were above the blood pressure goal. Combination therapy was used in 164 patients; approximately 32% of patients treated with combination therapy were above the blood pressure goal. Conclusion. Among ambulatory care

patients with diabetes, 79% also had hypertension. Hypertension was controlled in 65% of patients with that disorder.

Index terms: Age; Ambulatory care; Combined therapy; Diabetes mellitus; Hypertension; Hypotensive agents; Weight Am J Health-Syst Pharm. 2007; 64:97-103

is increased in patients with diabetes who have uncontrolled hypertension relative to patients with either disease alone.^{3,8} Patients with comorbid diabetes and hypertension also have an increased risk for mortality,

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The Notes section welcomes the following types of contributions: (1) practical innovations or solutions to everyday practice problems, (2) substantial updates or elaborations on work previously published by the same authors, (3) important confirmations of research findings previously published by others, and (4) short research reports, including practice surveys, of modest scope or interest.

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with a majority of the deaths in patients with diabetes resulting from cardiovascular and renal disease.^{3,9} However, appropriate management of hypertension has been shown to significantly reduce or delay complications associated with diabetes in patients with this comorbidity.^{5,8,10,11}

There are substantial and compelling data indicating that optimizing blood pressure in patients with diabetes significantly reduces cardiovascular morbidity and mortality. In the Hypertension Optimal Treatment (HOT) randomized trial, Hansson and colleagues¹⁰ evaluated the effects of targeting diastolic blood pressures (DBPs) of \leq 90, \leq 85, and \leq 80 mm Hg in patients with DBPs of 100-115 mm Hg. The lowest frequency of major cardiovascular events occurred at a mean DBP of 82.6 mm Hg. In patients with diabetes, there was a 51% reduction in the frequency of major cardiovascular events in patients whose DBP was lowered to ≤80 mm Hg compared with $\leq 90 \text{ mm Hg} (p = 0.005)$.

The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) compared the effect of three different types of antihypertensive medications on cardiovascular morbidity in patients ≥55 years of age with hypertension and at least one other coronary heart disease (CHD) risk factor and provided important knowledge regarding blood pressure reduction in patients with diabetes.¹¹ Of the 33,357 patients enrolled in the trial, approximately 36% had type 2 diabetes mellitus. The risk of nonfatal myocardial infarction and fatal CHD was similar in patients with diabetes and multiple cardiovascular risk factors regardless of whether they were randomized to amlodipine, chlorthalidone, or lisinopril. At the conclusion of ALLHAT, 63% of the patients were receiving two or more antihypertensive agents in an attempt to reach blood pressure targets. Therefore, it can be anticipated that combination therapy is needed in patients with and without diabetes to reach blood pressure goals.

In the U. K. Prospective Diabetes Study 38, researchers evaluated the effect of tight blood pressure control on microvascular and macrovascular complications in patients with type 2 diabetes mellitus.8 Mean blood pressure in the tight control group during follow-up was significantly lower (144/82 mm Hg) compared with the control group (154/87 mm Hg; p < 0.0001 for systolic and diastolic pressures). This reduction in blood pressure was associated with a 24% reduction in diabetes-related endpoints (p = 0.0046), a 32% reduction in deaths related to diabetes (p =0.019), a 44% reduction in strokes (p = 0.013), and a 37% reduction in microvascular endpoints (p = 0.0092).

Therefore, obtaining blood pressure control is critical in patients with diabetes to reduce the progression of disease complications. In the general population, a guideline-based blood pressure goal is <140/90 mm Hg.12 However, for patients with diabetes, guidelines suggest that the goal is <130/80 mm Hg.5,12,13 Randomized clinical trials suggest a significant benefit in targeting a DBP of <80 mm Hg. However, the goal for systolic blood pressure is not as clear. Based on a review of the literature, it is suggested that a systolic pressure goal of <135 mm Hg is reasonable.^{4,14}

The purpose of this study was to characterize the prevalence of hypertension in patients with diabetes. Furthermore, we were interested in determining the percentage of patients with diabetes and hypertension achieving a targeted blood pressure goal (<135/80 mm Hg). We also report key prescribing patterns of antihypertensive agents (i.e., the percentage of patients receiving diuretics or β -blockers, the percentage of patients receiving angiotensinconverting-enzyme [ACE] inhibitors or angiotensin-receptor blocker agents, and the percentage of patients receiving combination therapy). Finally, we identified potential factors associated with not achieving blood pressure goals.

Methods

Design and study population. This was a retrospective, crosssectional study conducted in an internal medicine ambulatory care clinic associated with an academic teaching institution. Eligible patients were identified from a patient care registry of individuals being managed for type 2 diabetes mellitus. Diabetes management was defined as receiving treatment in the clinic for a diabetes care-related issue at least once each year in two consecutive years (2002 and 2003 or 2003 and 2004). Blood pressure measurements that were recorded in the medical chart or written diagnoses of hypertension were used to determine the presence of comorbid hypertension. Patients were excluded from this study if they were under 18 years, no longer obtaining care from the clinic (i.e., did not meet management criteria outlined above), diagnosed with hypertension within six months before the most recent visit, or currently diagnosed with cancer. The health system's institutional review board approved the study protocol.

Data collection. Beginning with a patient's most recent clinic visit as the index, data were collected from the patient's chart and electronic medical record using a standardized form. Clinic visits over the previous 12

months were then reviewed to evaluate hypertension criteria and collect relevant data. Variables collected included medications prescribed, laboratory values, blood pressure, and weight. Blood pressure goal attainment was assessed using blood pressure measurement data from the patient's most recent visit, and patients not at goal were analyzed more in-depth. A blood pressure of ≥135/80 mg Hg was used to define hypertension.⁴ If multiple blood pressure measurements were available at any given clinic visit, the lower value was used for goal-assessment purposes. This method was used to provide a more conservative estimate of inadequate blood pressure goal attainment. At this site, usual medical care was provided by attending and resident physicians, nurses, and pharmacists during the observation period. Furthermore, physicians had access to a clinical pharmacist at the site. Laboratory values were made available to the primary physician so that health care providers would have adequate access to the information before the patient's appointment.

Data analysis. Data for this project were compiled and analyzed using standard spreadsheet software (Excel 2000, Microsoft, Redmond, WA) and the statistical software, SAS, version 9.1 (SAS Institute Inc., Cary, NC). A sample size of 384 subjects with type 2 diabetes mellitus was required for this study in order to estimate the prevalence of hypertension in this population with a 5% margin of error. Our final sample of 362 patients resulted in a margin of error of ±5.2%. Bivariate comparisons were made using chi-square tests (categorical data) and two-sample t tests (continuous data) for demographics, comorbid diseases, blood pressure measurement, use of antihypertensive agents, and lipid goal attainment. Logistic regression was used to identify variables associated with achieving blood pressure goals, and odds ratios (adjusted for age, sex, weight, and hypertensive medication use) along with 95% confidence intervals (CIs) are reported. The a priori level of significance was 0.05.

Results

A total of 362 patients were included in this study. Of these, 286 (79%) had concomitant diabetes and hypertension. Sixteen patients were excluded because of a recent diagnosis of hypertension (n = 5), a diagnosis of cancer (n = 5), a change of clinics (n = 3), or missing blood pressure data (n = 3). Complete analysis was conducted on the remaining 270 patients.

Characteristics of patients with concomitant diabetes and hypertension are summarized in Table 1. Blood pressure was controlled in 175 of 270 patients (65%). Patients who met the blood pressure goal tended to be older (95% CI for difference, 0.73-6.8; p = 0.02) and weigh less (95% CI for difference, 0.05-32.2; p = 0.054) than those who did not. The groups of patients whose blood pressure was or was not controlled did not differ with regard to the percentage of men or the distribution of comorbid diseases. Blood pressure measurements are summarized in Table 2 for patients who did and did not meet goal. Among the 175 patients whose blood pressure goal was met, 166 (95%) were receiving antihypertensive therapy, and among the 95 patients whose goal was not met, 87 (92%) were receiving such therapy (p = 0.29).

Most participants (253/270 [94%]) in this study were on at least one antihypertensive agent (Table 3). Of those treated with medication, 35% were receiving one agent, which was most commonly an ACE inhibitor. Approximately 39% of patients treated with monotherapy were above the blood pressure goal. Combination therapy was used in 164 patients (65%) in this study. Of those, 97 (59%) were receiving two-drug regimens while 67 (41%) were receiving regimens with three or more agents. Approximately 32% of patients treated with combination therapy were above the blood pressure goal. The difference in goal attainment between monotherapy and combination therapy was not significant (p = 0.35).

| Table 1. Characteristics of Patients with Diabetes and Hypertension ^a | | | | | | |
|---|----------------------|------------------------------------|-----------------------------|--|--|--|
| ltem | Overall (n = 270) | BP Goal Met (n = 175) | BP Goal Not Met (n = 95) | | | |
| No. (%) male | 150 (56) | 93 (53) | 57 (60) | | | |
| Mean \pm S.D. age (yr) | 60.4 ± 12.2 | 61.7 ± 11.9 | 58.0 ± 12.4 | | | |
| Mean \pm S.D. weight (lbs) | 215.0 ± 60.6 | $\textbf{209.0} \pm \textbf{58.8}$ | 226.0 ± 62.6 | | | |
| No. (%) with comorbid diseases | | | | | | |
| Hyperlipidemia | 172 (64) | 113 (65) | 59 (62) | | | |
| Obesity | 80 (30) | 54 (31) | 26 (27) | | | |
| Depression | 57 (21) | 33 (19) | 24 (25) | | | |
| CAD | 54 (20) | 36 (21) | 18 (19) | | | |
| GERD | 47 (17) | 32 (18) | 15 (16) | | | |
| Microalbuminuria | 29 (11) | 12 (7) | 17 (18) | | | |
| CHF | 19 (7) | 14 (8) | 5 (5) | | | |
| Stroke | 5 (2) | 5 (3) | 0 | | | |
| None | 12 (4) | 9 (5) | 3 (3) | | | |
| Other | 161 (60) | 101 (58) | 60 (63) | | | |

^aBP = blood pressure, CAD = coronary artery disease, CHF = congestive heart failure, GERD = gastroesophageal reflux disease.

| | Mean | \pm S.D. Blood Press | sure (mm Hg) | | |
|---------------------------------------|------------------------------|----------------------------------|-----------------------------|--------------------------|----------|
| Variable | Overall (<i>n</i> = 270) | BP Goal Met (<i>n</i> = 175) | BP Goal Not Met (n = 95) | 95% Cl for Difference | р |
| Overall | | | | | |
| SBP | 127 ± 16 | 119 ± 10 | 142 ± 15 | 20.3-26.4 | < 0.0001 |
| DBP | 74 ± 11 | 70 ± 9 | 82 ± 8 | 9.7–14.2 | < 0.000 |
| Receiving antihypertensive agents | | | | | |
| SBP | 127 ± 16 | 119 ± 10 | 142 ± 15 | 20.3-26.5 | < 0.0001 |
| DBP | 74 ± 11 | 70 ± 9 | 82 ± 8 | 9.6–14.3 | < 0.0001 |
| Not receiving antihypertensive agents | | | | | |
| SBP | 131 ± 19 | 121 ± 7 | 142 ± 22 | 5.2-38.5 | 0.03 |
| DBP | 79±7 | 75 ± 5 | 84 ± 5 | 4.2-15.0 | 0.002 |

*Between-group comparisons were made with the two-sample t test. BP = blood pressure, CI = confidence interval, DBP = diastolic blood pressure, SBP = systolic blood pressure.

| Variable $(n = 253)$ $(n = 1)$ Regimen typeMonotherapy89 (35)55 (3)Combination therapy164 (65)111 (6)Drug given as monotherapyACE55 (62)33 (6)D13 (15)10 (1)BB14 (16)8 (1)CCB5 (6)3 (5)ARB2 (2)1 (2)Combination therapy (22) 1 (2)D + ACE22 (13)15 (1)D + BB19 (12)12 (1)D + BB + ACE19 (12)12 (1)BB + ACE18 (11)13 (1)ACE + CCB14 (9)8 (7)D + ARB11 (7)8 (7) | | No. (%) Patie | | |
|--|-------------|----------------------------------|----------|---------------------------|
| Monotherapy 89 (35) 55 (3) Combination therapy 164 (65) 111 (6) Drug given as monotherapy ACE 55 (62) 33 (6) D 13 (15) 10 (1) BB 14 (16) 8 (1) CCB 5 (6) 3 (5) ARB 2 (2) 1 (2) Combination therapy 0 4 (16) 8 (1) D + ACE 2 (2) 1 (2) 1 (2) D + BB 19 (12) 12 (1) 15 (1) D + BB + ACE 19 (12) 12 (1) BB + ACE 18 (11) 13 (1) ACE + CCB 14 (9) 8 (7) D + ARB 11 (7) 8 (7) | | BP Goal Met (<i>n</i> = 166) | | Variable |
| Combination therapy 164 (65) 111 (6) Drug given as monotherapy ACE 55 (62) 33 (6) D 13 (15) 10 (1) BB 14 (16) 8 (1) CCB 5 (6) 3 (5) ARB 2 (2) 1 (2) Combination therapy D + ACE 22 (13) 15 (1) D + BB 19 (12) 12 (1) D + (12) 12 (1) D + BB + ACE 19 (12) 12 (1) BB + ACE 18 (11) 13 (1) ACE + CCB 14 (9) 8 (7) D + ARB 11 (7) 8 (7) | | | | Regimen type |
| Drug given as monotherapy ACE 55 (62) 33 (6 D 13 (15) 10 (1 BB 14 (16) 8 (1 CCB 5 (6) 3 (5 ARB 2 (2) 1 (2 Combination therapy 0 + ACE 22 (13) 15 (1 D + BB 19 (12) 12 (1 12 (1 12 (1 D + BB + ACE 19 (12) 12 (1 13 (1) 3 (1 ACE + CCB 14 (9) 8 (7 14 (9) 8 (7 D + ARB 11 (7) 8 (7 14 (7) 14 (7) | 33) 34 (39) | 55 (33) | 89 (35) | Monotherapy |
| ACE 55 (62) 33 (6 D 13 (15) 10 (1 BB 14 (16) 8 (1 CCB 5 (6) 3 (5 ARB 2 (2) 1 (2 Combination therapy D + ACE 22 (13) 15 (1 D + BB 19 (12) 12 (1 D + BB + ACE 19 (12) 12 (1 BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | 57) 53 (61) | 111 (67) | 164 (65) | |
| D 13 (15) 10 (1 BB 14 (16) 8 (1 CCB 5 (6) 3 (5 ARB 2 (2) 1 (2 Combination therapy 0 4 (16) 10 (1 D + ACE 2 (2) 1 (2 15 (1 D + BB 19 (12) 12 (1 15 (1 D + BB + ACE 19 (12) 12 (1 13 (1 BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 14 (7) 14 (7) 14 (7) | | | | Drug given as monotherapy |
| BB 14 (16) 8 (1 CCB 5 (6) 3 (5 ARB 2 (2) 1 (2 Combination therapy D + ACE 22 (13) 15 (1 D + BB 19 (12) 12 (1 D + BB + ACE 19 (12) 12 (1 BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | 50) 22 (65) | 33 (60) | 55 (62) | ACE |
| CCB 5 (6) 3 (5) ARB 2 (2) 1 (2) Combination therapy D + ACE 22 (13) 15 (1) D + ACE 22 (13) 15 (1) 12 (1) D + BB 19 (12) 12 (1) D + BB + ACE 19 (12) 12 (1) BB + ACE 18 (11) 13 (1) ACE + CCB 14 (9) 8 (7) D + ARB 11 (7) 8 (7) | 8) 3 (9) | 10 (18) | 13 (15) | D |
| ARB 2 (2) 1 (2) Combination therapy D ACE 22 (13) 15 (1) D + ACE 22 (13) 15 (1) 12 (1) D + BB 19 (12) 12 (1) D + BB + ACE 19 (12) 12 (1) BB + ACE 18 (11) 13 (1) ACE + CCB 14 (9) 8 (7) D + ARB 11 (7) 8 (7) | 5) 6 (18) | 8 (15) | 14 (16) | BB |
| Combination therapy 22 (13) 15 (1) D + ACE 22 (13) 15 (1) D + BB 19 (12) 12 (1) D + BB + ACE 19 (12) 12 (1) BB + ACE 19 (12) 12 (1) ACE + CCB 18 (11) 13 (1) ACE + CCB 14 (9) 8 (7) D + ARB 11 (7) 8 (7) | 5) 2 (6) | 3 (5) | 5 (6) | ССВ |
| | 2) 1 (3) | 1 (2) | 2 (2) | ARB |
| D + BB 19 (12) 12 (1 D + BB + ACE 19 (12) 12 (1 BB + ACE 19 (12) 12 (1 BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | | | | Combination therapy |
| D + BB + ACE 19 (12) 12 (1 BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | 4) 7 (13) | 15 (14) | 22 (13) | D + ACE |
| BB + ACE 18 (11) 13 (1 ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | 1) 7 (13) | 12 (11) | 19 (12) | D + BB |
| ACE + CCB 14 (9) 8 (7 D + ARB 11 (7) 8 (7 | 1) 7 (13) | 12 (11) | 19 (12) | D + BB + ACE |
| D + ARB 11 (7) 8 (7 | 2) 5 (9) | 13 (12) | 18 (11) | BB + ACE |
| | 7) 6 (11) | 8 (7) | 14 (9) | ACE + CCB |
| D + ACE + CCB 8 (5) 7 (6 | 7) 3 (6) | 8 (7) | 11 (7) | D + ARB |
| | 5) 1 (2) | 7 (6) | 8 (5) | D + ACE + CCB |
| D + BB + ACE + CCB 7 (4) 5 (5 | 5) 2 (4) | 5 (5) | 7 (4) | D + BB + ACE + CCB |
| D + BB + ARB 6 (4) 5 (5 | 5) 1 (2) | 5 (5) | 6 (4) | D + BB + ARB |

^aNumber in parentheses are percentages by column. ACE = angiotensin-converting-enzyme inhibitor, ARB = angiotensin-receptor blocker, BB = β -blocker, BP = blood pressure, CCB = calcium-channel blocker, D = diuretic.

From our bivariate analysis, meeting the glycosylated hemoglobin (HbA_{1c}) or low-density-lipoprotein (LDL) goals were significantly associated with meeting the blood pressure goal (Table 4; p = 0.04). By logistic regression, if the LDL goal is achieved, the odds of achieving the blood pressure goal are 1.9 times greater (95% CI, 1.1–3.4) compared with not achieving the LDL goal after adjusting for age, sex, weight, and use of any antihypertensive agents. Glycemic and cholesterol measurements are summarized in Table 5 for patients who did and did not meet blood pressure goals. In general, patients above their blood pressure goal had significantly higher total and LDL cholesterol.

When the blood pressure goal was not obtained, physicians made and documented treatment changes for 20 of 95 (21%) patients. Changes were not made or documented in 66 (69%) patients. Of these 66 cases where no changes were made or documented, the most common reason cited was that the physician was satisfied with the blood pressure control (41% of cases). The judgment to categorize physician response in this manner was based on chart notes such as "well controlled," "fairly controlled," "appears to be stable," and other similar comments. Other reasons cited were a conservative approach (15%) and the presence of a comorbid disease that was felt to preclude the initiation or modification of antihypertensive treatment at that particular time. A reason for not making a treatment change could not be identified for 26 cases (39%). Of the 20 treatment changes identified, 11 (55%) involved dose increases, 4 (20%) involved adding a medication, and 5 (25%) involved the reinforcement of diet and exercise.

Discussion

This study found a high prevalence of hypertension in patients with type 2 diabetes mellitus who were being treated by general internists in an academic community setting. In this cohort of patients, the prevalence of having both hypertension and

| Variable | No. (%) Patients Meeting BP Goal (n = 164–169) | No. (%) Patients Not Meeting BP Goal (n = 91 or 93) | р |
|--|--|---|------|
| HbA ₁ , concentration | | | 0.04 |
| At goal (<7%) ($n = 95$) | 69 (41) | 26 (28) | |
| Not at goal (<i>n</i> = 167) | 100 (59) | 67 (72) | |
| Total cholesterol | | | 0.11 |
| At goal (<200 mg/dL) ($n = 182$) | 122 (74) | 60 (65) | |
| Not at goal $(n = 76)$ | 43 (26) | 33 (35) | |
| LDL cholesterol | | | 0.03 |
| At goal (<100 mg/dL) ($n = 141$) | 99 (60) | 42 (46) | |
| Not at goal $(n = 114)$ | 65 (40) | 49 (54) | |
| HDL cholesterol | | | 0.11 |
| At goal (>40 mg/dL) (<i>n</i> = 160) | 109 (65) | 51 (55) | |
| Not at goal $(n = 101)$ | 59 (35) | 42 (45) | |
| Triglycerides | | | 0.87 |
| At goal (<150 mg/dL) (<i>n</i> = 128) | 83 (49) | 45 (48) | |
| Not at goal $(n = 133)$ | 85 (51) | 48 (52) | |

diabetes was 79%, which was consistent but somewhat higher than published estimates of 60-71%.2-5 It was encouraging that the rate of blood pressure control (<135/80 mm Hg) in this cohort was better than expected at 65% and comparable to previous reports of approximately 66% of patients with hypertension and diabetes who had their blood pressure controlled to <140/90 mm Hg.^{2,7} Although the target DBP in the intensive group in the HOT trial was 80 mm Hg, the mean actual achieved DBP was 81 mm Hg, resulting in less than 50% of patients achieving the target of ≤80 mm Hg.¹⁰

In ALLHAT, almost two thirds of the patients were receiving two or more antihypertensive agents, and blood pressure goal attainment rates were approximately 66%.¹¹ Similarly, in our cohort, combination therapy and goal attainment rates were approximately 65%. Although there was a numerically higher rate of

^aBetween-group comparisons were made with the chi-square test. BP = blood pressure, HbA_{1c} = glycosylated hemoglobin, HDL = high-density-lipoprotein, LDL = low-density-lipoprotein.

| Variable | Overall | Met BP Goal | Above BP Goal | р |
|--------------------------|-------------------|----------------------------------|----------------------------------|-------|
| HbA _{1c} (%) | | | | |
| Overall | 7.7 ± 1.6 | 7.6 ± 1.7 | 7.7 ± 1.5 | 0.75 |
| At goal (<7%) | 6.3 ± 0.5 | 6.4 ± 0.4 | 6.1 ± 0.5 | 0.04 |
| Not at goal | 8.4 ± 1.5 | 8.5 ± 1.7 | 8.3 ± 1.2 | 0.39 |
| otal cholesterol (mg/dL) | | | | |
| Overall | 183.0 ± 48.7 | 175.4 ± 37.0 | 196.8 ± 62.5 | 0.003 |
| At goal (<200 mg/dL) | 159.5 ± 23.1 | 158.2 ± 22.7 | 162.1 ± 23.8 | 0.30 |
| Not at goal | 239.7 ± 47.4 | 224.3 ± 23.4 | 259.9 ± 61.7 | 0.003 |
| .DL cholesterol (mg/dL) | | | | |
| Overall | 98.9 ± 33.1 | 94.3 ± 26.6 | 107.2 ± 41.3 | 0.008 |
| At goal (<100 mg/dL) | 77.0 ± 16.4 | 77.7 ± 15.9 | 75.4 ± 17.6 | 0.47 |
| Not at goal | 126.1 ± 28.2 | 119.7 ± 18.5 | 134.5 ± 35.8 | 0.01 |
| HDL cholesterol (mg/dL) | | | | |
| Overall | 45.7 ± 14.6 | 45.9 ± 15.3 | 45.3 ± 13.5 | 0.75 |
| At goal (>40 mg/dL) | 53.2 ± 13.8 | 52.8 ± 14.6 | 54.2 ± 12.0 | 0.52 |
| Not at goal | 33.8 ± 4.5 | $\textbf{33.3} \pm \textbf{4.7}$ | $\textbf{34.6} \pm \textbf{4.0}$ | 0.14 |
| riglycerides (mg/dL) | | | | |
| Overall | 206.9 ± 231.8 | 189.5 ± 136.6 | 238.2 ± 341.3 | 0.19 |
| At goal (<150 mg/dL) | 102.7 ± 27.9 | 101.7 ± 28.5 | 104.5 ± 27.1 | 0.59 |
| Not at goal | 307.2 ± 290.6 | 275.3 ± 145.7 | 363.6 ± 440.6 | 0.18 |

^aBetween-group comparisons were made with the two-sample *t* test. BP = blood pressure, HbA_{1c} = glycosylated hemoglobin, HDL = high-density-lipoprotein, LDL = low-density-lipoprotein.

blood pressure goal attainment in patients who received combination treatment (67%) as compared to monotherapy (61%), this difference was not significant. Taken together, this information implies that combination therapy is a clinically appropriate strategy in many patients, but additional factors must be considered for each patient.

We estimate that physicians did not make changes in antihypertensive regimens in patients not achieving adequate blood pressure control in about 69% of patients. Our evaluation indicates that the most common reason for this was that they were satisfied with their patients' blood pressure. Perhaps satisfaction of inadequate blood pressure control may stem from the patients' blood pressure only being slightly higher than the recommended goal. However, each mm Hg may be important, and the goal is to be <135/80 mm Hg for patients with diabetes, which is even lower than the recommended goal of <140/90 mm Hg for patients who do not have diabetes. This 5-10-mm Hg difference may help patients with diabetes avoid complications of concurrent disease states, and it is important that health care providers monitor blood pressure accordingly. Because it is difficult to assess the overall blood pressure status of a patient in one office visit, it is understandable that some health care providers may take a conservative approach in making changes to antihypertensive regimens. However, in further analysis of our data, only 15% of physicians failed to make changes because of a conservative approach, while approximately 40% of physicians indicated that they were satisfied with their patients' blood pressure when the goal was not achieved.

Our findings also reinforce the variety of factors that are important with respect to the overall management of patients with type 2 diabetes mellitus. After adjusting for confounders such as age, sex, weight, and antihypertensive usage, the odds of achieving the blood pressure goal in patients who achieved the LDL cholesterol goal were almost double those of patients who failed to achieve the LDL cholesterol goal. Unadjusted analysis also indicated that meeting the blood pressure goal was more likely in patients who achieved their HbA_{1c} goal.

There are several limitations to this study because it was retrospective. Medical records are often not complete, and helpful information such as diet, exercise, and other factors associated with blood pressure control may be left out of the record. This type of study draws from information that has been previously documented, and it is impossible to incorporate data that have been left out of the chart or obtain clarifications on confusing chart notes. Also, a single blood pressure measurement cannot adequately determine the achievement of a patient's blood pressure goal. Self-monitoring of blood pressure by patients performed outside of our clinic was not evaluated or addressed in our work.

As described in the methods section, we took deliberate steps to minimize the chance of overstating findings. Assessments were made using conservative criteria, and evaluations without adequate supporting information were avoided. As described, another potential limitation to the interpretation of these findings is that a variety of health care providers were involved in delivering care to these patients. Resident physicians had a significant role in the delivery of care we observed. However, attending physicians oversee all activities of the residents and have final approval of treatment decisions. Clinical pharmacist support is available to all physicians, and therefore to all patients, at the clinic. For these reasons, the data were not stratified to test the effect of these issues as independent variables.

Medication adherence was not the focus of this study and was not explicitly addressed. However, as described in a recent systematic review, adherence represents one of many important challenges in the appropriate management of patients with hypertension.¹⁵ This issue should be addressed as a routine component of care as clinicians work with their patients.

Optimizing blood pressure control in patients with diabetes is a complex and multifactorial challenge. However, there are considerable clinical trial evidence and guideline support for aggressively pursuing this objective. Approximately one third of patients in this study had uncontrolled blood pressure. Nonmedication-related factors that appear to be associated with reaching blood pressure goals include achieving LDL cholesterol and HbA_{1c} goals. Patients, physicians, and other health care providers must increase the vigilance of their hypertension management with respect to overall patient monitoring and modification of antihypertensive regimens.

Conclusion

Among ambulatory care patients with diabetes, 79% also had hypertension. Hypertension was controlled in 65% of patients with that disorder.

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Outcomes of pharmacist-managed diabetes care services in a community health center

DAVID M. SCOTT, STEVEN T. BOYD, MICHELLE STEPHAN, SAM C. AUGUSTINE, AND THOMAS P. REARDON

iabetes mellitus is a progressive disorder that leads to significant morbidity, mortality, and economic burden. More than 17 million Americans have diabetes mellitus, one of the top 10 leading causes of death in the United States.1 Heart disease is the leading cause of type 2 diabetes mellitus-related deaths. Adults with diabetes have a mortality rate twice as high as that for adults without the disease. Diabetes doubles the risk for stroke, remains the leading cause of new cases of blindness, and is responsible for more than half of nontraumatic lower-limb amputations.

The UK Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT) found that lowering blood glucose concentrations reduces patients' risk of microvascular complications.^{2,3} The American Diabetes Association (ADA) has stated that long-term maintenance of glycosylated hemoglobin (HbA_{1c}) levels of **Purpose.** The outcomes of pharmacistmanaged diabetes care services in a community health center were studied.

Methods. Eligible patients were over age 18 years and had a diagnosis of type 2 diabetes mellitus. Patients were randomly assigned by the clinical pharmacist and nurse to the intervention group (n = 76)or control group (n = 73). Patients in the intervention group were enrolled in a pharmacist-managed diabetes care program. Patients in the control group received the standard diabetes care. The primary endpoint was reduction in glycosylated hemoglobin (HbA₁); secondary outcome measures included weight loss, an improved body mass index, decreased blood pressure, and an improved lipid panel. Quality-of-life measures (health level, satisfaction, impact, worry about disease, and worry about social and vocational issues) were also assessed.

Results. Demographic differences between groups were not remarkable. Mean ${\rm HbA}_{1c}$ levels fell significantly (p < 0.05) from baseline to nine months in both groups. A difference of 1.0 was reported between the groups' ${\rm HbA}_{1c}$ levels (95% confidence interval, 0.08–1.78; p < 0.05). Satisfaction level improved from 63.7 to 77.4 in the intervention group, which was significant when compared with the control group, whose satisfaction score improved from 57.0 to 63.4 (p < 0.05).

Conclusion. Patients with type 2 diabetes mellitus who received pharmacistmanaged diabetes care demonstrated improved HbA_{1c}, systolic blood pressure, and low-density-lipoprotein cholesterol levels and quality-of-life measures and met treatment goals more often than patients receiving standard care.

Index terms: Ambulatory care; Clinical pharmacists; Diabetes mellitus; Interventions; Pharmaceutical services; Quality of life

Am J Health-Syst Pharm. 2006; 63:2116-22

 \leq 7% is an important indicator of blood glucose control.⁴

Pharmacists' responsibilities

have evolved from the traditional dispensing of medications to a patient-oriented pharmaceutical

ogy Services, UNMC.

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Randy Rouse, B.S., and Bruno Himmler, M.D., are acknowledged for their support of this project.

Supported by a grant from the Health Resources and Services Administration, Bureau of Primary Care, Office of Pharmacy Affairs, Rockville, MD.

Presented at the American Diabetes Association 63rd Scientific Sessions, New Orleans, LA, June 2003.

care. However, little prospective and randomized data are available that show the importance of pharmacistmanaged care in the health outcomes of the diabetes population.

The effect of pharmacist-managed care was assessed in 12 community pharmacies in the Asheville Project in North Carolina, where pharmacists have been providing services to patients with diabetes since 1997.5 Pharmacists received reimbursement from two local employers for providing cognitive services (i.e., education, assessment, monitoring, follow-up, and referral). When compared with a control group, the patients who received pharmacist-led care had significant improvements in HbA₁ concentrations. Cioffi et al.6 assessed the effect of a clinical pharmacistdirected diabetes management clinic on glycemic control and concluded that a pharmacist can effectively care for patients with diabetes with poor glycemic control. Leal et al.7 assessed the use of a collaborative practice agreement involving pharmacists in the management of diabetes, hypertension, and hyperlipidemia. Although a comparison group was not included, patients treated by pharmacists had a 2% drop in mean HbA_{1c}, blood pressure, and lowdensity-lipoprotein (LDL) cholesterol levels compared with baseline. The pharmacist-managed service resulted in an increase of almost sevenfold in the number of patients reaching target HbA_{1c} levels. While these studies did not have a robust design, they do provide supportive evidence that pharmacist-managed diabetes care services are effective.

The goals of this study were to (1) develop a cooperative practice arrangement between physicians and clinical pharmacist for the management of patients with type 2 diabetes mellitus and (2) assess the effect of the clinical pharmacist's interventions on patients' health outcomes. Primary endpoints were HbA_{lc} levels and quality of life. Secondary end-

points included body mass index (BMI), weight, blood pressure, cholesterol levels, use of therapeutic shoes, aspirin therapy, and influenza vaccination.

Methods

Siouxland Community Health Center (SCHC) is located in Sioux City, Iowa, and has an onsite pharmacy that fills approximately 225 prescriptions per day, 17% of which are filled for patients in patient assistance programs. Of the patients whose prescriptions are filled, most are Caucasian (40%) and Hispanic (39%). A total of 61% of patients are at or below the 100% poverty level, and 33% are eligible for Medicaid.

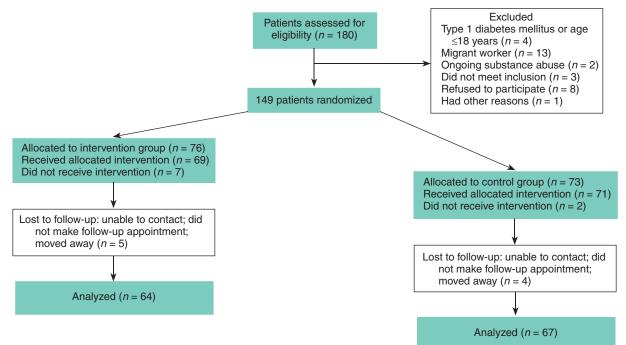
Study design. To be eligible for this study, patients had to be SCHC members, be over 18 years of age, and have a diagnosis of type 2 diabetes mellitus. Primary care providers referred patients with diabetes to the clinical pharmacist or the nurse to learn about the study and consent to study enrollment. Patients were excluded if they foresaw difficulties completing the study, were migrant workers, or abused drugs. Using a random numbers table, a group assignment list was made. After signing the consent form, each patient was randomly assigned by the clinical pharmacist and nurse to the intervention group or control group (Figure 1).

Patients in the intervention group were enrolled into a pharmacistmanaged diabetes care program (appendix). Patients in the control group received standard diabetes care and were managed by a nurse. All enrollees attended appointments at baseline and at three, six, and nine months. The nurse collecting the data for the control group was restricted to gathering information and instructed not to provide any additional education. Providers and staff were instructed to provide health care as usual (standard care), which included distributing patient education materials and monitoring blood glucose levels. Providers used their own discretion to educate, motivate, refer, and manage patients. Participants in both groups received an incentive package, paid by grant funds, to reduce study attrition. Participants received a free blood glucose monitor, blood glucose strips, and a \$5.00 gift certificate to a grocery store for each completed study visit. The study protocol was approved by University of Nebraska Medical Center's institutional review board.

Delivery of the care in the intervention group was over the initial three months and consisted of appointments every two weeks, group-session appointments, and telephone follow-up when necessary. The clinical pharmacist recruited for this project was a recent graduate of the University of Nebraska who had completed a one-year primary care residency program and had previous experience working with low-income patients. The clinical pharmacist worked closely with the physicians and other providers and consulted on pharmacotherapy for patients at SCHC. Each appointment focused on disease management, lifestyle adjustments, and goal setting. Group sessions lasted for two hours and consisted of six to eight patients. A pharmacist, dietitian, and nurse were also present and reviewed nutrition and basic diabetes management with participants. Each group meeting focused on patients' needs, and discussion was guided by topics chosen by the participants. Since 32% of participants were Hispanic, specific group meetings were available for Spanish-speaking patients. Throughout the study, the clinical pharmacist reminded patients of appointments and referred patients to their provider to address other health concerns.

Throughout the two-week followup sessions, patients in the intervention group were encouraged to monitor their blood glucose levels

Figure 1. The flow of participants.



twice daily. Medication reviews were conducted at each appointment, and recommendations to providers based on glucose monitoring were made and implemented by the pharmacist or physician. The pharmacist provided other therapeutic interventions, including initiating aspirin therapy, administering influenza vaccinations, referring patients for therapeutic shoes, and managing medications for hypertension and dyslipidemia.

Assessment of study outcomes. The primary endpoint was reduction of HBA_{1c} levels; secondary outcome measures included weight loss, an improved BMI, decreased blood pressure, and an improved lipid panel. They were measured at the baseline and at three-, six-, and nine-month appointments. Patients were also assessed for hypoglycemia, microalbuminuria, and foot monofilament sensitivity; these data are not reported here.

Quality-of-life measures were assessed using the Diabetes Quality of Life (DQOL) questionnaire, which has been used to assess quality of life in patients with type 1 and type 2 diabetes mellitus.^{8,9} Five different components (health level, satisfaction, impact, worry about disease, and worry about social and vocational issues) were assessed at baseline and at six and nine months.

Statistical analysis. Assessment measures were documented using Microsoft Access (Microsoft Corp., Redmond, WA) and then transferred to an SAS database (SAS Institute, Cary, NC). Data collected by DQOL questionnaires were entered into Microsoft Excel spreadsheets and transferred to SAS for analysis. DQOL was scored based on published criteria.¹⁰ SAS version 6 was used for all statistical analyses. The chi-square test of independence and Fisher's exact test were used to assess similarity in demographics between groups. Oneway analysis of variance (ANOVA) and t tests were used to compare groups at baseline and nine months. An alpha of 0.05 was used.

Results

No significant differences in sex, age, or racial distribution were found between groups (Table 1). There were no significant differences between groups for the presence of metabolic syndrome, prescription medications for hypertension, and dyslipidemia.

Changes in clinical endpoints from baseline are shown in Table 2. Mean HbA_{1c} levels fell significantly (p = 0.003) from baseline to nine months. ANOVA found a 1.0 difference in HbA_{1c} between means for the intervention and control groups (p < 0.05). The difference in systolic blood pressure after nine months was significant between groups (p = 0.023). Mean LDL cholesterol levels decreased in both groups, with a -11.2-mg/dL difference (p = 0.012). Net changes in other clinical variables were not remarkable.

The effects of diabetes on patients' quality of life are shown in Table 3. The health level of the intervention group was at a significantly higher level when the study began and improved over the nine-month study period, with a 10.1 difference in health level between groups (p = 0.002). Satisfaction level improved in both groups, with a 7.6 difference in satisfaction scores after nine months

| | No. (% | %) Participants | | |
|------------------------|--------------------------------|---------------------------|----------------------------|--|
| Characteristic | Intervention Group (n = 76) | Control Group (n = 73) | Total (<i>n</i> = 149) | |
| Female | 44 (57.9) | 47 (64.4) | 91 (61.1) | |
| Race | | | | |
| Caucasian | 43 (56.6) | 41 (56.2) | 84 (56.4) | |
| Hispanic | 26 (34.2) | 22 (30.1) | 48 (32.2) | |
| African American | 4 (5.3) | 1 (1.4) | 5 (3.4) | |
| American Indian | 1 (1.3) | 4 (5.5) | 5 (3.4) | |
| Asian | 0 | 1 (1.4) | 1 (0.7) | |
| Not reported | 2 (2.6) | 4 (5.5) | 6 (4.0) | |
| Age (yr) | | | | |
| <20 | 1 (1.3) | 1 (1.4) | 2 (1.3) | |
| 20–29 | 3 (3.9) | 0 | 3 (2.0) | |
| 30–39 | 8 (10.5) | 7 (9.6) | 15 (10.1) | |
| 40–49 | 26 (34.2) | 25 (34.2) | 51 (34.2) | |
| 50–59 | 23 (30.3) | 25 (34.2) | 48 (32.2) | |
| 60–69 | 15 (19.7) | 15 (20.6) | 30 (20.1) | |
| Diagnosis of metabolic | | | | |
| syndrome | 62 (81.6) | 62 (84.9) | 124 (83.2) | |
| Diabetes drugs | | | | |
| Metformin | 50 (65.8) | 56 (76.7) | 106 (71.1) | |
| Oral sulfonylurea | 44 (57.9) | 50 (68.5) | 94 (63.1) | |
| Thiazolinedione | 38 (50.0) | 36 (49.3) | 74 (49.7) | |
| Insulin | 21 (27.6) | 18 (24.7) | 39 (26.2) | |
| Antihypertensive | | | | |
| agents | 50 (65.8) | 51 (69.8) | 101 (67.7) | |
| Antilipemic agents | 49 (64.5) | 43 (58.9) | 92 (61.7) | |

Table 1. Characteristics of Particin

(p = 0.007). Both impact score and worry about disease changed significantly between groups (p = 0.002 and p = 0.037, respectively).

The number and percentage of patients who reached ADA treatment goals are shown in Table 4. More patients reached ADA goals in the intervention group. The primary endpoint (HbA_{1c} \leq 7%) was achieved in two thirds of the intervention group (43 of 64), compared with 24 of 67 patients in the control group (p =0.05). While blood pressure changed very little in the control group, 50 of 64 patients in the intervention group achieved the systolic blood pressure treatment goal (p = 0.04). Aspirin therapy was achieved in 52 of 64 patients in the intervention group, compared with 31 of 67 in the control group (p = 0.02). Of the 64 patients in the intervention group,

35 received an influenza vaccination, compared with 30 of the 67 in the control group (p = 0.05).

Discussion

The first goal of this study was to develop a collaborative practice arrangement between SCHC providers and a clinical pharmacist for pharmacist-led diabetes management. The data collected revealed that this collaboration was successful. After this study, a clinical pharmacist was hired, has become a standard component of SCHC's diabetes care program, and continues to work with physicians, physician assistants, and nurse practitioners to develop pharmacy services.

One limitation of this study was a potential "site-interaction effect," since the intervention group was not blinded. The intervention group could not be blinded because the pharmacist was not acting under a protocol for medication adjustments. The lack of blinding may have allowed providers to implement more aggressive care compared with the usual care they previously provided. This most likely had some effect on patients with diabetes in both study groups. However, it is important to note the changes that occurred within each group after nine months.

The second goal of this study was to assess the effect of a clinical pharmacist's interventions in patients with diabetes. The intervention group had significant clinically improved outcomes in the primary endpoint and some secondary endpoints.

While improvement was expected in the intervention group, the considerable change in HbA₁ in the control group from baseline to nine months was unexpected. One possible explanation for this is that the research was conducted in one setting, and during the study period providers improved the level of care provided. Providers were not blinded from pharmacist recommendations, and the site-interaction effect probably led to an improvement of HbA_{1c} levels in the control group. The pharmacist's recommendations were likely partially responsible for nurses' use of more appropriate forms of intervention. Another explanation for the improved HbA₁ levels in the control group is that incentives for participation (i.e., blood glucose monitors and testing strips) had a positive effect on both groups. Feedback of glucose monitoring results and regular HbA_{1c} testing may have led to improved HbA_{1c} levels in both groups, particularly among the patients with poorly regulated blood glucose levels. Hence, the extra activities and attention that patients received may have affected outcomes in both groups (Hawthorne effect).¹¹ Future research should examine pharmacist-managed diabetes care

| | | | Month | | Change from Baseline to | Net Difference Between |
|--------------------------|----------|------------------|------------------|--------------------|----------------------------|---------------------------|
| Variable ^a | Baseline | 3 | 6 | 9 | Month 9 | Groups |
| No. patients | | | | | | |
| Intervention | 76 | 69 | 64 | 64 | | |
| Control | 73 | 71 | 63 | 67 | | |
| HbA _{1c} (%) | | | | | | |
| Intervention | 8.8 | 7.1 ^b | 6.7 ^b | 7.08 ^c | -1.7 | -1.0 |
| Control | 8.7 | 7.8 | 7.7 | 8.0 | -0.7 | |
| BMI (kg/m ²) | | | | | | |
| Intervention | 36.4 | 36.4 | 34.8 | 36.0 | -0.4 | -0.2 |
| Control | 35.9 | 36.1 | 36.0 | 35.7 | -0.2 | |
| Weight (lb) | | | | | | |
| Intervention | 225.3 | 225.7 | 216.9 | 221.3 | -4.0 | -1.4 |
| Control | 217.5 | 218.2 | 217.4 | 214.9 | -2.6 | |
| Diastolic BP (mm Hg) | | | | | | |
| Intervention | 79.3 | 79.8 | 78.1 | 75.9 | -3.4 | -2.0 |
| Control | 79.6 | 78.5 | 80.0 | 78.2 | -1.4 | |
| Systolic BP (mm Hg) | | | | | | |
| Intervention | 130.0 | 130.6 | 127.9 | 126.6 ^d | -3.4 | -5.5 |
| Control | 130.7 | 127.9 | 132.2 | 132.8 | 2.1 | |
| LDL cholesterol (mg/dL) | | | | | | |
| Intervention | 116.1 | 103.5 | 96.7 | 96.7 ^e | -19.4 | -11.2 |
| Control | 120.5 | 112.0 | 103.4 | 112.3 | -8.2 | |
| HDL cholesterol (mg/dL) | | | | | | |
| Intervention | 41.3 | 44.0 | 42.2 | 42.9 | 1.6 | 0.7 |
| Control | 41.5 | 41.8 | 39.4 | 42.4 | 0.7 | |

Table 2.

^aHbA_{1c} = glycosylated hemoglobin, BMI = body mass index, BP = blood pressure, LDL = low-density-lipoprotein, HDL = high-density-lipoprotein. ^bp < 0.05.

p < 0.05. p = 0.003.

 ${}^{d}p = 0.023.$

 $e^{p} = 0.012.$

programs in multiple community health centers.

Regardless of these limitations, the 1.0 difference in HbA_{1c} levels between the intervention and control groups was significant. The UKPDS found that for every 1% reduction in HbA_{1c} that is maintained over 10 years, the relative risk for microvascular complications, diabetes-related deaths, and myocardial infarction declined by 37%, 21%, and 14%, respectively.^{12,13} The DCCT found that lowering the HbA_{1c} also reduced the risk for complications from type 1 diabetes mellitus.³ Although this study only lasted nine months, the investigators believed the 1.0 difference was clinically significant and, if maintained, should reduce the risk of complications associated with type 2 diabetes mellitus.

Regarding quality of life, patients in the intervention group were more satisfied, had a higher impact score, had less worry about their disease, and had a higher perceived health level over the nine-month study compared with the control group. Health level, satisfaction, and impact score changed slightly in the control group; their worry about disease decreased slightly. Therefore, some of the DQOL findings supported the hypothesis that the provision of pharmacist-managed care improves the quality of life of patients with type 2 diabetes mellitus.

The number of patients lost to follow-up may have affected the

study findings. Between baseline and nine months, 33 patients in the intervention group and 34 patients in the control group did not complete the DQOL. Since the study appointments were long, the DQOL questionnaire (with a postage-paid reply envelope) was sent home with the patient to complete. While this decision decreased the appointment time by 15 minutes, it also reduced the participation rate for the qualityof-life component.

The reduction in systolic blood pressure was attributed to adjustments to antihypertensive agents made by the clinical pharmacist working with the providers. Preventive measures, such as aspirin therapy and influenza vaccination, were more

| | | Мо | nth | Change from Baseline at | Net Difference Between |
|--|--------------------|-------------------|-------------------|----------------------------|---------------------------|
| Measure ^a | Baseline | 6 | 9 | Month 9 | Groups |
| No. responding | | | | | |
| Intervention | 76 | 53 | 43 | | |
| Control | 70 | 45 | 34 | | |
| Health level | | | | | |
| Intervention | 39.0 ^b | 60.0 ^b | 54.0 ^c | 15.0 | 10.1 |
| Control | 25.9 | 27.9 | 30.8 | 4.9 | |
| Satisfaction | | | | | |
| Intervention | 63.7 ^b | 77.4 ^b | 77.4 ^d | 13.7 | 7.6 |
| Control | 57.0 | 63.5 | 63.4 | 6.4 | |
| Impact | | | | | |
| Intervention | 70.5 | 77.7 ^b | 77.2 ^e | 6.7 | 4.9 |
| Control | 66.5 | 69.7 | 68.3 | 1.8 | |
| Worry about disease | | | | | |
| Intervention | 66.5 | 75.8 | 76.6 ^f | 10.1 | 11.6 |
| Control | 68.2 | 63.7 | 66.7 | -1.5 | |
| Worry about social and vocational issues | | | | | |
| Intervention | 67.3 | 69.6 | 75.5 | 8.2 | -3.1 |
| Control | 67.0 | 62.0 | 78.3 | 11.3 | |
| Total DQOL score | | | | | |
| Intervention | 262.0 ^b | 303.3 | 286.4 | 24.4 | 9.6 |
| Control | 232.5 | 236.8 | 247.3 | 14.8 | |

Table 3.

^aAssessed using the Diabetes Quality of Life (DQOL) questionnaire.

 $^{d}p = 0.0007.$ $e^{p} = 0.002.$

fp = 0.037.

Table 4.

Comparison of Patients Who Reached Treatment Goals^a

| | Change from Bas | eline at Month 9 | Net Difference | |
|---|--------------------------|------------------|----------------|-------------------|
| Goal ^b | Intervention (n = 64) | | | р |
| HbA _{1c} < 7% | 24 (42.2) | 4 (8.4) | 20 (33.8) | 0.05 |
| $HbA_{1c} > 9\%$ | -24 (-29.3) | –15 (–18.6) | -9 (-10.7) | 0.08 |
| LDL cholesterol < 100 mg/dL | 5 (14.8) | -5 (-4.7) | 10 (10.1) | 0.10 |
| HDL cholesterol > 40 mg/dL | -1 (-6.9) | -5 (-7.5) | -4 (-0.6) | 0.13 |
| Diastolic BP < 80 mm Hg | 1 (12.9) | 6 (13.9) | -5 (-1.0) | 0.11 |
| Systolic BP < 130 mm Hg | 19 (37.3) | -1 (-2.5) | 20 (34.8) | 0.04 ^c |
| Aspirin therapy | 26 (47.1) | -1 (-2.5) | 27 (44.6) | 0.02 ^c |
| Influenza vaccination | 25 (41.5) | 12 (20.1) | 13 (21.4) | 0.05 ^c |
| Therapeutic shoes (referral and purchase) | 12 (18.8) | 0 | 12 (18.8) | |

^aTreatment goals established by the American Diabetes Association in American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2004; 27(suppl 1):S1–35.) ^bHbA_{1c} = glycosylated hemoglobin, LDL = low-density-lipoprotein, HDL = high-density-lipoprotein, BP = blood pressure. ^cp < 0.05 (Fisher's exact test).

^b*p* < 0.05.

 $c^{c}p = 0.002.$

common in the intervention group. Significant improvement in HbA_{1c} levels in the intervention group suggests that pharmacist involvement increased the number of patients achieving ADA goals, compared with patients receiving standard care.

Conclusion

Patients with type 2 diabetes mellitus who received pharmacistmanaged diabetes care demonstrated improved HbA_{1c}, systolic blood pressure, and LDL cholesterol levels and quality-of-life measures and met treatment goals more often than patients receiving standard care.

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Appendix—Outline of pharmacist-led diabetes care program at Siouxland Community Health Center

I. Baseline (one-hour appointment)

- A. Gather information regarding diet, social history, underlying disease states, current therapy, etc.
- B. Patient education
 - 1. Brief diabetes overview
- 2. Testing blood glucose levels—how, when, why
 - 3. Training on glucose monitors
 - 4. Benefits, risks, options for improving blood glucose levels
 - 5. Drug therapy (use of insulin and hypoglycemic agents)
 - 6. Psychological adjustment in diabetes
 - Signs and symptoms of hyperglycemia, hypoglycemia, and diabetic ketoacidosis and course of action
 - 8. Patient concerns
 - 9. Implementation of pharmacotherapy management recommendations approved by provider

II. Week 2 (one-hour appointment)

- A. Compliance and reassurance
- B. Patient education
 - Set therapy goals, start selfmanagement, risk factor reduction, behavior changes
 - 2. Nutritional management (carbohydrate counting)
 - 3. Preconception care
 - 4. Sick days
 - 5. Food frequency questionnaire
 - 6. Patient concerns
 - Implementation of pharmacotherapy management recommendations approved by provider

III. Week 4 (one-hour appointment)

- A. Assess glucose control and diet modification
- B. Patient education
 - 1. Exercise benefits and invitation to a YMCA program^a

- 2. Family involvement
- 3. Foot care
- 4. Hypoglycemic reactions (reminder)
- 5. Exercise questionnaire
- 6. Patient concerns
- Implementation of pharmacotherapy management recommendations approved by provider

IV. Week 6 (two-hour group session)

- A. Assess patient activity level; reinforcementB. Patient education
 - 1. In-depth discussion of diabetes
 - 2. Nutritional management (dietitian)
 - 3. Self-management (nurse)
 - 4. Discuss relationship among nutrition, exercise, medication, and blood glucose levels
 - Cardiovascular education (lipids, blood pressure, peripheral vascular disease; set goals)
 - 6. Prevention, detection, and treatment of complications
 - 7. Patient concerns

V. Month 3 (one-hour appointment)

- A. Patient education
- B. Discuss HbA_{1c} from first visit
- C. Recommendations for acute care
 - 1. Eye and dental care—possible referral
 - 2. Problem-solving skills
 - 3. Psychosocial, daily stress concerns
 - 4. Patient questions or concerns
 - Implementation of pharmacotherapy management recommendations approved by provider

VI. Month 6 (one-hour appointment)

- A. Discuss HbA_{1c} from first and second visits, stress compliance, assess progress, what can we do if not meeting goals, positive reinforcement if reaching goals
- B. Patient education
 - 1. Health benefits of good glucose control
 - 2. Smoking cessation, if applicable
 - 3. Alcohol reduction, if applicable
 - 4. Patient questions or concerns
 - Implementation of pharmacotherapy management recommendations approved by provider

VII. Month 9 (one-hour appointment)

- A. Discuss HbA_{1c} from all visits, assess progress, and make recommendations if needed
- B. Patient education
 - 1. Community resources
 - 2. When to notify a physician
 - 3. How to continue goals/long-term plans
 - 4. Patient concerns
 - 5. Group dietitian meeting
- C. Implementation of pharmacotherapy management recommendations approved by provider

^aYMCA = Young Men's Christian Association. Each patient is required to receive a provider's approval before participating in the program.

PRACTICE REPORTS

Survey of care provided by ambulatory care pharmacists to patients with chronic kidney disease

ROBIN E. BENNETT, RENEE M. DEHART, AND STACY A. LAUDERDALE

• ach year a significant number of patients are affected by chronic kidney disease (CKD) that will progress to end-stage renal disease (ESRD) and result in the need for long-term dialysis treatment. The United States Renal Data System (USRDS) estimates that there are 8 million patients in the United States with an estimated glomerular filtration rate (GFR) under 60 mL/ min/1.73 m² and an additional 12 million with evidence of microalbuminuria.1 The USRDS reported that the size of the Medicare population with CKD grew 146% between 1992-93 and 2002-03.1 The economic effect of CKD is also tremendous and demands better treatment strategies be developed. In 2003, the federal government spent \$18.1 billion for the care of patients with ESRD.1 This affects many levels of society and supports the growing need to address CKD in its earliest stages.

The complications of CKD have been well established, but the care and treatment associated with the complications are currently lacking. Numerous studies document the **Purpose.** A survey was conducted to determine the role of ambulatory care pharmacists in the care of patients with chronic kidney disease (CKD).

Methods. Data from a survey of ambulatory care pharmacists in the treatment and management of patients with CKD were collected. A 22-item anonymous survey was sent to 1028 potential respondents in January 2004. Only pharmacists indicating routine provision of care to patients with risk factors for the development of CKD or with stages 1–4 of CKD were included in the analysis. Additional questions surveyed the timeliness and frequency of nephrology referrals and the pharmacists' familiarity with National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) guidelines.

Results. Of 1028 surveys, 535 were completed and returned. Only respondents who provided care in an outpatient setting to geriatric patients and patients with diabetes mellitus, hypertension, or decreased creatinine clearance were included in the analysis (n = 388). Initial assessment of CKD was performed by 85% of the surveyed pharmacists. Over one third of the pharmacists made nephrology referrals. However, even pharmacists who had a high percentage of patients with a known risk for CKD infrequently screened for kidney dysfunction, and only a small portion monitored the areas recommended by NFK-K/DOQI. The respondents' familiarity with the NFK-K/DOQI guidelines indicated that 7% were very familiar, 45% were somewhat familiar, 34% were not very familiar, 13% were not at all familiar, and 1% did not respond. Conclusion. The ambulatory care pharmacists surveyed were not consistently involved in the routine monitoring of common complications of CKD.

Index terms: Ambulatory care; Data collection; Diabetes mellitus; Geriatrics; Guidelines; Hypertension; Interventions; Kidney diseases; National Kidney Foundation; Pharmaceutical services; Pharmacists Am J Health-Syst Pharm. 2006; 63:2123-7

poor quality of care that patients with CKD receive.²⁻⁶ Israni et al.³ investigated the management of CKD in an academic primary care clinic. The

results showed suboptimal care in the areas of blood pressure control, use of angiotensin-converting-enzyme inhibitors (ACEIs) or angiotensin-

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No external financial support was received for the completion of this research.

Presented in poster form at the 2004 American College of Clinical Pharmacy Annual Meeting in Dallas, TX, October 27, 2004.

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receptor blockers (ARBs), identification of proteinuria, and the number of patients referred to nephrologists. In patients with a mean creatinine clearance (CL_{cr}) of 39 mL/min, only 41% received an ACEI or ARB, only 54% had urinalysis performed, and only 21% had been referred to a nephrologist. Kausz et al.6 also examined the care received by patients with CKD. Over 4000 patients were followed between October 1, 1994, and September 30, 1998. The average serum creatinine concentration of the patients was 3.2 mg/dL; the average estimated GFR was 22 mL/min. Only 18% and 15% had iron concentrations and serum parathyroid hormone concentrations measured, respectively. The percent of patients with a mean hematocrit of less than 30% was 38%. In addition, 55% did not have a proper calcium-phosphate balance.6

While specific monitoring guidelines can help the health care provider assess the progression of CKD, the patient may also need specialized nephrology care to adequately prepare for renal replacement therapy. Many patients begin and continue care with a health care provider who is not a nephrologist. Prospective trials have determined an association with early nephrologist referral and improved outcomes, although these trials have not been randomized.7-9 The role of the pharmacist in referring patients to nephrologists has not been well studied to date.

There are not much research and data on the pharmacist's contribution in the care of patients with CKD who are not yet dependent on dialysis, and the pharmacist's role has not been clearly established. Ambulatory care pharmacists are well positioned to care for patients who are seen on a regular basis. The potential for continuity of care provides the pharmacist an opportunity to identify and monitor signs of early disease in vulnerable patients with diabetes mellitus, hypertension, or decreased CL_{cr}. The primary objective of this project was to determine what the role of a specific group of ambulatory care pharmacists was in the care of patients with CKD.

Methods

A survey was created to investigate the role of ambulatory care pharmacists in the treatment and management of patients with CKD. A national sample of pharmacists who self-identified themselves as ambulatory care pharmacists through membership in the Ambulatory Care Practice and Research Network of the American College of Clinical Pharmacy was surveyed. The project was approved and received exempt status from informed consent by the local institutional review board (IRB). A cover letter, a 22-item anonymous survey, and a self-addressed, stampedreturn envelope were sent to 1028 potential respondents through the U.S. Postal Service in January 2004. The respondents were requested to return the survey within two weeks of receipt. No reminder notices or incentives for participation were provided. Only pharmacists indicating routine provision of care to patients with risk factors for development of CKD (e.g., hypertension, diabetes, and advanced age) or with stages 1-4 of CKD (as subjectively reported by these pharmacists) were included in the analysis. The survey included questions regarding the frequency of monitoring for anemia and calcium and phosphorus homeostasis, and respondents were asked to provide an estimate of the percentage of patients under their care with CKD, defined by a CL_{cr} of less than 60 mL/min. These questions were designed to assess pharmacists' involvement in the screening and management of anemia and renal osteodystrophy of CKD. Additional questions surveyed the timeliness and frequency of nephrology referrals and pharmacists' overall familiarity with all published National Kidney Foundation Kidney

Disease Outcomes Quality Initiative (NKF-K/DOQI) guidelines. Predefined subgroup analyses were performed to assess the relationship of the provision of pharmaceutical care to CKD patients and the status of board certification by the Board of Pharmaceutical Specialties (BPS), the highest level of formal pharmacy training completed, and the number of CKD patients managed as a percentage of the total number of patients managed by the responding pharmacist.

Survey data were entered into a Microsoft Access database (Microsoft Inc., Redmond, WA), and the comparative analysis of the prespecified subgroups was completed using Graphpad InStat, version 3.0 (Graphpad Software, San Diego, CA). Comparisons of nominal data were conducted using Fisher's exact test or the chi-square test for independence, and comparisons of continuous data were conducted using an unpaired t test and one-way analysis of variance. Alpha values of less than 0.05 were considered to be statistically significant.

Results

Of 1028 surveys, 535 were completed and returned for a survey response rate of 52%. Only respondents indicating that they provided care in an outpatient setting to geriatric patients and patients with diabetes, hypertension, or decreased CL_{cr} were included in the analysis. The results are based on the 388 surveys that fulfilled the preceding inclusion criteria.

Survey respondent demographics. Ambulatory care clinics were the primary patient care setting of 298 respondents (77%). The average time of practice in an outpatient setting was 5.6 years, and the majority of respondents participated in less than 10 direct patient encounters per day (n = 228, 59%). Thirty-eight percent (n = 149) of the respondents were certified by BPS, and 49% (n = 190) had completed a specialty residency as the highest level of pharmacy training. Survey responses were received from 45 of the 50 states as well as Puerto Rico and Canada. Survey responses indicated that 49% of respondents estimated that 10–25% of their patients had a $CL_{\rm cr}$ of less than 60 mL/min, 38% estimated that 26–50% of their patients had a $CL_{\rm cr}$ of less than 60 mL/min, and 8% estimated that greater than 50% of their patients had a $CL_{\rm cr}$ of less than 60 mL/min.

Assessment and monitoring of kidney dysfunction. Initial assessment and monitoring of CKD were clinical functions performed by 85% of the surveyed pharmacists. Rates of assessment and monitoring of kidney function did not differ significantly according to BPS certification, highest level of pharmacy education, or the estimated percentage of patients with a CL_{cr} of less than 60 mL/min (Table 1).

Monitoring for anemia. In patients diagnosed with anemia secondary to CKD, pharmacists reported that their most common role in the disease state management of these patients was recommendation of appropriate therapy and monitoring of established therapy (41%). Other reported roles included recommending appropriate therapy only (without any subsequent monitoring responsibilities) (23%), managing therapy after initiation by another provider (12%), and no participating role in the management of the patient (9%). Monitoring hemoglobin and hematocrit levels in patients with CKD was routine for 24% of survey respondents. Self-reported rates of hematologic monitoring differed significantly according to respondent subgroup (Table 2).

Monitoring calcium and phosphorus homeostasis. Monitoring of calcium and phosphate levels was reported to be routine by 16% of the survey respondents. The pharmacists who regularly assessed calcium and phosphorus homeostasis identified monitoring rates of monthly (16%), every three months (26%), every six months (29%), annually (8%), and other or no response (21%). Intact parathyroid hormone (i-PTH) levels were routinely monitored less frequently (4% of respondents) than other markers of renal osteodystrophy and secondary hyperparathyroidism.

Table 1.

| Routine Assessment/Monitoring | No. Respo | | |
|--|--------------|----------|--------------------|
| of Kidney Dysfunction | Yes | No | р |
| Overall survey population | 330 (85) | 58 (15) | |
| Subgroups | | | |
| Certification status | | | 0.104 ^b |
| BPS ^a (<i>n</i> = 149) | 133 (89) | 16 (11) | |
| Non-BPS (<i>n</i> = 239) | 198 (83) | 41 (17) | |
| Level of training | | | 0.072 ^c |
| Pharm.D. ($n = 68$) | 60 (88) | 8 (12) | |
| Pharmacy practice residency | | | |
| (<i>n</i> = 97) | 76 (78) | 21 (22) | |
| Specialty residency ($n = 190$) | 167 (88) | 23 (12) | |
| % of patients seen with CL _{rr} ^d <60 mL/min | | | 0.265 ^c |
| 10–25% (<i>n</i> = 190) | 36 (19) | 154 (81) | |
| 26–50% (<i>n</i> = 146) | 43 (29) | 103 (71) | |
| >50% (<i>n</i> = 32) | 12 (38) | 20 (63) | |

^aBPS = Board of Pharmaceutical Specialties.

^bFisher's exact test.

^cChi-square test for independence.

 ${}^{d}CL_{cr} = creatinine clearance.$

Table 2.

Assessment and Monitoring of Hemoglobin and Hematocrit Levels (n = 388)

| Routine Assessment/Monitoring | No. Respoi | | |
|--|---------------|----------|--------------------|
| of Hemoglobin and Hematocrit Levels | Yes | No | р |
| Overall survey population | 93 (24) | 295 (76) | |
| Subgroups | | | |
| Certification status | | | 0.027 ^b |
| BPS ^a (<i>n</i> = 149) | 45 (30) | 104 (70) | |
| Non-BPS (<i>n</i> = 239) | 48 (20) | 191 (80) | |
| Level of training | | | 0.027 ^c |
| Pharm.D. ($n = 68$) | 25 (37) | 43 (63) | |
| Pharmacy practice residency ($n = 97$) | 22 (23) | 75 (77) | |
| Specialty residency ($n = 190$) | 38 (20) | 152 (80) | |
| % of patients seen with CL _{cr} ^d <60 mL/min | | | 0.024 ^c |
| 10–25% (<i>n</i> = 190) | 36 (19) | 154 (81) | |
| 26–50% (<i>n</i> = 146) | 44 (30) | 102 (70) | |
| >50% (<i>n</i> = 32) | 12 (38) | 20 (63) | |

^aBPS = Board of Pharmaceutical Specialties.

^bFisher's exact test.

^cChi-square test for independence.

^dCL_{cr} = creatinine clearance.

Routine monitoring of i-PTH levels was conducted quarterly, biannually, and annually by 36%, 29%, and 14% of respondents, respectively. None of the respondents reported monthly monitoring of i-PTH levels, while 21% of respondents reported either another rate of monitoring or did not provide a response. Fifty percent of the pharmacists involved in monitoring calcium-phosphorus and i-PTH levels on a routine basis reported that their primary role in patient care was recommending and monitoring therapy. Similar to the survey responses regarding monitoring for anemia, other roles included recommending appropriate therapy only (without subsequent monitoring) (36%), managing therapy after initiation by another provider (7%), or no response (7%).

Subgroup analysis demonstrated that significantly more pharmacists with BPS certification routinely assessed and monitored calcium and phosphorus concentrations compared to pharmacists without BPS certification (p = 0.03). No significant differences in participation rates were identified when responses were analyzed on the basis of pharmacy training or the percentage of patients treated who had a CL_r of less than 60 mL/min. No statistically significant differences were noted in the percentages of pharmacists in the prespecified subgroups reporting routine monitoring of i-PTH levels (Table 3).

Participation in nephrology referrals. Over one third of the responding pharmacists participated in nephrology referrals (Table 4). Reported rates of nephrology referrals varied from daily (<1%) and weekly (5%) to monthly (20%). The modal response was less than monthly (65%). The extent and rate of nephrology referrals were not influenced by certification status, residency training, or the CL_{cr} of the patients.

Familiarity with NKF-K/DOQI guidelines. Respondents were re-

| Ta | ab | le | 3. |
|----|----|----|----|
| | | | |

Assessment and Monitoring of Serum Calcium, Phosphorus, and Intact Parathyroid Hormone (*n* = 388)

| | | . (%) ondents | |
|--|--------------|------------------|--------------------|
| Variable | Yes | No | р |
| Routine assessment/monitoring of serum calciur | n and phosp | horus | |
| Overall survey population | 62 (16) | 326 (84) | |
| Subgroups | | | |
| Certification status | | | 0.030 ^b |
| BPS ^a (<i>n</i> = 149) | 30 (20) | 119 (80) | |
| Non-BPS (<i>n</i> = 239) | 32 (13) | 207 (87) | |
| Level of training | | | 0.267 ^c |
| Pharm.D. (<i>n</i> = 68) | 14 (21) | 54 (79) | |
| Pharmacy practice residency ($n = 97$) | 11 (11) | 86 (89) | |
| Specialty residency ($n = 190$) | 30 (16) | 160 (84) | |
| % of patients seen with CL _{cr} <60 mL/min | | | 0.138 ^c |
| 10–25% (<i>n</i> = 191) | 27 (14) | 164 (86) | |
| 26–50% (<i>n</i> = 146) | 25 (17) | 121 (83) | |
| >50% (<i>n</i> = 32) | 9 (28) | 23 (72) | |
| Routine assessment/monitoring of intact parathy | yroid hormor | ne | |
| Overall survey population | 14 (4) | 374 (96) | |
| Subgroups | | | 0.782 ^b |
| Certification status BPS ($n = 149$) | 6 (4) | 143 (96) | |
| Non-BPS (<i>n</i> = 239) | 8 (3) | 231 (97) | |
| % of patients seen with CL _{cr} ^d <60 mL/min | | | 0.916 ^c |
| 10–25% (<i>n</i> = 190) | 8 (4) | 182 (96) | |
| 26–50% (<i>n</i> = 146) | 5 (3) | 141 (97) | |
| >50% (<i>n</i> = 32) | 1 (3) | 31 (97) | |

^aBPS = Board of Pharmaceutical Specialties.

^bFisher's exact test.

Table 4.

^cChi-square test for independence.

 ${}^{d}CL_{cr} = creatinine clearance.$

| Participation | in Nephrology | Referrals (n = 388) |
|---------------|---------------|---------------------|

| | | (%) ndents | |
|--|----------|---------------|--------------------|
| Participation in Nephrology Referrals | Yes | No | р |
| Overall survey population | 153 (39) | 235 (61) | |
| Subgroups | | | |
| Certification status | | | 0.155 [♭] |
| BPS ^a (<i>n</i> = 149) | 66 (44) | 83 (56) | |
| Non-BPS (<i>n</i> = 239) | 88 (37) | 151 (63) | |
| Level of training | | | 0.063° |
| Pharm.D. (<i>n</i> = 68) | 27 (40) | 41 (60) | |
| Pharmacy practice residency ($n = 97$) | 29 (30) | 68 (70) | |
| Specialty residency training ($n = 190$) | 84 (44) | 106 (56) | |
| % of patients seen with CL _{rr} ^d <60 mL/min | | | 0.405° |
| 10–25% (<i>n</i> = 190) | 72 (38) | 118 (62) | |
| 26–50% (<i>n</i> = 146) | 64 (44) | 82 (56) | |
| >50% (<i>n</i> = 32) | 15 (47) | 17 (53) | |

^aBPS = Board of Pharmaceutical Specialties.

^bFisher's exact test.

^cChi-square test for independence.

^dCL_{cr} = creatinine clearance.

quested to provide an assessment of their level of familiarity, ranging from not at all familiar to very familiar, with current NKF-K/DOQI guidelines. Responses indicated that 7% of surveyed pharmacists were very familiar, 45% were somewhat familiar, 34% were not very familiar, and 13% were not at all familiar with the current guidelines. One percent of the returned surveys did not have a reported estimate.

Discussion

The NKF-K/DOQI guidelines offer health care professionals specific methods for patient care. In light of these guidelines, the primary objective of this investigation was to determine the current role of the ambulatory care pharmacists in the care of patients with CKD and to identify areas where pharmacists' roles could be expanded in relation to the NKF-K/DOQI. In comparison with previous studies,^{3,6} pharmacists were not providing significantly better care related to CKD than other health care disciplines. A majority of pharmacists initially assessed the presence of kidney dysfunction. Even pharmacists who had a significant percentage of patients with a known risk for CKD infrequently screened for kidney dysfunction, no more than other respondents. Only a small portion monitored the areas recommended by the NKF-K/DOQI, such as anemia and secondary hyperparathyroidism. Therefore, areas for potential expansion can be identified; two main areas are the pharmacist's roles in monitoring CKD-associated anemia and secondary hyperparathyroidism and in referring patients to a nephrologist. Our sample focused

on patients who were at risk for or who already had CKD. The practice patterns noted in this study were especially troubling given the high-risk patient population of this study.

There were some limitations to the study. The first limitation is the sample size; a nonresponse bias may be present. The second limitation is the survey population. The survey results and any conclusions drawn need to be considered within the identified population and may not necessarily be characteristic of all ambulatory care pharmacists or of all pharmacists. In addition, the frequency of monitoring of the laboratory tests demonstrated in this study needs to be interpreted within the context of the routine patient follow-up. For example, patients with a CL of 30-60 mL/min require less frequent monitoring than patients with a CL_a of 15–29 mL/min.

The NKF-K/DOQI recommendation is that patients be referred to a nephrologist when their GFR falls below 30 mL/min. It may be possible that other members of the health care team, such as a nephrologist, may already be performing some of the monitoring discussed in our survey. If the patient has already seen a nephrologist, this could also explain why some pharmacists in this study may not have made referrals to nephrology.

Ambulatory care pharmacists are not the only health care professionals to encounter patients with CKD, but because of the previously discussed gap in current care, ambulatory care pharmacists are well positioned to affect the care of these patients. The current study indicates that pharmacists need to take more ownership of this opportunity to improve patient care with these patients. Because barely one half of respondents were familiar with NKF-K/DOQI guidelines, enhanced attempts at systematic pharmacist education of these guidelines is a reasonable first step in addressing this study's findings.

Conclusion

The ambulatory care pharmacists surveyed were not consistently involved in the routine monitoring of common complications of CKD.

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REPORTS

Development and clinical outcomes of pharmacist-managed diabetes care clinics

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Purpose. The development and outcomes of two pharmacist-managed diabetes care clinics (DCCs) are described.

Methods. Retrospective data analysis was performed to determine the outcomes for patients with type 2 diabetes mellitus who were treated in two pharmacist-managed DCCs. Primary outcome measures included changes in glycosylated hemoglobin (HbA_{1c}), fasting plasma glucose, body mass index, low-density-lipoprotein (LDL) cholesterol, high-density-lipoprotein cholesterol, triglycerides, and blood pressure and documented annual retinal and microalbumin screening. Secondary outcome measures included the use of aspirin and kidney-sparing agents and annual screening for thyroid-stimulating hormone.

n estimated 20.8 million Americans have diabetes mellitus, accounting for 7% of the U.S. population.¹ By 2050 or possibly sooner, the number of Americans living with diabetes is projected to Results. Data from 113 patients in the DCCs were analyzed. After one year, the mean reduction in HbA_{1c} levels was 1.3%, with a mean HbA_{1c} of 7.8%. HbA_{1c} goals were based on the institution's HbA1c normal range of 4.1-6.5%. Compared with baseline, over one third of patients met the HbA_{1c} and blood pressure goals of <7.5% and <130/80 mm Hg, respectively. Mean LDL cholesterol concentration decreased from 110 to 94 mg/dL. The mean concentration of triglycerides decreased from 243 to 178 mg/dL. Mean systolic blood pressure decreased from 136 to 132 mm Hg. Whereas the national average for uncontrolled diabetes (HbA_{1c} > 9.5%) was 36.9%, only 3.5% of patients at the pharmacist-managed DCCs had uncontrolled diabetes. Attainment rates of LDL cholesterol goals and annual retinal and microalbumin screenings were significantly higher in clinic patients compared with national averages. Threeyear postclinic inception data revealed similar favorable outcomes, most notably an average HbA_{1c} of 7.6% and 55% of patients meeting their target HbA_{1c} goal of <7.5%. **Conclusion.** Compared with national averages, DCCs managed by clinical pharmacists achieved higher screening rates and attained treatment goals more often.

Index terms: Ambulatory care; Clinical pharmacists; Diabetes mellitus; Interventions; Pharmaceutical services Am J Health-Syst Pharm. 2006; 63:1325-31

more than double.^{2,3} Type 2 diabetes mellitus represents approximately 90% of patients with this disease.¹ In 2002, the total cost for treating diabetes in our country was an estimated \$132 billion, with the majority

spent on treatment of long-term complications.⁴ Poor glycemic control manifests in costly, lifelong morbidities, including blindness, kidney failure, amputations, and cardiovascular disease. The economic burden

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mentation, or operation of the diabetes care clinics at NMCSD.

The authors acknowledge CAPT Richard Daly, M.D., CDR B. Jill Pettit, Pharm.D., BCPS, Linda Reynolds, Pharm.D., Rheta Sandoval, Pharm.D., and Christopher Abbott, M.D., for their help in initial clinic and protocol development; Keith Agent, M.S., for helping with statistical analysis; and Brookie Best, Pharm.D., and Kim E. Barrett, Ph.D., for reviewing the manuscript.

Presented in part at the ASHP Midyear Clinical Meetings in New Orleans, LA, December 6, 2001, and December 8, 2003.

The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or U.S. government.

DOI 10.2146/ajhp050430

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of treating long-term diabetes complications is well documented.^{4,5} Improving glycemic control in patients with type 2 diabetes mellitus can prevent or delay the onset, or slow the progression, of microvascular and some macrovascular complications.⁶⁻⁹

Patients can benefit from an individualized approach to comprehensive diabetes care. Comprehensive care involves a multidisciplinary approach with evaluation and education from specialty practitioners, such as endocrinologists, pharmacists, exercise physiologists, diabetes educators, nurses, dietitians, podiatrists, and ophthalmologists. A cornerstone of diabetes treatment is drug therapy, often with complex regimens, including multiple oral and injectable agents. A collaborative agreement between physicians and pharmacists is an innovative strategy to treat patients with diabetes that takes advantage of pharmacists' expertise in disease management and drug monitoring. Improved patient outcomes and reduced cost to health care systems are potential benefits of implementing an innovative ambulatory clinic model for diabetes treatment.

The Naval Medical Center San Diego (NMCSD) treats over 5000 patients with diabetes. NMCSD is a 500-bed comprehensive teaching hospital with more than 20 general and specialty ambulatory care clinics. In mid-1999, ambulatory care pharmacist specialists were specifically hired to expand the current pharmacist-managed ambulatory care services in anticoagulation and lipid clinics and to create new clinics. This article describes the development of two pharmacist-managed diabetes care clinics (DCCs) established at NMCSD and the diabetesrelated outcomes of enrolled patients, comparing these outcomes to national averages.

Methods

Clinic development. In early 2000, the ambulatory care pharma-

cist team at the NMCSD developed two DCCs for patients in the endocrinology and primary care clinics. Working in collaboration with a board-certified endocrinologist and primary care physicians, clinical practice guidelines and treatment algorithms were created based on national standards of care for diabetes and related comorbidities, including hypertension and hyperlipidemia.¹⁰⁻ ¹³ Patient encounter notes, care flow sheets, and patient care plan documents were developed.14 All pharmacist providers had similar educational backgrounds. Each held a doctor of pharmacy degree and completed at least one year of pharmacy practice residency in addition to undergoing significant scrutiny to attain prescribing privileges at the NMCSD to provide disease management under physician-approved protocols. Prescribing privileges are medicalcenter-approved guidelines authorizing pharmacists to perform specific clinical tasks related to patient care (e.g., prescribe medications, place and interpret laboratory orders, order various medical procedures). Moreover, the clinical pharmacists attended additional diabetes training courses held by the American Association of Diabetes Educators. Two pharmacist-managed DCCs were created: (1) a primary care DCC, managed by two pharmacists, and (2) an endocrinology DCC, managed by one pharmacist who was also a certified diabetes educator.

Initial outcomes analysis. One year after clinic inception, a continuous-improvement report was required to analyze the effectiveness of the pharmacist-managed DCCs. Hence, we conducted a retrospective chart review from April 2000 through May 2001. Patientidentifying information was not collected. Data from patients with type 2 diabetes mellitus who were enrolled in the pharmacist-managed DCCs and had two or more clinic encounters with a clinical pharmacist were analyzed. The few patients with type 1 diabetes mellitis, who received care in the endocrinology DCC, were excluded from data analysis.

Primary outcome measures were changes from baseline (at clinic enrollment) in diabetes-related markers, including glycosylated hemoglobin (HbA_{1c}), fasting plasma glucose, body mass index (BMI), low-density-lipoprotein (LDL) cholesterol, high-density-lipoprotein (HDL) cholesterol, triglycerides, and blood pressure. The numbers of patients receiving retinal and microalbumin annual screenings were also recorded. HbA₁, LDL cholesterol, and annual retinal screening and microalbumin screening clinical markers were benchmarked against available corresponding national averages of patients being treated for diabetes.¹⁵ The National Committee for Quality Assurance (NCQA) reported the mean percentages of patients achieving specified outcomes from combined data available from commercially accepted plans of the NCQA Health Plan Employer Data and Information Set (HEDIS) from 2000 through 2003. The NCQA HEDIS 2001 data set supplied the national averages to which DCC outcomes were compared.

The American Diabetes Association (ADA) HbA₁ target of less than 7.0% is less than 1% above the upper normal limit of 4.0-6.0% when measured by a Diabetes Control and Complications Trial-based assay.^{10,16,17} ADA's HbA_{1c} goal is based on data from prospective randomized clinical trials showing that a reduction in the average HbA_{1c} to approximately 7% (approximately 1% above the upper limit of normal) was associated with fewer long-term complications.^{6,7,16} Since no standardized HbA_{1c} assay existed, each laboratory based its normal HbA_{1c} range on its nondiabetic population and the particular assay used. During our study, the normal HbA₁ range of nondiabetic patients at NMCSD was

4.1–6.5%. Using ADA's target goal for HbA_{1c} (<1% above the upper limit of normal), the target HbA_{1c} was set at <7.5% for NMCSD's diabetic patients.

Secondary outcome measures included the percentage of patients who (1) received aspirin for cardioprotection, (2) had microalbuminuria or proteinuria and were taking a kidney-sparing agent (e.g., angiotensin-converting-enzyme inhibitor, angiotensin-receptor blocker, or calcium channel blocker), and (3) received annual thyroidstimulating hormone (TSH) screening by study end.

Statistical analysis. Patients served as their own control for within-patient comparisons of outcome variables. All comparisons for continuous variables were analyzed using a two-tailed paired *t* test. Chisquare analysis was used to analyze categorical data. The α level was set at 0.05. Outcomes from the study cohort were compared with corresponding national averages obtained from NCQA.¹⁵

Follow-up outcomes analysis. To assess sustainability of the initial outcomes, a cross-sectional assessment of outcome measures was conducted three years after DCC inception. All patients with type 2 diabetes mellitus enrolled in both DCCs as of March 2003 were included. Outcomes measures collected and summarized included HbA_{1c}, BMI, triglycerides, LDL and HDL cholesterol, and systolic and diastolic blood pressure.

Results

Clinic implementation. Even though other ambulatory care programs were successfully operating at NMCSD, collaborative work in a disease requiring such comprehensive management as diabetes was unfamiliar at NMCSD. Because initial pharmacist-managed DCC development met with some resistance from physicians, particularly the primary care DCC, a physician-mandated level of care specifying the extent of care that a pharmacist could provide was conceived and implemented. After several iterations with physician input, we developed three levels of diabetes care from which referring physicians could select. Each level indicated the care each physician was comfortable with the pharmacist providing and did not reflect the severity of patients' diabetes and comorbid conditions. Depending on the scope of the referral, clinical pharmacists provided patients with one of the following care levels: diabetes self-care education and counseling (level 1), level 1 care plus diabetes treatment and monitoring (including evaluation, laboratory monitoring, and modification of pharmacotherapy) (level 2), and level 2 care plus education, treatment, and monitoring of comorbid conditions (including hypertension and hyperlipidemia) (level 3). The pharmacists performed limited physical assessments for level 2 and level 3 patients, including blood pressure measurements and foot examinations. The primary care DCC enrolled level 1-3 patients, and the endocrinology DCC enrolled only level 3 patients. In the primary care DCC, a physician could choose to move a patient from one level to another at any time. As their comfort level increased with the pharmacistprovided care, physicians advanced the majority of their patients to level 3 care. Because of the dynamic nature of this process, the number of patients at each level was constantly changing. Therefore, a clean comparison among levels of care could not be achieved. A designated physician oversaw and participated in the collaborative effort of each pharmacist-managed DCC.

Patients who were not meeting their metabolic goals or who needed in-depth disease education and counseling were referred to the DCCs from the internal medicine and primary care clinics. After a 90minute initial visit, patients met with a DCC pharmacist every 4-12 weeks (45-60 minutes per session) for individualized diabetes education, monitoring, and pharmacotherapy assessment and treatment. The frequency of visits and telephone follow-up were determined by each patient's specific needs (e.g., evaluation of dosage adjustment or drug tolerability). Physicians were located in the same clinic space, so patients were immediately evaluated if the pharmacist identified acute symptoms requiring physician evaluation or diagnosis. Individualized treatment plans were created with patient input to emphasize the patient's role in the process and to empower participants to take control of their diabetes. Comprehensive patient education focused on diabetes and long-term complications, identification and self-treatment of hypoglycemia and hyperglycemia, self-monitoring of blood glucose and pattern management, the importance of preventive care, proper foot and skin care, and nutrition and physical activity guidelines. Pharmacists referred patients to other health care providers when indicated (e.g., ophthalmologists, podiatrists, exercise physiologists, dieticians, urologists, nephrologists, cardiologists). Once patients met all of their metabolic targets, they were referred back to their primary care physicians for ongoing management.

Initial outcomes analysis. A total of 113 DCC patients with type 2 diabetes mellitus met the inclusion criteria, with 36 patients referred to the endocrinology DCC and 77 to the primary care DCC. Sixty-three patients (56%) were women. The mean age was 55.5 years, and the mean time since diabetes diagnosis was 9.1 years. Baseline and final primary clinical outcome measures are reported in Table 1. Improvements were realized in most clinical markers, particularly glycemic control, with a 1.3% reduction in HbA_{1c} and an average end-of-study HbA₁ of 7.8%.

For non-glycemic-related laboratory test values, the number of patients varies since not all patients received comprehensive level 3 care. LDL cholesterol values were not reported in seven patients due to excessively elevated triglyceride levels, and the LDL and HDL cholesterol levels of one patient were not available due to laboratory error. A significantly higher proportion of patients achieved a Joint National Committee (JNC) VI blood pressure goal of <130/80 mm Hg and an ADA HbA₁ goal of <1% above the upper limit of normal after treatment in the DCCs than at baseline (Figure 1).

In addition to achieving glycemic and other diabetes-related clinical goals, patients in the DCCs received other comprehensive preventive care. After the first year of the study, 77% of patients were taking aspirin daily for cardiovascular protection. Patients not taking aspirin included those who had a relative or absolute contraindication to therapy. Of the 53 patients with microalbuminuria or proteinuria, 98% were treated with a kidney-sparing antihypertensive agent at study end. The 2% of patients not taking a kidney-sparing medication had a relative or absolute contraindication to therapy with these agents. Within the previous 12 months, TSH screening had been performed on 94% of patients. Laboratory tests were ordered for the few patients who did not have a TSH screening, but due to laboratory error or patient choice, blood was not analyzed for the TSH evaluation.

National average comparisons. To put the DCC outcomes in perspective, DCC initial outcomes data were compared with corresponding national averages. After one year of DCC operation, substantially fewer DCC patients had poor glycemic control (HbA_{1c} > 9.5% defined by HEDIS 2001), with only 4 of 113 DCC patients (3.5%) reaching this threshold, compared with 36.9% of patients nationally (p < 0.001) (Figure 2). HEDIS 2001 set an LDL cholesterol goal of <130 mg/dL, whereas the target goal for the DCCs was the more stringent target established by the National Cholesterol Education Program (NCEP) (<100 mg/dL).¹² A greater number of patients in the DCCs achieved an LDL cholesterol

Table 1.

| Primary Clinical Outcomes for All Patients Treated in Diabetes |
|--|
| Care Clinics |

| | Mean Baseline | Mean Final | |
|--|------------------|---------------|--------|
| Variable ^a | Value | Value | Change |
| $HbA_{1c}(\%)^{b,c} (n = 113)$ | 9.1 | 7.8 | -1.3 |
| FPG (mg/dL) (<i>n</i> = 113) | 175 | 142 | -33 |
| BMI (kg/m^2) (n = 113) | 30.9 | 31.0 | 0.1 |
| Total cholesterol (mg/dL) ($n = 83$) | 208 | 182 | -26 |
| LDL cholesterol (mg/dL) ($n = 75$) | 110 | 94 | -16 |
| HDL cholesterol in men (mg/dL) | | | |
| (<i>n</i> = 39) | 44 | 45 | 1 |
| HDL cholesterol in women (mg/dL) | | | |
| (<i>n</i> = 43) | 61 | 58 | -3 |
| Triglycerides (mg/dL) ($n = 83$) | 243 | 178 | -65 |
| SBP (mm Hg) ($n = 87$) | 136 | 132 | -4 |
| DBP (mm Hg) ($n = 87$) | 75 | 73 | -2 |

^aBecause some patients did not receive level 3 comprehensive diabetes care, including treatment of blood pressure and lipid levels, *n* differs per variable.

 ${}^{b}HbA_{1c}$ = glycosylated hemoglobin, FPG = fasting plasma glucose, BMI = body mass index, LDL = low-density-lipoprotein, HDL = high-density-lipoprotein, SBP = systolic blood pressure, DBP = diastolic blood pressure.

^cFor HbA_{1c}, the upper limit of normal for the nondiabetic patient population at the Naval Medical Center San Diego (NMCSD) was 6.5%. The American Diabetes Association's target HbA_{1c} is <1% above the upper limit of normal; therefore, the target HbA_{1c} at NMCSD was <7.5%.

Figure 1. Achievement of glycemic and blood pressure targets. For HbA_{1c}, the upper limit of normal for the nondiabetic patient population at the Naval Medical Center San Diego (NMCSD) was 6.5%. The American Diabetes Association's target HbA_{1c} is <1% above the upper limit of normal; therefore, the target HbA_{1c} at NMCSD was <7.5%. Of the patients evaluated for achievement of the American Diabetes Association goal for glycosylated hemoglobin (HbA_{1c}) (n = 113), 20 (18%) and 41(36%) had an HbA_{1c} of <7.5% at baseline and study end, respectively (p < 0.01, χ^2 test). Of the 87 patients evaluated for achievement of the Joint National Committee's blood pressure goal for diabetic patients, 18 (21%) and 30 (34%) had a blood pressure reading of <130/80 mm Hg at baseline and study end, respectively (p < 0.05, χ^2 test).

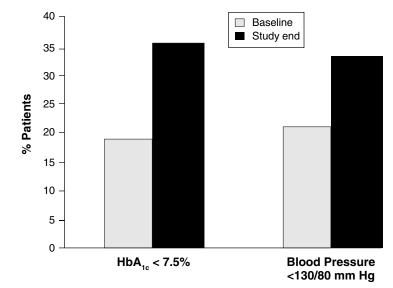
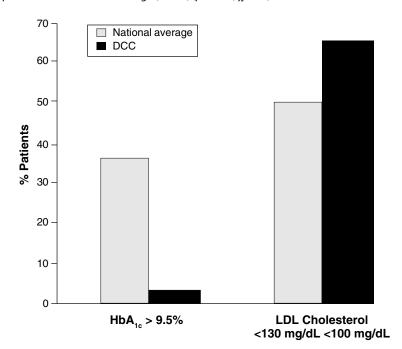


Figure 2. Comparison of glycosylated hemoglobin (HbA_{1c}) and low-density-lipoprotein cholesterol values of patients in diabetes care clinics (DCCs) with the national averages of diabetic patients. For HbA_{1c}, the upper limit of normal for the nondiabetic patient population at the Naval Medical Center San Diego (NMCSD) was 6.5%. The American Diabetes Association's target HbA_{1c} is <1% above the upper limit of normal; therefore, the target HbA_{1c} at NMCSD was <7.5%. Significantly fewer patients in the DCCs had poor glycemic control (4/113 [3.5%]) compared with the national average (36.9%) (p < 0.001, χ^2 test). Despite the more rigorous LDL cholesterol goal set by the DCCs, a higher proportion of DCC patients (49/75 [65.3%]) achieved substantially better LDL cholesterol control when compared with the national average (49.8%) (p < 0.01, χ^2 test).



concentration of <100 mg/dL, despite the more rigorous goal (Figure 2). Almost 87% (98 of 113) of DCC patients received annual retinal screening compared with a national average of 52.1% of diabetes patients (p < 0.001). Annual testing for diabetic nephropathy was performed by DCC pharmacists more than twice as frequently as reported nationally (109 of 113 patients [96.4%] versus 46.3%, respectively) (Figure 3).

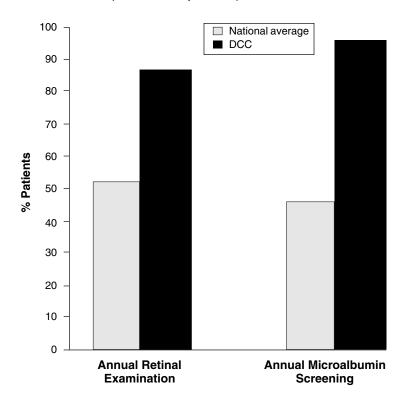
Subset analysis of endocrinology DCC. Unlike the primary care DCC, which was run by two pharmacists, the endocrinology DCC was managed by one clinical pharmacist. Moreover, all patients in this clinic received comprehensive level 3 diabetes care. To determine if large differences in patient outcomes existed between the two DCCs, a subset comparison of the endocrinology DCC to the larger group was performed (Table 2). Of the 113 patients, 36 were enrolled in the endocrinology DCC. Of these, 20 (56%) were female. The mean \pm S.D. age was 51.8 ± 10.8 years, and the mean \pm S.D. time since diabetes diagnosis was 9.3 ± 8.4 years. Six patients, who were referred to the pharmacist for intense insulin regimen or other comorbid evaluation, achieved the HbA_{1c} goal at referral and maintained this threshold throughout the study and were therefore excluded from the analysis. Results were similar to those for all DCC patients. Patients achieved significantly improved glycemic control, with a 1.2% reduction in HbA_{1c} and a mean final HbA_{1c} of 8.0%. In addition, preventive care outcomes were similar to

the larger group. By study end, 29 of 36 patients (81%) were taking aspirin daily, 35 (97%) had an annual TSH screening, and 32 (89%) had retinal screening. Annual microalbumin screenings were completed for 35 patients (97%), and all patients (100%) who tested positive for microalbuminuria or proteinuria received a kidney-sparing antihypertensive agent.

Three-year follow-up data. Compared with 2001, the 2003 crosssectional clinical outcomes evaluation of the DCCs showed similar favorable outcomes, with some improvement in glycemic control, triglycerides, and blood pressure. In March 2003, 133 patients with type 2 diabetes mellitus were enrolled in the DCCs, with an average HbA₁ of 7.6%, and 55% of patients (73 of 133) met the target HbA_{1c} goal of <7.5%. Mean BMI was 32 kg/m². Patients' average triglyceride concentration was 168 mg/dL, and the percentage of patients achieving a systolic blood pressure of <130 mm Hg and a diastolic blood pressure of <80 mm Hg was 65% (86 of 133) and 77% (102 of 133), respectively. Overall LDL and HDL cholesterol concentrations were 107 and 41 mg/dL, respectively.

Discussion

The goal of this project was to determine if pharmacist providers in the NMCSD DCCs, working collaboratively with physicians, could improve diabetes-related outcomes. As with all new clinical pharmacy programs, continuation of services should be justified with outcomes data. Pharmacist-managed diabetes clinics in ambulatory clinic and community pharmacy models have shown positive outcomes when pharmacists are involved in the care of patients with diabetes.18-22 Oneyear outcomes data from the NMCSD DCCs demonstrated that pharmacist involvement in caring for patients with type 2 diabetes mellitus significantly improved clinical out**Figure 3.** Comparison of the number of patients in pharmacist-managed diabetes care clinics (DCCs) who received annual retinal and microalbumin screenings with national averages. Most DCC patients received annual retinal screening (98/113 [86.7%]) compared with the national average of 52.1% (p < 0.0001). Annual testing for diabetic nephropathy (microalbumin screening) was performed by DCC pharmacists more than twice as frequently (109/113 [96.4%]) as reported nationally (46.3%) (p < 0.0001).



| Table 2. |
|---|
| Primary Clinical Outcomes for Level 3 Endocrinology Diabetes Care |
| Clinics |

| | Me | | | |
|---|--------------|----------------|--------|--------|
| Endpoint | Baseline | Final | Change | pa |
| HbA _{1c} (%) ^{b,c} ($n = 30$) | 9.2 ± 1.7 | 8.0 ± 0.8 | -1.2 | <0.001 |
| FPG (mg/dL) $(n = 36)$ | 165 ± 71 | 140 ± 53 | -25 | < 0.05 |
| BMI (kg/m^2) $(n = 36)$ | 31 ± 4.6 | 31.1 ± 4.5 | 0.1 | NS |
| Total cholesterol (mg/dL) ($n = 36$) | 202 ± 58 | 182 ± 40 | -20 | < 0.05 |
| LDL cholesterol (mg/dL) $(n = 36)$ | 109 ± 35 | 95 ± 31 | -14 | < 0.05 |
| HDL cholesterol in men (mg/dL) ($n = 16$) | 45 ± 13 | 46 ± 10 | 1 | NS |
| HDL cholesterol in women (mg/dL) | | | | |
| (n = 20) | 61 ± 17 | 59 ± 14 | -2 | NS |
| Triglycerides (mg/dL) (n = 36) | 209 ± 187 | 166 ± 68 | -43 | NS |
| SBP (mm Hg) ($n = 36$) | 138 ± 15 | 132 ± 14 | -6 | NS |
| DBP (mm Hg) ($n = 36$) | 74 ± 9 | 75 ± 10 | 1 | NS |

^aTwo-tailed t test.

 b HbA_{1c} = glycosylated hemoglobin, FPG = fasting plasma glucose, BMI = body mass index, NS = not significant, LDL = low-density-lipoprotein, HDL = high-density-lipoprotein, SBP = systolic blood pressure, DBP = diastolic blood pressure.

^cFor HbA_{1c} the upper limit of normal for the nondiabetic patient population at the Naval Medical Center San Diego (NMCSD) was 6.5%. The American Diabetes Association's target HbA_{1c} is <1% above the upper limit of normal; therefore, the target HbA_{1c} at NMCSD was <7.5%.

comes. For this time period, the overall mean reduction in HbA_{1c} was 1.3%.

These outcomes remained consistent or improved three years postclinic inception, with an average HbA_{1c} of 7.6% and the majority of patients achieving a target HbA_{1c} of <7.5%. A large study at a staff-model health maintenance organization found a cost saving of \$685-\$950 per patient whose HbA_{1c} declined by at least 1% for the first year and continued improvement for the additional three years of the study.5 Based on this model and accounting for pharmacist time and salaries, the estimated cost avoidance to NMCSD was \$17,157 per year. When extrapolated to the entire NMCSD diabetes population, cost avoidance analysis indicated a potential annual saving of \$616,000-\$735,000.

Other diabetes-related markers, including blood pressure and lipid values, also improved in the DCC patients. All final mean cholesterol values were within the NCEP goals at the time of the initial outcomes study. Although the mean HDL cholesterol in female patients decreased by 3 mg/dL, the final HDL cholesterol mean of 58 mg/dL was well above the NCEP target goal. While improved glycemic control due to increased oral diabetes medication or insulin use may result in weight gain, patients managed in the DCCs maintained their BMI without significant weight gain at the end of year 1.

The results of the subset analysis of the 36 endocrinology DCC patients indicate that outcomes of the larger group were similar to the outcomes of the endocrinology DCC patients receiving level 3 care and that similar improvements were seen in patients at all levels of treatment intensity. The cross-sectional assessment of outcome markers three years after DCC inception shows that the pharmacist-managed DCCs can provide sustained outcomes in glycemic, blood pressure, and lipid control. Moreover, outcomes measures achieved in our DCCs were superior to HEDIS national averages. These successful outcomes justified continuation of the pharmacist-managed DCCs at NMCSD.

Offering different levels of care allowed referring physicians to dictate the degree of pharmacist involvement in diabetes management in the primary care DCC. One year after clinic inception, most physician referrals were for level 3 care, the most comprehensive care offered. By 2003, approximately 90-95% of patients were referred for level 3 care. This suggests an increasing level of comfort on the part of physicians for this collaborative model, likely due in part to our successful outcomes. We also found that working collaboratively with physicians in a clinic setting and having multidisciplinary team members available for consultation were valuable.

Some study limitations included the retrospective nature of data collection and evaluation, the lack of a control group, and multiple pharmacist providers. However, patients served as their own control since previous care came from their primary care providers who made referrals to the DCCs when their patients were not achieving target metabolic goals. Increased physician confidence in the pharmacists' abilities demonstrated that the changes seen in clinical markers were valued. Another possible confounder was that patients were provided different levels of care by multiple pharmacist providers in two clinics; however, subset analysis revealed that patients receiving the more comprehensive care achieved similar clinical outcomes to the larger patient group across clinic settings and treatment levels. Thus, having multiple pharmacist providers did not seem to affect overall care and clinical outcomes.

With the recent implementation of Medicare Part D and the growth of

medication therapy management services, pharmacists will become acknowledged as patient care providers for diseases such as diabetes, asthma, hyperlipidemia, hypertension, and congestive heart failure. With their extensive education and pharmacotherapy expertise, pharmacists can help patients achieve clinical goals.

Conclusion

Compared with national averages, DCCs managed by clinical pharmacists achieved higher screening rates and attained treatment goals more often.

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Considerations in the long-term management of asthma in ambulatory patients

he National Asthma Education and Prevention Program (NAEPP) Expert Panel Report 2 (EPR 2) released in 1997, with an update on selected topics released in 2002, provides considerable evidence-based guidance on the long-term management of asthma in ambulatory patients.^{1,2} According to EPR 2, there are four key components to long-term control of asthma: (1) assessment and monitoring, including self-monitoring, (2) pharmacologic therapy, (3) control of factors that contribute to asthma severity (especially exposure to environmental allergens and other asthma triggers), and (4) patient education for a partnership in patient care.1 Drug therapies used for the treatment of asthma by ambulatory patients are categorized as quickrelief agents and long-term-control agents (Table 1).

The goals of asthma therapy (Table 2) are ambitious and require patients to acquire considerable knowledge of the disease process and treatment and skills in using devices to objectively measure lung function (e.g., peak expiratory flow [PEF]) and deliver inhaled medications (e.g., pressurized metered-dose inhalers [pMDIs], dry-powder inhal-

DENNIS M. WILLIAMS

Purpose. The goals of treatment and drug therapies used for long-term asthma control, classification of the disease by severity, and treatment based on severity are reviewed, with an emphasis on recent controversies in treatment approach and safety concerns.

Summary. Patient education and written asthma self-management and action plans are essential components of asthma treatment because of the need for patients to acquire substantial knowledge and skills in self-care. Inhaled corticosteroids are the most effective long-term-control therapy and usually suffice as monotherapy for mild persistent asthma. Adding a long-acting, inhaled β_2 agonist to the inhaled corticosteroid is preferred for moderate and severe persistent disease despite safety concerns. Omalizumab use is limited to selected patients with moderate-to-severe allergic asthma and an inadequate response to inhaled corticosteroids.

Conclusion. The long-term control of asthma requires substantial patient knowledge and skill. Persistent disease is best managed by inhaled corticosteroids and if it is moderate or severe, long-acting, inhaled β_2 agonists in combination with inhaled corticosteroids.

Index terms: Ambulatory care; Antibodies; Asthma; Combined therapy; Omalizumab; Patient information; Steroids, cortico-; Sympathomimetic agents

Am J Health-Syst Pharm. 2006; 63(Suppl 3):S14-21

ers, nebulizers).¹ As a result of the chronic nature of asthma, many patients with asthma accept substantial limitation in their activities, and they may need to redefine expectations from drug therapy and establish personal goals. The complexity of asthma therapy is increasing, and some patients require multiple inhalation devices with different administration techniques.

Written asthma self-management and action plans should be developed to improve asthma control and outcomes.^{1,2} These plans should provide individualized instructions for steps to take on a daily basis to prevent asthma attacks and as needed in response to signs, symptoms, and changes in PEF reflecting worsening of asthma. Patient use and appropriateness of the plan should be monitored during periodic visits to health-care providers.

Evaluation of asthma control in clinical studies often focuses on ob-

symposium and for the preparation of this article. Dr. Williams reports that he serves on the speakers bureaus for Sepracor Inc. and Norvartis and that his spouse is employed by GlaxoSmithKline.

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Based on the proceedings of a symposium held December 5, 2005, during the ASHP Midyear Clinical Meeting, Las Vegas, NV, and supported by an unrestricted educational grant from Sepracor Inc. Dr. Williams received an honorarium for his participation in the

Table 1. Drug Therapies Used for Asthma by Ambulatory Patients^a

Quick-relief agents

- Short-acting, inhaled β_2 agonists^b
- Systemic corticosteroids^b
- Inhaled anticholinergic agents (e.g., ipratropium bromide) Long-term-control agents
- Systemic and inhaled corticosteroids^b
- Inhaled cromolyn sodium and nedocromil
- Long-acting, inhaled β_2 agonists (e.g., salmeterol, formoterol)
- Leukotriene modifiers (montelukast, zafirlukast, zileuton)
- Theophylline^b
- Omalizumab (given by s.c. injection every 2 weeks or 4 weeks in a physician's office or clinic)

^as.c. = subcutaneous

^bInjectable forms are available for use in the institutional setting.

Table 2. Goals of Therapy for Asthma Control¹

- Maintain near "normal" pulmonary function.
- Maintain normal activity levels, including exercise.
- Prevent chronic and troublesome symptoms (e.g., coughing and breathlessness at night, in the early morning, and after exertion).
- Provide optimal pharmacotherapy with minimal or no adverse effects.
- Prevent recurrent exacerbations and minimize the need for emergency department visits and hospitalization.
- Meet patients' and families' expectations for and satisfaction with asthma care.

jective measures of pulmonary function (e.g., PEF) as primary outcome measures, with other measures (e.g., nocturnal awakenings, symptoms) as secondary endpoints. However, a composite of a variety of outcome measures might be more useful for evaluating asthma control than objective measures of pulmonary function alone (Figure 1).^{3,4}

In EPR 2, asthma is classified by severity (Table 3), although this classification scheme is sometimes difficult to apply in clinical practice because it assumes that a patient enters the health-care system with undiagnosed and untreated asthma.² A patient's current level of asthma control may be the basis for classifying asthma in the future.

Mild intermittent asthma

Treatment of mild intermittent asthma entails the use of a shortacting, inhaled β_2 agonist only as needed for symptoms.² Daily longterm-control medication is not needed. The intensity of treatment of exacerbations depends on the severity of the exacerbation. Even a patient with mild disease may experience a severe exacerbation. A course of systemic corticosteroids may be needed.² Use of short-acting, inhaled β_2 agonists more often than twice weekly in patients with intermittent asthma may indicate the need to initiate long-term-control therapy.²

Most patients with mild intermittent asthma carry pMDIs because the devices are convenient. Many of these pMDIs contain albuterol because it is available as a generic product that is inexpensive. These generic albuterol pMDIs contain chlorofluorocarbon (CFC) propellants, which are gradually being phased out on a worldwide basis because CFCs deplete ozone in the atmosphere. Ozone depletion increases exposure to ultraviolet light and the risk for malignant melanoma and other skin cancers, cataracts, and other health problems. The Food and

Drug Administration (FDA) ruling pertaining to phasing out of ozonedepleting substances (ODS) in drugs requires the availability of non-ODS products with the same active moiety and route of administration for the same indication and approximately the same level of convenience of use as the ODS product containing that active moiety.5 Four albuterol pMDIs containing hydrofluoroalkane (HFA) propellants currently are available. However, these products are protected by patents and are more costly than older products containing CFC propellants. The earliest patent expiration date for an albuterol pMDI containing an HFA propellant is 2010, and patents for other products expire as late as 2021. Nevertheless, albuterol pMDIs containing CFCs will cease to be available by the end of 2008. The recent introduction of a pMDI form of levalbuterol (a drug that has been available in solution form for nebulization since 1999) with an HFA propellant provides an alternative to albuterol pMDIs that contain HFA. The costs of the various HFA products are similar and substantially more than generic products.

Persistent asthma

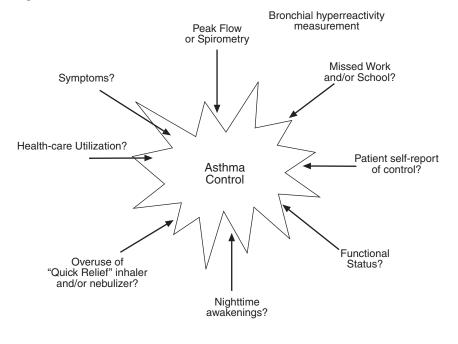
Daily long-term-control therapy and a short-acting, inhaled β_2 agonist as needed for the quick relief of symptoms are recommended for patients with mild, moderate, and severe persistent asthma (Table 4).² The use of short-acting, inhaled β_2 agonists more often than daily or increasingly often in patients with persistent asthma may indicate the need to increase long-term-control therapy.

Mild persistent asthma. Mild persistent asthma usually can be controlled with a single long-termcontrol agent, preferably an inhaled corticosteroid at a low dosage.² Inhaled corticosteroids are the most potent and effective long-termcontrol therapy for asthma.¹ Alternative monotherapies for long-term control include cromolyn sodium, nedocromil, leukotriene modifiers, and sustained-release theophylline with a target serum concentration of $5-15 \mu g/mL^2$

The Childhood Asthma Management Program (CAMP) study was a long-term, randomized, placebocontrolled study comparing the inhaled corticosteroid budesonide (200 μ g twice daily) with inhaled nedocromil (8 mg twice daily) in 1041 children 5–12 years of age with mild-to-moderate asthma.⁶ Budesonide improved airway responsiveness to methacholine (a substance used to provoke bronchoconstriction and measure the bronchodilating effects of test drugs in an experimental setting) to a greater extent than inhaled nedocromil or placebo over a four-year period.⁶

In a shorter, randomized, doubleblind, double-dummy, parallelgroup study of 533 patients (>15 years old) with persistent asthma and an inadequate response to shortacting, inhaled β_{2} agonists, inhaled fluticasone (88 µg twice daily) was significantly more effective than the oral leukotriene modifier montelukast (10 mg once daily) in improving morning PEF over a 24-week period.7 Significantly greater improvements in other measures of lung function and other outcome measures (e.g., symptoms; short-acting, inhaled β_{2} agonist dosage requirements) were observed in the fluticasone group

Figure 1. Elements of Asthma Control.



compared with the montelukast group.

A nested case–control study of more than 30,000 Canadians 5–44 years of age with asthma who were followed for a 16-year period revealed an inverse relationship between the number of canisters of inhaled corticosteroids used and death from asthma.⁸ The rate of death from asthma decreased by 21% with each additional canister of inhaled corticosteroids used in the preceding year. Thus, inhaled corticosteroids are the preferred therapy for persistent asthma, regardless of age.

Corticosteroid safety. Safety concerns associated with the long-term use of corticosteroids include a slowed rate of linear growth in children and reduced bone mineral density (i.e., osteoporosis), which increases the risk of fractures.⁹ These concerns are greater when therapy is systemic than when it is administered by inhalation, but safety remains an issue with inhaled therapy.

In the CAMP study of children 5– 12 years of age, the growth rate in children treated with inhaled budesonide was slower than that in children receiving nedocromil during the first year of the study.^{6,10} However, there was no difference between treatment groups in growth rates in the subsequent three years of the study.^{6,10}

In another prospective study of 142 children (3–13 years of age at the start of treatment) with asthma treated with inhaled budesonide, growth rates were significantly reduced during the first years of treatment compared with 51 healthy siblings and 18 control patients with asthma who

Table 3. NAEPP Classification of Asthma Severity^{2,a,b}

| Severity | Days with Symptoms | Nights with Symptoms | PEF or FEV ₁ | PEF Variability |
|---------------------|-----------------------|-------------------------|----------------------------|--------------------|
| Severe Persistent | Continuous | Frequent | ≤60% | >30% |
| Moderate Persistent | Daily | ≥5 times per month | >60%-<80% | >30% |
| Mild Persistent | 3–6 times per week | 3–4 times per month | ≥80% | 20%-30% |
| Mild Intermittent | ≤2 times per week | ≤2 times per month | ≥80% | <20% |

 a FEV₁ = forced expiratory volume in 1 second; PEF = peak expiratory flow; NAEPP = National Asthma Education and Prevention Program.

Table 4.

| NAEPP Recommendations for Daily Long-Term Asthma Control |
|---|
| Medications for Adults and Children More than 5 Years of Age ^{2,a,b} |

| Asthma Severity | Medication for Long-Term Control |
|---------------------|--|
| Severe Persistent | High-dose inhaled corticosteroid plus long-acting, inhaled β_2 agonist or other long-term-control therapies (and if needed, systemic corticosteroid) |
| Moderate Persistent | Low-to-medium dose inhaled corticosteroid plus long-acting, inhaled β_2 agonist Alternatives: (1) medium-dose inhaled corticosteroid or (2) low-to-medium dose inhaled corticosteroid plus either leukotriene modifier or theophylline |
| Mild Persistent | Low-dose inhaled corticosteroid Alternatives: cromolyn sodium, leukotriene modifier, nedocromil, or sustained-release theophylline |
| Mild Intermittent | None |

^aNAEPP = National Asthma Education and Prevention Program.

^bShort-acting, inhaled β_2 agonists are recommended as needed for quick relief of symptoms for all patients, regardless of the asthma severity classification. The intensity of treatment depends on the severity of the exacerbation. A course of systemic corticosteroids may be needed.

never received inhaled corticosteroids.¹¹ However, the final adult height after treatment for a mean of 9.2 years was not significantly different from the target adult height or the final adult height in the healthy siblings or control patients.

In the CAMP study, there was also no significant difference in bone mineral density between the children treated with inhaled budesonide and the placebo-treated children at the end of the study.¹⁰ According to EPR 2, the low and medium dosages of inhaled corticosteroids used for asthma do not appear to cause clinically important adverse effects on bone metabolism.1 However, elderly women may be at risk for developing osteoporosis while receiving corticosteroids because of estrogen changes associated with aging and other risk factors for the disease.¹

Although the inhalation route of administration minimizes systemic availability of and the risk of adverse effects from corticosteroids, clinicians should use the lowest effective dosage. These agents should be used in the safest manner possible (e.g., with a spacer or holding chamber, followed by mouth rinsing [a "rinse and spit" technique] after each dose to minimize systemic exposure to the drug).¹

The use of intermittent, short courses of inhaled or oral corticosteroids instead of daily use of inhaled corticosteroids has been proposed for patients with mild persistent asthma to minimize corticosteroid exposure and the cost of therapy. In a double-blind study, 225 adults with mild persistent asthma were randomized to receive (1) intermittent inhaled budesonide for 10 days or oral prednisone for 5 days based on a symptom-based action plan, (2) daily inhaled budesonide therapy, or (3) daily oral zafirlukast therapy for 1 year.¹² On average, subjects in the intermittent treatment group used budesonide for 1/2-week of the year. There were no significant differences between the treatment groups in morning PEF (the primary outcome) or the rate of asthma exacerbations. Daily budesonide therapy produced significantly greater improvements in FEV, measured before bronchodilator use, bronchial hyperreactivity, exhaled nitric oxide levels (an emerging strategy to evaluate ongoing inflammation in the airways), and the number of symptom-free days compared with intermittent therapy and daily zafirlukast therapy. There were no significant differences between intermittent therapy and daily zafirlukast in treatment outcomes. Thus, the use of intermittent, short courses of inhaled or oral corticosteroids may be feasible in patients with mild persistent asthma. This approach is consistent with the use of the lowest effective corticosteroid dosage. However, daily use of inhaled corticosteroids may provide benefit in preventing airway remodeling.¹ Whether this benefit is provided is controversial.

Moderate and severe persistent asthma. Moderate persistent and severe persistent asthma usually are best controlled with combination daily long-term therapy, preferably an inhaled corticosteroid (at a lowto-medium and high dosage, respectively) plus a long-acting, inhaled β_{α} agonist (Table 4).² Alternatives to this approach for patients with moderate persistent asthma include increasing the inhaled corticosteroid dosage within the medium dosage range or adding a leukotriene modifier or theophylline. Systemic corticosteroids may be added to an inhaled corticosteroid and a longacting, inhaled β_{α} agonist for patients with severe persistent asthma if needed, but should be avoided if possible.2

The preference for adding a second long-term-control agent rather than increasing the dosage of the inhaled corticosteroid and the preference for adding a long-acting, inhaled β_{2} agonist rather than a leukotriene modifier or theophylline to inhaled corticosteroid therapy in patients with moderate persistent or severe persistent asthma are based on the results of clinical trials. In a sixmonth, randomized, double-blind, parallel-group study of 429 adults with asthma symptoms despite daily use of the inhaled corticosteroid beclomethasone dipropionate (200 µg twice daily), the effect of adding the long-acting, inhaled β_{2} agonist salmeterol xinafoate (50 μg twice daily) to beclomethasone dipropionate was compared with increasing the beclomethasone dipropionate dosage (to 500 μ g twice daily).¹³ A significantly greater increase in PEF was observed in the group receiving salmeterol xinafoate plus low-dose beclomethasone dipropionate than in the group receiving high-dose beclomethasone dipropionate.

In a 12-week, randomized, double-blind trial, 62 patients with moderate persistent asthma received (1) low-dose inhaled budesonide (400 μ g twice daily) plus theophylline 250 mg or 375 mg (depending on body weight) twice daily or (2) high-dose inhaled budesonide (800 μ g twice daily).¹⁴ Combination therapy with low-dose budesonide plus theophylline produced significantly greater improvements in pulmonary function (e.g., FEV₁) than high-dose budesonide throughout the study.

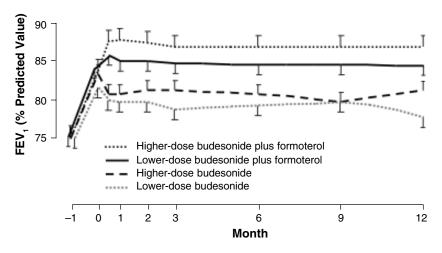
The efficacy of an inhaled corticosteroid plus a long-acting, inhaled β_{2} agonist was compared with that of the same corticosteroid plus oral montelukast in a 12-week, multicenter, double-blind, doubledummy, parallel-group study of 447 patients with symptomatic asthma.15 The combination of fluticasone propionate 100 µg plus salmeterol xinafoate 50 µg as a dry-powder inhalation twice daily produced a significantly greater mean increase from baseline in morning PEF than fluticasone propionate 100 µg twice daily by dry-powder inhaler plus oral montelukast (10 mg once daily).

The linearity of the dose–response relationship of inhaled corticosteroids and the wisdom of increasing the dosage instead of adding a longacting, inhaled β_{γ} agonist in patients with moderate persistent asthma have been questioned.16 In a oneyear study, 852 patients with symptomatic moderate persistent asthma despite treatment with inhaled budesonide (800 µg twice daily) were randomized to receive twice daily treatment by dry-powder inhaler with (1) lower-dose budesonide (100 µg) plus placebo, (2) lower-dose budesonide (100 µg) plus the longacting, inhaled β_{α} agonist formoterol $(12 \mu g)$, (3) higher-dose budesonide (400 µg) plus placebo, or (4) higherdose budesonide (400 µg) plus formoterol (12 µg).¹⁷ The higher budesonide dose was used initially to ensure optimal control of airway inflammation prior to randomization. The FEV, as a percentage of the predicted value was greater in the higherdose budesonide group compared with the lower-dose budesonide group, but it was even higher in the lower-dose budesonide plus formoterol group and it was highest in the higher-dose budesonide plus formoterol group (Figure 2). Adding formoterol to both higher- and lower-dose budesonide significantly reduced the incidence of severe asthma exacerbations. The lowest incidence of exacerbations was observed with higher-dose budesonide plus formoterol treatment. The investigators concluded that increasing the inhaled corticosteroid dosage or adding a long-acting, inhaled β_{2} agonist may be beneficial for patients with symptomatic moderate persistent asthma.17

The possibility that adding a longacting, inhaled β_2 agonist to inhaled corticosteroid therapy might allow a reduction in dosage or discontinuation of the corticosteroid was explored in a 24-week, randomized, controlled, blinded, double-dummy, parallel-group study of 175 adults and adolescents with persistent asthma despite six weeks of inhaled corticosteroid therapy (triamcinolone acetonide 400 µg twice daily).¹⁸ Patients were randomized to receive inhaled salmeterol xinafoate (42 µg twice daily) or placebo in addition to the inhaled corticosteroid for two weeks. All of the placebo-treated patients and half of the salmeteroltreated patients chosen randomly reduced their triamcinolone dosage by 50% for eight weeks and discontinued the triamcinolone (i.e., received placebo or salmeterol alone) for the subsequent eight weeks. The other half of the salmeterol-treated patients continued triamcinolone at the full dosage for 16 weeks.

The treatment failure rate after eight weeks was not significantly different between the patients receiving salmeterol plus 50% of the triamcinolone dosage (8.3%) and patients receiving salmeterol plus the full triamcinolone dosage (2.8%).¹⁸ However, the treatment failure rate after 16 weeks was significantly higher in the group receiving salmeterol alone (46.3%) than in the group receiving salmeterol plus the full triamcino-

Figure 2. Effect of Higher-Dose Inhaled Corticosteroid and Formoterol. Reprinted with permission from reference 17.



lone dosage (13.7%). The investigators concluded that it may be feasible to reduce the inhaled corticosteroid dosage when a long-acting, inhaled β_2 agonist is added, but the corticosteroid should not be discontinued. These findings have important implications for clinicians who anticipate adherence problems with inhaled corticosteroids in patients with moderate or severe persistent asthma. The use of a combination inhaler containing both a corticosteroid and a long-acting β_2 agonist may be advisable.

Inhaled β_2 agonist safety. The use of inhaled β_2 agonists is not without safety concerns. In a cohort of 12,301 patients with asthma who were followed for 47,842 person-years, the rate of death from asthma increased significantly with the use of inhaled β_2 agonists, particularly with fenoterol and less so with albuterol.¹⁹

In 2005, FDA held a hearing and reviewed evidence of the possible link between β_{2} agonist use and asthma-related deaths. No evidence of an increase in asthma-related deaths beyond what was predicted was found in a 16-week study of 25,180 patients with asthma who were randomized in a 2:1 ratio to receive salmeterol (50 µg twice daily) or albuterol (200 µg four times a day).²⁰ However, in the Salmeterol Multicenter Asthma Research Trial, a large, 28-week, placebo-controlled study known as SMART, a small but significant increase in asthma-related deaths was observed in patients receiving inhaled salmeterol 42 µg twice daily (13 deaths in 13,176 patients) compared with patients receiving placebo (3 deaths in 13,179 patients).21 The study was terminated early in part because there was an eightfold higher incidence of asthmarelated deaths in African Americans treated with salmeterol compared with placebo.²² The FDA-approved labeling for products containing salmeterol was modified to reflect the SMART findings.23,24

Data from three prospective, randomized, double-blind, placebocontrolled studies of formoterol 12 μ g and 24 μ g twice daily submitted to FDA to support product approval were reanalyzed by the FDA committee concerned with asthma-related deaths.²⁵ In all three studies, an increased incidence of severe asthma exacerbations was reported in patients receiving formoterol 24 μ g twice daily (a dosage twice as high as the maximum recommended dosage) compared with placebo.²⁵

A meta-analysis of randomized controlled trials and systematic reviews of the impact of various longterm-control therapies, including long-acting β_{2} agonists and inhaled corticosteroids, on asthma exacerbations found no increase in asthma exacerbations from the use of longacting, inhaled β_{2} agonists alone (a treatment approach that is not advocated because these agents should be used as part of combination therapy) or in combination with inhaled corticosteroids.26 The addition of longacting, inhaled β_{γ} agonists to inhaled corticosteroid therapy was associated with 26% fewer exacerbations than inhaled corticosteroid monotherapy, even when the dosage of inhaled corticosteroid was increased.26

In November 2005, FDA issued a public health advisory based largely on the results of the SMART study.27 The advisory states that although long-acting, inhaled β_2 agonists decrease the frequency of asthma episodes, they may increase the risk of severe asthma episodes and death when those episodes occur. The public health advisory cautions against using long-acting, inhaled β_{λ} agonists as first-line monotherapy for asthma and emphasizes the importance of adding these agents only if asthma is not controlled with other medications, especially low or medium dosages of corticosteroids. FDA also requested that the manufacturers of products that contain salmeterol (Advair Diskus, which also contains

fluticasone propionate, and Serevent Diskus) or formoterol (Foradil Aerolizer) add warnings about the problem to the product labeling. Patient information sheets and letters for health-care professionals explaining the safety concerns have been developed.²⁷ A change in the labeling for long-acting inhaled β_2 agonist products, alone and in combination, has been effected to reflect this language.

Genetic polymorphism in codon 16 of the β_{γ} receptor could explain cases of inadequate response to or even death from some or all β_{α} agonists, although the findings are preliminary and further research is required. It is also uncertain whether the presence of the polymorphism is relevant for all β_{α} agonists or only the specific ones studied. A homozygous variant arginine-arginine genotype is found in 15% of patients with asthma instead of the "wild type" (i.e., normal) homozygous glycine-glycine genotype.28 Individuals with this polymorphism can exhibit an altered response to β -agonists.

Genotype and pulmonary function (morning PEF) in response to 16 weeks of regularly scheduled albuterol or placebo treatment were measured in 78 patients with mild asthma in a placebo-controlled, masked, crossover study.29 Ipratropium bromide was used as needed. Albuterol improved pulmonary function (morning PEF) to a significantly greater extent than placebo in subjects with the wild type glycineglycine genotype. However, in patients with the variant argininearginine genotype, morning PEF was significantly lower during albuterol treatment than during placebo treatment. Genotype testing currently is not done, but it might become routine in the future if this early observation is proven to have clinical relevance for β -agonist therapy in general. Additional research is needed to evaluate the impact of pharmacogenetics on response to β_{2} agonists.

Omalizumab

A recent addition to the armamentarium for asthma treatment is a biotechnology product that may be appropriate to consider for specific subsets of patients. Omalizumab is a monoclonal antibody that is specific for immunoglobulin E (IgE), which mediates allergic asthma (see Schreck's article on asthma pathophysiology in this supplement). The drug was not available at the time EPR 2 was published, so it was not addressed in recommendations for drug therapy.

Omalizumab interrupts the allergic cascade that leads to asthma symptoms by binding selectively to free (i.e., unbound) IgE, which prevents it from binding to mast cells, basophils, and other cells containing inflammatory mediators.³⁰ Omalizumab is used only for selected patients with moderate-to-severe persistent asthma, a positive skin test or in vitro reactivity to a perennial aeroallergen, and an inadequate response to inhaled corticosteroids.³¹ The drug has a viscous consistency when it is reconstituted, which makes it cumbersome to manipulate. It is administered every two weeks or four weeks by subcutaneous injection, which takes 5-10 seconds and often causes pain at the injection site.³¹ Dosing of omalizumab is based on pretreatment serum IgE levels and body weight.

The efficacy of omalizumab was evaluated in a 28-week, randomized, double-blind, placebo-controlled, parallel-group study of 419 adults and adolescents with inadequately controlled severe persistent asthma despite treatment with high-dose inhaled corticosteroids and longacting, inhaled β_2 agonists. Compared with placebo, omalizumab significantly reduced the rate of severe asthma exacerbations and the need for emergency department visits, and it improved pulmonary function (morning PEF) and asthma symptoms.32

Omalizumab therapy is costly. The current annual cost of omalizumab treatment is approximately \$10,000 per patient, although it varies depending on the dosage requirement and ranges from \$7,500 to \$40,000.

A retrospective analysis of the cost-effectiveness of omalizumab was performed using data from two 52-week, randomized, double-blind, placebo-controlled trials involving 1071 adults and adolescents with moderate-to-severe allergic asthma.33 The wholesale acquisition cost of omalizumab was \$523 per day in 2003 dollars, an amount that is markedly higher than that for other long-term asthma control therapies, even in today's dollars. Significantly lower rates of emergency department visits and hospitalization were associated with omalizumab treatment (1.16 per 100 patient-years and 0.39 per 100 patient-years, respectively) compared with placebo (2.98 per 100 patient-years and 2.77 per 100 patient-years, respectively). The mean daily treatment cost (in 2003 dollars) for hospitalization, emergency department and physician office visits, rescue albuterol, inhaled beclomethasone dipropionate, and omalizumab was \$39.85 in omalizumab-treated patients and \$2.07 in placebo-treated patients.³³

Although the cost of omalizumab is substantial, its use might be justified for select patients with severe allergic asthma that is inadequately controlled by inhaled corticosteroids and a high rate of emergency department visits and hospitalizations. Additional pharmacoeconomic analyses are needed for carefully selected populations of patients to determine the cost-effectiveness of this treatment. However, it appears that the use of this monoclonal antibody is not appropriate for asthma management for the majority of patients.

Conclusion

Patient education and written

asthma self-management and action plans are essential components of asthma treatment because of the need for patients to acquire substantial knowledge and skills in self-care. Inhaled corticosteroids are the most effective long-term-control therapy and usually suffice as monotherapy for mild persistent asthma. Adding a long-acting, inhaled β_2 agonist to the inhaled corticosteroid is preferred for moderate and severe persistent disease despite safety concerns.

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Lipid Levels and Use of Lipid-Lowering Drugs for Patients in Pharmacist-Managed Lipid Clinics Versus Usual Care in 2 VA Medical Centers

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ABSTRACT

OBJECTIVE: The objective of this study was to assess the effectiveness of pharmacist-managed dyslipidemia clinics at 2 Veterans Affairs medical centers since the release of the 2001 National Cholesterol Education Panel Adult Treatment Panel III (NCEP ATP III) guideline compared with the usual care (UC) provided by other health care professionals in the same setting.

METHODS: Analysis was performed through retrospective chart review of patients with a diagnosis of dyslipidemia who received care in either the Amarillo or Lubbock, Texas, pharmacist-managed lipid clinics (LCs) or UC from a primary care physician. Data from medical charts were abstracted for dates of service from July 2001 to December 2003 for 115 patients selected randomly from LC rolls matched with 115 patients with a diagnosis of dyslipidemia selected randomly from UC. All patients had to have had at least 3 visits with the LC or 3 visits in UC with a billing code of dyslipidemia; they were followed for at least 6 months after an initial visit in July 2001 or thereafter and were enrolled in the VA health care system for at least 1 year. Baseline lipid values were available for LC but not UC patients. Cholesterol target goals were determined according to NCEP ATP III guideline.

RESULTS: After an average of 21.6 months of follow-up, the proportion of patients in the LC group that attained goal level increased from 45.2% at baseline to 82.6% for total cholesterol (TC) and from 36.5% at baseline to 64.3% for lowdensity lipoprotein cholesterol (LDL-C [P < 0.001 for both comparisons]). There was an average 24.5 mg/dL absolute reduction (relative reduction, 19.4%) in LDL-C along with significant improvements in the other lipid levels (P < 0.001 for TC and LDL-C, P = 0.007 for triglycerides [TGs]) with the exception of highdensity lipoprotein cholesterol (HDL-C), which declined from 40.0 mg/dL to 36.3 mg/dL (P < 0.001). A total of 50 patients (43.5%) were on lipid-lowering pharmacotherapy at baseline versus 108 patients (93.9%) at follow-up. Compared with UC, LC patients were more likely to have achieved goal LDL-C (64.3% vs. 15.7% for UC. P < 0.001) and TC (82.6% vs. 40.9%, P < 0.001), but there was no difference in the proportion of patients at TG goal for LC (65.2%) compared with UC (52.2%, P = 0.061) or at HDL-C goal (23.5% for LC vs. 33.0% for UC, P = 0.143). A higher proportion of LC patients (93.9%) used lipid-lowering agents compared with UC patients (24.3%, P < 0.001). Subanalysis of patients on a lipid-lowering agent found that a significantly higher proportion (85.2%) in the LC group were at goal total cholesterol compared with 60.7% for UC (P = 0.012) and at goal LDL-C (66.7% for LC vs. 39.3% for UC, P = 0.016). However, a lower proportion were at goal HDL-C for LC (21.3%) versus 42.9% for UC (P = 0.043). Overall, only 11 LC patients (9.6%) attained goal levels for all 4 serum lipid values by the end of follow-up versus 2 UC patients (1.7%, P = 0.019).

CONCLUSIONS: Nearly two thirds of patients diagnosed with dyslipidemia and enrolled in a pharmacist-managed LC had LDL-C levels at or below NCEP ATP III target goal compared with 16% of dyslipidemia patients who received UC from their primary care provider. The pharmacist-managed LC patients were also twice as likely (83 vs. 41%) to have attained the TC target goal, but there was no difference between the 2 groups in the proportion of patients who attained either TG or HDL-C target goals. Only 9.6% of LC patients were at goal for all 4 individual lipid measures at the end of follow-up.

KEYWORDS: Lipid clinics, Pharmacist, Dyslipidemia

J Manag Care Pharm. 2005;11(9):763-71

ardiovascular disease (CVD) continues to be one of the most prevalent and costly diseases in America, accounting for nearly 6.3 million hospital discharges in 2001 and estimated to cost more than \$393 billion in 2005.¹ It has continued to be the number one cause of death in America, resulting in more than 900,000 deaths in 2001.

Most of these deaths were attributed to coronary heart disease (CHD). Dyslipidemia is a well-documented risk factor for the development of CHD, e.g., myocardial infarction and angina pectoris. Despite numerous clinical trials touting the benefits of cholesterol management and largely publicized consensus recommendations on its management, dyslipidemia remains poorly controlled in this country, with an estimated 29 million Americans having a cholesterol level of 240 mg/dL or higher.²⁻⁸

Serum total cholesterol (TC) levels in the United States changed little according to the National Health and Nutrition Examination Surveys (NHANES) between 1994 and 2000 from 205 mg/dL to 203 mg/dL, respectively.⁹ The latest guidelines from the National Cholesterol Expert Panel Adult Treatment Panel III (NCEP ATP III) in 2001 emphasize that the degree of lipid control should match a patient's overall risk for a CHD event.⁷ Yet, frequently, even those at greatest risk, i.e., with established CHD or CHD risk equivalents (REs) as defined in the NCEP ATP III guidelines, fail to achieve lowdensity lipoprotein cholesterol (LDL-C) goals with or without

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medication use, although those who do receive drug therapy are more likely to reach these goals. $^{10,11}\,$

Shortly after publication of NCEP ATP III guidelines in 2001, a group of investigators evaluated the impact of these guidelines versus the previous NCEP ATP II guidelines on a sample of NHANES III participants with known cardiovascular risk factors.¹² The investigators found a 140% increase in the number of patients eligible for LDL-C-lowering therapy, a 157% increase among males versus a 122% increase among females.

Among the ever-expanding roles pharmacists perform in the health care system, collaborative drug therapy management is one particular role where pharmacists can have a significant impact in improving patient care outcomes. Studies assessing the impact of pharmacist management of dyslipidemia have shown improved lipid goal attainment and appropriate medication use either compared with a baseline or a control group.¹³⁻²⁰ However, only one of these studies was performed on intermediate outcomes that occurred after the release of the most recent NCEP guidelines in 2001.20 These guidelines significantly altered LDL-C goals for patients newly classified as having an increased risk for a CHD event (e.g. diabetics and those with a >20% 10-year risk), altered classifications for other lipid parameters (e.g., triglycerides [TGs] and high-density lipoprotein cholesterol [HDL-C]), and increased the number of patients who require lipid-lowering therapy as a result.7 Quilliam et al. found that 21% of 1,962 managed care organization (MCO) patients on a statin drug moved to a more stringent LDL-C goal when the ATP III criteria were applied over ATP II, and substituting the ATP III criteria for ATP II criteria resulted in a 7% decrease in the percentage of patients who had their most recent LDL-C value below the suggested goal, from 69% under ATP II to 53% under ATP III.²¹ The objective of this study was to compare the outcomes of care provided by the pharmacistmanaged clinic with the care provided by other health care professionals in the same setting in the context of the NCEP ATP III guidelines.

Methods

Design and Patient Selection

This study was a retrospective review of medical charts for patients who received lipid management care at the Veterans Administration Medical Center (VAMC) in Amarillo, Texas, or the Lubbock, Texas, VA Outpatient Clinic. The population served by the VAMC in Amarillo is approximately 95,000 and approximately 63,000 at the Outpatient Clinic in Lubbock. The study design was approved by the Texas Tech University Health Sciences Center Institutional Review Board and the Amarillo VA Research and Development Committee.

The pharmacist-managed referral lipid clinics (LCs) at these sites were initiated in 1995 and, combined, they currently serve more than 3,500 patients. Patients are referred for enrollment in the LC after a diagnosis of dyslipidemia has been made by their primary care provider. Patients are typically referred to the LC with abnormal lipid levels and/or a history of CHD. The referral process is voluntary, and the primary care provider can manage the patient's dyslipidemia without the involvement of the LC. Primary care providers at these VAMC's are composed of physicians, physician assistants, and nurse practitioners.

Patients included in the LC group were randomly selected from a generated list of all patients who had been seen in the lipid education class between July 2001 and December 2003. This time period was chosen to coincide with the publication of the NCEP ATP III Executive Summary to make sure that all patients without known CHD would be evaluated for the presence of other CHD REs. Patients included in the usual care (UC) groups were randomly selected from a generated list of patients seen by a primary care provider with an International Classification of Disease, Ninth Revision (ICD-9) code for dyslipidemia (either 272.0 [pure hypercholesterolemia], 272.1 [pure hypertriglyceridemia], 272.2 [mixed hyperlipidemia], 272.3 [severe mixed hyperlipidemia], or 272.5 [low HDL-C]). Criteria for inclusion into the study were as follows: had a diagnosis of dyslipidemia; had a minimum of 3 visits with the pharmacistmanaged specialty clinic or 3 visits with the primary care provider, with an ICD-9 billing code listed above; were followed in either clinic for at least 6 months with an initial clinic visit on or after July 2001; and were enrolled in the VA health care system for at least 1 year. Patients were excluded from the study if they had documented noncompliance in their medical records as defined by missing 2 or more scheduled routine appointments. Patients were also excluded if they had a thyroid-stimulating hormone level >4.5 m IU/ml at any time during study period, to eliminate patients with uncontrolled hypothyroidism. Charts were reviewed until there were 115 patients in each group.

The Lipid Clinic Intervention

Upon enrollment in the LC, the clinical pharmacists assessed and treated the patients' dyslipidemia to achieve goal lipid levels based on the NCEP ATP III guideline and recent recommendations.^{7,22} The clinical pharmacists in these clinics have prescribing authority for all VA formulary lipid-lowering agents. Any changes made to lipid-lowering medications can be performed only by one of the clinical pharmacists once the patient has been enrolled in the LC.

The initial visit to the specialty LC included an educational class session where the patients received information about the treatment of dyslipidemia and therapeutic lifestyle modifications. Education at these classes was provided by a dietitian and one of the clinic pharmacists. After this visit, patients were scheduled for appropriate follow-up visits (20-minute appointments) in the LC, during which the patient's lifestyle (diet and exercise), changes in health status, and current lipid profile were reviewed with the patient and any necessary changes in lipid-lowering medications were made. Patients were discharged from

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the clinic after they had achieved and maintained goal lipid levels for 2 or more consecutive clinic visits and no longer required the focused services of the specialty clinic.

Outcome Measures

The primary outcomes of this study were the absolute values and the percentage changes in serum LDL-C at the most recent fasting lipid panel (FLP) and the proportion of patients who attained goal LDL-C for the LC compared with UC and for the LC group compared with baseline. Secondary outcomes of interest included the absolute values and percentage changes in the other FLP values and the proportions of patients who attained, goal TC, HDL-C, TGs, TC to HDL-C ratio (TC/HDL-C), and non–HDL-C. A Framingham risk analysis score was calculated for all patients with no known history of CHD or other CHD RE and 2 or more CAD risk factors. Calculation was performed with the Web-based Framingham risk calculator provided by the National Heart, Lung, and Blood Institute (http://hin.nhlbi.nih.gov/atpiii/calculator.asp).

Data Collection

Electronic medical records were reviewed and data were collected as described below. Patient's age, gender, and weight were recorded for the patient's most recent visit. The most recent FLP values were recorded for the LC and UC groups, and the FLP values at enrollment in the pharmacist-managed specialty clinic (baseline) were recorded. CHD or CHD RE diseases (e.g., myocardial infarction, diabetes) and coronary artery disease risk factors (e.g., tobacco use, hypertension), as defined by NCEP III guidelines, were recorded. The number of clinic visits and duration of enrollment in the clinic (months) were recorded to determine the number of visits per year. Use of a lipid-lowering agent was determined through review of electronic medical records as well as documentation in any clinic note that the patient was using an agent obtained outside of the VA from a private physician.

Data Analysis

The data are presented as mean \pm standard deviation or as proportions when appropriate. When available, a 95% confidence interval is presented. This study required 80 patients in each group to have an 80% power to detect a 20% difference in the primary outcome (percentage obtaining goal LDL-C) between LC and UC ($\alpha = 0.05$). All statistical analyses were performed using Analyse-It version 1.71 electronic software (Leeds, United Kingdom). All comparisons of nominal data were performed using chi-square or Fisher's exact test when appropriate. For comparison of all continuous variables, the assessment of the LC for values at the most recent visit compared with baseline was done using a paired *t* test. When these variables were not normally distributed, comparisons of all continuous variables are using a Wilcoxon signed rank test. Comparisons of all continuous variables

| LE 1 | Demographic and Patient Characteristics |
|------|---|
| | at Baseline for Lipid Clinic and at First |
| | Measurement for Usual Care* |

| Characteristic | Lipid Clinic (n=115) | Usual Care (n=115) | P Value |
|----------------------------------|-------------------------|-----------------------|---------|
| Age (years) [mean ± SD] | 67.9 ± 9.8 | 66.4 ± 11.4 | 0.285† |
| Gender | 2 females | 1 female | |
| Weight (lbs.) | 198.5 ± 37.43 | 196.8 ± 39.2 | 0.722† |
| Average annual number of visits | 2.96 ± 0.71 | 2.98 ± 1.34 | 0.055† |
| CHD or CHD RE | 85.2% (98) | 80.0% (92) | 0.388‡ |
| CAD RFs | | | |
| Age (years) >45 male, >55 female | 98.3% (113) | 98.3% (113) | 0.614‡ |
| Tobacco use | 16.5% (19) | 30.4% (35) | 0.020‡ |
| Family history§ | 19.1% (22) | 7.0% (8) | 0.011‡ |
| HTN or HTN-med | 73.9% (85) | 81.7% (94) | 0.204‡ |
| HDL-C <40 mg/dL | 52.2% (60) | 66.1% (76) | 0.044‡ |
| Average number of CAD RFs | 2.65 ± 0.974 | 2.83 ± 0.700 | 0.110‡ |
| CHD or CHD RE type | | | |
| MI | 26.1% (30) | 20.9% (24) | 0.464‡ |
| DM | 28.7% (33) | 26.1% (30) | 0.768‡ |
| CABG | 18.3% (21) | 8.7% (10) | 0.052‡ |
| FRAM >20% | 17.4% (20) | 22.6% (26) | 0.506‡ |
| PAD/PVD | 6.1% (7) | 2.6% (3) | 0.333‡ |
| PTCA | 13.0% (15) | 9.6% (11) | 0.533‡ |
| LDL-C goal¶ | | | |
| 100 mg/dL | 84.3% (97) | 80.0% (92) | 0.491‡ |
| 130 mg/dL | 9.6% (11) | 19.1% (22) | 0.060‡ |
| 160 mg/dL | 6.1% (7) | 0.9% (1) | 0.072‡ |

* Plus-minus values are means ± standard deviation.

† Student's t test.

‡ Chi-square test.

§ Family history = family history of premature heart disease (primary relative; male <55 years, female <65 years).</p>

|| Patient could have CHD (coronary heart disease) or CHD RE (risk equivalent) disease documented more than once. CHD RE=diabetes mellitus, symptomatic carotid artery disease, peripheral arterial disease, abdominal aortic aneurysm, and/or Framingham risk score >20%.

¶ LDL target goal according to NCEP ATP III.

CABG=coronary artery bypass graft; CAD=coronary artery disease;

CAD RFs=coronary artery disease risk factors; DM=diabetes mellitus; FRAM=Framingham risk analysis score; HDL=high-density lipoprotein; HTN=hypertension; HTN-med=antihypertensive medication; MI=myocardial infarction; NCEP ATP III=National Cholesterol Education Panel Adult Treatment Panel III; PAD=peripheral arterial disease; PTCA=percutaneous transluminal coronary angioplasty; PVD=peripheral vascular disease.

between groups were performed with the Student's *t* test. If these variables were not normally distributed, comparisons were made using a Mann-Whitney *U* test. A *P* value of <0.05 was considered significant.

| | Lipid Clinic | Usual Care | Difference | 95% CI of Difference | |
|---------------------------------------|----------------|----------------|---------------|----------------------|-----------|
| | (n=115) | (n=115) | Between Means | Between Means | P Value |
| Fasting lipid panel (mg/dL) mean ± SD | | | | | |
| TC | 166.4 ± 31.1 | 209.7 ± 43.5 | 43.4 | 35.5-53.2 | < 0.001 † |
| LDL-C | 101.7 ± 28.2 | 135.4 ± 11.9 | 33.7 | 25.3-42.1 | <0.001† |
| HDL-C | 36.2 ± 7.6 | 39.0 ± 11.9 | 2.7 | 0.2-5.3 | <0.001‡ |
| TG | 143.5 ± 77.8 | 181.9 ± 137.0 | 38.4 | 9.5-67.4 | <0.001‡ |
| TC/HDL-C ratio | 4.7 ± 1.1 | 5.7 ± 1.7 | 1.0 | 0.6-1.3 | < 0.001 † |
| Non-HDL-C§ | 130.1 ± 29.5 | 170.7 ± 42.9 | 40.6 | 31.1-50.2 | < 0.001 † |
| Proportion of patients at goal | | | | | |
| TC | 82.6% (95/115) | 40.9% (47/115) | | | <0.001 |
| LDL-C | 64.3% (74/115) | 15.7% (18/115) | | | < 0.001 |
| HDL-C | 23.5% (27/115) | 33.0% (38/115) | | | 0.143 |
| TG | 65.2% (75/115) | 52.2% (60/115) | | | 0.061 |
| All at goal¶ | 9.6% (11/115) | 1.7% (2/115) | | | 0.019 |

* Plus-minus values are means ± standard deviation.

† Students t test.

‡ Mann-Whitney U test.

|| Fisher exact test.

§ Non–HDL-C=total cholesterol minus high-density lipoprotein cholesterol.

¶ All=all measured lipid levels at goal.

CI=confidence interval; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol; TC=total cholesterol;

TC/HDL-C ratio = total cholesterol to high-density lipoprotein cholesterol ratio; TG=triglycerides.

Results

LC and UC Comparison Analysis

There were 115 patients in the LC group and 115 in the UC group. Patient characteristics were similar between the groups with the exception of the percentage of patients who had documented tobacco use, a documented family history of premature heart disease, and a low HDL-C (Table 1). There were no differences in the type of CHD or CHD RE diseases between the groups. The annual number of clinic visits was not significantly different between patients enrolled in the LC (2.97) and UC (2.98) group (P=0.055).

All measured lipid levels at the most recent FLP were found to be significantly lower in patients enrolled in the LC (Table 2): 48.6% more patients in the LC were at goal LDL-C compared with UC (64.3% vs. 15.7%, *P* <0.001). Significant differences were also seen in TC and those at all goal lipid levels (*P* <0.001 and *P* = 0.019, respectively), but not in the proportion at goal HDL-C (*P*=0.143), and the UC group had a significantly higher mean HDL-C (39.0 vs. 36.2 for LC, *P* <0.001)

Use of a lipid-lowering agent was found in 28 patients (24.3%) in the UC group compared with 108 (93.9%) in the LC group, nearly a 4-fold difference (Table 3). Based on the large difference in medication use between the groups, further analysis was performed evaluating the same outcomes in those patients from both LCs that were known to be on one or more lipid-lowering agents. The proportion attaining goal LDL-C in the LC group remained significantly different compared with UC,

66.7% versus 39.3%, a 27.4% absolute difference between the groups (P=0.016).

Further analysis was performed between and within both groups for patients who had a Framingham 10-year analysis risk score calculated. For 20 patients in LCs and 26 patients in UC with a Framingham risk score >20%, the LC patients had lower absolute TC, LDL-C, and TG values but not higher HDL-C values (Table 4). For the proportion of patients at goal, the LC patients were more likely to be at goal for TC, LDL-C, and TGs but not for HDL-C or for all 4 values.

The mean age for the 115 LC patients who satisfied the inclusion criteria was 67.9 years. The group included only 2 females and 85.2% had CHD or a CHD RE disease (Table 1). The mean duration of enrollment in the clinic was 21.56 ± 5.2 months, with an average of 5.16 ± 1.3 visits to clinic (data not presented). Compared with baseline, TC, LDL-C, HDL-C, and TGs were reduced by 16.2%, 19.5%, 9.3%, and 14.6%, respectively (TC, LDL-C, and HDL-C, P < 0.001; TGs, P=0.007) (Table 5). The proportion of patients attaining goal TC and LDL-C at the most recent LC visit increased by an absolute 37.4% and 27.8% from baseline (P < 0.001). The proportion of patients attaining goal HDL-C decreased by an absolute 20% from baseline (P=0.002), and the mean HDL-C level dropped from 40.0 mg/dL to 36.3 mg/dL (P<0.001) although the TC/HDL-C ratio decreased by a relative 8%, from 5.1 at baseline to 4.7 at follow-up (P < 0.001). At enrollment, 8 patients (7.0%) were found to be at all 4 goal lipid levels, and all 8 of these patients were on a

| | Lipid Clinic | Usual Care | Difference | 95% CI of Difference | |
|---------------------------------------|------------------|---------------|---------------|----------------------|---------|
| | (n = 108, 93.9%) | (n=28, 24.3%) | Between Means | Between Means | P Value |
| Average annual visits | 2.96 ± 0.7 | 2.98 ± 1.5 | 0.02 | 0.036 to 0.040 | 0.91371 |
| Fasting lipid panel (mg/dL) mean ± SD | | | | | |
| TC | 164.0 ± 28.9 | 189.3 ± 57.2 | 25.25 | 9.8-40.5 | 0.029‡ |
| LDL-C | 99.4 ± 26.3 | 109.4 ± 38.7 | 10.08 | 2.5-22.7 | 0.241‡ |
| HDL-C | 35.9 ± 6.9 | 39.9 ± 12.5 | 3.95 | 0.5-7.4 | 0.231‡ |
| TG | 145.2 ± 79.2 | 194.1 ± 190.3 | 48.91 | 2.4-95.5 | 0.653‡ |
| TC/HDL-C ratio | 4.7 ± 1.1 | 5.10 ± 2.2 | 0.409 | 0.2-1.0 | 0.162‡ |
| ercentage achieving goal levels | | | | | |
| TC | 85.2% (92/108) | 60.7% (17/28) | | | 0.012§ |
| LDL-C | 66.7% (72/108) | 39.3% (11/28) | | | 0.016§ |
| HDL-C | 21.3% (23/108) | 42.9% (12/28) | | | 0.043§ |
| TG | 64.8% (70/108) | 60.7% (17/28) | | | 0.847§ |
| All at goal | 10.2% (11/108) | 7.1% (2/28) | | | 0.947§ |

* Plus-minus values are means ± standard deviation.

† Independent samples t test.

‡ Mann-Whitney U test.

§ Fisher exact test.

|| All=all measured lipid levels at goal.

CI=confidence interval; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol; TC=total cholesterol;

TC/HDL-C ratio = total cholesterol to high-density lipoprotein cholesterol ratio; TG = triglycerides.

lipid-lowering drug therapy. A total of 11 patients (9.6%) were found to be at all goal lipid levels at the most recent visit (P = 0.639). At baseline, 50 patients (43.5%) were on lipid-lowering pharmacotherapy versus 108 patients (93.9%) at the most recent LC visits, an increase of 116% (P < 0.001, data not presented in tables).

Discussion

To our knowledge, this report is the first published study evaluating the effectiveness of a pharmacist-managed LC in the treatment of patients with dyslipidemia, including those without known CHD or CHD REs, based on NCEP ATP III guidelines. The findings of this study demonstrated significant improvements in the level of care provided to patients enrolled in the pharmacistmanaged LCs as defined by the proportion of patients who attained goal lipid levels at follow-up compared with baseline for TC and LDL-C but not for HDL-C, TGs, or patients at goal for all 4 serum lipid values. Comparison of these patients to randomly identified patients who were treated in UC by the primary care provider demonstrated significantly lower lipid levels, a higher percentage of patients achieving goal TC and LDL-C, and a greater utilization of lipid-lowering agents; there was no difference for LC versus UC for the proportion of patients at goal for HDL-C or TGs. Therefore, by these outcomes, the pharmacist-managed clinics were able to make effective drug therapy selection as well as provide important lifestyle education, resulting in a larger proportion of patients attaining LD and TC goals of therapy compared with UC.

The results of the subgroup analysis of patients with a

| TABLE 4 | Comparison of Patients With |
|---------|-----------------------------|
| | Calculated Framingham CHD |
| | Risk Analysis Score >20%* |

| | Lipid Clinic >20% Risk | Usual Care >20% Risk | |
|--------------------------------|---------------------------|-------------------------|----------|
| | (n = 20) | (n = 26) | P Value |
| Age (years) mean ± SD | 72.1 ± 6.8 | 68.7 ± 11.8 | 0.026† |
| No. of CAD risk factors | 2.9 ± 0.8 | 2.9 ± 0.7 | 0.945† |
| Fasting lipid panel (mg/dL) | | | |
| TC | 161.6 ± 25.9 | 223.4 ± 47.4 | < 0.001† |
| LDL-C | 102.6 ± 24.7 | 145.3 ± 41.4 | < 0.001† |
| HDL-C | 34.8 ± 6.9 | 36.6 ± 8.4 | 0.448‡ |
| TG | 121.7 ± 44.2 | 207.5 ± 152.5 | 0.019‡ |
| Percentage of patients at goal | | | |
| TC | 95.0% (19/20) | 38.5% (10/26) | <0.001§ |
| LDL-C | 50.0% (10/20) | 3.85% (1/26) | <0.001§ |
| HDL-C | 10.0% (2/20) | 23.1% (6/26) | 0.448§ |
| TG | 75.0% (15/20) | 34.6% (9/26) | 0.014§ |
| All at goal¶ | 5.0% (1/20) | 0.0% (0/26) | 0.870§ |
| % patients on lipid lowering | 85.0% (17/20) | 3.85% (1/26) | <0.001§ |

* Plus-minus values are means ± standard deviation.

‡ Mann-Whitney U test.

† Independent samples t test.

§ Fisher exact test.

|| CAD risk factors as defined by age (men ≥45 years, women ≥55 years), a history of hypertension (blood pressure ≥140/90 mmHg or on an antihypertensive agent, a low HDL-C(<40 mg/dL), cigarette smoking, and family history of premature CAD (CAD in male first-degree relative <55 years; CAD in female first-degree relative <65 years).</p>

¶ All = all measured lipid levels at goal.

CAD = coronary artery disease; CHD = coronary heart disease; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol; TC=total cholesterol; TG=triglycerides.

Comparison of Fasting Lipid Panel Levels Among Patients (n=115)

| | | | | Mean Cl | hange |
|---|----------------|----------------|--------------|-----------|----------|
| | Baseline | Most Recent | Mean Change | 95% CI | P Value |
| Fasting lipid panel (mg/dL) | | | | | |
| TC | 198.6 ± 43.5 | 166.4 ± 31.1 | -32.2 ± 42.2 | 24.4-40.0 | < 0.001† |
| LDL-C | 126.3 ± 39.2 | 101.7 ± 28.2 | -24.5 ± 37.7 | 17.4-31.5 | < 0.001† |
| HDL-C | 40.0 ± 9.1 | 36.3 ± 7.6 | -3.7 ± 7.6 | 2.5-5.0 | <0.001‡ |
| TG | 168.1 ± 113.7 | 143.5 ± 77.8 | -24.6 ± 96.6 | 6.7-42.4 | 0.007‡ |
| TC/HDL-C ratio | 5.1 ± 1.3 | 4.7 ± 1.1 | -0.4 ± 1.2 | 0.2-0.6 | < 0.001† |
| Non–HDL-C§ | 158.6 ± 41.6 | 130.1 ± 29.5 | -28.5 ± 40.5 | 21.0-36.0 | <0.001† |
| Percentage of patients at goal level(s) | | | | | |
| TC | 45.2% (52/115) | 82.6% (95/115) | | | < 0.001 |
| LDL-C | 36.5% (42/115) | 64.3% (74/115) | | | < 0.001 |
| HDL-C | 43.5% (50/115) | 23.5% (27/115) | | | 0.002 |
| TG | 56.5% (65/115) | 65.2% (75/115) | | | 0.224 |
| All at goal¶ | 7.0% (8/115) | 9.6% (11/115) | | | 0.639 |

* Plus-minus values are means ± standard deviation.

† Paired t test.

‡ Wilcoxin signed rank test.

TABLE 5

§ Non-HDL-C=total cholesterol minus high-density lipoprotein cholesterol.

|| Chi-square test.

 \P All=all measured lipid levels at goal.

CI=confidence interval; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein cholesterol; TC=total cholesterol;

TC/HDL ratio=total cholesterol to high-density lipoprotein cholesterol ratio; TG=triglycerides.

calculated Framingham CHD risk score showed significant differences between the LC and UC patients, with a Framingham risk score >20%. Perhaps the health care providers in the UC group are not utilizing the Framingham risk analysis score as a clinical tool in the care of their patients. On the other hand, only 50% of the LC patients with a Framingham risk score >20% attained LDL-C goal, only 10% attained HDL-C goal, and only 5% attained all 4 serum lipid goals.

Patients enrolled in the LC had a significant decrease in mean HDL-C levels. This is an unfavorable outcome in these patients, but there were offsetting favorable findings in the significant decrease in the non–HDL-C and a significant increase in the TC/HDL-C ratio. Overall, there were generally favorable serum lipid values for the LC patients, with a presumed lowering of the CHD risk in these paients.

The results of our study are in accordance with other previously published results in similar settings. Bozovich et al. prospectively evaluated the level of care provided by a pharmacistmanaged LC as compared with standard care provided by cardiologists in the same private practice clinic in the treatment of patients with a known history of CHD.¹⁸ The investigators found that after 6 months of treatment, 69% of patients enrolled in the LC were at goal LDL-C compared with 50% of patients being treated by the cardiologists (P = 0.016), which compares favorably with our finding of 64.3% of LC patients but much higher for UC patients in Bozovich et al. (50%) compared with 16% in the present study. Bozovich et al. attributed the significant difference to more aggressive treatment and follow-up for patients enrolled in the pharmacist-managed LC.

Cording et al. investigated the efficiency of their pharmacistmanaged LC approximately 12 months after its inception in the treatment of patients with dyslipidemia; there was no comparison with a control group.¹⁴ The proportion of patients attaining goal LDL-C based on the NCEP ATP II guidelines²³ increased from 40% at enrollment to 77% at the most recent visit, a 92.5% relative increase (*P* value was not provided).

A study with a similar design and similar outcomes by O'Donnell et al. found that 73% of patients enrolled in their pharmacist-managed LC were at goal LDL-C¹⁶ compared with 64.3% in the present study. O'Donnell et al. concluded that patients were more likely to achieve and maintain goal LDL-C in their clinic if (1) the goal was attained in the clinic, (2) the patient had known CHD (i.e., lipid-lowering pharmaco-therapy for secondary prevention), and (3) the patient had fewer risk factors.

Geber et al. compared the care provided by their pharmacist-managed pharmacotherapy clinic with that provided by primary care providers at their institution in patients with a known history of CHD and a baseline LDL-C above goal (100 mg/dL) level.¹³ The proportion of patients attaining NCEP LDL-C goal (<100 mg/dL) in the pharmacist-managed clinic was 72% compared with 39% in the primary care group (*P* <0.001). An additional 18% of patients in the pharmacist-managed clinic were on a lipid-lowering medication (*P* value was not provided).

Till et al. compared a pharmacist-managed LC versus UC provided by primary care providers in the primary care clinics at the William Jennings Bryan Dorn VA Medical Center in South Carolina.²⁰ They evaluated 47 patients in the pharmacistmanaged group and 41 patients in the UC group. There was an 18.5% reduction in LDL-C in the pharmacist-managed patients compared with a 6.5% reduction in those patients treated in the UC group (P = 0.049). In that study, the mean LDL-C between the 2 groups was not found to be significantly different. However, the magnitude of LDL-C reduction was found to be related to the number of clinical pharmacy visits in a fairly linear manner and statistically different from the nonlinear relationship of LDL-C reduction and the number of UC visits (P = 0.038). Similar to the findings of our study, the proportion of patients with goal HDL-C (>40 mg/dL) was significantly lower in the pharmacist-managed patients (36%) compared with UC patients (56%, P = 0.037).

The multicenter IMPROVE (Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers) Study investigated efficacy of pharmacist-managed ambulatory care clinics in the treatment of a multitude of problems as compared with care provided by a control group of primary care providers.²⁴ The investigators found that 39.5% of patients with known CHD in the pharmacist-managed clinics were at goal LDL-C compared with 34.5% of those receiving UC.

Limitations

The foremost limitation of the present study was the absence of baseline fasting lipid panel values for patients enrolled in the UC group. This limitation makes the precomparison and post-comparison for the LC group more robust than the comparison of the LC with the UC group. For the patient characteristics other than lipid values, the LC group and the UC group were significantly different. The UC group had a much higher proportion of use of tobacco (30.4% vs. 16.5%, P = 0.02) but a lower proportion with a family history of premature heart disease (7.0% vs. 19.1%, P = 0.011). The lower proportion of patients in the UC group with a family history of premature heart disease may explain the lower use of lipid-lowering drugs in this group.

Second, these study results are not generalizable since the patient population served at these 2 VA clinics is predominantly male and older than patients in most private MCOs. Third, we did not measure medication compliance in this study, and it is also possible that some of the patients obtained a lipid-lowering agent outside of the VA system that was not documented in the medical record. Fourth, the retrospective chart review did not permit elimination of the possibility that the recorded lipid

values could have been nonfasting (i.e., there was no documentation in the record to confirm that the patient followed the explicit instructions to fast 8 to 12 hours prior to the medical visit to determine serum lipid values). There is also the possibility that the primary care provider could have deferred lipid management in patients who were concurrently seeing a private physician and/or specialist.

This study measured only the intermediate clinical outcomes of serum lipid values. There was no assessment of direct and administrative costs of providing pharmacist-managed LC services. Therefore, it was not possible to estimate a return on investment or to suggest that the pharmacist-managed LC service was cost effective.

Despite these limitations, the effectiveness of pharmacistmanaged specialty clinics has been demonstrated in numerous studies establishing the ability of similar specialty clinics to deliver appropriate care based on specific goals of therapy.^{13-18,25-28} These clinics are likely successful because of their ability to have a focused visit devoting the majority of time on patient assessment and education.²⁹ In addition to these factors, the pharmacist services have demonstrated significant cost savings to both the patient and the health care organization.³⁰⁻³² A pharmacist's time is often less costly to the patient and health care organization than is a physician's. Thus, if a pharmacist is able to achieve a similar or improved level of care in treating a specific disease state, then a pharmacist-managed specialty clinic could be a cost-effective method to improve the efficiency of a health care system.

Based largely on these factors, physicians have voiced support of collaborative drug therapy management agreements between themselves and appropriately trained pharmacists.³³ Yet, there are additional potential roles for pharmacists in the treatment and identification of patients with dyslipidemia.^{29,34} Such roles outside of drug therapy management can include providing education to patients and health care providers, community screening projects, and the traditional role of dispensing medications. Community pharmacists are a source of information for many patients, giving the pharmacist numerous educational opportunities. In a community setting, the access to pharmacists has been associated with significant improvements in the level of care provided to patients with dyslipidemia through screening projects and recommendations provided to the patients' primary care providers.^{10,35-37}

Conclusions

The operation of pharmacist-managed LCs was associated with improved serum lipid values of enrolled patients compared with baseline for 5 of 6 measures and for the proportion of patients at goal levels for TC and LDL-C but not for HDL-C, TGs, or for all 4 goal levels. A smaller proportion of patients in the UC group, treated only by their primary care provider, received drug therapy for their dyslipidemia, contributing to a comparatively higher proportion of patients in the LC group that attained goal lipid levels. After nearly 2 years of follow-up, these 2 pharmacist-managed VA LCs had an effect on some but not all lipid panel values for enrolled patients. These pharmacistmanaged LCs, in which pharmacists had prescribing authority for referred patients, received more pharmacotherapy for dyslipidemia compared with UC groups.

DISCLOSURES

No outside funding supported this study. The authors disclose no potential bias or conflict of interest relating to this article. Author Timothy A. Mazzolini served as principal author of the study. Study concept and design were contributed primarily by Mazzolini and author Brian K. Irons, with input from authors Charles F. Seifert and Evans C. Schell. Data collection was the work of Mazzolini and author Charles F. Seifert, with contributions from Irons and Schell. Drafting of the manuscript and its critical revision were primarily the work of Mazzolini, with contributions from the coauthors.

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Effect of Access to Anticoagulation Management Services on Warfarin Use in Patients with Atrial Fibrillation

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- **Study Objective.** To determine the effect of access to ambulatory anticoagulation management services (AMS) on the rate of warfarin use in patients with atrial fibrillation.
- Design. Retrospective medical record review.
- **Setting.** Two ambulatory care clinics in the same managed care system: one with and one without access to pharmacist-managed AMS.
- **Patients**. One hundred seventy-eight patients with atrial fibrillation diagnosed between June 2000 and June 2001.
- **Measurements and Main Results.** Warfarin use was assessed overall and by contraindications and risk factors for stroke. Independent predictors of therapy were identified. The overall rate of warfarin use in atrial fibrillation was higher in the clinic with access to AMS than in the clinic without access (77.9% vs 61.7%, p=0.03). In patients with no known contraindications, warfarin use increased by 20.2% with access to AMS versus no access (80.2% vs 60.0%, p=0.023). Patients aged 65 years or older with one or more risk factors for stroke and no contraindications were more likely to receive warfarin in the clinic with access to AMS than in the clinic without access (85.1% vs 53.8%, p=0.001). Access to AMS was an independent predictor of warfarin use (odds ratio 2.19, 95% confidence interval [CI] 1.05–4.56). Female sex was an independent negative predictor of warfarin use (odds ratio 0.48, 95% CI 0.24–0.96).
- **Conclusion**. In the managed care setting, use of warfarin for stroke prophylaxis in patients with atrial fibrillation was higher in the ambulatory care clinic with access to pharmacist-managed AMS than in the clinic without access.
- Key Words: anticoagulation, atrial fibrillation, warfarin, stroke, prescription practices.

(Pharmacotherapy 2005;25(8):1062-1067)

Atrial fibrillation is a major independent risk factor for stroke, increasing the risk 5-fold.¹ The risk of embolic stroke is further increased in women² and as age increases.¹ In patients with atrial fibrillation, the first stroke is often a fatal or debilitating event and underscores the importance of adequate anticoagulation in these patients.² Randomized studies have shown that warfarin therapy can reduce the risk of ischemic stroke by 68%, with an even greater relative risk reduction of 84% in women.² In comparison, alternatives to warfarin such as aspirin, have a

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Presented in part as a poster at the Midyear Clinical Meetings of the American Society of Health-System Pharmacists, New Orleans, Louisiana, December 2–6, 2001, and Atlanta, Georgia, December 8–12, 2002, and at the Spring Practice and Research Forums of the American College of Clinical Pharmacy, Savannah, Georgia, April 7–10, 2002, and Palm Springs, California, April 27–30, 2003.

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significantly lower effective rate of stroke prevention, with a risk reduction of 21%.³

According to guidelines from the American College of Chest Physicians, optimal long-term antithrombotic therapy for patients with atrial fibrillation is stratified on the basis of risk factors for stroke.⁴ High-risk factors are poor leftventricular function, age older than 75 years, presence of a prosthetic heart valve, and previous stroke, transient ischemic attack, or systemic embolus. Moderate-risk factors are age 65-75 years, diabetes mellitus, and coronary artery disease. Recommended therapy for patients with any high-risk factor or more than one moderaterisk factor is warfarin with a target international normalized ratio (INR) of 2.5 (range 2.0-3.0).³ For patients with one moderate-risk factor and atrial fibrillation, aspirin 325 mg/day or warfarin therapy (target INR 2.0-3.0) is recommended. In patients with no high- or moderate-risk factors, aspirin 325 mg/day is recommended.

Despite these recommendations and the effectiveness of warfarin for stroke prevention, underuse of antithrombotic therapy in patients with atrial fibrillation is well documented. Among studies in the ambulatory care setting in the United States, only 24-55% of eligible patients without contraindications receive appropriate anticoagulation therapy.⁵⁻¹¹ Predictors of warfarin use vary. In two studies, patients with a history of stroke were more likely than those without a previous stroke to receive warfarin.^{9, 11} However, in another study, previous stroke or transient ischemic attack were not independent predictors of warfarin use.¹² In addition, patterns of warfarin use may differ geographically. In one report, patients in the southern states were less likely than those in other geographic regions to receive warfarin.¹¹ Although increased age is associated with an increased risk of stroke, an age of 85 years or older was a predictor of decreased warfarin use.12

Patient-, physician-, and health care system– related barriers to the use of warfarin in atrial fibrillation have been identified.¹³ For instance, patients' perceptions of the risks of embolism and hemorrhage can influence prescribing decisions. Patient education with the use of visual aids to depict the benefits and risks of warfarin helped to overcome this barrier. In addition, physicians report that anticoagulation monitoring is inconvenient and that receiving advice from consultants increases their willingness to prescribe anticoagulation therapy. Anticoagulation clinics, including those with pharmacistmanaged services, decrease the risk associated with anticoagulation therapy.¹⁴ A coordinated method of patient education and monitoring by ambulatory care anticoagulation management services (AMS) may help overcome these barriers.¹⁵

In a retrospective review of patients with atrial fibrillation, warfarin use in two medical practices with access to AMS was compared with that of 17 local practices without these services.¹⁰ Warfarin use was higher in 97 patients examined at practices with access to AMS than in 185 patients examined at those without such access. However, little is known about the similarities and differences of the practices. Although they were within a managed care organization and although each had four or more physicians, differences in specialist care or demographics might have been confounding variables.

The objective of the study was to determine the effect of access to AMS in ambulatory care clinics on the use of warfarin to prevent stroke in patients with atrial fibrillation. Because of the potential importance of demographics (e.g., age, sex) and specialists, warfarin use was compared in two settings that primarily differed in the availability of AMS. As regional variations in warfarin use have been observed,¹¹ this study was also designed to provide useful data regarding patterns of use in the urban Midwest.

Methods

Study Design and Patients

This study was a retrospective medical record review performed at two ambulatory care clinics in a managed care system. The two clinics were located within 0.5 mile of each other and served the same population demographic. Although the same cardiologists served both centers, the clinics had different primary care physicians, and only one of the clinics had access to pharmaciststaffed point-of-care AMS. At the clinic with AMS, each primary care physician had the option of referring patients to the service for monitoring. The physicians accepted the AMS well and had a high referral rate. During the study period, one clinical pharmacist staffed the AMS. At the clinic without AMS, the method of anticoagulation monitoring was selected at the discretion of the primary care physician. Phlebotomy followed by a phone call from a nurse or physician was the usual process of care.

All patients with a diagnostic code for atrial fibrillation (427.31 from the *International*

| | Patients with | Patients without | |
|--|---------------|------------------|---------|
| | Access to AMS | Access to AMS | |
| Characteristic | (n=131) | (n=47) | p Value |
| Age, mean ± SD (yrs) | 71.7 ± 11.3 | 74.7 ± 11.5 | 0.13 |
| | No. (%) | of Patients | |
| Women | 66 (50.4) | 24 (51.1) | 0.94 |
| Atrial fibrillation confirmed | | | |
| on electrocardiography | 63 (48.1) | 26 (55.3) | 0.40 |
| Risk factors for stroke | | | |
| Previous ischemic stroke | 17 (13.0) | 3 (6.4) | 0.29 |
| Previous transient ischemic attack | 4 (3.1) | 2 (4.3) | 0.66 |
| Hypertension | 120 (91.6) | 44 (93.6) | 0.99 |
| Heart failure | 65 (49.6) | 18 (38.3) | 0.18 |
| Diabetes mellitus | 46 (35.1) | 13 (27.7) | 0.35 |
| Coronary artery disease | 43 (32.8) | 13 (27.7) | 0.02 |
| Valve replacement | 2 (1.5) | 1 (2.1) | 0.99 |
| Potential contraindications to warfarin ^a | | | |
| Previous gastrointestinal hemorrhage | 8 (6.1) | 2 (4.3) | 0.99 |
| Previous other hemorrhage | 14 (10.7) | 8 (17.0) | 0.26 |
| Previous fall | 7 (5.3) | 4 (8.5) | 0.44 |
| Dementia | 5 (3.8) | 0 (0) | 0.33 |
| Hepatitis or cirrhosis | 1 (0.8) | 2 (4.3) | 0.17 |
| History of seizure | 1 (0.8) | 1 (2.1) | 0.46 |
| Alcoholism | 3 (2.3) | 2 (4.3) | 0.61 |

Table 1. Baseline Characteristics of the Ambulatory Patients with Atrial Fibrillation

AMS = anticoagulation management services.

^aPrevious intracranial hemorrhage or hypersensitivity to warfarin was not identified in any patient.

Classification of Diseases, Ninth Revision, Clinical Modification¹⁶) were identified by means of a computerized database review of visits between June 1, 2000, and May 31, 2001, and were included in the study. The institutional review board approved the study protocol.

The appropriateness of warfarin therapy was assessed by documenting risk factors for stroke and contraindications to warfarin therapy. Risk factors for stroke were previous ischemic stroke, previous transient ischemic attack, hypertension, left ventricular dysfunction or clinical heart failure, diabetes mellitus, coronary artery disease, and prosthetic valve replacement. Potential contraindications to warfarin were hypersensitivity to warfarin, history of intracranial hemorrhage, gastrointestinal or other bleeding, previous fall, dementia, hepatitis or cirrhosis, seizure disorder, or chronic alcohol use. Warfarin use, defined as any documented prescription for warfarin during the study period, was recorded. Aspirin use was similarly defined and noted. Patient sex and age on the index date were documented. The rate of warfarin use in ideal candidates for warfarin therapy was examined. Ideal candidates were those with a high risk of stroke and a low risk of bleeding, which was defined as age 65 years or older, one or more risk factors for stroke, and no contraindications to warfarin.

Statistical Analysis

Nominal data were analyzed by using the χ^2 or Fisher exact test, as appropriate. Parametric data were analyzed by using the Student *t* test. An a priori α of less than 0.05 was chosen to indicate statistical significance. Multivariate logistic regression analysis of the entire cohort was used to identify independent predictors of warfarin use. Access to AMS, sex, age of 65 years or older, and risk factors for stroke or contraindications to warfarin were included in the multivariate model. Sex, age, risk factors, and contraindications were included in a model based on those of previous studies.⁹ All data analysis was performed by using statistical software (SPSS version 12.0; SPSS Inc., Chicago, IL).

Results

A total of 239 patients in the two clinics had a diagnostic code indicating atrial fibrillation. After patients with a primary care physician at another facility and patients without a documented history of atrial fibrillation were excluded, 178 patients remained in the study cohort. Of these patients, 131 received follow-up with a primary care physician at the clinic with access to AMS, and 47 received follow-up with a primary care physician at the clinic without such

| | No. (%) | | |
|--------------------------|-----------------------|--------------------------|---------|
| Variable | With Access to AMS | Without Access to AMS | p Value |
| Warfarin use | | | 1 |
| Overall | 102/131 (77.9) | 29/47 (61.7) | 0.03 |
| One or more risk factors | 99/125 (79.2) | 27/45 (60.0) | 0.01 |
| Two or more risk factors | 83/101 (82.2) | 23/32 (71.9) | 0.21 |
| Aspirin use | 16/131 (12.2) | 7/47 (14.9) | 0.64 |

Table 2. Use of Warfarin and Aspirin According to Risk Factors for Stroke

AMS = anticoagulation management services.

access. Table 1 presents the patients' characteristics, including demographic information, risk factors for stroke, and potential contraindications to anticoagulation.

In both groups, hypertension and heart failure were the most prevalent risk factors for stroke, and the most frequent potential contraindications were previous gastrointestinal or other hemorrhage and a previous fall. No patient had previous intracranial hemorrhage or hypersensitivity to warfarin. The two groups were similar in age and sex and did not statistically differ with respect to the percentage of patients with atrial fibrillation, as documented on electrocardiography. In the clinic with and in that without access to AMS, 125 (95.4%) of 131 and 45 (95.7%) of 47 patients, respectively, had at least one risk factor for stroke other than age (p=0.927). At least one potential contraindication was documented in the medical records of 34 patients (26.0%) from the clinic with AMS and in 17 patients (36.2%) from the clinic without AMS (p=0.184).

Of the 131 patients from the clinic with access to AMS, 102 were prescribed warfarin, 16 were prescribed aspirin, and 19 were prescribed neither. Of the 47 patients from the clinic without access to AMS, 29 were prescribed warfarin, 7 were prescribed aspirin, and 11 were prescribed neither. Table 2 shows the overall rates of warfarin use in these patients with atrial fibrillation and rates categorized by the number of risk factors for stroke. Overall, 102 patients with access to AMS (77.9%) were prescribed warfarin, compared with 29 (61.7%) of those at the clinic without access (p=0.03).

Access to AMS was an independent predictor of warfarin use (odds ratio [OR] 2.19, 95% confidence interval [CI] 1.05–4.56; Table 3). Among patients not receiving warfarin, 10 (34.5%) of 29 received aspirin in the clinic with access to AMS compared with 7 (38.9%) of 18 in

Table 3. Multivariate Predictors of Warfarin Use in the178 Patients with Atrial Fibrillation

| Variable | Adjusted OR (95% CI) |
|-------------------------------------|----------------------|
| Access to clinic with AMS | 2.19 (1.05-4.56) |
| Female sex | 0.48 (0.24-0.96) |
| Age ≥ 65 yrs | 1.08 (0.43-2.70) |
| One or more risk factors for stroke | 1.41 (0.29-6.82) |
| One or more potential | |
| contraindications to warfarin | 0.75 (0.36–1.58) |
| | 1 4146 |

OR = odds ratio; CI = confidence interval; AMS = anticoagulation management services.

the clinic without access (p=0.760). Among patients with no contraindications to warfarin, the rate of use was 80.2% for those with access to AMS compared with 60.0% for those without access (p=0.023). Among patients in whom atrial fibrillation was confirmed on electrocardiography, warfarin was used in 51 (81.0%) of 63 patients from the clinic with access to AMS compared with 18 (69.2%) of 26 in the clinic without access (p=0.228).

Warfarin use also differed when age was considered. In patients aged 65 years or older, 84 (80.0%) of 105 with access to AMS received warfarin compared with 23 (57.5%) of 40 without access (p=0.006). Of those aged 75 years or older, 41 (75.9%) of 54 patients in the clinic with AMS received warfarin compared with 16 (53.3%) of 30 in the clinic without AMS (p=0.034). However, an age of 65 years or older was not an independent negative predictor of warfarin use (OR 1.08, 95% CI 0.43-2.70; Table 3). In the subgroup of patients who were considered ideal candidates for anticoagulation, 63 (85.1%) of 74 received warfarin in the clinic with AMS, whereas 14 (53.9%) of 26 received warfarin in the clinic without AMS (p=0.001).

Overall, warfarin use was more common in men than women $(71 \ [80.7\%] \ of \ 88 \ vs \ 60 \ [66.7\%] \ of \ 90, \ p=0.034)$. In men, the rate of use was higher in the clinic with access to AMS than

in the clinic without access (56 [86.2%] of 65 vs 15 [65.2%] of 23, p=0.029). However, access to AMS did not significantly affect the percentage of women with atrial fibrillation who received warfarin. Rates of warfarin use was 46 [69.7%] of 66 women with AMS access compared with 14 [58.3%] of 24 without access (p=0.312). Overall, female sex was an independent negative predictor of warfarin use (OR 0.48, 95% CI 0.24-0.96; Table 3). In the subgroup of ideal candidates, 28 (80.0%) of 35 women in the clinic with access to AMS received warfarin compared with eight (53.3%) of 15 women in the clinic without access (p=0.054), whereas 35 (89.7%) of 39 men received warfarin when AMS was available compared with 6 (54.5%) of 11 when it was not (p=0.007).

Discussion

Despite evidence of its effectiveness for preventing stroke in atrial fibrillation, warfarin is not prescribed to many patients in whom it is appropriate.^{5–11} In our study, the rate of warfarin use in the clinic without access to AMS was 61.7%, similar to the 55% rate reported in a comparable practice setting.9 However, the 77.9% rate of warfarin use in the clinic with access to AMS was higher than that reported from most studies. Methods to decrease the burden of anticoagulation monitoring on patients and providers have been suggested as means to increase the appropriate use of warfarin in atrial fibrillation.9 In anecdotal reports, physicians in the clinic with access to AMS felt more comfortable in starting warfarin to prevent stroke in patients with atrial fibrillation because close monitoring by the AMS minimized the risks. Although specific barriers to warfarin therapy were not explored, its increased use in the clinic with access to AMS suggested that the availability of a coordinated service to manage warfarin therapy may overcome some of them. In fact, the writers of one editorial theorize that implementing AMS may improve warfarin use in patients with atrial fibrillation.¹⁵ Our results confirm the findings of a retrospective review of medical records¹⁰ while minimizing the potential confounding effects of age, sex, and specialist care.

The increased use of warfarin in the clinic with access to AMS persisted in patients aged 65 years or older and in those aged 75 years or older. Studies indicate that the prevalence of atrial fibrillation and the risk of stroke increase with advancing age.¹ However, an age of 75 years or

older7 or 85 years or older9, 12 are independent negative predictors of warfarin use. In one study, elderly patients older than 75 years were not at an increased risk of hemorrhage compared with control subjects aged 60–69 years.¹⁷ Although the risk of stroke in the elderly remains high and although their risk of hemorrhage is similar to that of younger patients, physicians are reluctant to prescribe warfarin for stroke prevention in this population. In one study, physicians were less likely to recommend warfarin for an 81-year-old patient than for a 76-year-old patient in similar case vignettes.¹⁸ Physicians tended to overestimate the risk of bleeding in clinical vignettes compared with risks of bleeding reported in the literature. Findings in the present study suggest that access to AMS may allay some of the concerns associated with warfarin use in elderly patients with atrial fibrillation, possibly because such services provide close monitoring and decrease the risk of therapy.

Despite the increased use of warfarin in our study compared with rates in the literature, many patients with atrial fibrillation at risk for stroke did not receive warfarin therapy. Women have an increased risk of stroke compared with men²; however, men were more likely than women to receive warfarin. Access to AMS significantly increased the percentage of men and ideal male candidates who received warfarin. However, this effect was not statistically significant in women, a finding consistent with that of other studies. In a large study in a health maintenance organization, female sex was associated with a decrease in warfarin use (OR 0.87, 95% CI 0.81–0.93).⁹ Findings suggest that access to AMS attenuated some of the health-system barriers to warfarin use, but barriers related to physicians' concerns about warfarin-associated bleeding and underestimations of stroke risk may persist. Efforts to educate physicians about the risk of stroke in women with atrial fibrillation and about the availability of AMS may prove beneficial.

This study had several limitations. With a lack of access to inpatient records, the diagnosis of atrial fibrillation was not electrographically confirmed in about half of the patients. The use of the diagnostic codes to identify patients with atrial fibrillation may have failed to identify those whose diagnosis was not coded during a visit in the designated period, patients whose atrial fibrillation was diagnosed after hospitalization, or patients who were noncompliant with medical follow-up. In addition, use of over-the-counter drugs tends to be underdocumented in medical records; therefore, aspirin use might have been underestimated. Although atrial fibrillation could not be categorized as being permanent, intermittent atrial fibrillation poses a risk of stroke similar to that of the permanent condition, and the same recommendations for stroke prophylaxis apply.⁴ Because the data did not include hospital records, the inappropriate inclusion of transient or perioperative atrial fibrillation in the analysis was unlikely.

Further limitations were the inability to assess practice patterns at the clinics before AMS were accessible. Although the absence of these data did not exclude the possibility that baseline differences existed between the physicians at the two clinics, this study had other strengths. Because the same specialists (including cardiologists and hematologists) practiced at both clinics, variations in patient education or patient care due to the specialists were unlikely to explain differences between groups. In addition, because the two clinics were in the same managed care system, patients in the clinics had similar access to care.

Conclusion

The rate of warfarin use for stroke prophylaxis in patients with atrial fibrillation was higher in the clinic with access to pharmacist-managed AMS than in the clinic without such access. This increase in warfarin use persisted in patients aged 65 or older and in patients aged 75 or older. However, access to AMS did not significantly affect the use of warfarin for stroke prevention in women.

Acknowledgments

The contributions of Karen M. Merrill, Pharm.D., in data collection and of David P. Zgarrick, Ph.D., in statistical consultation are acknowledged.

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Chest 2005;127;1515-1522 DOI 10.1378/chest.127.5.1515

The online version of this article, along with updated information and services can be found online on the World Wide Web at: http://chestjournal.org/cgi/content/abstract/127/5/1515

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(http://www.chestjournal.org/misc/reprints.shtml). ISSN: 0012-3692.



Effect of a Centralized Clinical Pharmacy Anticoagulation Service on the Outcomes of Anticoagulation Therapy*

Daniel M. Witt, PharmD, FCCP; Melanie A. Sadler, PharmD; Roberta L. Shanahan, PharmD; Georgann Mazzoli, PharmD; and Donald J. Tillman, PharmD

Context: A growing body of reports has documented the ability of anticoagulation management services to help patients receiving warfarin therapy achieve better outcomes compared to the care provided by their personal physicians (*ie*, usual care).

Objective: To compare clinical outcomes associated with anticoagulation therapy provided by a clinical pharmacy anticoagulation service (CPAS) to usual care.

Design: Retrospective, observational cohort study, 6 months in duration.

Setting: Large nonprofit, group-model health maintenance organization.

Patients: A total of 6,645 patients receiving warfarin therapy were included in the final analyses (intervention group, 3,323 patients; control group, 3,322 patients).

Intervention: Anticoagulation therapy for patients in the intervention group was managed by a centralized, telephonic CPAS. Therapy for patients in the control group was managed in the usual manner by their personal physicians.

Main outcome measures: The primary outcome was the occurrence of anticoagulation therapyrelated complications. A secondary outcome was the proportion of time spent in the target international normalized ratio (INR) range for each patient. Cox proportional hazards regression analyses were used to examine the risk of complications in relation to the study group.

Results: Patients in the CPAS were 39% less likely to experience an anticoagulation therapyrelated complication than were patients in the control group (hazard ratio, 0.61; 95% confidence interval, 0.42 to 0.88). The number of patients needed to treat to prevent an anticoagulation therapy complication was 52. Additional analyses revealed that improved outcomes associated with CPAS were mediated largely through improved therapeutic INR control. Patients in the CPAS group spent 63.5% of study period days within their target INR range compared to 55.2% in the control group (p < 0.001).

Conclusions: A centralized, telephonic, pharmacist-managed anticoagulation monitoring service reduced the risk of anticoagulation therapy-related complications compared to that with usual care. The cumulative evidence supporting the superior care associated with implementing a pharmacist-managed anticoagulation monitoring service was sufficient to recommend wide-spread implementation. (CHEST 2005; 127:1515–1522)

Key words: anticoagulant drugs; health-care quality assessment; pharmacists

Abbreviations: AMS = anticoagulation management service; CPAS = clinical pharmacy anticoagulation service; DVT = deep vein thrombosis; HMO = health maintenance organization; ICD-9 = *International Classification of Diseases*, ninth revision; INR = international normalized ratio; KPCR = Kaiser Permanente Colorado Region; KPOR = Kaiser Permanente Ohio Region

 ${f E}$ nsuring optimal outcomes in patients receiving warfarin therapy requires a well-coordinated systematic approach. A growing body of reports^{1–5} has suggested that implementing an anticoagulation

management service (AMS) helps patients to achieve better clinical outcomes than care provided by their personal physicians (*ie*, usual care). However, many of the available studies comparing AMS to usual care have been limited by relatively small numbers of patients, usual care control groups that included

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Manuscript received October 25, 2004; revision accepted November 25, 2004.

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medical residents and other less experienced clinicians, or patient populations with limited indications for anticoagulation therapy (*eg*, those with atrial fibrillation or a mechanical heart valve prosthesis).²⁻⁶

Much of the available information in the medical literature describes AMS models in which practitioners conduct in-depth face-to-face interviews at each patient visit. Descriptive reports^{7,8} of AMS models utilizing telephone or mail systems for most patient care activities exist, but formal assessments of clinical outcomes associated with these models are not available. The quantification of the clinical outcomes associated with telephonic services would be useful since this model allows large numbers of patients to be managed by relatively few anticoagulation therapy providers. This study addresses some of the limitations of prior studies and provides insights into the effectiveness of telephonic anticoagulation management by comparing clinical outcomes associated with anticoagulation therapy provided by a centralized, pharmacist-managed AMS that provides the majority of care via the telephone to usual care in a large, diverse sample of anticoagulated patients enrolled in a group model health maintenance organization (HMO).

MATERIALS AND METHODS

Setting

Study subjects were members of the Kaiser Permanente Colorado Region (KPCR), a nonprofit, group-model HMO. The physicians of the Colorado Permanente Medical Group contract exclusively with the Kaiser Foundation Health Plan to provide comprehensive health care to approximately 400,000 plan members. Outpatient medical, radiology, pharmacy, and laboratory services are provided at 16 medical offices throughout the Denver, CO, metropolitan area. Inpatient care is provided by medical group physicians at local hospitals that have contracted to provide care for the KPCR plan members. Blood samples for prothrombin times are processed at in-house laboratories. Additional subjects were drawn from among the 150,000 members of the Kaiser Permanente Ohio Region (KPOR), which has an integrated operational structure that is similar to KPCR.

Study Design

This was a retrospective, observational cohort study with a combined historical and parallel control group. The intervention group consisted of patients who received warfarin anticoagulation therapy that was managed by the staff of the KPCR Clinical Pharmacy Anticoagulation Service (CPAS) during the 6-month evaluation period (April 1, 1999, to September 30, 1999). The historical control group was composed of KPCR patients who received warfarin anticoagulation therapy that was managed by their KPCR physician during the 6-month evaluation period (April 1, 1996, to September 30, 1996, just prior to the implementation of CPAS in October 1996). The parallel control group was composed of KPOR patients who had received warfarin anticoagulation therapy that was managed by their physician during the 6-month evaluation period (April 1, 1996, to September 30, 1996), just prior to the implementation of CPAS in October 1996). The parallel control group was composed of KPOR patients who had received warfarin anticoagulation therapy that was managed by their physician during the 6-month evaluation period (April 1, 1999, to September 30, 1996), just prior to the implementation of CPAS in October 1996). The parallel control group was composed of KPOR patients who had received warfarin anticoagulation therapy that was managed by their physician during the 6-month evaluation period (April 1, 1999, to September 30, 1999).

ber 30, 1999, the same time period evaluated for the CPAS group). Some KPCR patients who were receiving long-term warfarin therapy were managed both by their physician and later by CPAS. These patients were randomly assigned to the control or intervention group (*ie*, patients only contributed data to either the CPAS or the control group).

Intervention

The CPAS is a centralized team of pharmacy technicians, clinical pharmacists (ie, those with a BS or PharmD degree without residency training), and clinical pharmacy specialists (ie, those with a PharmD degree with residency training), with specialized knowledge and skill in the coordination and management of anticoagulation therapy. This team is available by pager 24 h per day, 7 days per week. Most CPAS patient care activities are conducted via telephone and mail. CPAS staff members act as the agent of the referring physician and facilitate all aspects of anticoagulation therapy, including patient education, the ordering of relevant laboratory tests including international normalized ratios (INRs), the adjustment of anticoagulation medication doses, the planning for interruption of anticoagulation therapy during invasive procedures, and the management of adverse events. All related activities and outcomes were documented in a comprehensive computerized patient monitoring system (Dawn AC; 4S Systems, Ltd; Cumbria, UK).

Patients

Patients were included in the analysis if they were at least 18 years of age, had received at least one prescription for warfarin, and had at least two INR values measured during the 6-month evaluation period (Fig 1). Patients who received anticoagulation therapy while residing in a nursing home facility were excluded from the study because access to INR data was not routinely available for these patients. Patients were also excluded if the sole indication for warfarin anticoagulation therapy was the prevention of thrombosis in an indwelling central venous catheter, since these patients typically receive unmonitored, fixed-dose warfarin therapy. Patients receiving warfarin for the prevention of venous thromboembolism following a high-risk surgical procedure (*eg*, hip or knee replacement surgery) were also excluded because the duration of warfarin therapy following high-risk surgery is often only days to weeks.

Outcomes

The primary study outcome was the time to the first occurrence of an anticoagulation therapy-related complication during the 6-month evaluation period. This outcome was operationalized as a diagnosis of a major bleeding episode or thromboembolic complication, or the documentation of a fatal event that was directly attributable to bleeding or thromboembolism. Bleeding episodes resulting in hospitalization or an emergency department visit were identified through computerized claims and referral data using predefined International Classification of Diseases, ninth revision (ICD-9) codes, and were verified through medical record review using a standardized abstraction form. Major bleeding episodes were defined as those requiring transfusion of 2 or more units of RBCs causing a decrease in hemoglobin concentration of ≥ 2 g/dL, or any intracranial, intraarticular, intraocular, or retroperitoneal bleeding. The occurrence of thromboembolic complications was identified using computerized claims and referral data, and was verified by medical record review. Because patients with recurrent deep vein thrombosis (DVT) are often managed as outpatients in our health-care system, low-molecular-weight heparin dispensing information

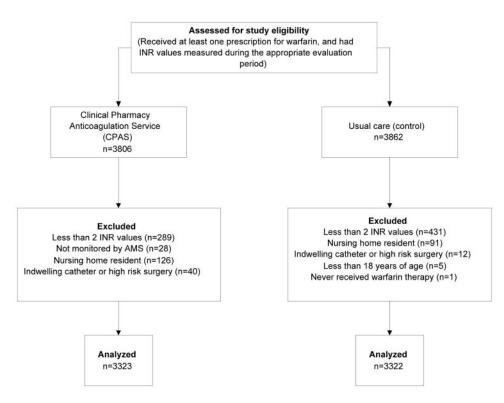


FIGURE 1. Participant selection process.

and medical record review were used to identify and confirm recurrent DVT episodes that were treated outside of the hospital. Thromboembolic recurrence was defined as an embolic or thrombotic cerebrovascular accident, pulmonary embolism, DVT, or other systemic thromboembolic event. Fatal events that were directly attributable to bleeding or thromboembolic recurrence were verified through medical record and/or death certificate review. When available, the INR value occurring at the time of an anticoagulation therapy-related adverse event was recorded. If the INR was not measured on the day of the adverse event, the most recently measured INR prior to the event was used.

The secondary outcome was time spent in the target INR range. This was estimated using linear interpolation between actual INR values and was reported as a percentage of total patient-days of therapy for each patient. The elapsed time in days between successive measurements of INR values was used to calculate the mean interval between INR values for each patient. The elapsed time, in days, between INR values $\geq 4.0~{\rm or} \leq 1.5$ and the next measured INR was used to assess the timeliness of the response to INR values that would generally require clinical intervention.⁶

Demographic data (*ie*, gender and age), information regarding all indications for warfarin therapy, and the target INR range were collected for each patient. When multiple indications for warfarin therapy were recorded, the primary indication was designated as the one requiring the highest target INR range or the longest duration of therapy. When the target INR range was unknown (CPAS group, 1 patient; control group, 83 patients), a range of 2.0 to 3.5 (which encompasses the most commonly used target ranges) was arbitrarily assigned to allow the calculation of time spent in the target INR range during the evaluation period.

Statistical Analysis

To compare the baseline characteristics between patients in the intervention and control groups, the χ^2 test, the Mann-

Whitney rank-sum test, and the Student t test were used. The χ^2 test was also used to compare the intervention and control groups with regard to overall therapeutic INR control, as measured by the proportion of time that the patient spent in their target INR range. Kaplan-Meyer survival analysis was performed to compare the rates of complications between the groups. Cox proportionalhazards regression modeling with censoring was used to estimate the hazard ratios and 95% confidence intervals (CIs) for anticoagulation therapy-related complications among patients in the intervention group in relation to patients in the control group, with adjustment for the effects of age, gender, and indication for warfarin therapy. A global model was constructed with the time interval from enrollment in the study until the first occurrence of any anticoagulation therapy-related complication as the dependent variable. In addition, Cox modeling was performed to estimate the hazard ratios for each of the individual complications (ie, major bleeding, thromboembolism, and fatal events). To assess whether any apparent benefits of the anticoagulation clinic were mediated by differences in therapeutic INR control, an additional regression analysis was conducted that included the proportion of time spent within the target INR range as an additional covariate in the global model.

To assess the soundness of the method for assessing the relationship between the study group and the occurrence of anticoagulation therapy-related complications, we repeated the analyses using a general linear model. The outcome was the presence or absence of any anticoagulation therapy-related complication. Models were adjusted for age, gender, indication for warfarin therapy, and the duration of patient-days spent in the study. Since the results obtained in this manner were very similar to those obtained in the primary analysis, only the results from Cox proportional-hazards regression are presented.

Initial analyses were conducted to compare outcomes between the KPCR and KPOR control groups. The results of these analyses indicated that these groups were similar (Table 1). Thus,

Table 1—Comparisons of the KPOR (Parallel) and
KPCR (Historical) Control Groups*

| | | - | |
|-----------------------------------|----------------|-------------|---------|
| Characteristics | KPOR | KPCR | p Value |
| Male gender, % | 54.6 | 54.2 | NS |
| Mean age, yr (SD) | $69.1\ (11.9)$ | 67.1 (13.1) | < 0.001 |
| Time in INR range, % | 55.1 | 55.4 | NS |
| Anticoagulation-related | 4.7 | 5.7 | NS |
| complications, %/patient-yr | | | |
| Indication for anticoagulation, % | | | < 0.001 |
| Atrial fibrillation/flutter | 48.8 | 31.6 | |
| CVA/Stroke | 11.4 | 7.7 | |
| DVT/PE | 20.6 | 27.2 | |
| Arterial thromboembolism | 2.9 | 2.3 | |
| Prosthetic heart valve | 8.7 | 13.6 | |
| Cardiomyopathy | 2.4 | 6.3 | |
| Coronary artery disease | 3.4 | 8.2 | |
| Other | 1.8 | 3.1 | |

*NS = not significant; CVA = cerebrovascular accident; PE = pulmonary embolism.

the analyses presented compare only the intervention group to the single, combined control group.

Results

Study Sample

A total of 7,668 subjects were initially identified for potential study inclusion (Fig 1). One thousand twenty-three patients were excluded, resulting in a total of 6,645 patients who were eligible for inclusion in the final analyses (CPAS group, 3,323 patients; control groups, 3,322 patients). The two groups were similar in age, but the proportion of men was slightly higher in the control group (p = 0.05) [Table 2]. More patients in the control group had a goal INR range other than 2.0 to 3.0 or 2.5 to 3.5, but this difference was not statistically significant (p = 0.07). A higher proportion of patients in the CPAS group were receiving anticoagulation therapy for venous thromboembolic disease (p < 0.001), whereas a greater proportion of control group patients were receiving treatment for cerebrovascular accident/ stroke and coronary artery disease (p = 0.01 andp = 0.03, respectively).

INR Monitoring

Overall, patients in the CPAS group spent a greater proportion of the follow-up period within their target INR range (63.5%) compared to those in the control group (55.2%; p < 0.001) [Table 3, Fig 2]. There was no difference in the average time interval connecting successive INR tests between the two groups (p = 0.41). The percentage of total INR values of ≥ 4.0 or ≤ 1.5 was significantly lower in the CPAS group compared to that in the control group

Table 2—Sample and Subject Characteristics*

| | CPAS | Control | |
|---|--------------|--------------|---------|
| | Group | Group | р |
| Characteristics | (n = 3,323) | (n = 3,322) | Value |
| Warfarin therapy, patient-yr | 1,412 | 1,390 | |
| Age,† yr | 67.5 (13.3) | 68.1 (12.6) | 0.12 |
| Male gender, % | 52.0 | 54.4 | 0.05 |
| Goal INR‡ | | | |
| 2.0-3.0 | 2,641 (79.5) | 2,612 (78.6) | 0.41 |
| 2.5–3.5 | 382(11.5) | 365 (11.0) | 0.54 |
| Other | 300 (9.0) | 345(10.4) | 0.07 |
| Indication for anticoagulation [‡] | | | |
| Atrial fibrillation/flutter | 1,270 (38.2) | 1,333 (40.1) | 0.11 |
| CVA/Stroke | 252 (7.6) | 315(9.5) | 0.01 |
| DVT/PE | 968 (29.1) | 795 (23.9) | < 0.001 |
| Arterial thromboembolism | 71(2.1) | 84 (2.5) | 0.26 |
| Prosthetic heart valve | 362 (10.9) | 370 (11.1) | 0.72 |
| Cardiomyopathy | 168 (5.1) | 144 (4.3) | 0.16 |
| Coronary artery disease | 153(4.6) | 193 (5.8) | 0.03 |
| Other | 79(2.4) | 88 (2.7) | 0.53 |

* See Table 1 for abbreviations not used in the text.

†Values given as mean (SD).

‡Values given as No. (%).

(15.1% vs 20.4%, respectively; p < 0.001). The time between INR values of ≥ 4.0 or ≤ 1.5 and follow-up INR testing was also significantly lower in the CPAS group (p = 0.03).

Anticoagulation Therapy-Related Complications

The primary end point (*ie*, a major bleeding episode, thromboembolic complication, or fatal event directly attributable to bleeding or thromboembolism) occurred at a rate of 3.26% per patientyear in the CPAS group compared to 5.19% per patient-year in the control group. Adjusted for age, gender, and indication for anticoagulation therapy, patients in CPAS group were 39% less likely to experience any anticoagulation therapy-related com-

| Study Variable | $\begin{array}{c} \text{CPAS} \\ \text{Group} \\ (n=3,323) \end{array}$ | $\begin{array}{c} \text{Control} \\ (n = 3,322) \end{array}$ | p Value |
|--|---|--|------------|
| Mean interval between INR results, d (SD) | 20.7 (14.0) | 21.8 (17.8) | 0.41† |
| Therapeutic INR control, % | | | |
| Days below INR target | 24.7 | 30.3 | < 0.001 |
| Days within INR target | 63.5 | 55.2 | < 0.001 |
| Days above INR target | 11.8 | 14.5 | < 0.001 |
| Mean interval to next INR following INR | | | |
| $\geq 4.0 \text{ or } \leq 1.5, \text{ d} (\text{SD})$ | 12.0 (12.2) | 13.5 (15.4) | 0.03† |
| Total INRs ≥ 4.0 or ≤ 1.5 , % | 15.1 | 20.4 | < 0.001 |

*Values given as mean (SD) or %, unless otherwise indicated. †Determined by Mann-Whitney rank-sum test.

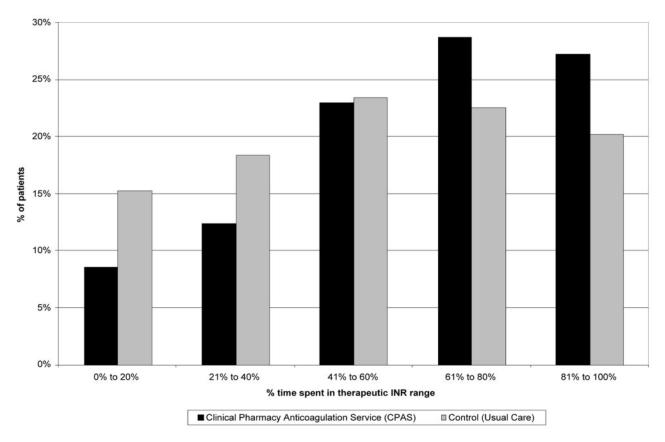


FIGURE 2. Comparison of the amount of time spent in various degrees of therapeutic INR control.

plication (hazard ratio, 0.61; 95% CI, 0.42 to 0.88) [Fig 3]. The addition of therapeutic INR control to the regression model attenuated the effect of study group assignment on the occurrence of any anticoagulation therapy-related complications (hazard ratio, 0.82; 95% CI, 0.56 to 1.20).

The occurrence rate of thromboembolic complications in the CPAS group was 62% lower than that for the control group (hazard ratio, 0.38; 95% CI, 0.21 to 0.69) [Table 4]. Differences in the occurrence rates of major bleeding and fatal adverse events between the study groups were not statistically significant after adjustment for age, gender, and indication for anticoagulation therapy.

DISCUSSION

The results of this study indicate that a centralized, telephonic, pharmacist-managed AMS improved therapeutic INR control and reduced the risk of anticoagulation therapy-related complications compared to the usual anticoagulation therapy management provided by the patient's physician. The CPAS reduced the risk of experiencing a major bleeding, thromboembolic, or fatal event while receiving anticoagulant therapy by 39% compared to usual care. The absolute risk reduction of the intervention equates to the prevention of one anticoagulation therapy-related complication for every 52 patients managed by CPAS over a 6-month period. In addition, therapeutic INR control was shown to be superior in the CPAS group.

To assess whether any apparent benefits of the anticoagulation clinic were mediated by differences in therapeutic INR control, we conducted an additional regression analysis that included the percentage of time spent within the target INR range as a covariate in the model. The addition of therapeutic INR control to the model attenuated the effect of study group assignment on the occurrence of complications, suggesting that the clinical benefits associated with the intervention were largely mediated through the superior INR management achieved by CPAS pharmacists. Improved INR control in the CPAS group likely resulted from several factors, including the use of a computerized patient monitoring system that assisted in the timely identification of patients who failed to return for INR testing as instructed and the specialized anticoagulation management experience of CPAS pharmacists. Control group patients were managed by providers with less

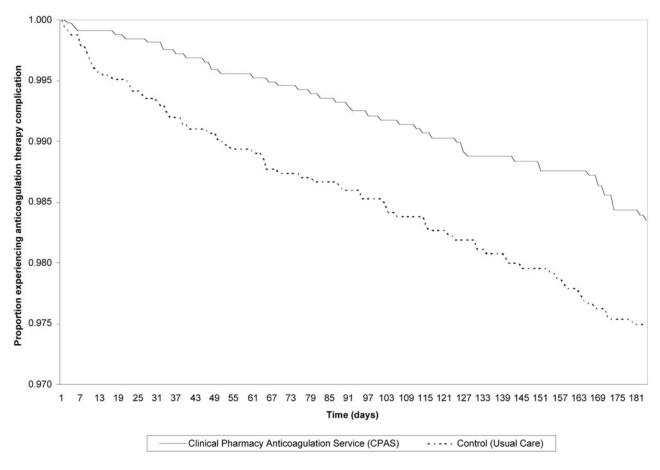


FIGURE 3. Kaplan-Meyer survival analysis of anticoagulation therapy-related complications.

hands-on experience in the management of warfarin therapy who were using more basic monitoring systems (eg, paper flow-sheets stored in three-ring binders).

The results of this study support other research^{1-3,5} that has shown that clinically trained pharmacists using a structured, specialized approach to managing oral anticoagulation therapy can achieve superior outcomes compared to those using an *ad hoc* approach. Other investigators⁶ have documented the feasibility of implementing various AMS models in managed care settings. These investigators noted variability in outreach efforts and physician acceptance among the study sites. Some physicians desired to maintain direct oversight of anticoagulation therapy, while others who cared for patients from several managed care organizations hesitated to use an AMS that was available only to certain patients. These potential barriers were overcome in our organization by the aligned relationship between physicians and CPAS pharmacists within the integrated structure of KPCR.

The large number of patients included in this analysis allowed for precise estimates of anticoagulation therapy-related complication rates, including fatal adverse events. The diverse study sample included a wide variety of indications for and durations of anticoagulation therapy, and patients with newly initiated and long-standing warfarin therapy were included. Thus, we think that the patients in this study provided a realistic representation of typical patients receiving anticoagulation therapy.

Of note, this study utilized a control group that consisted of patients managed by experienced physicians from two geographic regions who were practicing in an integrated managed care setting. Other studies^{2,3,9} evaluating the impact of an AMS on anticoagulation therapy outcomes have utilized control groups that included medical residents or other less experienced clinicians. The rate of anticoagulation therapy complications seen in our control group was comparable to that associated with a structured anticoagulation service in another study.³ Despite the high quality of anticoagulation therapy provided by the physicians in the control group, the CPAS was able to demonstrate a statistically significant reduction in anticoagulation therapy complications.

The CPAS had the greatest impact on reducing thromboembolic complications. This may be attributable to the greater percentage of time that CPAS

| Table 4—Cox Pro | portional Hazards | Modeling of | f Adverse | Events | Related to | Anticoagulant | Therapy* |
|-----------------|-------------------|-------------|-----------|---------------|------------|---------------|----------|
| | | | | | | | |

| - | •• | ° ° | |
|---|--------------------------|-----------------------------|--------------------------|
| Study Variable | CPAS Group $(n = 3,323)$ | Control Group $(n = 3,322)$ | Hazard Ratio (95% CI) |
| Major bleeding† | 29 (2.1) | 31 (2.2) | 0.93 (0.54-1.59) |
| GI hemorrhage | 15(1.1) | 21 (1.5) | |
| Intracranial hemorrhage | 7(0.5) | 3 (0.2) | |
| Hemarthrosis | 0 | 1(0.1) | |
| Hemoptysis | 1(0.1) | 0 | |
| Hematuria | 1(0.1) | 0 | |
| Other | 5(0.4) | 6(0.4) | |
| Median INR at time of major bleeding event‡ | 3.1 | 4.3 | |
| 25th, 75th percentile | 2.7, 5.4 | 2.8, 7.2 | |
| Range | 1.4-10.0 | 1.5-20.2 | |
| Thromboembolism [†] | 17 (1.2) | 41 (3.0) | 0.38 (0.21-0.69) |
| Stroke/CVA | 6 (0.4) | 18(1.4) | |
| DVT/PE | 8 (0.6) | 15(1.1) | |
| Arterial thromboembolism | 1(0.1) | 3 (0.2) | |
| Other | 2(0.1) | 5(0.4) | |
| Median INR at time of thromboembolic event [‡] | 1.8 | 1.6 | |
| 25th, 75th percentile | 1.4, 2.3 | 1.2, 2.1 | |
| Range | 1.0-3.3 | 0.9-7.9 | |
| Fatal events | 5(0.4) | 7(0.5) | 0.89 (0.30-2.66) |
| Intracranial hemorrhage | 3 (0.2) | 2(0.1) | |
| Stroke/CVA | 1(0.1) | 2(0.1) | |
| GI hemorrhage | 0 | 2(0.1) | |
| Other | 1(0.1) | 1(0.1) | |

*Values given as No. (%/patient-year), unless otherwise indicated. CI = confidence interval. See Table 1 for abbreviations not used in the text. †Includes fatal events.

Difference not statistically significant.

patients spent in their target INR range compared to those in the control group. Subgroup analyses of major clinical trials¹⁰ evaluating stroke prevention in patients with atrial fibrillation have demonstrated that most patients who experienced strokes while receiving anticoagulation therapy had subtherapeutic INR values. Therefore, increasing the amount of time that patients spend in their target INR range is likely to reduce the number of patients experiencing a stroke. In this study, the rate of stroke in the control group was approximately three times that of the intervention group. The differences in occurrences of major bleeding and fatal complications between the CPAS and control groups were not statistically significant. However, an earlier evaluation¹¹ of the outcomes of excessive anticoagulation (INR, > 6.0) in our CPAS demonstrated a dramatic reduction in the rate of major bleeding complications compared to usual care (1.3% vs 6.3%), respectively). Patients in the control group tended to present with higher INRs during major bleeding episodes compared to those in the intervention group (4.3)vs 3.1, respectively), although this difference was not statistically significant.

An acknowledged limitation of this study was the inability to randomly assign patients into the CPAS or control group. It is unlikely that unaccounted for differences between the groups explained the benefit of CPAS, since overall the groups appeared to be

demographically and clinically similar. In addition, differences between the groups were controlled for in the analysis. Another limitation that was common to retrospectively collected data related to extracting complete historical information from patient medical records. The availability of comprehensive laboratory datasets facilitated the almost complete capture of INR data in both the KPCR and KPOR study samples. Similarly, the initial identification of potential anticoagulation therapy adverse events was facilitated by the availability of electronic claims and referral datasets. The use of predefined ICD-9 codes reduced potential bias in adverse event selection. This study was conducted in a group model HMO with an integrated structure. The results may therefore not be generalizable to other settings.

The control group was composed of patients from two different Kaiser Permanente regions (KPCR and KPOR) and two different time periods (1996 and 1999). This resulted in qualitative differences in the 1996 and 1999 medical records. Medical records from 1999 were available electronically, and were more complete and easily abstracted than were paper medical records from 1996. This may have led to an underestimation of control group complication rates. However, subgroup analyses of data from the two control samples did not reveal substantial differences in study outcomes between these groups.

Appendix G-3

Methods of Knowledge Transmission

Complications were identified through administrative claims and referral datasets using predefined ICD-9 codes, and were, therefore, mostly limited to events that resulted in hospitalization or emergency department visits. Because DVT is generally treated on an outpatient basis in our organization,¹² we used information about the dispensing of low-molecularweight heparin to identify this type of thromboembolic complication. All adverse events were verified through medical record review; however, it was not possible to blind review the study group assignment. We attempted to minimize the effects of bias in complication ascertainment by using a standardized abstraction form with objective criteria during medical record reviews. The cause of death was verified for all patients who died during the study period using medical records and death certificates. It is well-known that death certificates may not always provide accurate information regarding the cause of death. Eighty-three patients in the control group were arbitrarily assigned a target INR range of 2.0 to 3.5 per the study protocol compared to only one patient in the CPAS group. This likely biased the comparison of the apeutic INR control rates between the two groups toward the null hypothesis.

Most patients receiving warfarin therapy in the United States are not enrolled in a structured AMS.¹³ This study provides evidence that a centralized clinical pharmacist-managed AMS, in which the majority of patient care activities are conducted by phone or through the mail, improves anticoagulation therapy outcomes compared to those with usual care. A coordinated, systematic approach to anticoagulation therapy may be more important than the method of management (*ie*, by telephone or in-person). Health-care organizations should strive to develop AMS models that meet system-specific needs. An AMS utilizing point-ofcare INR testing and serving a relatively small number of patients may efficiently utilize in-person management. A centralized telephonic model like CPAS may provide the leverage needed for a relatively small number of providers to efficiently manage a large patient population over a wide geographic area. AMS models that include a systematic process utilizing a knowledgeable provider, reliable laboratory monitoring, and an organized system for timely patient follow-up and education will result in improved outcomes regardless of model type.¹³ Health-care systems with less-than-adequate approaches for managing patients who are receiving warfarin are likely to receive even greater benefits from implementing a pharmacist-managed AMS, provided that there is acknowledgment of the need for the improvement in anticoagulation therapy practices. Not all health-care systems meet this criterion.⁶

Although we did not specifically evaluate the economic impact of the CPAS, other studies have demonstrated that reduced complication rates result in reduced health-care costs.^{2,3,14} Significant cost savings associated with services provided by our CPAS have been demonstrated previously.¹² Implementation of an AMS could also reduce the need to prescribe more expensive anticoagulants like ximelagatran that have not been shown to be superior to well-managed warfarin therapy. We think that the cumulative evidence supporting the superior care associated with implementing a pharmacist-managed AMS is sufficient to recommend their widespread implementation.

ACKNOWLEDGMENT: The authors thank David Magid, MD, Ella Lyons, MS, Dennis Helling, PharmD, and Tom Delate, PhD, for their assistance with the preparation of this article.

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Effect of a Centralized Clinical Pharmacy Anticoagulation Service on the Outcomes of Anticoagulation Therapy Daniel M. Witt, Melanie A. Sadler, Roberta L. Shanahan, Georgann Mazzoli

Daniel M. Witt, Melanie A. Sadler, Roberta L. Shanahan, Georgann Mazzoli and Donald J. Tillman *Chest* 2005;127;1515-1522 DOI 10.1378/chest.127.5.1515

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Appendix G-3

Methods of Knowledge Transmission

RESEARCH INSTITUTE OF THE AMERICAN COLLEGE OF CLINICAL PHARMACY

Application Instructions

for

Anticoagulation Training Program

Provided through the University of Texas and the Anticoagulation Clinics of North America

Supported by an educational grant from Sanofi-Aventis



All applications and correspondence should be addressed to: Cathy Englund Executive Secretary, Research Institute American College of Clinical Pharmacy 13000 W. 87th St. Parkway Lenexa, KS 66215-4530 (913) 492-3311 (913) 492-0088 Fax cenglund@accp.com

Application Deadline: November 1st, 2007

ACCP Anticoagulation Training Program Provided through the University of Texas and the Anticoagulation Clinics of North America

DESCRIPTION and PURPOSE:

The rapid growth in outpatient anticoagulation has created a tremendous demand for anticoagulation clinics. These services dramatically reduce major bleeding and thromboembolic complications while advancing therapy through clinical research and the systematic analysis of patient data for quality control purposes. This interest has created a significant demand for anticoagulation training programs. Funded through an educational grant from Sanofi-Aventis, this anticoagulation training program is conducted in collaboration with the University of Texas and the Anticoagulation Clinics of North America in San Antonio, Texas.

The ACCP-UT-ACNA Anticoagulation Traineeship is a minimum of a four-week intensive training program for pharmacy students, residents, and fellows that includes a structured didactic component; extensive clinical experience and participation in ongoing clinical research. The training period can be extended 1 or 2 weeks if needed to meet academic requirements of the trainee's academic institution.

Goals: The primary goals of the anticoagulation traineeship are to:

- 1. Develop the knowledge and skills necessary to evaluate a patient's need for antithrombotic therapy; design an appropriate antithrombotic regimen; and initiate, monitor, and manage such therapy. This is accomplished through direct patient interaction and assessment, and includes outpatient treatment of venous thromboembolism.
- 2. Understand how such issues as professional collaboration, clinical efficiency, and billing have to be integrated for an anticoagulation service to remain viable in today's health care environment.
- 3. Participate in ongoing applied clinical research and/or to complete a clinically useful project.
- **Structure and schedule of activities**: Under the current system, the trainee spends five halfdays per week actively involved in clinics providing patient care under the direct supervision of one of the ACNA clinicians. Because this is a private practice referral service, the patient population is varied and includes college students, retired business leaders, professionals (including physicians, nurses, and lawyers), and others. The remaining five half-days per week include time to provide two seminars each week, attend internal medicine grand rounds, Pharmacotherapy Conference, Pharm.D., Residents' conference, and time for independent study [library research and assigned project(s)]. Clinical research activities are integrated into the routine clinic time, but optional participation in an outpatient clinical trials facility also is available.

The didactic component of the traineeship is accomplished by providing the participant with a notebook of selected readings and a copy of the most recent American College of Chest Physicians Consensus Conference on Antithrombotic Therapy, and by having the trainee present two seminars each week on an assigned therapeutic topic (e.g., atrial fibrillation, prosthetic heart valves, deep vein thrombosis, inherited hypercoagulable states, etc.). The seminars may be attended by ACNA clinicians and the presentation is followed by dialogue and information sharing within the entire group. Additionally, the trainee is expected to supplement their reading materials by utilizing the most current primary literature and, through this process, each trainee is expected to critique the notebook of selected readings and recommend additions and deletions as appropriate so that this resource can be continually improved for each trainee.

Certificate of completion: Trainees will be provided a certificate of completion upon successfully meeting all program requirements.

ELIGIBILITY:

A maximum of two trainees will be accepted during any given month.

The program is targeted to doctoral-level pharmacy students enrolled in their final year of professional study, residents, and fellows. The necessary arrangements will be made with the student's home institution so the traineeship qualifies for academic and clerkship credit. Students actively enrolled in a Pharm.D. degree program need not be members of ACCP to be eligible. Residents and fellows must be current members of ACCP to be eligible.

PROCEDURES FOR APPLICATION:

Application Deadline:

Applications received by November 1, 2007 Applicants notified by December 15, 2007

Applications must be <u>received</u> by the ACCP Research Institute no later than the noted deadline to be considered.

- **Funding and Other Support of Trainee:** Trainees whose usual residence is outside the metropolitan San Antonio area will receive a grant-in-aid of \$1000 to partially offset travel and living expenses incurred in conjunction with the traineeship. University of Texas personnel can provide information on available housing.
- Acceptance Deposit: Upon notification of acceptance to the traineeship, applicants must secure their position and provide evidence of their intention to participate in the program by providing a deposit of \$100. (This is intended to preclude situations wherein a previously accepted applicant decides not to participate in the program, thereby denying the opportunity to participate to other applicants.) The acceptance deposit will be fully refunded when the trainee begins the program.

Application and Selection Process:

- 1. All applications must be submitted on the forms provided in this packet. To facilitate completion, ACCP members can obtain a copy of these forms in word processor format from the "Research Institute" pages of the ACCP website (www.accp.com). Non-members can obtain these forms in word processor format by contacting ACCP (cenglund@accp.com).
- Applicants must adhere to noted page or space limitations. Do not attach addenda unless specifically requested. All submissions should be typed single-spaced on 8.5" x 11" paper, must be clear and readily legible, and conform to the following requirements: (1) the height of the letters must not be smaller than 10 point; (2) type density must be no more than 15 characters per inch; and (3) no more than 6 lines of type must be within a vertical inch.
- 3. Selection: Applications will be evaluated and acceptance decisions will be made by program faculty from the Anticoagulation Clinics of North America.

OBLIGATIONS OF RECIPIENTS:

Upon completing the traineeship, all participants must provide ACNA a written summary description of their training program and complete a formal evaluation of the experience.

CONTACT FOR ADDITIONAL INFORMATION:

| Anticoagulation Clinics of North America | Henry I. Bussey, Pharm.D., FCCP Phone: (210) 567-8355 Fax: (210) 567-8328 E-Mail: bussey@uthscsa.edu |
|--|---|
| ACCP Research Institute | Cathy Englund, Executive Secretary Phone: (913) 492-3311 Fax: (913) 492-0088 E-Mail: cenglund@accp.com |

Please email a copy of your application to <u>cenglund@accp.com</u> Also, please mail the completed application and 3 copies to: Cathy Englund, Research Institute American College of Clinical Pharmacy 13000 W. 87th Street Pkwy Lenexa, KS 66215

Application Form ACCP-UT-ACNA Anticoagulation Traineeship

| Applicant: | | |
|---|--|----------------------------|
| Mailing Address: | | |
| | | |
| Telephone: | | Fax: |
| E-Mail: | | _ |
| Check as applicable: π Student. School of Phar | macy: | |
| π Resident π Fellow | } | Institution:* Address:* |
| | | * If different from above. |
| Desired dates of traineeship: | Preferred: 1st Alternate: 2nd Alternate: | fromto fromto fromto |

Affiliation Agreement: For students who desire academic credit for the traineeship, does your school of pharmacy have a current affiliation agreement with the Anticoagulation Clinics of North America?

 π Yes π No. If no, please attach a copy of your institution's standard affiliation agreement so it can be evaluated and executed if appropriate.

In making this application, I hereby indicate my full intention to participate in the traineeship if accepted and agree to:

- 1. Immediately notify the ACCP Research Institute of any change in my situation that will prevent me from participating in the traineeship.
- 2. Abide by all policies, procedures, and guidelines of the Anticoagulation Clinics of North America during my traineeship.
- 3. Provide a summary description of my training program and complete a formal evaluation of the experience.
- 4. Also, it is understood that the trainee is not considered an employee of ACCP, the University of Texas, nor the Anticoagulation Clinics of North America. Financial support provided to the trainee is considered a grant-in-aid to partially offset travel and living expenses incurred in conjunction with the traineeship, and is not considered a salary or stipend. There is no provision for institutional or administrative overhead expenses to the trainee's home institution.

| Signature, Applicant | Print Name/Title | Date |
|------------------------------|------------------|---------------|
| Signature, Department Chair | Print Name/Title | Date |
| Signature, Financial Officer | Print Name/Title | Date |
| November 14, 2008 | | 4 Page 537 |

1. In the space below, please describe why you want to participate in the traineeship and how the experience will contribute to your professional goals.

2. In the space below please describe coursework in therapeutics, clerkship experiences, rotations, or any other relevant experience (to be) completed prior to the traineeship. Indicate specifically their relevance to this traineeship.

- 3. Please attach a copy of your curriculum vitae or resume. (For students, make certain this addresses appropriate extracurricular activities.)
- 4. Please attach two (2) letters of reference from faculty, preceptors, or supervisors.

RESEARCH INSTITUTE OF THE AMERICAN COLLEGE OF CLINICAL PHARMACY

Application Instructions

For

2008

Heart Failure Training Program

Provided through the University of Illinois in Chicago, University of Michigan, University of North Carolina at Chapel Hill, Ohio State University, University of Southern California, and University of Utah

Supported by a grant from Scios, Inc.



All applications and correspondence should be addressed to: Sheila Carter, Executive Assistant Research Institute American College of Clinical Pharmacy 13000 W. 87th St. Parkway Lenexa, KS 66215-4530 (913) 492-3311 (913) 492-0088 Fax scarter@ accp.com

Application Deadline: May 1st, 2008

ACCP Heart Failure Training Program

DESCRIPTION and PURPOSE:

Funded through an educational grant from Scios this heart failure training program is conducted at six different sites within the U.S; the University of Illinois Medical Center, the University of Michigan Health System, the University of North Carolina Heart Failure Program, the Ohio State University, the University of Southern California Medical Center, and the University of Utah Medical Center UTAH Affiliated Heart Failure Program.

Depending on the specific site, the ACCP Heart Failure Traineeship is a two to four week, intensive training program that includes extensive clinical experience in either the ambulatory care and/or inpatient setting(s), a structured didactic component, and exposure to ongoing clinical research.

The primary goals of the heart failure traineeship are to provide pharmacy practitioners, fellows, and residents with specific knowledge and skills central to the management of patients with heart failure. For practitioners, the traineeship will provide sufficient knowledge and experience such that they should have the basis to establish a heart failure clinic or disease management program within their own practices.

The main educational objectives of the traineeship are to:

- 1. Discuss the epidemiology and pathophysiology of heart failure.
- 2. Recognize and evaluate the signs and symptoms commonly encountered in a patient with left ventricular dysfunction.
- 3. Based on the history and physical exam, determine the New York Heart Association (NYHA) Functional Class of a patient with heart failure.
- 4. Using an evidence-based approach, outline an appropriate therapeutic regimen (both nonpharmacologic and pharmacologic) for a patient with heart failure.
- 5. Design and implement a patient monitoring plan for a patient with heart failure.
- 6. Understand the financial considerations associated with the management of heart failure patients.
- 7. Participate as a member of an interdisciplinary healthcare team to provide comprehensive health care to patients with heart failure.

TRAINING SITES:

Each of the training sites provides a somewhat different learning experience. Also, because of institution-specific considerations, the sites vary in their eligibility requirements and minimum length of the traineeship. Applicants should match their interests with the strengths and characteristics of each site to determine which site would provide them with the optimal training experience. Applicants are encouraged to contact the program preceptors directly to discuss their programs and obtain more specific information.

The University of Illinois Medical Center

- 1. Primary Preceptor: Robert J. DiDomenico, PharmD.
- 2. Eligibility: licensed pharmacy practitioners, fellows, and residents.
- 3. **Length:** three four weeks. Trainees can be accepted January through mid-August and October. 1 trainee at a time
- 4. **Site/Program Description:** The University of Illinois Medical Center (UIMCC) includes a 450-bed tertiary care hospital and attached clinic building. The Medical Director of the Heart Failure Program at UIMCC is Thomas D. Stamos, MD. He oversees a heart failure "team" that includes a dedicated heart failure fellow, two advanced practice nurses (APN), two clinical pharmacists [one in ambulatory care; one hospital-based (primary preceptor)], and two APNs who serve as research coordinators. The outpatient heart failure clinic utilizes a multidisciplinary disease management approach. The clinic manages 1,500 outpatient visits annually, and actively follows over 350 patients. Each year, approximately 350 patients are discharged from UIMCC with the principal discharge diagnosis of acute decompensated heart failure (ADHF). The University is also affiliated with neighboring hospitals, where patients with advanced, refractory heart failure may be referred for heart transplant work-up.

The goal of this training program is to develop the knowledge and skills necessary to care for patients with heart failure in both the acute and chronic settings using an evidence-based approach. Trainees will have the opportunity to learn basic cardiovascular physical assessment utilizing a hands-on Cardiovascular Physical Examination Simulator ("Harvey"). At least twice weekly, trainees will participate in patient care rounds on the inpatient Medicine-Cardiology team which cares for the majority of patients hospitalized at UIMCC for ADHF. Additionally, trainees will spend 1 - 2 days per week working with the clinical pharmacist in the Emergency Department (ED) to experience the treatment of ADHF from the ED perspective. For their outpatient experience, trainees will spend two half-days weekly in the multidisciplinary Heart Failure Clinic. Trainees will also have the opportunity to attend Ouality Improvement and other organizational meetings related to heart failure, as appropriate. On a daily basis, trainees will meet with their preceptor (primary preceptor, outpatient clinical pharmacist, or ED clinical pharmacist) to discuss patient cases and other assigned heart failure topics. The trainee may have the opportunity to spend some time at an affiliated institution to gain experience caring for patients with end-stage, refractory heart failure awaiting heart transplant. Finally, throughout the training experience, trainees will be exposed to ongoing research in patients with heart failure.

University of Michigan Health Care System

- 1. **Primary Preceptors:** Barry E. Bleske, Pharm.D., FCCP and Michael Dorsch, Pharm.D., BCPS
- 2. Eligibility: licensed pharmacy practitioners, fellows, and residents.
- 3. Length: two-four weeks. Trainees can be accepted January November.
- 4. **Site/Program Description:** The University of Michigan Health System in Ann Arbor, MI, includes the University hospital, an 800-bed tertiary care center, and Taubman Medical Center. The Taubman Medical Center has a number of outpatient clinics including heart failure clinics. The heart failure clinics at the University of Michigan see over 1000 patients a year.

This traineeship can offer a variety of settings to see and treat heart failure patients. This includes treatment of acutely decompensated patients in the inpatient setting (major focus) as well as chronic management of heart failure in the outpatient setting. Whether in the inpatient or outpatient setting, it is anticipated that the trainee will participate on a multidisciplinary health care team responsible for total patient care. The trainee will meet with the primary preceptor two to three times weekly to discuss assigned heart failure topics. The trainee's primary objectives are to gain a thorough understanding of the evidence-based approach used in the care of patients with chronic heart failure, while gaining experience in the symptomatic and physical assessment of these patients in the outpatient and/or inpatient setting. Seminar, teaching rounds, and independent study will be an integrated part of the program. The trainee will also gain exposure to investigator-initiated and pharmaceutical industry-sponsored clinical research within a university healthcare system.

University of North Carolina (UNC) at Chapel Hill

- 1. **Primary Preceptors:** J. Herbert Patterson, Pharm.D., FCCP and Jo E. Rodgers, Pharm.D., BCPS (AQ Cardiology)
- 2. Eligibility: licensed pharmacy practitioners, fellows and residents.
- 3. Length: four weeks. Trainees can be accepted January November.
- 4. **Site/Program Description:** The UNC Heart Failure Program (HFP) was formed in 1984 with the goal of providing a multidisciplinary approach to the clinical care and research of the heart failure patient. Faculty include Kirkwood F. Adams, Jr., MD (Director), J. Herbert Patterson, Pharm.D., and Jo E. Rodgers, Pharm.D. Additionally, the HFP employs 2 research nurses and 8 administrative, clerical, and laboratory support staff.

This traineeship focuses on the outpatient and inpatient management of patients with chronic and acute heart failure. The trainee's primary responsibilities include attending and participating in research clinic (Tuesday), general heart failure clinic (Thursday), along with administrative and research meetings each week (Dr. Patterson). Additionally, the trainee will round on the inpatient heart failure service with Dr. Rodgers, attend weekly cardiomyopathy/cardiac transplant meetings and meet with the preceptors two to three times weekly to discuss assigned heart failure topics. The primary objectives of the traineeship are to gain a thorough understanding of the evidence-based approach utilized in the care of patients with chronic and acute heart failure, while gaining experience in the symptomatic and physical assessment of these patients in an ambulatory and inpatient setting. The trainee will also gain significant exposure to investigator-initiated and pharmaceutical industry-sponsored clinical research conducted by the UNC Heart Failure Program within a university health-care system.

The Ohio State University Medical Center

- 1. Primary Preceptor: Kerry Pickworth, Pharm.D.
- 2. Eligibility: licensed pharmacy practitioners, fellows, and residents.
- 3. Length: two four weeks. Trainees can be accepted January May and September November.
- 4. **Site/Program Description:** The Richard M. Ross Heart Hospital is a 90-bed teaching facility and outpatient clinic located on The Ohio State University Medical Center campus in Columbus, Ohio. The Ross Heart Hospital is a comprehensive heart center housing the disciplines of cardiology, including heart failure/transplant, cardiothoracic surgery, and peripheral vascular surgery. The Ambulatory Care Center is located on the first floor of the facility and sees in excess of 400 patients per month.

The goal of this training program is to develop skills to effectively manage acute and chronic heart failure in the inpatient and outpatient settings. Trainees will round with the multidisciplinary Heart Failure Team daily. Patient case discussions and pertinent heart failure topics will be presented two – three times per week with the primary preceptor. The trainee also will be exposed to other aspects of therapy such as: ventricular assist devices, ultrafiltration devices, heart transplant evaluation, and clinical heart failure trial research. A half-day per week will be spent in the Ambulatory Care Center. Trainees may also opt to spend time with the investigational trial coordinators if time permits.

Los Angeles County/University of Southern California Medical Center

- 1. Primary Preceptor: Tien M.H. Ng, Pharm.D., BCPS
- 2. Eligibility: licensed pharmacy practitioners, fellows, and residents. .
- 3. Length: Two to four weeks Optional two site experience available*. Trainees can be accepted Feb-Jul and Nov-Dec.
- 4. **Site/Program Description:** The LAC/USC Medical Center is located near downtown Los Angeles and is the main tertiary care hospital for the county. The LAC General Hospital is a 800-bed teaching hospital, level 1 trauma center, with a 16-bed intensive cardiac care unit and 6-bed telemetry unit. Heart failure patients are managed in these units by the inpatient CCU team. The heart failure research program is led by Uri Elkayam, MD.

This traineeship offers experiences in the management of heart failure from the perspective of stabilizing acute heart failure and optimization of chronic heart failure medications in an inpatient setting. Currently we are unable to offer an ambulatory experience. The site is also

active in on-going inpatient heart failure trials of both investigational medications and devices. The trainee will participate in daily patient care rounds with the inpatient CCU team, attend educational conferences of the cardiology department, and meet with the primary preceptor on a regular basis to discuss assigned heart failure topics. Depending on the trainee's interest, there will be opportunities to attend weekly meetings of the heart failure research program and possibly participate in ongoing research of the primary preceptor. The primary objectives of the program are to 1) enhance evidence-based knowledge and practice of acute and chronic heart failure, 2) provide experience in the assessment (physical, hemodynamic and diagnostic) of acute heart failure patients, and 3) provide experience in the optimal use of acute and chronic heart failure medications. Self-directed learning by the trainee is paramount to the success of the experience.

*A two-site four-week option:

Primary Preceptor: Tien M.H. Ng, Pharm.D., BCPS Secondary Preceptor: Sheryl L. Chow, PharmD, BCPS The experience would include the two weeks at LAC/USC Medical Center with Tien Ng, Pharm.D., BCPS, followed by two weeks at Centinela Hospital with Sheryl Chow, Pharm.D., BCPS. Dr. Chow is an Assistant Professor at Western University of Health Sciences. Centinela Regional Medical Center, located in Los Angeles County in Inglewood, CA, is a 370-bed acute care center with a 12-bed cardiovascular care unit, 19-bed adult critical care unit, 30-bed intermediate care unit, and five 32-bed telemetry units. The Tommy Lasorda Heart Institute at the Centinela Campus of the Centinela-Freeman Regional Medical Center provides a wide range of cardiovascular services including a 24/7 cardiac team and one of the busiest EP labs in the state. The goal of the heart failure training program is to provide clinical skills to manage acute and chronic heart failure in an inpatient community hospital setting. Patient case discussions, physical assessment rounds, and assigned topics in heart failure will occur with the preceptor two to three times per week. The trainees will also round with the multidisciplinary teams in the cardiovascular intensive care unit or intermediate care unit and evaluate heart failure patients as they acutely present to the emergency department. In addition to applying their clinical skills, the trainees will receive exposure to investigator-initiated heart failure studies within a community hospital.

University of Utah

- 1. Primary Preceptor: Mark A. Munger, Pharm.D., FCCP
- 2. Eligibility: licensed pharmacy practitioners, fellows, and residents.
- 3. Length: four weeks. Trainees can be accepted January May, and September November.
- 4. **Site/Program Description:** The UTAH Affiliated Heart Failure Program is led by E.M. Gilbert, M.D. and includes three hospitals: the University of Utah Medical Center, Salt Lake Veterans Affairs Medical Center, and LDS Hospital. The three centers have an active inpatient and outpatient heart failure and heart transplant programs. The multidisciplinary team includes physicians, pharmacists, nurse practitioners, and study coordinators.

The traineeship provides an ambulatory care clinical experience in heart failure and heart transplant clinics and exposure to ongoing clinical research in heart failure. The trainee will spend a minimum of four half-days per week in ambulatory clinics of the UTAH Affiliated

Heart Failure Program under the direct supervision of heart failure physician specialists. The trainee will meet with the preceptor daily to discuss specific didactic issues associated with heart failure. These topics will include; pathophysiology of the human failing heart; pharmacology and therapeutics of heart failure drugs, devices, and commonly prescribed concomitant agents; and the clinical art of treating patients with heart failure. Additional topics of interest to the trainee will be considered for discussion. If the trainee expresses interest in contributing to any ongoing clinical research during the four-week period, and the contribution is considered to be practical in terms of time and effort, that interest will be accommodated.

CERTIFICATE OF COMPLETION:

Trainees will be provided a certificate of completion upon successfully meeting all program requirements.

ELIGIBILITY:

Residents, fellows, or practicing clinical pharmacists must be current members of ACCP at the time of application to be eligible.

PROCEDURES FOR APPLICATION:

Between January 2008 – December 2009, The ACCP Research Institute will fund up to 30 traineeships across the six sites. Because the number of trainees that can be accommodated at a given site at any one time is limited, individuals are requested to indicate three preferred dates for their traineeship at the time of application. Because of the number of traineeships, the call for applications will have two deadlines.

Application Deadline:

Applications received by May 1, 2008 Applicants notified by June 15, 2008

Applications must be <u>received</u> by the ACCP Research Institute no later than the noted deadline to be considered. If accepted into the program, the site preceptor will contact the trainee to determine the exact dates for the experience.

- **Funding and Other Support of Trainee:** Trainees will receive a grant-in-aid of \$1000 to partially offset travel and living expenses incurred in conjunction with the traineeship, regardless of its length. This grant will be provided to the trainee at the time he/she begins the program. The site preceptor can provide information on available housing.
- Acceptance Deposit: Upon notification of acceptance to the traineeship, applicants must secure their position and provide evidence of their intent to participate in the program by providing the ACCP Research Institute with a deposit of \$100. (This is intended to preclude situations

wherein a previously accepted applicant decides not to participate in the program, thereby denying the funding opportunity to other potential applicants.) The acceptance deposit will be fully refunded when the trainee begins the program, and will be forfeited by the trainee should he/she decide to withdraw his/her application after being accepted into the program.

Application and Selection Process:

- All applications must be submitted on the forms provided in this packet. To facilitate completion, ACCP members can obtain a copy of these forms in word processor format from the "Research Institute" pages of the ACCP website (www.accp.com). Non-members can obtain these forms in word processor format by contacting ACCP (accp@accp.com). In addition to the on-line application, applicants must submit 7 hard copies of the completed application to the ACCP Research Institute.
- Applicants must adhere to noted page or space limitations. Do not attach addenda unless specifically requested. All submissions should be typed single-spaced on 8.5" x 11" paper, must be clear and readily legible, and conform to the following requirements: (1) the height of the letters must not be smaller than 10 point; (2) type density must be no more than 15 characters per inch; and (3) no more than 6 lines of type must be within a vertical inch.
- 3. Selection: Applications will be evaluated and acceptance decisions will be made by the site preceptors.

OBLIGATIONS OF RECIPIENTS:

- 1. **Professional Liability Insurance:** During the term of the traineeship, each participant is required to obtain and maintain professional liability insurance with liability limits of no less than \$1,000,000 per incident / \$3,000,000 per aggregate. Each participant will furnish to his/her host institution in advance of the program a Certificate of Insurance verifying this coverage and naming the host institution as the certificate holder. Participants should check with their employer or school of pharmacy to confirm if this coverage is already in place and obtain copies of the Certificate of Insurance.
- 2. **Program Evaluation:** Upon completing the traineeship, all participants must provide the ACCP Research Institute with a written summary description of their training program and complete a formal evaluation of the experience.

CONTACT FOR ADDITIONAL INFORMATION:

University of Illinois Medical Center

University of Michigan

University of North Carolina at Chapel Hill

Ohio State University

University of Southern California

University of Utah

ACCP Research Institute

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Mark A. Munger, Pharm.D., FCCP Phone: (801) 942-9211 E-Mail: <u>mmunger@hsc.utah.edu</u>

Sheila Carter, Executive Assistant Phone: (913) 492-3311 Fax: (913) 492-0088 E-Mail: scarter@accp.com

Please email a copy of your application to scarter@accp.com Also please mail the original completed application to: Sheila Carter, Research Institute American College of Clinical Pharmacy 13000 W. 87th Street Pkwy Lenexa, KS 66215

Application Form ACCP Heart Failure Traineeship ACCP Research Institute

| Applicant: | | | |
|---|----------------|----------------------------|----|
| Mailing Address: | | | |
| | | | |
| Telephone: | | Fax: | |
| E-Mail: | | | |
| Check as applicable: | | | |
| $ \pi \ \begin{array}{c} \pi \ \text{Resident} \\ \pi \ \text{Fellow} \\ \pi \ \text{Clinical Pharmacy Practitioner} \end{array} \right\} $ | | Institution:* | |
| | | | |
| | | * If different from above. | |
| Desired location of traineeship: | | | |
| Desired dates of traineeship: | Preferred: | from | to |
| - | 1st Alternate: | from | to |
| | 2nd Alternate: | from | to |
| | | | |

In making this application, I hereby indicate my full intention to participate in the traineeship if accepted and agree to:

- 1. Immediately notify the ACCP Research Institute of any change in my situation that will prevent me from participating in the traineeship.
- 2. Abide by all policies, procedures, and guidelines of the host institution during my traineeship.
- 3. Provide the host institution with a Certificate of Insurance to verify that I am covered by professional liability insurance with liability limits no less than \$1,000,000 per incident / \$3,000,000 per aggregate.
- 4. Provide a summary description of my training program and complete a formal evaluation of the experience.
- 5. Also, it is understood that the trainee is not considered an employee of the ACCP, the University of Illinois, the Ohio State University, the University of Michigan, the University of North Carolina at Chapel Hill, the University of Southern California or the University of Utah. Financial support provided to the trainee is considered a grant-in-aid to partially offset travel and living expenses incurred in conjunction with the traineeship, and is not considered a salary or stipend. There is no provision for institutional or administrative overhead expenses to the trainee's home institution.

| Signature, Applicant | Print Name/Title | Date |
|------------------------------|------------------|------|
| Signature, Department Chair | Print Name/Title | Date |
| Signature, Financial Officer | Print Name/Title | Date |

1. In the space below, please describe why you want to participate in the traineeship and how the experience will contribute to your professional goals.

2. For residents, and fellows, in the space below please describe coursework in therapeutics, rotations, or any other relevant experience (to be) completed prior to the traineeship. Indicate specifically their relevance to this traineeship.

- 3. Please attach a copy of your curriculum vitae or resume.
- 4. Please attach two (2) letters of reference from faculty, preceptors, or supervisors.



ANTITHROMBOTIC PHARMACOTHERAPY TRAINEESHIP®

Application Policies and Guidelines

Program presentation funded by an educational grant from Bristol-Myers Squibb, Inc.



The American Society of Health-System Pharmacists is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of continuing pharmaceutical education. Universal Program Number (Self-Study): 204-000-06-032-H01 (10 Hours) Universal Program Number (Experiential): 204-000-06-033-L01 (35 Hours)



The ASHP Antithrombotic Traineeship is an ACPE Certificate Program that provides CE credit for both the self-study and the experiential components: Participants must successfully complete the online self-study component test before they can participate in the experiential component in order to earn full credit for this Certificate Program.

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Traineeship Description

Overview of the Traineeship

The Antithrombotic Pharmacotherapy Traineeship is designed for pharmacists who are providing, or wish to provide, specialized services for patients requiring antithrombotic therapy. The traineeship prepares participants (who have little experience in providing pharmaceutical care to patients with thromboembolic conditions) to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of such patients.

The curriculum consists of a self-study program and a **5**-day experiential program, which provides intensive didactic and clinical training for selected pharmacists. The self-study program offers **10** continuing education hours (**1.0** CEUs) via the Antithrombotic Pharmacotherapy Traineeship Self-Study program and is a prerequisite for attending the experiential program. The experiential program offers **35** continuing education hours (**3.5** CEUs) and allows participants to observe and participate in the pharmaceutical care of patients at a health system with an established antithrombotic pharmacotherapy service. The ASHP Antithrombotic Traineeship is an ACPE Certificate Program that provides CE credit for the self-study and the experiential components, a certificate will be given to participants who successfully complete all parts of the program.

Educational Goals

Self-Study Program

Trainees selected to participate in the self-study program of the traineeship (see Trainee Selection Criteria) will receive a copy of the ASHP Antithrombotic Pharmacotherapy Traineeship Self-Study Book, which will provide the problemsolving skills required for clinical practice in this area. The materials included in the Self-Study Book concentrate on acquiring knowledge about the disease states most likely to be encountered and the medications used in the management and prevention of thromboembolic conditions.

It is presumed that participants will already have a solid foundation in the following areas as they relate to the care of patients with thromboembolic conditions:

- Pathophysiology
- Clinical pharmacology and therapeutics
- Clinical laboratory data interpretation
- Clinical pharmacokinetics
- Medical terminology and abbreviations

The self-study element of this traineeship is to prepare the trainee for the experiential program with sound background knowledge so they can be an effective member of a team managing patients with thromboembolic conditions. The self study focuses on providing an understanding and awareness about disease states most likely to be encountered and the medications used in their management. After completing the self study, trainees should be able to:

• Design, recommend, monitor, and evaluate patient-specific therapeutic regimens that incorporate the principles of evidence-based medicine in the care of individual patients with thromboembolic conditions.

- Build an information database that will assist in designing medication therapy regimens for patients with thromboembolic conditions by collecting, organizing and generating patient-specific problem lists to prevent, detect, and resolve medication-related problems and make appropriate medication therapy recommendations. This will require the ability to:
 - Explain signs and symptoms, epidemiology, risk factors, pathogenesis, pathophysiology, clinical course, etiology and treatment of thromboembolic conditions.
 - Explain the meaning of results of diagnostic and laboratory tests, physiologic monitoring and physical assessment commonly performed in this setting.
 - Explain the mechanism of action and therapeutics of medications (e.g. pharmacokinetics, pharmacodynamics, indications, contraindications, interactions and adverse reactions) used in an antithrombotic pharmacotherapy service.
- Redesign therapeutic regimens and corresponding monitoring plans based on evaluation of monitoring data. In order to do this, trainees should to be able to accurately assess the patient's progress toward their therapeutic goals and be able to:
 - Accurately interpret the meaning of each test parameter measurement.
 - Explain factors that may contribute to the unreliability of monitoring results (e.g., patientspecific factors, timing of monitoring tests, equipment errors, outpatient versus inpatient monitoring.)
 - Explain the need to consider multiple organ system function when interpreting a group of individual test parameter measurements.
 - Explain the importance of the analysis of trends over time in monitoring test parameter measurements.

The self-study program includes selected readings, study questions and a Continuing Education test. In order to advance to the experiential program and obtain continuing education credits, participants must pass the continuing education test with a 70% score.

Experiential Program

During the 5-day experiential program, participants observe experienced clinicians and design, monitor, and evaluate patient-specific pharmacotherapy for patients with thromboembolic conditions. The program focuses on critical thinking, decision-making, and communication skills. At the completion of the experiential program, participants should have learned and developed skills for goals in three key areas.

Practice Foundation Skills

- 1. Use an organized system for staying current with the antithrombotic pharmacotherapy literature.
- 2. Communicate clearly when speaking or writing.
- 3. Function effectively as a member of an antithrombotic pharmacotherapy service.
- 4. Maintain confidentiality of patient health information.
- 5. Understand with regard to antithrombotic therapies, direct and consultative patient care delivery systems in multiple practice settings.

Patient Care Skills

- 1. Identify the components of an effective collaborative working relationship with physicians and other health care providers.
- 2. Design, recommend, administer (when applicable), monitor, and evaluate patient-specific antithrombotic regimens that incorporate the principles of evidence-based medicine to make conscientious, explicit, and judicious decisions about the care of individual patients with thromboembolic conditions.
- 3. Document direct and consultative antithrombotic patient-care activities appropriately.
- 4. Provide antithrombotic in-service education to physicians and/or other healthcare providers.
- 5. Participate in the components of antithrombotic pharmacotherapy management: identify the need to develop, implement and assess treatment guidelines/protocols related to individuals and population-based patient care.
- 6. Exercise leadership in the health system's continuous quality improvement (CQI) approach to patientspecific processes in order to enhance antithrombotic medication safety and to proactively implement systems to prevent medication errors and/or adverse events and to identify, assess, report and manage those that occur.

Practice Management Skills

- 1. Identify informatics systems appropriate for an antithrombotic management practice.
- 2. Participate in the development or modification of policies for the use of antithrombotic medications in a health system.
- 3. Identify elements of the political and decision-making structure needed to accomplish one's antithrombotic practice area goals.
- 4. Identify components of clinical, humanistic and economic outcomes analyses that relate to antithrombotic management.
- 5. Understand steps that must be taken to ensure antithrombotic service adherence with accreditation, legal, regulatory, and safety requirements (e.g., NCQA and Joint Commission requirements; HIPAA requirements; Medicare/Medicaid requirements; ASHP standards, statements, and guidelines; state and federal laws regulating laboratory and pharmacy practice; and OSHA regulations).
- 6. Participate in the antithrombotic service performance improvement program.
- 7. Contribute to the development of a new antithrombotic service or to the enhancement/expansion of an existing anticoagulation-related service.

Post-Experiential Requirements

Upon completion of the traineeship, the follow requirements must be met before a certificate will be issued. Trainees are required to provide:

- A copy of the proposed policies and procedures that they have submitted to their health system as part of their proposal to institute a new or enhance an existing antithrombotic pharmacotherapy service.
- A report demonstrating that the trainee has become actively involved in antithrombotic pharmacotherapy management at his/her health-system site.
- An outline of a presentation about the role of a pharmacist providing antithrombotic pharmacotherapy service that they have made to associated healthcare providers.

Qualifications of Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state in the U.S. and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have 2 years of experience in clinical practice.

Applicants must have a command of basic knowledge areas as they relate to patients with a thromboembolic condition including pathophysiology, clinical pharmacology and therapeutics, clinical laboratory data interpretation, clinical pharmacokinetics, and medical terminology and abbreviations. In addition, applicants should have experience with writing pharmaceutical care plans, conducting patient interviews, and delivering educational programs to other members of the health care team.

Upon completion of the program, the applicant will be responsible for personally providing pharmaceutical services to patients with thromboembolic condition management.

Qualifications of the Applicant's Health System

The applicant's employer must be a health-care system in the U.S. with resources for the provision of services for patients with thromboembolic conditions. The chief executive officer of the system, and the physician who is responsible for the management or prevention of patients with thromboembolic conditions must provide documentation of their commitment to the establishment of a pharmaceutical service for patients with thromboembolic conditions.

Application Procedures

To apply to the traineeship, the applicant must submit five copies of the completed application form and "Applicant's Statement," plus the following items (the original plus four photocopies):

- 1. Curriculum vitae, including publication citations.
- 2. A letter from the chief executive officer of the applicant's organization confirming a commitment to establishing a service in which the pharmacist routinely provides pharmaceutical care for patients with thromboembolic conditions, and an expected implementation date.
- 3. A letter from the physician responsible for the management and supporting of a pharmaceutical service for patients with thromboembolic conditions.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The panel will review the applicant's materials and score them according to the following application criteria:

| Points | Criteria |
|---------------|---|
| 20 | Academic preparation |
| 25 | Clinical practice |
| 30 | Training expectations and institutional viability for service |
| 25 | Support of administration and physician(s) |

Applicants receiving the highest scores will be selected as participants in the self-study program. Those selected to participate in the self-study program must pass the continuing education test in order to advance to the experiential program.

Qualifications of the Site

Health-systems selected as a site for the experiential segment of the traineeship must have pharmacy services that include a pharmacist or pharmacists who routinely provide care for patients with thromboembolic conditions. The administration of the participating institution supports the role and recognizes the value of pharmacists and other participants to conduct the experiential segment of the Antithrombotic Pharmacotherapy Traineeship. In addition, the faculty should have an availability of space for lectures, seminars, conferences, and hands-on clinical experiences should be adequately provided.

An experiential training site must be accredited by the Joint Commission or other appropriate organization, when applicable. The institution's department of pharmacy should meet the ASHP Minimum Standards for Pharmacies in Hospitals or other appropriate standards.

In addition, a site must be able to provide 5 days of continuous experiential training, with at least 5 hours per day of direct patient contact (in any combination of time blocks) with patients with thromboembolic conditions.

The site must submit letters from the administrator and the physician's service where the experiential portion of the traineeship occurs stating that the health system supports the traineeship program. The availability of multiple experiences is desirable and encouraged to provide a diverse training experience.

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with thromboembolic conditions. They must submit a letter from a physician specializing in the management of patients with thromboembolic conditions indicating that the preceptor participates in the design, recommendation, monitoring, and evaluation of patient-specific pharmacotherapy for patients with thromboembolic conditions and provides medication-use education to patients and their caregivers where appropriate.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Program Administration and Responsibilities

The Antithrombotic Pharmacotherapy Traineeship Program is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, MD 20814, and funded through an educational grant from Bristol-Myers Squibb, Inc. Other administrative policies applying to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- No stipend or honorarium is awarded to the participant.
- The participant is responsible for providing their own transportation and lodging while at the experiential site.
- In accordance with the ASHP Foundation guidelines and consistent with PhRMA guidelines, the ASHP Foundation will reimburse a trainee for food up to a maximum amount of \$40 per day.
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and preceptor at least 4 weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement appropriate to the specific experiential training site.
- The participant will be required to attend all sessions of the program and complete the program evaluation form.

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ASHP FOUNDATION CARDIOVASCULAR RISK/DYSLIPIDEMIA TRAINEESHIP

Application Policies and Guidelines

Program development funded by an educational grant from AstraZeneca Pharmaceuticals.



Universal Program Number (Self-Study): 204-000-06-034-H01 (10 hours/1.0 CEUs) Universal Program Number (Experiential): 204-000-06-035-L01 (35 hours/3.5 CEUs) The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.



ASHP Cardiovascular Risk/Dyslipidemia Traineeship is an ACPE Certificate Program that provides CE credit for both the self-study and the experiential components: Participants must successfully complete the online self-study component test before they can participate in the experiential component to earn full credit for this Certificate Program.

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ASHP FOUNDATION CARDIOVASCULAR RISK/DYSLIPIDEMIA TRAINEESHIP

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Traineeship Description

Overview of the Traineeship

The Cardiovascular Risk/Dyslipidemia Traineeship is designed for pharmacists in acute and ambulatory settings who are providing or wish to provide these specialized services. The traineeship prepares participants (who have little experience in providing pharmaceutical care to patients with dyslipidemia or who otherwise would benefit from cardiovascular risk reduction) to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of such patients.

The curriculum, consisting of a self-study program and a 5-day experiential program, provides intensive didactic and clinical training for selected pharmacists. The self-study program offers 10 continuing education hours (1.0 CEUs) via the modules provided by the ASHP Foundation. This is a prerequisite for attending the experiential program. The experiential program offers 35 continuing education hours (3.5 CEUs) and allows participants to observe and participate in the pharmaceutical care of patients at a health system with an established dyslipidemia and cardiovascular risk reduction service. A certificate will be given to participants who successfully complete all parts of the program.

Educational Goals

Self-Study Program

After being selected to participate in the self-study program of the traineeship (see Selection Criteria for an explanation of the selection process), participants will receive a copy of the ASHP Foundation Dyslipidemia and Cardiovascular Risk Reduction Training Self-Study Program which will provide the problem-solving skills required for clinical practice in this area. It concentrates on acquiring knowledge about the disease states and conditions most likely to be encountered and the medications used in their management.

It is presumed that participants will already have a solid foundation in the following areas as they relate to the care of patients at risk for a cardiovascular event:

- pathophysiology
- clinical pharmacology and therapeutics
- clinical laboratory data interpretation
- clinical pharmacokinetics
- medical terminology and abbreviations

The purpose of the self study element of this traineeship is that the trainee comes to the experiential stage with the sound background knowledge required in the specialized areas necessary to become an effective member of a team managing patients who are at risk for a cardiovascular event. It therefore concentrates on acquiring knowledge about the disease states most likely to be encountered and the medications used in their management in order to be able to:

• Design, recommend, monitor, and evaluate patient-specific therapeutic regimens that incorporate the principles of evidence-based medicine (the conscientious, explicit, and judicious use of current

best evidence in making decisions about the care of individual patients with dyslipidemia), and specifically to:

- Build the information base needed to design a medication therapy regimen for a patient with dyslipidemia by collecting, organizing and generating patient-specific problem lists using all information needed by the pharmacist to prevent, detect, and resolve medication-related problems and to make appropriate medication therapy recommendations. Specifically this will require the ability to:
 - Explain signs and symptoms, epidemiology, risk factors, pathogenesis, natural history of disease, pathophysiology, clinical course, etiology, and treatment of dyslipidemia.
 - Explain the meaning of results of diagnostic and laboratory tests, physiologic monitoring and physical assessment commonly performed in this setting.
 - Explain the mechanism of action, pharmacokinetics, pharmacodynamics, pharmacoeconomics, usual regimen (dose, schedule, route, and method of administration), indications, contraindications, interactions, adverse reactions, and therapeutics of medications used in the environment of a dyslipidemia and cardiovascular risk reduction service.
 - Redesign therapeutic regimens and corresponding monitoring plans based on evaluation of monitoring data. In order to do this the trainee should to be able to accurately assess the patient's progress toward their therapeutic goals and be able to:
 - Accurately interpret the meaning of each test parameter measurement.
 - Explain factors that may contribute to the unreliability of monitoring results (e.g., patient-specific factors, timing of monitoring tests, equipment errors, outpatient versus inpatient monitoring.)
 - Explain the need to consider multiple organ system function when interpreting a group of individual test parameter measurements.
 - Explain the importance of the analysis of trends over time in monitoring test parameter measurements.
 - Build the information base needed to design a medication therapy regimen and therapeutic management plan for a patient with dyslipidemia.
 - Redesign therapeutic regimens and corresponding monitoring plans based on evaluation of monitoring data giving consideration to secondary treatment options.

The self-study program includes study questions and a continuing education test. In order to advance to the experiential program and obtain continuing education credits, participants must pass the continuing education test with a 70% score.

Experiential Program

During the 5-day experiential program, participants observe experienced clinicians and design, monitor, and evaluate patient-specific pharmacotherapy for patients with dyslipidemia and/or requiring cardiovascular risk reduction management. The program focuses on critical thinking, decision-making, and communication skills. At the completion of the experiential program, participants should be able to:

Foundation skills

- Use an organized system for staying current with the dyslipidemia and cardiovascular risk reduction literature
- Communicate clearly when speaking or writing
- Function effectively as a member of a cardiovascular risk service
- Solve practice problems effectively
- Display a caring attitude toward patients with dyslipidemia in all aspects of job responsibilities
- Deliver effective education and training programs, that may include in-services, to health care providers or patients

Patient Care

- Establish a collaborative working relationship with physicians and other health care providers working with patients with dyslipidemia and/or requiring cardiovascular risk reduction management.
- Design, recommend, monitor, and evaluate patient-specific therapeutic regimens that incorporate the principles of evidence-based medicine (the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients). (When provided as part of the practice of direct patient care, this goal always involves a series of integrated, interrelated steps. To facilitate teaching and assessment, the eight steps relevant to patients requiring treatment for dyslipidemia are detailed below as separate, but related sub-goal areas.)
 - Build the information base needed to design a medication therapy regimen for a patient with dyslipidemia.
 - Design therapeutic regimens that incorporate the principles of evidence-based medicine, patient-specific data and ethics.
 - Design monitoring plans for therapeutic regimens.
 - Recommend or communicate therapeutic regimens and corresponding monitoring plans.
- Implement the therapeutic regimen and/or corresponding monitoring plan for patients with dyslipidemia
- Redesign therapeutic regimens and corresponding monitoring plans based on evaluation of monitoring data giving consideration to secondary treatment options.
- Collect and evaluate outcome data on patients.
- Use processes that help to ensure continuity of direct patient care across health care delivery settings.
- Understand the components of disease management: identification of need for, and development, implementation and assessment of, treatment guidelines/protocols related to individual and population-based patient care with the potential of incorporating into the department/institution's overall CQI plan.
- Understand approaches to designing a process to prevent medication misadventures and to identify, assess, and manage those that occur.
- Understand the role of the pharmacist in the management of medical emergencies.

Practice Management

- Understand the development or modification of policies involving the use of medications in a health system.
- Contribute to the development of a new pharmacy service or to the enhancement of an existing service.

Post-Experiential Requirements

On completion of the experiential section of the traineeship, trainees will be required to provide to ASHP Foundation the following documentation before a certificate will be issued:

- A copy of the proposed policies and procedures that they have submitted to their health system as part of their proposal to institute a new or enhance an existing dyslipidemia/cardiovascular risk reduction service.
- A report demonstrating that the trainee has become actively involved in dyslipidemia/cardiovascular risk reduction management their health-system site.
- An outline of a presentation about the role of a pharmacist providing dyslipidemia and cardiovascular risk reduction service that they have made to associated healthcare providers

Qualifications of Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state in the U.S. and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have two years experience in clinical practice.

Applicants must have a command of basic knowledge areas as they relate to patients with dyslipidemia including pathophysiology, clinical pharmacology and therapeutics, clinical laboratory data interpretation, clinical pharmacokinetics, and medical terminology and abbreviations. In addition, applicants should have experience with writing pharmaceutical care plans, conducting patient interviews, and delivering educational programs to other members of the health care team.

Upon completion of the program, the applicant will be responsible for personally providing pharmaceutical services to patients with dyslipidemia and requiring cardiovascular risk reduction management.

Qualifications of the Applicant's Health System

The applicant's employer must be a health-care system in the U.S. with resources for the provision of services for patients at risk for a cardiovascular event. The chief executive officer of the system and physician who is responsible for the cardiovascular risk services must confirm, in writing, their commitment to the involvement of the pharmacist and/or establishment of a formal pharmaceutical service for patients at risk for a cardiovascular event.

Application Procedures

To apply to the traineeship, the applicant must submit five copies of the completed application form plus the following items (the original plus four photocopies):

- Applicant's curriculum vitae, including a listing of publication citations.
- A letter from the chief executive officer of the organization confirming a commitment to the involvement of the pharmacist and/or establishment of a formal pharmaceutical service for patients at risk for a cardiovascular event (in which the pharmacist routinely provides pharmaceutical care for patients with dyslipidemia), including the expected implementation date.
- A letter from the physician responsible for the management of patients at risk for a cardiovascular event supporting a pharmaceutical service and/or involvement of the pharmacist on the patient care team.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The panel will review the applicant's materials and score them according to the following application criteria:

| Points | Criteria |
|--------|--|
| 15 | Academic preparation (degree, residency, certificate programs) |
| 20 | Clinical practice and ambulatory care experience (general clinical experience as described qualification of applicant section) |
| 20 | Training expectations (expectations of the applicant and proposed duties of pharmacist after training) |
| 20 | Institutional viability for service (involvement of pharmacist in care team) |
| 25 | Support of administration and physician(s) (support for pharmacist to attend training and commitment of institution to start or enhance service) |
| 100 | Total |

Applicants receiving the highest scores will be selected as participants in the self-study program. Those selected to participate in the self-study program must pass the continuing education test in order to advance to the experiential program.

Criteria for Training Sites and Preceptors

Qualifications of the Training Site

The health system selected as a site for the experiential portions of the traineeship must have a pharmacy service providing care for patients at risk for a cardiovascular event. The site should have a pharmacist or pharmacists who routinely provide pharmaceutical care for patients with dyslipidemia in either an ambulatory clinic or service connected to a health-system. The administration(s) of the participating institution(s) will provide adequate time to pharmacists and other practitioners to conduct the Dyslipidemia and Cardiovascular Risk Reduction Traineeship Program. Additionally, the availability of space for lectures, seminars, conferences, and hands-on clinical experiences should be adequately provided.

The proposed training site must be accredited by the JCAHO or other appropriate organization, when applicable. The institution's department of pharmacy should meet the ASHP Minimum Standards for Pharmacies in Hospitals or other appropriate standards.

In addition, a site must be able to provide 5 days of continuous experiential training, with at least 4 hours per day of direct patient contact (in any combination of time blocks) with patients with dyslipidemia or requiring cardiovascular risk reduction management. In cases where the primary training site can not provide at least 4 hours per day of direct patient contact, other affiliated clinics or services within the training site city can be used to augment the training experience. In cases where the training site city has relationships affiliated clinics and other services that service patients at risk for a cardiovascular event or dyslipidemia, the primary training site is encouraged to partner with these sites to provide the trainee with diverse experiences.

The site must submit a letter from the administrator and physician (on whose service the experiential portion of the traineeship will take place) stating that the health system supports the traineeship program.

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with dyslipidemia. He or she must submit a letter from a physician specializing in critical care indicating that the preceptor participates in the design, recommendation, monitoring, and evaluation of patient-specific pharmacotherapy for patients with dyslipidemia and provides medication-use education to patients and their caregivers where appropriate.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Administration of the Traineeship

The Cardiovascular Risk/Dyslipidemia Traineeship Program is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, Maryland 20814, and funded through an educational grant from AstraZeneca Pharmaceuticals. Other administrative policies applying to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- No stipend or honorarium is awarded to the participant.
- The participant is responsible for providing his or her transportation to the experiential site. The receptor will be responsible for providing a list of recommend living accommodations for the participant.
- The ASHP Foundation will reimburse the participant for food (up to a daily total of \$40).
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and preceptor at least four weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement and/or submit proof of liability insurance as appropriate to the assigned experiential training site.
- The participant will be required to attend all sessions of the program and complete the posttraining requirements and program evaluation form.

Appendix A

The Role of a Pharmacist in Dyslipidemia and Cardiovascular Risk Reduction Services¹

The impact of cardiovascular disease has on this country's health is well known. In order to have a greater impact on reducing the number of cardiovascular events, it is desirable to reduce cardiac risk factors prior to the initial clinical event. Considering the American Heart Association (AHA) and National Cholesterol Education Program ((NCEP) guidelines promoted in recent years, several institutions have established intervention clinics and programs aimed at preventing these cardiovascular events.² Many of these services are provided by pharmacists.

The pharmacist is in a unique position to offer testing and counseling to the patient, as well as to provide therapeutic feedback to the physician.² A pharmacist providing assistance in managing dyslipidemia should be viewed as a physician "extender" rather than as a substitute care provider. The pharmacist's expertise is in individualizing drug therapy and managing outcomes of drug therapy. Management includes the effective, safe use of drugs, monitoring for potential adverse drug reactions and patient education.

Depending on the practice environment, this pharmacist role can be accomplished in many ways. Many pharmacists choose to be consultants, evaluating patients as requested by the primary provider. Other pharmacists have created an environment where they will schedule and see patients "in-between" physician visits, thus decreasing the number of times the primary provider must see the patient. Once the diagnosis of dyslipidemia is made, the physician will refer the management to the pharmacist who then provides education, follow-up and manipulation of drug therapy. The physician maintains his or her regular schedule of patient visits.

Pharmacist run, physician-referred clinical practices revolving around cardiovascular risk management programs have been created and implemented in a wide variety of practice areas, but most notably within health-systems. An alternative and more integrated approach is to have a clinic dedicated to seeing patients (perhaps the more complicated ones) by a team, including a physician, pharmacist, dietician, nurse and other healthcare providers, who can integrate their unique knowledge and skills into the evaluation of each patient. In this environment there is a tremendous opportunity for these groups to work closely with one another to develop a therapeutic plan.

In these ways pharmacist-managed lipid clinics can be developed and integrated into a primary care medical clinic and in this way pharmacists can have an effective role in dyslipidemia and cardiovascular risk management.

- 1-Based on Covey, DF; Cziraky MJ and Shibley, MSH. NCPP Notebook pp 149-150.
- 2-Cording, MA; Engelbrecht-Zadvorny, EB; Pettit, BJ; Eastham, JH and Sandoval R. Development of a Pharmacist-Managed Lipid Clinic. Annals of Pharmacotherapy, 2002 May, Volume 36, pp 892-9

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TYPE 2 DIABETES PATIENT CARE TRAINEESHIP

Application Policies and Guidelines

Program presentation funded by an educational grant from GlaxoSmithKline



The American Society of Health-System Pharmacists is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of continuing pharmaceutical education. ASHP Ambulatory Care Clinical Skills Program Type 2 Diabetes Mellitus Management Module (total 11.5 hours or 1.15 CEU) Universal Program Numbers (Self-Study): Part 1 204-000-99-046-H01 Universal Program Numbers (Self-Study): Part 2 204-000-99-047-H01 Universal Program Numbers (Self-Study): Part 3 204-000-99-048-H01

Universal Program Number (Experiential): 204-000-02-049-L01 (35 Hours)

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Traineeship Description

Overview of the Traineeship

The Type 2 Diabetes Patient Care Traineeship is designed for pharmacists in acute, ambulatory, and home care settings who are implementing specialized services for improving outcomes for patients with type 2 diabetes. The traineeship prepares participants (who have little or no experience in providing pharmaceutical care to patients with type 2 diabetes) to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of such patients.

The curriculum, consisting of a self-study program and a five-day experiential program, provides intensive didactic and clinical training for selected pharmacists. The self-study program offers 11.5 continuing education hours (1.15 CEUs) via the ASHP Ambulatory Care Clinical Skills Program Type 2 Diabetes Mellitus Management Module, and is a prerequisite for attending the experiential program. The experiential program offers 35 continuing education hours (3.5 CEUs) and allows participants to observe and participate in the pharmaceutical care of patients at a health system with an established type 2 diabetes patient care service. A certificate will be given to participants who successfully complete all parts of the program.

Educational Goals

• <u>Self-Study Program</u>

After being selected to participate in the self-study program of the traineeship (see Selection Criteria for an explanation of the selection process), participants will receive a copy of the ASHP module from the *Ambulatory Care Clinical Skills Program - Type 2 Diabetes Management -* which will provide the problem-solving skills required for clinical practice in this area. It is presumed that participants will already have a solid foundation in the following areas as they relate to type 2 diabetes:

- pathophysiology
- clinical pharmacology and therapeutics
- clinical laboratory data interpretation
- clinical pharmacokinetics
- medical terminology and abbreviations

The self-study program includes study questions and a continuing education test. In order to advance to the experiential program and obtain continuing education credits, participants must pass the continuing education test with a 70% score.

November 14, 2008

At the completion of the self-study program, participants should be able to:

- 1) Explain the epidemiology, etiology and risk factors associated with the development of type 2 diabetes mellitus.
- 2) Explain the clinical manifestations of type 2 diabetes mellitus.
- 3) Explain the acute and chronic complications of diabetes mellitus and its management.
- 4) Explain the mechanism of action, pharmacokinetics, pharmacodynamics, usual therapeutic dosing regimen, indications, contraindications, interactions, adverse reactions and pharmacotherapeutics for the following drugs and newer treatments as they become available:
 - a) insulin
 - b) sulfonylureas
 - c) metformin
 - d) acarbose
 - e) troglitazone
 - f) repaglinide
- Understand the rationale behind the design and implementation of a patient self-care plan for type 2 diabetes mellitus.
- 6) Identify subjective and objective monitoring parameters for medication used in the management of type 2 diabetes mellitus.
- 7) Obtain a complete medical, nutritional, drug and social history.
- 8) Develop an individualized education and treatment plan appropriate for the patient's needs.
- 9) Develop and implement changes to the education and treatment plan based upon use of accepted data gathering methods and assessment techniques.
- 10) Explain the specific information that a person with diabetes must know and understand to achieve the desired outcomes from the overall treatment plan.
- 11) Understand the importance of nutrition and exercise in the overall management of persons with type 2 diabetes mellitus.
- 12) Explain the role of the pharmacist in the formulation and implementation of treatment guidelines/clinical algorithms for persons with type 2 diabetes.

- 13) Describe the principles behind establishing a working relationship with other health care providers
- 14) Explain the role of the pharmacist as information resource and consultant to other health care providers.
- 15) Explain the role of the pharmacist as a referral source for persons with type 2 diabetes mellitus.

• Experiential Program

During the five-day experiential program, participants observe experienced clinicians and design, monitor, and evaluate patient-specific pharmacotherapy for patients with diabetes. The program focuses on critical thinking, decision-making, and communication skills. At the completion of the experiential program, participants should be able to:

- 1. Design, recommend, monitor and evaluate patient specific pharmacotherapy for persons with type 2 diabetes mellitus and its complications.
- 2. Participate in the interviewing and clinical evaluation of the patient, and assist in the process of normalization of glycemic control for persons with type 2 diabetes mellitus.
- 3. Participate in the clinical evaluation and management of the patient with type 2 diabetes mellitus.
- 4. Prepare written and verbal type 2 diabetes management consults.
- 5. When appropriate, identify necessary personnel and resources required to enable adequate home-based self care for the person with type 2 diabetes mellitus.
- 6. Provide essential self-care skills education to persons with type 2 diabetes mellitus and/or their care givers.
- 7. Provide continuing education programming about diabetes pharmacotherapy to various health care providers.
- 8. Demonstrate a caring approach to the treatment and management of patients with type 2 diabetes.
- 9. Utilize the appropriate life long learning strategies to maintain currency in the field of diabetes mellitus and its management

Application Requirements and Procedures

Qualifications of Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state in the U.S. and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have two years experience in clinical practice.

Applicants must have a command of basic knowledge areas as they relate to type 2 diabetes including pathophysiology, clinical pharmacology and therapeutics, clinical laboratory data interpretation, clinical pharmacokinetics, and medical terminology and abbreviations. In addition, applicants should have experience with writing pharmaceutical care plans, conducting patient interviews, and delivering educational programs to other members of the health care team.

Upon completion of the program, the applicant will be responsible for personally providing diabetes patient care services.

Qualifications of the Applicant's Health System

The applicant's employer must be a health-care system in the U.S. with resources for the provision of inpatient and outpatient services for patients with diabetes. The chief executive officer of the system and physician who is responsible for diabetes care must confirm, in writing, their commitment to the establishment of a pharmacist-managed or physician-supervised (in which a pharmacist routinely provides pharmaceutical care for patients) type 2 diabetes patient care service.

Application Procedures

To apply to the traineeship, the applicant must submit five copies of the completed application form and "Applicant's Statement," plus the following items (the original plus four photocopies):

- Your *curriculum vitae*, including a listing of your publication citations.
- A letter from the chief executive officer of your organization confirming a commitment to the establishment of a pharmacist-managed type 2 diabetes patient care service, including the expected implementation date.
- A letter from the physician responsible for the diabetes patient service supporting a pharmacistmanaged type 2 diabetes patient care service.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The panel will review the applicant's materials and score them according to the following application criteria:

| <u>Points</u> | <u>Criteria</u> |
|---------------|---|
| 20 | Academic preparation |
| 25 | Clinical practice and ambulatory care experience |
| 30 | Training expectations and institutional viability for service |
| 25 | Support of administration and physician(s) |

Applicants receiving the highest scores will be selected as participants in the self-study program. Those selected to participate in the self-study program must pass the continuing education test in order to advance to the experiential program.

Criteria for Sites and Preceptors

Qualifications of the Site

The health system selected as a site for the experiential portions of the traineeship must have an ambulatory service for patients with type 2 diabetes. The site should have a pharmacist-managed or physician-supervised clinic for patients with type 2 diabetes in which a pharmacist routinely provides pharmaceutical care for patients with diabetes. The administration(s) of the participating institution(s) will provide adequate time to pharmacists and other participants to conduct the Diabetes Patient Care Traineeship Program. Additionally, the availability of space for lectures, seminars, conferences, and hands-on clinical experiences should be adequately provided.

The proposed training site must be accredited by the JCAHO or the American Osteopathic Association or other appropriate organization, when applicable. The institution's department of pharmacy should meet the ASHP Minimum Standards for Pharmacies in Hospitals or other appropriate standards.

In addition, a site must be able to provide five days of continuous experiential training, with at least 5 hours per day of direct patient contact (in any combination of time blocks) in the acute, ambulatory, and/or home care setting.

The site must submit a letter from the administrator and physician (on whose service the experiential portion of the traineeship will take place) stating that the health system supports the traineeship program. The availability of multiple site experiences is desirable and encouraged to provide a diverse training experience (e.g., community hospital, managed care, group practice, etc.)

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with type 2 diabetes. He or she must submit a letter from a physician specializing in the care of diabetes indicating that the preceptor participates in the design, recommendation, monitoring, and evaluation of patient-specific pharmacotherapy for diabetes and provides medication-use education to patients with type 2 diabetes and their caregivers.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Administration of the Traineeship

Program Administration and Responsibilities

The Type 2 Diabetes Patient Care Traineeship Program is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, Maryland 20814, and funded through an educational grant from GlaxoSmithKline. Other administrative policies applying to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- Funds are to be used solely for the participant's on-site travel and living expenses. No stipend or honorarium is awarded to the participant.
- The participant is responsible for providing his or her transportation to the experiential site. The ASHP Foundation will recommend living accommodations for the participant.
- The ASHP Foundation will reimburse the participant for food (up to a daily total of \$40) and accommodations to the extent allowed by ASHP Foundation policy.
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and preceptor at least four weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement appropriate to the specific experiential training site.
- The participant will be required to attend all sessions of the program and complete the program evaluation form.



PAIN MANAGEMENT TRAINEESHIP

Application Policies and Guidelines

Program sponsored by an educational grant from Endo Pharmaceuticals, Inc.



Universal Program Numbers (Self-Study): 204-000-07-036-HO1P (**12** Hours/1.2 CEUs)) Universal Program Number (Experiential): 204-000-07-059-L01P (**70** Hours/7.0 CEUs) The American Society of Health-System Pharmacists is accredited by the American Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.



ASHP Pain Management Traineeship is an ACPE Certificate Program that provides CE credit for both the self-study and the experiential components: participants must successfully complete the online self-study component test before they can participate in the experiential component in order to earn full credit for this Certificate Program.

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The ASHP Research and Education Foundation's Pain Management Traineeship Program was developed for pharmacists practicing in acute settings and providing specialized services for patients in pain. The traineeship prepares participants to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies and procedures for the treatment of such patients.

The curriculum, consisting of a self-study program and a 10-day experiential program, provides intensive didactic and clinical training for selected pharmacists. The self-study program offers 12 continuing education hours (1.2 CEUs) via the modules provided by the ASHP Research and Education Foundation. Completion of the self-study program is a requirement for attending the experiential program. The experiential program offers 70 continuing education hours (7.0 CUEs) and allows participants to observe and participate in the pharmaceutical care of patients in a health system with an established pain management service. The ASHP Research and Education Foundation's Pain Management Traineeship Program is an ACPE Certificate Program that provides CE for the self-study and the experiential components; a certificate will be given to trainees who successfully complete all parts of the program.

Educational Goals

Self-Study Program

After being selected to participate in the traineeship (see Selection Criteria), trainees will receive a copy of the ASHP Research and Education Foundation's Pain Management Traineeship Self-Study Program, which will provide the problem-solving skills required for clinical practice in this area. It concentrates on acquiring knowledge about the disease states and conditions most likely to be encountered and the medications used in pain management. Participants should already have a solid foundation in the following areas as they relate to the care of patients with pain:

- Pathophysiology
- Clinical pharmacology and therapeutics
- Clinical laboratory data interpretation
- Clinical pharmacokinetics
- Medical terminology and abbreviations

Self-Study Program Objectives

- 1. Effectively design, recommend, monitor and evaluate patient-specific therapeutic regimens for the management of pain that incorporate the principles of evidence-based medicine (the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients).
- 2. Build the information base needed to design a medication therapy regimen for a patient with pain by collecting, organizing and generating patient-specific problem lists using all information needed by the pain management pharmacist to prevent, detect and resolve medication-related problems and to make therapeutic medication therapy recommendations.
- 3. Design a regimen, including modifications to existing medication therapy, that meets the therapeutic goals established for a patient in pain; integrates patient-specific information, disease

and drug information, ethical issues and quality-of-life issues; and considers pharmacoeconomic principles.

- 4. Design a monitoring plan for a therapeutic regimen that effectively evaluates achievement of the patient-specific therapeutic goals.
- 5. Design a patient-specific education program for the patient or the patient's caregiver that will enable successful implementation of the therapeutic and monitoring plans.

The self-study program includes study questions and a CE test. In order to advance to the experiential program and obtain CEUs, participants must pass the CE test with a score of 70%.

Experiential Program

During the 10-day experiential program, participants observe experienced clinicians and design, monitor and evaluate patient-specific pain management pharmacotherapy. This program focuses on critical thinking, decision-making and communication skills.

Experiential Program Objectives

- 1. Establish a collaborative working relationship with all health care providers involved in a pain management service.
- 2. Develop an effective collaborative pharmacist-patient relationship required to elicit information, undertake the development of a pharmacist plan and establish a monitoring process.
- 3. Design, recommend, administer (when applicable), monitor and evaluate patient-specific pain management regimens that incorporate the principles of evidence-based medicine to make conscientious, explicit and judicious decisions about the care of individual patients and specifically to:
 - Build the information base needed to design a medication therapy regimen for a patient with pain by collecting, organizing and generating patient-specific problem lists using all information needed by the pain management pharmacist to prevent, detect and resolve medication-related problems and to make therapeutic medication therapy recommendations.
 - Design a regimen, including modifications to existing medication therapy, that meets the therapeutic goals established for a patient in pain; integrates patient-specific information, disease and drug information, ethical issues and quality-of-life issues; and considers pharmacoeconomic principles.
 - Design a monitoring plan for a therapeutic regimen that effectively evaluates achievement of the patient-specific therapeutic goals.
 - Implement the pharmacotherapeutic regimen and/or corresponding monitoring plan.
 - Design an educational program plan that will enable successful implementation of the therapeutic regimen and monitoring plan.
- 4. Design and deliver education to health care professionals on therapies used in the treatment of pain management.
- 5. Demonstrate a caring attitude toward patient's pain in all aspects of care.
- 6. Develop effective written and verbal pain management consults.
- 7. Appropriately document all activities related to pain management in the appropriate locations (e.g., The Joint Commission documentation requirements).

8. Develop policies and procedures for pain management in a multidisciplinary practice.

Post-Training Requirements

Four months after completing the experiential section of the traineeship, trainees will be required to provide the ASHP Foundation with the following documentation before a certificate will be issued:

- A copy of the proposed policies and procedures that they have submitted to their health system as part of their proposal to institute a new or enhance an existing pain management service.
- A report demonstrating that the trainee has become actively involved in the pain management service at his or her health system site.
- An outline of a presentation about the role of a pharmacist providing pain management services that he or she has made to associated health care providers.

Qualifications of Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state in the United States, and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have 2 years of experience in clinical practice.

Applicants must have a command of basic knowledge areas as they relate to pain management, including pathophysiology, clinical pharmacology and therapeutics, clinical laboratory data interpretation, clinical pharmacokinetics and medical terminology and abbreviations. In addition, applicants should have experience with writing pharmaceutical care plans, conducting patient interviews and delivering educational programs to other members of the health care team. In the application process, applicants must also attest to their understanding and ability to practice according to HIPAA regulations.

Upon completion of the program, the applicant will be responsible for personally providing pharmaceutical services to patients with pain.

Qualifications of the Applicant's Health System

The applicant's employer must be a health care system in the United States with resources for the provision of specialized pain management services. The chief executive officer of the system and the physician who is responsible for pain management services must provide documentation of their commitment to the establishment of pharmacist-managed or physician-supervised (in which a pharmacist routinely provides pharmaceutical care for patients) pain management services. If the service is already established, the chief executive officer of the system and the physician who is responsible for

pain management services must confirm that the pharmacist applying for the traineeship will be or is already involved in pain management services or with a team.

Important Traineeship Polices

Administrative policies related to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- No stipend or honorarium is awarded to the participant.
- The participant is responsible for providing his or her transportation to the experiential site and lodging.
- Upon acceptance into the program, the trainee will be asked to provide proof of liability insurance to his or her preceptor and training site and to submit evidence of TB and Hepatitis B vaccinations before traveling to the training site.
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and preceptor at least 4 weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement appropriate to the specific experiential training site.
- The participant will be required to attend all sessions of the program and to complete the posttraining requirements and program evaluation form.

Application Procedures

To apply to the traineeship, the applicant must submit five copies of the completed application form and "Applicant's Statement," plus the following items (the original plus four photocopies):

- Applicant's curriculum vitae.
- A letter from the chief executive officer of the organization confirming a commitment to the establishment of a pharmaceutical pain management service or other such organized care system for pain management pharmacotherapy (in which the pharmacist routinely provides pharmaceutical care for patients in the health system), including the expected implementation date.
- A letter from the physician responsible for the pain management services supporting a pharmaceutical service and/or involvement of the pharmacist on the patient care team.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The following criteria will be used to review and score applications:

| Points | Criteria | |
|--------|--|--|
| 10 | Academic preparation (degree, residency, certificate programs) | |
| 15 | Clinical practice and ambulatory care experience (general clinical | |
| | experience as described in the "Qualification of Applicant" section) | |
| 20 | Training expectations (expectations of the applicant and proposed duties of | |
| | pharmacist after training) | |
| 25 | Support of administration and physician(s) (support for pharmacist to | |
| | attend training and commitment of institution to start or enhance service) | |
| 30 | Institutional viability for service (involvement of pharmacist in care team) | |
| 100 | Total | |

Criteria for Sites and Preceptors

Qualifications of the Training Site

The health systems selected as a site for the experiential portion of the traineeship must have a pharmacotherapy pain management service or other such organized care system for patients with pain. The site should have a pharmacist or pharmacists who routinely provide pharmaceutical care for patients with pain. The administration(s) of the participating institution(s) will provide adequate time to pharmacists and other participants to conduct the Pain Management Traineeship. Additionally, the availability of space for lectures, seminars, conferences, and hands-on clinical experiences should be adequately provided.

The proposed training site must be accredited by The Joint Commission or other appropriate organization, when applicable. The institution's department of pharmacy should meet the ASHP Minimum Standards for Pharmacies in Hospitals or other appropriate standards.

In addition, a site must be able to provide 10 days of continuous experiential training, with at least 5 hours per day of direct-patient contact (in any combination of time blocks) with patients with pain or health care colleagues working in a pharmaceutical pain management service or other such organized care system for patients in pain. In cases where the training site city has relationships, affiliated clinics, and other services that provide pharmaceutical care for patients with pain, the primary training site is encouraged to partner with these sites to provide the trainee with diverse experiences.

The site must submit a letter from the administrator and physician (on whose service the experiential portion of the traineeship will take place) stating that the health system supports the traineeship program.

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with pain. He or she must submit a letter from a physician specializing in or responsible for pain management indicating that the pharmacist participates in the design, recommendation,

monitoring and evaluation of patient-specific pain management pharmacotherapy and provides medication-use education to patients and their caregivers where appropriate.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Administration of the Traineeship

The Pain Management Traineeship is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, MD 20814, and is funded by an educational grant from Endo Pharmaceuticals. Questions regarding this traineeship should be directed to Cynthia L. LaCivita, Pharm.D. at clacivita@ashp.org or 301-664-8609.

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Asthma Patient Care Traineeship®

Developed in cooperation with the National Asthma Education and Prevention Program of the National Heart, Lung, and Blood Institute, National Institutes of Health

Application Policies and Guidelines

Program presentation funded by an educational grant from Merck & Co., Inc.



The American Society of Health-System Pharmacists is approved by the American Council on Pharmaceutical Education (ACPE) as a provider of continuing pharmaceutical education. Universal Program Number (Self-Study): 204-000-98-043-H01; 1.5 CEUs Universal Program Number (Experiential): 204-000-98-044-L01; 3.5 CEUs

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Traineeship Description and Curriculum

Overview of the Traineeship

The Asthma Patient Care Traineeship is designed for pharmacists in acute, ambulatory, and home care settings who are implementing specialized services for improving outcomes of adult and pediatric patients with asthma. The traineeship prepares participants (who have little or no experience in providing pharmaceutical care to asthma patients) to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of patients who have chronic and acute asthma.

The curriculum, consisting of a self-study program and a 5-day experiential program, provides intensive didactic and clinical training for selected pharmacists. The self-study program is a prerequisite for attending the experiential program where participants observe and participate in the pharmaceutical care of patients at a health system with an established asthma patient care service. A certificate will be given to participants who successfully complete both the self-study and experiential programs.

Self-Study Program

After being selected to participate in the self-study program of the traineeship (see Selection Criteria for an explanation of the selection process), participants will receive a copy of the self-study materials. During this program, participants learn about the clinical aspects of asthma and medications used in the management of the disease.

The self-study program includes the clinical practice guidelines from *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma* (National Asthma Education and Prevention Program), study questions, and a continuing education test. In order to advance to the experiential program and obtain continuing education credits, participants must pass the continuing education test.

At the completion of the self-study program, participants should be able to:

- Explain the epidemiology of asthma, etiology, and risk factors that lead to the development of asthma, and signs and symptoms of asthma.
- Explain the mechanism of action, pharmacokinetics, pharmacodynamics, pharmacoeconomics, usual regimen (dose, schedule, form, route, and method of administration), indications, contraindications, interactions, adverse reactions and therapeutics for corticosteroids (inhaled and oral); cromolyn; nedocromil; theophylline; beta₂-agonists; anticholinergics; and leukotriene biosynthesis inhibitors and receptor antagonists.

- Explain the purpose of designing a plan for self-treatment of acute exacerbations of asthma.
- Identify the customary monitoring parameters for asthma medication regimens and the customary value ranges for those parameters specified for use in monitoring asthma therapy.
- Explain how disease severity and response to therapy influence adjustments to the customary desired value range for parameters used in asthma therapy monitoring.
- Explain social issues that should be considered when designing a monitoring plan.
- Explain appropriate drug therapy for acute exacerbations of asthma.
- Explain effective communication techniques for obtaining agreement on what the patient and health care professional intend to do.
- Explain the algorithms for patient management of asthma as specified in the National Asthma Education Program guidelines.
- Explain the specific information that a patient with asthma must understand to gain optimal benefit from a medication regimen.

Experiential Program

During the five-day experiential program, participants observe experienced clinicians and design, monitor, and evaluate patient-specific pharmacotherapy for patients with asthma. The program focuses on critical thinking, decision-making, and communication skills. At the completion of the experiential program, participants should be able to:

- Design, recommend, monitor, and evaluate patient-specific pharmacotherapy for patients with asthma.
- Be familiar with the management of an acute exacerbation of asthma.
- When indicated, identify appropriate personnel for managing the health care needs of patients with asthma.
- Provide medication-use education to patients and their caregivers.
- Ability to provide continuing education about the pharmacotherapy of asthma to physicians, nurses, pharmacists, and other practitioners.

- Discuss an organized system for staying current with pertinent asthma and allergy literature.
- Select a core library appropriate for asthma and allergies.
- Develop a proposal for new pharmaceutical services for patients with asthma.

Application Requirements and Procedures

Qualifications of Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have two years experience in clinical practice.

Upon completion of the program, the applicant will be responsible for personally providing asthma care services to patients.

Qualifications of the Applicant's Health System

The applicant's employer must be a health care system with resources for the provision of inpatient and outpatient services for patients with asthma. The chief executive officer and physician who is responsible for asthma care must confirm, in writing, their commitment to the establishment of a pharmacist-managed asthma patient care service.

While an institution/organization may submit applications for more than one staff member, only one applicant per institution/organization will be accepted unless there are insufficient applicants to fill all available traineeship positions.

It is the responsibility of the trainee and his/her organization to train other staff members immediately upon completion of the traineeship program.

Application Procedures

To apply to the traineeship, the applicant must submit five copies of the completed application form and "Applicant's Statement," plus the following items (the original plus four photocopies):

- Your *curriculum vitae*, including a listing of your publication citations.
- Applicant Statement form
- A letter from the chief executive officer of your organization confirming a commitment to the establishment of a pharmacist-managed asthma patient care service, including the expected implementation date.
- A letter of recommendation from a supervisor or residency preceptor with whom the pharmacist has worked directly, indicating his or her interpersonal skills, written and verbal communication skills, and quality of clinical skills.

• A letter from the physician responsible for the asthma patient service supporting a pharmacist-managed asthma patient care service.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The panel will review the applicant's materials and score them according to the following application criteria:

| Points | <u>Criteria</u> |
|---------------|---|
| 20 | Academic preparation |
| 25 | Clinical practice and ambulatory care experience |
| 30 | Training expectations and institutional viability for service |
| 25 | Support of administration and physician(s) |
| | |
| 100 | Total Possible points |

Applicants receiving the highest scores will be selected as participants in the self-study program. Those selected to participate in the self-study program must pass the continuing education test in order to advance to the experiential program.

Criteria for Experiential Sites and Preceptors

Qualifications of the Experiential Site

The health system selected as a site for the experiential portion of the traineeship must have an ambulatory service for patients with asthma. The site should have a pharmacist-managed or physician-supervised clinic for patients with asthma in which a pharmacist routinely provides pharmaceutical care for patients with asthma.

In addition, a site must be able to provide five (5) days of continuous experiential training, and provide the trainee with at least five (5) hours per day of direct patient contact (in any combination of time blocks) in the acute, ambulatory, and/or home care setting. It is desirable for the site to offer experience with both pediatric and adult patients.

The site must submit a letter from the administrator and physician (on whose service the experiential portion of the traineeship will take place) stating that the health system supports the traineeship.

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with asthma. He or she must submit a letter from a physician specializing in the care of asthma indicating that the preceptor participates in the design, recommendation, monitoring, and evaluation of patient-specific pharmacotherapy for asthma and provides medication-use education to patients with asthma and their caregivers.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Administration of the Traineeship

Program Administration and Responsibilities

The Asthma Patient Care Traineeship Program is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, Maryland 20814, and funded by Merck & Co., Inc. Other administrative policies applying to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- Funds are to be used solely for the participant's on-site travel and living expenses. No stipends or honorarium is awarded to the participant.
- The participant is responsible for providing his or her transportation to the experiential site. The ASHP Foundation will recommend living accommodations for the participant.
- The ASHP Foundation will reimburse the participant for food and accommodations to the extent allowed by ASHP Foundation policy.
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and preceptor at least four (4) weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement appropriate to the specific experiential training site.
- The participant will be required to attend all sessions of the program and complete the program evaluation form.

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ONCOLOGY PATIENT CARE TRAINEESHIP

Application Policies and Guidelines

Program presentation funded by an educational grant from Amgen®



The American Society of Health-System Pharmacists is accredited by the Accreditation Council on Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The ASHP Oncology Traineeship is a certificate program that provides CE credit for both the self-study and the experiential components. Participants must successfully complete the online self-study test before they can participate in the experiential component to earn full credit for this certificate program.

Universal Program Numbers (Self-Study): 204-000-07-023-H01 (28 hours) Universal Program Number (Experiential): 204-000-07-024-L01 (70 Hours)



The ASHP Oncology Patient Care Traineeship is an ACPE Certificate Program that provides CE credit for both the self-study and the experiential components. To earn full credit for this Certificate Program participant must successfully pass the online self-study test and complete the experiential component of the traineeship.

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This program has been structured to meet the practice-based educational needs of pharmacists.

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Oncology Patient Care Traineeship Overview

The ASHP Oncology Patient Care Traineeship Program was developed for pharmacists in acute, ambulatory, and home care settings who are implementing specialized services to improve outcomes of adult patients with cancer.

The curriculum, consisting of a self-study program and a 10-day experiential program, provides intensive didactic and clinical training for selected pharmacists. The self-study program offers 28 continuing education hours (2.8 CEUs) via the Oncology Patient Care Traineeship Self-Study program. A passing score of 70% on the Oncology Patient Care CE Exam is a prerequisite for attending the experiential program. The experiential program offers 70 continuing education hours (7.0 CEUs) and allows participants to observe and participate in the pharmaceutical care of patients at a health system with an established oncology patient care service. The ASHP Research and Education Foundation's Oncology Patient Care Traineeship Program is an ACPE Certificate Program that provides CE credit for the self-study and the experiential components. This program has been structured to meet the practice-based educational needs of pharmacists.

Educational Goals

The goals of the traineeship are to provide pharmacists with the knowledge and skills to:

- Maintain active involvement in organizations that support care of the cancer patient and excellence in oncology pharmacy practice.
- Use an organized system for staying current with pertinent oncology literature.
- Use resources that help to access oncology information.
- Communicate clearly (e.g., verbal or written) when providing information about oncology diseases and treatment.
- Use appropriate behavioral and cognitive techniques in interactions with cancer patients, their families, their caregivers and health care professionals.
- Function effectively as a member of an oncology patient care team.
- Design, recommend, monitor, and evaluate patient-specific pharmacotherapy for patients with cancer.
- Solve pharmacotherapy problems efficiently.
- Provide medication-use education to cancer patients and their caregivers.
- Ensure continuity of pharmaceutical care of oncology patients as they transition to and from the

acute, ambulatory, home care and hospice patient-care settings.

- Document pharmaceutical care activities performed for oncology patients appropriately.
- Understand the health system's decision-making process as it relates to medication use in the care of oncology patients.
- Participate in the development or modification of policies for the use of cancer-related medications in a health system.
- Understand the purpose of oncology and oncology-related medication utilization evaluations.
- Understand the role of the oncology pharmacist in the development or revision of policies for assessment, management, prevention, and reporting of adverse drug reactions in cancer patients.
- Understand the oncology pharmacist's role in assessing, managing, preventing and reporting medication errors for patients with cancer.
- Provide education to health care professionals on therapies used in the treatment of cancer.
- Understand the process of developing a proposal for a new initiative within the trainee's current oncology program.
- Understand local, state and federal laws and regulations impacting the use of cancer and cancerrelated medications.
- Participate in the review and evaluation of selected pharmacy department cancer and cancer-related policies and procedures.
- Review and evaluate the use of cancer investigational drug products according to established protocols and the health-system setting's policies and procedures.
- Understand the oncology pharmacist's role in reviewing cancer and cancer-related research protocols.
- Understand the role of the pharmacist in handling and dispensing of medications used in the treatment of cancer.

To accomplish these goals, participants in the traineeship will complete a self-study program and a 2week experiential program. The self-study program instructs participants on the clinical aspects of oncology therapeutics and approaches to successful management of the patient with cancer. During the experiential program, participants apply the approaches of successful disease management to the pharmaceutical care of patients. The 2-week experiential program will be led by experienced clinicians at a health system that has specialized services for patients with cancer.

Self-Study Program

The 2008 Oncology Pharmacy Practice Preparatory Review Course is used for the self-study program. The selfstudy program focuses on acquiring the necessary disease state and therapeutic information required to provide pharmaceutical care for patients with cancer. The participant should have a solid foundation in the following knowledge areas as they relate to oncology and related conditions:

- Pathophysiology
- Clinical pharmacology and therapeutics
- Clinical laboratory data interpretation
- Clinical pharmacokinetics
- Medical terminology and abbreviations

Trainees are required to complete all topic areas and pass the Self-Study Continuing Education test with a score of 70% or higher.

The 2008 Oncology Pharmacy Practice Preparatory Review Course covers the following subject areas:

- Oncology Drug Literature: Biostatistics and Study Design
- The Anticancer Drug Development Process
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Chronic Leukemias and Myelodysplastic Syndromes
- Pediatric Malignancies
- Lung Cancer
- Lymphomas and Multiple Myeloma
- Ovarian Cancer
- Acute Leukemias
- Drug Information, Guidelines and HIPAA
- GI Cancers-Pancreatic, Liver and Stomach
- Hematopoietic Stem Cell Transplantation (HSCT)/ Blood and Marrow Transplantation (BMT) Part I
- Genitourinary Cancers-Bladder, Renal Cell and Testicular Cancers
- Symptom Treatment Management-Part I
- Hematopoietic Stem Cell Transplantation (HSCT)/Blood and Marrow Transplantation (BMT) Part
 II
- Melanoma and Skin Cancer
- Disease Related Symptoms
- Symptom Treatment Management-Part II
- Pain Management, Bone Metastases and Spinal Cord Compression
- Pharmacology
- GYN Cancers-Cervical and Endometrial
- Sarcomas
- Head and Neck Adults CNS Tumors

Experiential Program

During the 10-day experiential program, participants observe experienced clinicians and design, monitor and evaluate patient-specific pharmacotherapy for patients with cancer and supportive treatment. The program focuses on critical thinking, decision-making and communication skills.

Post-Experiential Requirements

Four months after completing the experiential portion of the traineeship, trainees will be required to provide to the ASHP Foundation the following documentation before a certificate will be issued:

- A copy of the proposed policies and procedures that they have submitted to their health system as part of their proposal to institute a new or enhance an existing oncology care service.
- A report demonstrating that the trainee has become actively involved in providing care to patients with cancer. (e.g. number of patients treated or consulted per week)
- An outline of a presentation about the role of a pharmacist providing oncology services that they have made to associated health care providers. Please include intended audience and number of attendees (e.g. a sign-in roster)

Qualifications of the Applicant

To qualify for application to the traineeship, the applicant must be a licensed pharmacist in any state in the U.S. and be a graduate of an ACPE-accredited college or school of pharmacy. The applicant must have completed an ASHP-accredited residency or have 2 years experience in clinical practice. **Residents are not eligible to apply**.

Applicants must have a command of basic knowledge areas as they relate to oncology patient care, including pathophysiology, clinical pharmacology and therapeutics, clinical laboratory data interpretation, clinical pharmacokinetics and medical terminology and abbreviations. In addition, applicants should have experience with writing pharmaceutical care plans, conducting patient interviews and delivering educational programs to other members of the health care team. In the application process, applicants must also attest to their understanding and ability to practice according to HIPAA regulations.

Upon acceptance into the program, applicants will be asked to provide proof of liability insurance to their preceptor and training sites. Also, applicants must submit evidence of TB and Hepatitis B vaccinations before traveling to the training site.

Upon completion of the program, the applicant will be responsible for personally providing oncology patient care services.

Qualifications of the Applicant's Health System

The applicant's employer must be a health-care system in the U.S. with resources for the provision of services for patients with cancer and related conditions. The chief executive officer of the system and the physician who is responsible for the care of oncology patients and related conditions, must provide documentation of their commitment to the establishment of a pharmacist-managed or physician-supervised (in which a pharmacist routinely provides pharmaceutical care for patients), oncology patient care service. If the service is already established, the chief executive officer of the system and the physician who is responsible for care of oncology patients must confirm that the pharmacist applying for the traineeship will be or is already involved in the oncology patient care team and provides pharmacotherapy to oncology patients. They must also confirm that the patient care service must continue after the traineeship program.

Application Procedures

To apply to the traineeship, the applicant must submit six copies of the completed application form, plus the following items (the original plus five photocopies):

- 1. Curriculum vitae, including publications.
- 2. A letter from the chief executive officer of the applicant's organization confirming a commitment to establishing a service in which the pharmacist routinely provides pharmaceutical care for patients with cancer, and an expected implementation date.
- 3. A letter from the physician responsible for the management and supporting of a pharmaceutical service for oncology patient care.

Selection Criteria

All applications will be reviewed by a panel appointed by the ASHP Foundation Board of Directors. The panel will review the applicant's materials and score them according to the following application criteria:

| Points | | Criteria |
|--------|--------|--|
| 15 | | Academic preparation (degree, residency, certificate programs) |
| 20 | | Clinical practice and ambulatory care experience (general clinical |
| | | experience as described qualification of applicant section) |
| 20 | | Training expectations (expectations of the applicant and proposed duties of |
| | | pharmacist after training) |
| 20 | | Institutional viability for service (involvement of pharmacist in care team) |
| 25 | | Support of administration and physician(s) (support for pharmacist to |
| | attend | training and commitment of institution to start or enhance service) |
| 100 | | Total |

Applicants receiving the highest scores will be selected as participants in the self-study program. Those selected to participate in the self-study program must pass the continuing education test in order to advance to the experiential program.

Criteria for Experiential Sites and Preceptors

Qualifications of the Experiential Site

Health systems selected as a site for the experiential segment of the traineeship must have pharmacy services that include a pharmacist or pharmacists who routinely provide care for patients with cancer and related conditions. The administration of the participating institution supports the role and recognizes the value of pharmacists and other participants to conduct the experiential segment of the Oncology Patient Care Traineeship. In addition, the faculty should have an availability of space for lectures, seminars, conferences and hands-on clinical experiences should be adequately provided.

An experiential training site must be accredited by the Joint Commission or other appropriate organization when applicable. The institution's department of pharmacy should meet the ASHP Minimum Standards for Pharmacies in Hospitals or other appropriate standards.

In addition, a site must be able to provide 10 days of continuous experiential training, with at least 5 hours per day of direct patient contact with patients with cancer and related conditions. Direct patient time can be in any combination of time blocks in the acute, ambulatory, and/or home care setting.

The site must submit letters from the administrator and the physician's service where the experiential portion of the traineeship occurs stating that the health system supports the traineeship program. The availability of multiple experiences is desirable and encouraged to provide a diverse training experience.

Qualifications of the Preceptor

The primary preceptor for the traineeship must be a pharmacist who routinely provides pharmaceutical care for patients with cancer and related conditions. They must submit a letter from a physician specializing in the management of oncology patients indicating that the preceptor participates in the design, recommendation, monitoring, and evaluation of patient-specific pharmacotherapy for patients with cancer and related conditions and provides medication-use education to patients and their caregivers where appropriate.

All preceptors for the traineeship must be currently involved in practice-based teaching of pharmacy students or other health care professionals. It is desirable for preceptors to have demonstrated the impact of their practice on outcomes or to have participated in scholarly achievement.

Administration of the Traineeship

The Oncology Patient Care Traineeship Program is administered by the ASHP Research and Education Foundation, 7272 Wisconsin Avenue, Bethesda, MD 20814, and funded in part by Amgen. Other administrative policies applying to this ASHP Foundation traineeship include the following:

- The traineeship is awarded to an individual participant.
- No stipend or honorarium is awarded to the participant.
- The participant will be provided a hard copy of the 2008 Oncology Pharmacy Practice Preparatory *Review Course* at no charge.
- The participant is responsible for providing their own transportation, lodging, and meals while at the experiential site.
- If the participant must cancel his or her participation, he or she must notify the ASHP Foundation and their preceptor at least 4 weeks in advance of the starting date of the experiential portion of the program.
- The participant may be required to sign a liability statement appropriate to the specific experiential training site.
- The participant will be required to attend all sessions of the program and complete the program evaluation form.

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2007 PROGRAM OVERVIEW

Pharmaceutical Care for Patients with Diabetes is an innovative and intensive certificate program that focuses on the pharmacist's role in the area of diabetes management. The program, which emphasizes a health care team approach, seeks to foster the implementation of pharmaceutical care interventions that will promote disease self-management.

Goals of the program:

- Provide comprehensive instruction in the pathophysiology of diabetes and the acute and longterm complications of the disease
- Teach current approaches to the medical management of diabetic patients, with special emphasis on nutrition and pharmacologic therapies
- Help pharmacists understand their important role as drug therapy experts on the diabetes health care team
- Provide pharmacists with information about becoming a Certified Diabetes Educator, and about other diabetes management-related credentialing opportunities
- Introduce pharmacists to their broader responsibilities as a diabetes educator, with special emphasis on communication skills and the psychosocial aspects of diabetes

Pharmaceutical Care for Patients with Diabetes is conducted in two parts. The first part – a self-study learning component – has three modules that address the following subjects:

- The disease state and its complications
- Management and monitoring strategies
- Educational strategies and psychosocial issues

The self-study program includes exercises and a self-assessment test that are designed to help reinforce and evaluate participants' understanding of key information and concepts.

After completing the self-study modules, the pharmacist should be able to:

- Describe the team approach to diabetes education and define the pharmacist's role on that team
- Discuss the growing prevalence of diabetes
- Describe the etiology and pathophysiology of type 1 and type 2 diabetes, including long-term complications
- Understand the various tests that are used to diagnose and monitor diabetes
- Define pre-diabetes and describe strategies to prevent or delay type 2 diabetes
- Discuss the results of the Diabetes Control and Complications Trail, the United Kingdom Prospective Diabetes Study, and other pertinent trials and explain how these studies have influenced approaches to the management and treatment of diabetes
- Describe various current strategies for the medical management and treatment of diabetes
- Explain the rationale and recommendations for meal planning and physical activity for persons with diabetes
- Describe the exogenous insulin preparations currently available and discuss important considerations regarding the mixing and storage of insulin
- Discuss insulin injection techniques
- Describe the oral agents used in the treatment of type 2 diabetes and the rationale for combination therapy

- Discuss treatment options for complications of diabetes and management strategies for patients with co-morbid dyslipidemias or hypertension
- List special precautions that persons with diabetes should take in the areas of general skin, foot, dental, and eye care
- Understand the elements of the patient teaching process as described by the National Standards for Diabetes Self-Management Education
- Describe teaching techniques that are most effective for adult learners
- Explain the importance of facilitating patient empowerment in diabetes education
- Discuss the impact of psychosocial issues, culture, and health beliefs on diabetes self-care practices
- Explain the components of and rationale for a multidisciplinary team approach to diabetes education
- Develop a patient education plan for use in one's own practice
- Explain the components of a focused diabetes education practice

After the completion of the second part of the program, the live training seminar, the participants should be able to:

- Discuss medications used to treat diabetes
- Conduct a comprehensive patient self-management assessment
- Describe a documentation and record-keeping system
- Provide diabetes self-care instruction, including use of devices, products, and equipment
- Design and implement a pharmacy-based diabetes education program

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The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.



Successful completion of the self-study learning component results in 15 hours of continuing pharmacy education credit (1.5 CEU) – Universal Program Number: 202-XXX-05-145-H01. An additional 8 hours of continuing pharmacy education credit (0.8 CEU) is granted for attending and successfully completing the live training seminar – Universal Program Number: 202-XXX-06-114-L01. Successful completion includes obtaining 70% or better on both the self-study assessment exam and final exam and successful assessment of breakout session activities. Statement of continuing education credit and Certificate of Achievement will be mailed by APhA directly to participants 4-6 weeks following the conclusion of the program

Pharmaceutical Care for Patients with Diabetes was developed jointly by the American Pharmacists Association and the American Association of Diabetes Educators and supported in part by an educational grant from Eli Lilly and Company.











Delivering Medication Therapy Management Services in the Community

The certificate training program has been developed as a joint project by APhA and ASCP and is intended to enhance pharmacists' clinical expertise in evaluating complicated medication regimens, identifying drug-related problems, and making recommendations to patients, caregivers, and health care professionals. Through self-study modules, case studies, and hands-on patient interview and assessment practice sessions, pharmacists will obtain the clinical knowledge and skills needed to establish MTM services. The program is supported by educational grants from Boehringer Ingelheim Pharmaceuticals and Eli Lilly and Company.

Program goals include:

- Improve public health through improved medication use.
- Provide training to enhance pharmacists' ability to effectively provide Medication Therapy Management services.
- Motivate increased numbers of pharmacists to establish MTM practices.
- Communicate benchmark practices for providing MTM services

Continuing Education Information



Certificate Programs in Pharmacy are structured and systematic post-graduate continuing education experiences for pharmacists designed to instill, expand, or enhance practice competencies through the acquisition of specified knowledge, skills, attitudes and

performance behaviors. APhA and ASCP certificate programs involve in-depth commitment on the part of learners, including both self-study and attendance at live seminar presentations. APhA and ASCP are accredited by the Accreditation Council for Pharmacy Education and adhere to the *Standards and Quality Assurance Procedures for ACPE-Accredited Providers of Continuing Pharmacy Education Offering Certificate Programs in Pharmacy.*

Delivering Medication Therapy Management Services in the Community is CPN # 202-012. It consists of a selfstudy carrying 10 hours of continuing education credit 202-203-07-089-H04 (1.0 CEU) and a live seminar program, which is approved for 8 hours (0.8 CEU) of continuing education credit (UPN 202-999-07-236-L04-P). The post-seminar exercise is approved for 3 hours (0.3 CEU) of continuing education credit (UPN 202-999-08-098-H04-P). To earn a statement of credit for each portion of the program, participants must complete all requirements for that component. To earn a certificate of achievement for the entire program, participants must complete all program requirements. Program requirements:

<u>Self-study</u> Read self-study modules Earn a 70% or better on the self-study exam Complete two patient interviews prior to attendance at the live seminar

Live Seminar Participate in the full live seminar program

<u>Post-Program</u> Submit three post-program patient interviews

Statements of credit and certificates of achievement will be mailed to participants within 4-6 weeks of completion of all program requirements.



PROGRAM OVERVIEW

Pharmacy-Based Lipid Management is a two part (self-study and live seminar) certificate training program that enhances pharmacists' current knowledge of the pathophysiology and treatment of dyslipidemias using the *Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* guidelines. This innovative program will enable pharmacists to recommend optimal treatment strategies for patients with lipid disorders in collaboration with other healthcare professions by focusing on practical tools, techniques, and information to assist in establishing successful pharmacist-conducted lipid management services.

Goals of the program:

- Enhance participants' current knowledge of the pathophysiology and treatment of lipid disorders
- Educate participants about the optimal treatment strategies for patients at varying degrees of cardiovascular risk with various co-morbidities
- Introduce participants to point-of-care testing technology that can be employed in the management of patients with lipid disorders
- Provide practical tools, techniques, and information to assist participants in establishing successful pharmacist-conducted lipid management services

Pharmacy-Based Lipid Management is conducted in two parts – a self-study component and a live training seminar. Individuals who plan to complete the entire certificate program must review each self-study module and complete all self-assessment test questions.

The first part – a self-study learning component – features seven modules that address the following subjects:

- Lipids and Coronary Heart Disease
- Identifying Patients and Initiating Treatment
- Lifestyle Modifications for Cardiac Risk Reduction
- Drug Therapy for Lipid Testing
- Behavioral Counseling and Medication Adherence Interventions
- Point of Care Lipid Testing
- Providing Pharmacy-Based Lipid Management Services

The second part of the program – the live training seminar – concentrates on the following:

- Review of pathophysiology, clinical trials, and drug treatment regimens
- Development of clinical monitoring skills
- Communicating with patients and members of the health care team
- Case-based problem solving
- Practice implementation

The training seminar learning objectives are as follows:

- Use the National Cholesterol Education Program nine-step process to determine cardiovascular risk and identify treatment goals and strategies for various types of patients
- Select the most appropriate initial drug therapy for a patient, based on the patient's current and target LDL cholesterol levels and other relevant factors
- Explain how drug therapy should be modified based on progress toward target lipid goals, tolerability, etc.
- Demonstrate proper techniques for obtaining a fingerstick blood sample from patients
- Apply the "5 A's" framework to specific behavioral interventions in patients with dyslipidemias, including interventions involving medication non-adherence
- Discuss specific strategies for building and running a successful pharmacy-based lipid management service



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education and complies with Criteria for Quality for continuing pharmacy education programming.



Successful completion of all the self-study learning component results in 11 hours of continuing pharmacy education credit (1.1 CEU) – Universal Program Numbers: 202-XXX-05-147-H01. An additional 8 hours of continuing pharmacy education credit (0.8 CEUs) is granted for attending and successfully completing the live training seminar – Universal Program Number: 202-XXX-06-112-L01. Successful completion includes obtaining 70% or better on all self-study assessment tests and the final exam. Statement(s) of continuing education credit and Certificate of Achievement will be mailed by APhA directly to eligible participants 4-6 weeks following the conclusion of the program.

Pharmacy-Based Lipid Management was developed by the American Pharmacists Association and supported by an educational grant from Johnson&Johnson • Merck Consumer Pharmaceuticals Co.

American Pharmacists Association Improving medication use. Advancing patient care.

Johnson Johnson O MERCK CONSUMER PHARMACEUTICALS CO. A National Certificate Program for Pharmacists



August 2007 Course Description



Pharmacy-Based Immunization Delivery is an innovative and interactive training program that provides pharmacists with skills necessary to become a primary source for vaccine advocacy, education, and administration. The program teaches the basics of immunology and focuses on practice implementation and legal/regulatory issues.

The goals of the program are to:

- Provide comprehensive immunization education and training;
- Provide pharmacists with the skills, resources and materials necessary to establish and promote a successful immunization service;
- Train pharmacists to identify at-risk patient populations needing immunizations; and
- Train pharmacists to maintain necessary immunization records.

Pharmacy-Based Immunization Delivery is conducted in two parts. The first part—a selfstudy learning component—is designed to ensure that all participants have a solid understanding of the role of pharmacists as vaccine advocates. The self-study includes five learning modules that present in-depth information on implementing a pharmacy immunization program and the clinical as well as practical considerations of vaccine administration, with appropriate references to the Centers for Disease Control and Prevention (CDC) resource publication, *Epidemiology and Prevention of Vaccine-Preventable Disease*. The self-study program includes a self-assessment test and real-life case studies that are designed to help reinforce and evaluate participants' understanding of key information and concepts.

Following are the learning objectives for each self-study module:

Module 1 – Pharmacists as Vaccine Advocates

- 1. Describe the epidemiology of vaccine-preventable diseases and the effects of immunization on morbidity and mortality rates.
- 2. List five key factors that influence patients when making vaccination decisions.
- 3. Define the role and advantages of pharmacy-based immunization programs.
- 4. Identify key resources available for immunization providers and educators.
- 5. Describe how state pharmacy practice acts impact pharmacists as immunizers.

Module 2 – Diseases and Vaccines

- 1. Discuss the current status of vaccine-preventable illness around the world.
- 2. Explain the basic concepts of immunology and the role of vaccines in eliciting an immune response.
- 3. List vaccines currently available on the U.S. market and compare and contrast their indications for use in various patient populations.

- 4. Identify an appropriate vaccination regimen, including vaccine dose, patient counseling parameters, and follow-up recommendations for any vaccines dosed in a series.
- 5. Describe Advisory Committee for Immunization Practices recommendations for the use of vaccines.
- 6. Explain the role of immune globulins in providing short-term immunity upon likely exposure to a vaccine-preventable disease.
- 7. Discuss the process of antigenic shifts and drifts related to influenza virus and the impact of such viral mutations on vaccine development.
- 8. Identify the contraindications and precautions for use of the vaccines.
- 9. Outline the Centers for Disease Control and Prevention recommendations for testing antibodies after hepatitis B vaccination.
- 10. List resources available for immunization providers and educators.

Module 3 – Clinical Considerations

- 1. List methods to identify patients who are at highest risk of vaccine-preventable illness.
- 2. Evaluate pediatric patients' immunization records and recommend appropriate immunizations using the current pediatric immunization schedule.
- 3. Determine the vaccine needs of healthy adults and those with medical conditions using the current adult immunization schedule.
- 4. Explain the rationale for timing and spacing of vaccines, including vaccine-vaccine spacing and vaccine-antibody spacing.
- 5. List recommended patient screening questions for vaccination and identify valid contraindications for vaccinations.
- 6. Describe signs of allergic reactions to vaccines and the emergency procedures that immunizing pharmacists should follow in the event of anaphylaxis.
- 7. Describe techniques for administration of vaccines via the intramuscular, subcutaneous, and intranasal routes.

Module 4 – Practical Considerations

- 1. Explain the legal, regulatory, and liability issues involved in offering a pharmacy-based immunization program.
- 2. List federally available programs to protect vaccine administrators and recipients and recall the requirements of those programs.
- 3. Describe Occupational Safety and Health Administration regulations designed to prevent employees' exposure to blood-borne pathogens and needlestick injury in worksites where immunizations are given.
- 4. Prepare immunization records for pharmacy logs, primary health care provider reports, and patients' personal vaccination records.
- 5. Explain principles and procedures for vaccine storage and handling.
- 6. Describe the process for obtaining Medicare reimbursement for vaccines and their administration.
- 7. Identify key marketing messages and strategies that can be used to promote a pharmacy-based immunization service.

Module 5 – Case Studies

1. Formulate immunization plans for individual patients based on age, sex, past medical history, immunization records, and lifestyle factors (e.g., occupation, travel itinerary).

- 2. Provide advocacy, education, and counseling for the vaccination needs of various types of patient encounters.
- 3. Identify appropriate sites and routes of vaccine administration in specific patient cases.
- 4. Specify emergency procedures to manage patients with severe allergic reactions to a vaccine.

The second part of the program—*the live training seminar*—involves an active learning experience. It reinforces and expands on the self-study learning component and discusses such issues as immunizations needs, legal and regulatory considerations, marketing, patient care strategies, billing and reimbursement, documentation and record keeping. In addition, participants receive hands-on injection technique training.

Following are learning objectives for the live training seminar:

- 1. Define the pharmacist's role in immunization advocacy, education, and administration.
- 2. Analyze basic immunology and its relationship to vaccination.
- 3. Describe microbial and immunologic characteristics of vaccine preventable diseases.
- 4. Demonstrate understanding of immunization schedules for both children and adults.
- 5. List common adverse reactions and contraindications of vaccines
- 6. Review the legal, regulatory, and liability issues involved with pharmacy-based immunization programs.
- 7. Outline documentation and record-keeping methods and requirements.
- 8. Explain the planning elements required to establish a pharmacy-based immunization service including storage and handling requirements for vaccines.
- 9. Describe general principles of emergency response to anaphylaxis.
- 10. Describe and demonstrate appropriate intramuscular, subcutaneous, and intranasal administration technique for adult immunization.

All participants are strongly encouraged to obtain CPR or BCLS certification. However, certification is not a prerequisite of the program. A *Certificate of Achievement* is awarded to participants who successfully complete all program requirements. The *Certificate of Achievement* is invalid, however, without written proof of current CPR or BCLS certification.

Successful completion of the self-study learning component results in 12 hours of continuing pharmacy education credit (1.2 CEU) – Universal ACPE #202-XXX-06-118-H01. An additional 8.0 hours of continuing pharmacy education credit (0.8 CEU) is granted for attending and successfully completing the live training seminar – Universal ACPE #202-XXX-06-111-L01. CPN: 202-0011. Note: Final program credit may be provided under different UPNs than listed above.

Pharmacy-Based Immunization Delivery has been developed by the American Pharmacists Association and is supported in part by an educational grant from VaxServe.







Program Description

OTC Advisor® Pharmacy-Based Self-Care Services – A National Certificate Training Program for *Pharmacists* is an innovative certificate training program that explores the pharmacist's role in providing self-care services to patient, and presents cutting-edge information about self-care products and services, as well as a review of nonprescription therapeutics and self-care counseling techniques. The program examines economically viable options for pharmacists interested in providing services to self-treating patients in their communities, and discusses practice implementation strategies.

The overall objectives of OTC Advisor® Pharmacy-Based Self-Care Services are to:

- Explore the pharmacist's role in providing self-care services to patients.
- Present cutting-edge information about self-care products and services.
- Review nonprescription therapeutics and self-care counseling techniques.
- Examine economically viable options for providing self-care services.
- Discuss implementation strategies for self-care services.

The seminar objectives of OTC Advisor® Pharmacy-Based Self-Care Services are to:

- Explain why asking the right questions, listening actively, and expressing empathy are critical to
 effective communication with patients
- Discuss strategies for managing challenging encounters with self-treating patients
- Demonstrate and explain the features and benefits of common home diagnostic products
- Compare and contrast possible approaches to make a self-care practice economically viable
- Describe techniques for optimizing a business plan to establish self-care services in a community pharmacy

OTC Advisor® Pharmacy-Based Self-Care Services is conducted in two parts: a web-based preseminar self-study component, and a 1-day live training seminar. Both program components provide continuing pharmacy education credits.

The self-study component is composed of eight online interactive learning modules that address:

- The role of the pharmacist as a self-care advisor.
- Practical strategies for developing a self-care counseling service.
- Issues related to self-care for pain; cough, cold, fever, and allergy; gastrointestinal disorders; herbals and dietary supplements; and skin and mucous membrane disorders.
- Home diagnostic products available in pharmacies.

The live training seminar includes interactive training in:

- Patient assessment and counseling techniques.
- Self-care product demonstration and review.
- The discussion of business plan worksheets for implementing self-care services.



This Program was developed by APhA and supported by an education grant from Procter & Gamble



The American Pharmacists Association is approved by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education and complies with Criteria for Quality for continuing pharmacy education programming. The live training seminar of the *OTC Advisor® Pharmacy-Based Self-Care Services*, series is approved for 8 hours (0.8 CEUs) of continuing education credit ACPE #202-XXX-07-113-L04. Statement of credit for the self-study and the training seminar will be awarded upon achieving a passing grade of 70% or better for both program components. This program is acceptable for 24 Certificate of Achievement only when completed in conjunction with the *OTC Advisor® Pharmacy-Based Self-Care Services* self-study program. **CPN: 202-0008**.

APhA2008 EDUCATION SUPPLEMENT

Use this document to find detailed course descriptions and speaker information about each session.

With over 80 educational sessions on a wide variety of topics for any practice level, APhA2008 is your ticket to education and resources that advance your practice.

To help you choose the sessions that are right for you, APhA has designated education sessions according to program themes, education tracks, and learning levels.

APhA2008 Education Program Themes*

Each year, APhA develops education program themes to help you keep up with the growing trends affecting pharmacy practice. These themes include in-depth sessions that cover the most current and relevant issues in pharmacy. Program themes are noted just below the session title. APhA2008 education program themes are:

Navigating the Communication Channels to Improve Patient Care:

Sessions within this theme focus on enhancing the communication skills of pharmacy professionals. Intercultural communication, pharmacist–patient communication, and business communication strategies are explored.

Prevention is the Best Medicine:

Sessions within this theme highlight the importance of disease prevention and self-care strategies to improve patient care and decrease health care expenditures. Patient education and empowerment are emphasized throughout.

Enhancing Your MTM Services: Sessions in this theme will review the current state of pharmacist-provided medication therapy management (MTM) services and deliver practical steps

*Note: Not all sessions are included within a theme.

to enhancing and implementing MTM services. Emphasis will be placed on the more complex issues encountered by MTM providers and build on MTM activities already under way.

Cardiovascular Risk Reduction: Sessions within this theme will address the risk factors, complications, and treatment strategies for patients with significant cardiometabolic risk and specific cardiovascular disease. Practical techniques and therapies will be addressed, as well as the role of the pharmacist in lifestyle counseling.

Women's Health: Pharmacists attending these sessions will be better prepared to discuss women's health and educate both men and women regarding the diseases and conditions specific to the female population.

APhA2008 Education Tracks

In addition to the education program themes, APhA also categorizes Annual Meeting education sessions into specific tracks. The tracks are designed to help pharmacy professionals enhance their knowledge and careers by identifying ways to translate theory into practice, by becoming more efficient managers and caregivers, and by having a positive impact across practice settings. Each education session has been assigned to one of these tracks:

Certificate Training Program: Post-graduate continuing education experiences offered during APhA2008. (Ticket required.)

Clinical Patient Care: Updates on the management of a variety of disorders, conditions, and therapies.

Hospital Practice: Clinical and administrative topics of particular interest to those in hospital and institutional practice.

Integrating Science into Practice: The science that shapes the pharmacy profession.

Nuclear Pharmacy: Updates on products, practices, and policies within the area of nuclear pharmacy.

Pharmacy Administration: Creative strategies for managing pharmacy services.

Pharmacy Law: Laws, rules, regulations, and court cases affecting pharmacists and pharmacy practice.

Pharmacy Technicians: Topics of particular importance to pharmacy technicians and those interested in effectively working with pharmacy technicians to advance patient care.

Professional Development: Guidance on personal and professional growth.

Preceptors: Strategies for creating meaningful active learning experiences for student pharmacists and residents, as well as guidance for pharmacists who want to step into this valuable and essential role.



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Continuing Education Information

Attendees can earn up to 24 hours of continuing pharmacy education credit. Sessions approved for continuing education (CE) credit are indicated by an ACPE number and number of CEU's in both the Final Program and Education Supplement. Learning objectives for all CE sessions are provided on the APhA2008 Web site, www.aphameeting.org, and will be announced at the beginning of each session.

Target Audience

APhA2008 education sessions are designed for pharmacists and pharmacy technicians from all practice settings.

Courses appropriate for pharmacist participation are designated by an ACPE universal program number ending in the letter "P."

Courses appropriate for pharmacy technician participation are designated by an ACPE universal program number ending in the letter "T."

Accreditation



APhA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education and complies with the Criteria for Quality for continuing education programs.



This symbol indicates a certificate program in pharmacy. See pages 7 and 8 for more information.

State Requirements

Check with the Board of Pharmacy in your state regarding specific continuing education requirements.

Selected sessions have been approved by the State of Florida for state-mandated continuing eduation credit. Please visit the CE Booth located in the third floor foyer to receive a Florida CE form or download information from www.aphameeting.org.

Grievance Policy

Should any attendee of an approved CE session be dissatisfied with the quality of the program, a request in writing must be submitted to the APhA Department of Education within five days of the conclusion of the session.

Learning Objectives

Specific session learning objectives and self-assessment questions can be viewed in advance of the session on the Web at www.aphameeting.org. Select the specific education session from the Event Search. Learning objectives and self-assessment questions will also be repeated at the beginning of each session.

APhA Learning Levels

To help you more efficiently plan your time, the content of the education programs has been categorized into three levels of expertise:

Level 1:

Baseline knowledge of the subject area is required. The information presented will be mostly introductory.

Level 2:

Some prior subject area knowledge and experience are required, but extensive expertise is not.

Level 3:

Substantial knowledge and experience of the subject area are required. Information will be provided at a level to expand current expertise.

November 14, 2008

YOUR TICKET TO A BRIGHTER PHARMACY FUTURE

Friday, March 14

| Event/Program | Time | Location | Page # | Theme | Level |
|---|--------------------|--------------|--------|------------|---------|
| Certificate Training Programs | | | | | |
| Delivering Medication Therapy Management Services in Your Community (Pre-registration Required) | 7:30 am – 6:00 pm | Room 30B | 7 | _ | Level 3 |
| OTC Advisor: Advancing Patient Self-Care (Pre-registration Required) | 7:30 am – 6:00 pm | Room 30D | 7 | _ | Level 3 |
| Pharmaceutical Care for Patients with Diabetes (Pre-registration Required) | 7:30 am – 6:00 pm | Room 29C | 7 | _ | Level 3 |
| Pharmacy-Based Immunization Delivery (Pre-registration Required) | 7:30 am – 6:00 pm | Room 30A | 7 | _ | Level 3 |
| Pharmacy-Based Lipid Management (Pre-registration Required) | 7:30 am – 6:00 pm | Room 29D | 8 | - | Level 3 |
| Clinical Patient Care | | | | | |
| HIV Update 2008 | 3:30 pm – 5:30 pm | Room 32A/B | 9 | _ | Level 2 |
| New Drugs of 2007 | 3:30 pm – 5:30 pm | Room 31A/B/C | 9 | _ | Level 1 |
| Colorectal Care: The Pharmacist's Role in Cancer Prevention and Screening | 4:00 pm – 5:00 pm | Room 33A/B | 10 | Prevention | Level 1 |
| Hospital Practice | | | | | |
| Transitioning the Clinical Pharmacist into an Emergency Medicine Environment | 1:00 pm – 3:00 pm | Room 32A/B | 9 | _ | Level 2 |
| Integrating Science into Practice | | | | | |
| Research Methods: Instrumental Variables and Outcome Inferences from Observational Data | 3:30 pm – 5:30 pm | Room 30E | 9 | - | Level 3 |
| Nuclear Pharmacy | | | | | |
| Disease States and the Cardiac Kingdom | 2:00 pm – 5:00 pm | Room 29A/B | 9 | _ | Level 3 |
| Pharmacy Administration | | | | | |
| RLS Workshop for Community Practice Residencies (CPRLS) (Pre-registration Required) | 8:00 am – 4:00 pm | Room 30C | 8 | - | Level 2 |
| How to Find the Right Partner: Building a High Quality Clinical Services Pharmacy Business Model | 12:30 pm – 3:00 pm | Room 30E | 8 | - | Level 1 |
| The Permissible Scope of Compounding by Pharmacists | 1:00 pm – 3:00 pm | Room 31A/B/C | 8 | _ | Level 1 |
| Transitioning the Clinical Pharmacist into an Emergency Medicine Environment | 1:00 pm – 3:00 pm | Room 32A/B | 9 | _ | Level 2 |
| Pharmacy Law | | | | | |
| The Permissible Scope of Compounding by Pharmacists | 1:00 pm – 3:00 pm | Room 31A/B/C | 8 | _ | Level 1 |
| Pharmacy Technicians | | | | | |
| The Permissible Scope of Compounding by Pharmacists | 1:00 pm – 3:00 pm | Room 31A/B/C | 8 | _ | Level 1 |
| Colorectal Care: The Pharmacist's Role in Cancer Prevention and Screening | 4:00 pm – 5:00 pm | Room 33A/B | 10 | Prevention | Level 1 |
| Preceptors | | | | | |
| RLS Workshop for Community Practice Residencies (CPRLS) (Pre-registration Required) | 8:00 am – 4:00 pm | Room 30C | 8 | - | Level 2 |
| Creating a Mutually Beneficial IPPE (Introductory Pharmacy Practice Experience) | 1:00 pm – 3:00 pm | Room 33A/B | 8 | _ | Level 1 |

Earn a Liability Insurance Discount. Participate in CE

APhA and the Healthcare Providers Service Organization (HPSO) have teamed up to offer a special discount rate to APhA2008 attendees. Attending education programs during the meeting will qualify you for a 10% discount off your new or renewal HPSO professional liability insurance. Visit HPSO's Booth 1027 for complete details of this money saving offer.

- *The discount does not apply to credit received for the following CE sessions:
- APhA–APRS ESAS Contributed Papers Podium Sessions
- APhA-APRS ESAS Research Roundtable Breakfast
- Career Awareness Roundtable
- Colleagues in Research
- Establishing a Financially Viable MTM Practice

Saturday, March 15

| Event/Program | Time | Location | Page # | Theme | Level |
|--|----------------------|------------|--------|---------------------------|---------|
| Clinical Patient Care | | | | | |
| Filling Up on Fiber: The Beneficial Health Effects | 1:00 pm – 2:00 pm | Room 30E | 11 | Prevention/Cardiovascular | Level 1 |
| Report Cards for Pharmacy Performance: What's Your Grade? | 1:00 pm – 2:00 pm | Room 29A/B | 11 | _ | Level 1 |
| Asthma and COPD: New Treatment and Education Strategies | 1:00 pm – 3:00 pm | Room 31A/B | 12 | _ | Level 2 |
| Cough and Cold Management for Children: A Patient's Perspective | 1:00 pm – 3:00 pm | Room 30C/D | 12 | Communication | Level 1 |
| Successful Approaches to Initiating Medication Therapy Changes | 2:15 pm – 3:15 pm | Room 30E | 13 | MTM/Communication | Level 2 |
| The Good, the Bad, and the Probiotics | 2:15 pm - 3:15 pm | Room 33A/B | 13 | Prevention | Level 1 |
| Immunization Update 2008 | 3:30 pm – 5:30 pm | Room 30E | 14 | _ | Level 2 |
| MTM Grand Rounds | 3:30 pm – 5:30 pm | Room 32A/B | 14 | MTM | Level 2 |
| Opportunistic Infections and Hepatitis Coinfection in Patients with HIV | 3:30 pm – 5:30 pm | Room 31A/B | 14 | Prevention | Level 2 |
| Self-Care and Nonprescription Therapy for Cardiovascular Disease | 3:30 pm – 5:30 pm | Room 33A/B | 14 | Prevention/Cardiovascular | Level 2 |
| The Changing Landscape of Pain Management: New Approaches, Treatments, and Regulations | 3:30 pm – 5:30 pm | Room 31C | 15 | _ | Level 2 |
| Hospital Practice | | | | | |
| Joint Commission Pharmacy Update 2008 | 1:00 pm – 3:00 pm | Room 32A/B | 13 | _ | Level 2 |
| Integrating Science into Practice | | | | | |
| APhA-APRS ESAS Research Roundtable Breakfast | 7:00 am - 8:30:00 AM | Room 29C/D | 10 | - | Level 3 |
| APhA-APRS ESAS Contributed Papers Podium Session I | 1:00 pm - 3:00 pm | Room 30A/B | 12 | _ | Level 2 |
| Colleagues in Research: Power in Numbers or | 3:30 pm – 5:30 pm | Room 30A/B | 13 | _ | Level 2 |
| How to Build Interdisciplinary Relationships to Advance Pharmacy Practice | | | | | |
| Nuclear Pharmacy | | | | | |
| Homeland Security | 2:30 pm – 5:30 pm | Room 29A/B | 13 | _ | Level 3 |
| Pharmacy Administration | | | | | |
| Report Cards for Pharmacy Performance: What is Your Grade? | 1:00 pm – 2:00 pm | Room 29A/B | 11 | _ | Level 1 |
| Implementation of the PGY1 Community Pharmacy Residency Standard: Roundtable Discussion | 1:00 pm – 2:30 pm | Room 29C/D | 11 | _ | Level 2 |
| Conflict Management for Pharmacists and Preceptors | 3:30 pm – 5:30 pm | Room 30C/D | 13 | Communication | Level 1 |
| Pharmacy Law | 1.00 2.00 | Dec. 21C | 10 | | 1 |
| A Malpractice Primer for Pharmacists | 1:00 pm – 3:00 pm | Room 31C | 12 | — | Level 1 |
| Hot Law Topic Roundtable | 3:30 pm – 5:30 pm | Room 29C/D | 14 | _ | Level 1 |
| Pharmacy Technicians | 1.00 | D 004/D | | | |
| Continuing Professional Development: A Systematic Approach to Learning and Professional Development | 1:00 pm – 2:00 pm | Room 33A/B | 11 | _ | Level 1 |
| Filling Up on Fiber: The Beneficial Health Effects | 1:00 pm – 2:00 pm | Room 30E | 11 | Prevention/Cardiovascular | Level 1 |
| Report Cards for Pharmacy Performance: What is Your Grade? | 1:00 pm – 2:00 pm | Room 29A/B | 11 | _ | Level 1 |
| A Malpractice Primer for Pharmacists | 1:00 pm – 3:00 pm | Room 31C | 12 | _ | Level 1 |
| Joint Commission Pharmacy Update 2008 | 1:00 pm – 3:00 pm | Room 32A/B | 13 | _ | Level 2 |
| The Good, the Bad, and the Probiotics | 2:15 pm – 3:15 pm | Room 33A/B | 13 | Prevention | Level 1 |
| Conflict Management for Pharmacists and Preceptors | 3:30 pm – 5:30 pm | Room 30C/D | 13 | Communication | Level 1 |
| Preceptors | | | | | |
| Implementation of the PGY1 Community Pharmacy Residency Standard: Roundtable Discussion | 1:00 pm – 2:30 pm | Room 29C/D | 11 | _ | Level 2 |
| Conflict Management for Pharmacists and Preceptors | 3:30 pm – 5:30 pm | Room 30C/D | 13 | Communication | Level 1 |
| Professional Development | | | | | |
| Continuing Professional Development: A Systematic Approach to Learning and Professional Development | 1:00 pm – 2:00 pm | Room 33A/B | 11 | _ | Level 1 |
| Satellite Symposia | | | | | |
| Counterfeit Drugs: How Pharmacists Can Help Protect the Medication Supply | 5:30 am – 8:00 am | Hyatt | 10 | _ | - |
| Case Studies in Allergic Rhinitis: Focus on | 6:00 pm – 9:00 pm | Hyatt | 15 | _ | _ |
| Nonprescription Antihistamines | | | | | |

November 14, 2008

YOUR TICKET TO A BRIGHTER PHARMACY FUTURE

Sunday, March 16

| Event/Program | Time | Location | Page # | Theme | Level |
|--|--------------------|------------|--------|---------------------------|---------|
| Clinical Patient Care | | | | | |
| Cervical Cancer Prevention Strategies | 7:00 am - 9:00 am | Room 31A/B | 16 | Prevention/Women's Health | Level 2 |
| Documenting MTM and Patient Care Activities | 7:00 am - 9:00 am | Room 30C/D | 16 | MTM | Level 1 |
| Parkinson's Disease: Moving Forward with Treatment Modalities | 7:00 am - 9:00 am | Room 30A/B | 16 | _ | Level 1 |
| The Prevention and Management of Diabetes Complications | 7:00 am - 9:00 am | Room 29C/D | 16 | Prevention/Cardiovascular | Level 2 |
| What's New in Cardiovascular Care | 7:00 am - 9:00 am | Room 29A/B | 17 | Cardiovascular | Level 2 |
| When It's Lost, Replace It: Micro- and Macronutrient Supplementation | 7:00 am - 9:00 am | Room 30E | 17 | _ | Level 1 |
| Migraine Management: A Pharmacist's Guide to Improving Outcomes and Quality of Life | 1:00 pm – 3:00 pm | Room 31A/B | 18 | _ | Level 2 |
| Patience with Your Patients: Communication and Interviewing Techniques for Challenging MTM Encounters | 1:00 pm – 3:00 pm | Room 30A/B | 19 | MTM/Communication | Level 2 |
| Screening for Disease: Risk Assessment and Point-of-Care Testing by Pharmacists | 1:00 pm – 3:00 pm | Room 33A/B | 19 | Prevention/Cardiovascular | Level 1 |
| The Boom in Biologics I: Unique Treatment Options for Chronic Conditions | 3:30 pm – 4:30 pm | Room 29C/D | 20 | _ | Level 1 |
| Advances in the Treatment of Fibromyalgia | 3:30 pm – 5:30 pm | Room 33A/B | 20 | _ | Level 1 |
| Growing in the Wrong Direction: Managing Childhood Obesity | 3:30 pm – 5:30 pm | Room 31A/B | 20 | Prevention/Cardiovascular | Level 2 |
| Menopause: The Onset of New Health Care Needs | 3:30 pm – 5:30 pm | Room 30A/B | 20 | Women's Health | Level 1 |
| Safe Travels: Advice for International Travelers | 3:30 pm – 5:30 pm | Room 30C/D | 21 | Prevention | Level 1 |
| The Boom in Biologics II: The Emergence of Biosimilar Products | 4:45 pm – 5:45 pm | Room 29C/D | 21 | _ | Level 2 |
| Integrating Science into Practice | | | | | |
| 2008 Health Policy Forum: Medication Safety Reform in the U.S. Health Care System | 7:00 am – 9:00 am | Room 32A/B | 16 | _ | Level 2 |
| Practice-Based Research to Improve Health Outcomes | 1:00 pm – 3:00 pm | Room 29C/D | 19 | _ | Level 1 |
| AIHP Contributed Papers Podium Session | 1:00 pm – 4:00 pm | Hyatt | 19 | _ | _ |
| APhA-APRS ESAS Contributed Papers Podium Session II | 3:30 pm – 5:30 pm | Room 30E | 20 | _ | Level 2 |
| Nuclear Pharmacy | | | | | |
| Development and Production of PET Radiopharmaceuticals | 11:00 am - 1:00 pm | Room 29A/B | 17 | _ | Level 3 |
| Regulatory Update | 2:00 pm – 5:00 pm | Room 29A/B | 19 | _ | Level 3 |
| Pharmacy Administration | | | | | |
| A Team Approach to Improving Medication Use and Decreasing Medication Errors | 1:00 pm – 3:00 pm | Room 32A/B | 18 | Communication | Level 1 |
| Movin' on Up: Advancing the Roles of the Pharmacy Team | 1:00 pm – 3:00 pm | Room 30E | 18 | _ | Level 1 |
| Pharmacy Law | | | | | |
| Case Law Update | 7:00 am - 9:00 am | Room 33A/B | 16 | _ | Level 1 |
| Legislative and Regulatory Update | 1:00 pm – 3:00 pm | Room 30C/D | 18 | _ | Level 1 |
| FDA Update Pharmacy Technicians | 3:30 pm – 5:30 pm | Room 32A/B | 20 | _ | Level 2 |
| When It's Lost, Replace It: Micro- and Macronutrient Supplementation | 7:00 am - 9:00 am | Room 30E | 17 | _ | Level 1 |
| A Team Approach to Improving Medication Use and Decreasing Medication Errors | 1:00 pm – 3:00 pm | Room 32A/B | 18 | Communication | Level 1 |
| Legislative and Regulatory Update | 1:00 pm – 3:00 pm | Room 30C/D | 18 | _ | Level 1 |
| Movin' on Up: Advancing the Roles of the Pharmacy Team | 1:00 pm – 3:00 pm | Room 30E | 18 | _ | Level 1 |
| Patience with Your Patients: Communication and Interviewing Techniques for Challenging MTM Encounters | 1:00 pm – 3:00 pm | Room 30A/B | 19 | MTM/Communication | Level 2 |
| FDA Update | 3:30 pm – 5:30 pm | Room 32A/B | 20 | _ | Level 2 |
| Growing in the Wrong Direction: Managing Childhood Obesity | | Room 31A/B | 20 | Prevention/Cardiovascular | Level 2 |
| Safe Travels: Advice for International Travelers | 3:30 pm – 5:30 pm | Room 30C/D | 21 | Prevention | Level 1 |
| Preceptors | | | | | |
| Practice-Based Research to Improve Health Outcomes | 1:00 pm – 3:00 pm | Room 29C/D | 19 | _ | Level 1 |
| Satellite Symposia | | | | | |
| Reducing Risk of Coronary Heart Disease in Patients with Hypertriglyceridemia-Associated Mixed Dyslipidemia | 5:30 am – 7:30 am | Hyatt | 15 | - | - |
| Direct Renin Inhibitors: A Novel Approach to Hypertension Managaement | 5:45 am – 7:30 am | Hyatt | 15 | _ | _ |
| COPD: Expanding the Key Role of the Pharmacist | 6:00 pm – 9:00 pm | Hyatt | 21 | _ | _ |
| Setting Expectations with Weight Loss Patients | 6:00 pm – 9:00 pm | Hyatt | 21 | _ | _ |
| | | | | | |

Monday, March 17

| Event/Program | Time | Location | Page # | Theme | Level |
|---|---------------------|------------|--------|---------------------------|---------|
| Clinical Patient Care | | | | | |
| Advances in the Treatment of Opioid-Induced Constipation | 7:30 am – 9:30 am | Room 31C | 22 | Prevention | Level 2 |
| Drug Diversion: The Inside Scoop | 7:30 am – 9:30 am | Room 31A/B | 22 | — | Level 1 |
| New Drugs of 2007 | 7:30 am – 9:30 am | Room 32A/B | 23 | | Level 1 |
| Not If, But When: Preparing Pharmacists for an Influenza Pandemic | 7:30 am – 9:30 am | Room 30C/D | 23 | Prevention | Level 2 |
| The Appropriate Treatment and Management of ADHD | 7:30 am – 9:30 am | Room 33A/B | 23 | — | Level 1 |
| Venous Thromboembolism: Prevention and Treatment Strategies | | Room 29C/D | 23 | Prevention/Cardiovascular | Level 1 |
| OSHA Training Course: Maintaining Compliance with the Bloodborne Pathogens Standard | 10:00 am - 11:00am | Room 33A/B | 24 | _ | Level 1 |
| Protecting Patients from the Threat of Counterfeit Drugs | 10:00 am - 11:00am | Room 32A/B | 24 | | Level 2 |
| New Products, Technology, and Treatment Options for Patients with Diabetes | 10:00 am – 12:00 pm | Room 31A/B | 25 | Cardiovascular | Level 2 |
| Psychological Issues in Adolescents and Young Adults | 10:00 am – 12:00 pm | Room 29C/D | 25 | _ | Level 2 |
| Show Me the Numbers: Simple Approaches to Interpreting Clinical Trials and Patient Safety Data | 10:00 am – 12:00 pm | Room 31C | 25 | _ | Level 2 |
| Assisted Reproduction: Cycling Through the Treatment Options | 1:00 pm – 3:00 pm | Room 31C | 26 | Women's Health | Level 2 |
| Establishing a Financially Viable MTM Practice | 1:00 pm – 3:00 pm | Room 31A/B | 26 | MTM | Level 2 |
| Managing the 3 D's in the Elderly: Depression, Dementia, and Delirium | 1:00 pm – 3:00 pm | Room 30A/B | 27 | _ | Level 2 |
| MRSA: A Growing Bug in the Community | 1:00 pm – 3:00 pm | Room 32A/B | 27 | Prevention | Level 1 |
| The Outpatient Management of Heart Failure | 1:00 pm – 3:00 pm | Room 29A/B | 27 | Cardiovascular | Level 1 |
| Hospital Practice Mental Health and Substance Abuse Disorders: From Inpatient to Outpatient | 1:00 pm – 3:00 pm | Room 30C/D | 27 | - | Level 2 |
| Integrating Science into Practice | | | | | |
| APhA-APRS ESAS Contributed Papers Podium Session III | 7:30 am – 9:30 am | Room 30A/B | 22 | _ | Level 2 |
| The Smithsonian's National Pharmacy Collection As a Resource for Pharmacists | 9:00 am - 11:00 am | Room 30E | 24 | _ | Level 1 |
| Show Me the Numbers: Simple Approaches to Interpreting Clinical Trials and Patient Safety Data | 10:00 am – 12:00 pm | Room 31C | 25 | _ | Level 2 |
| Nuclear Pharmacy | | | | | |
| Dark Age Magic to New Age Hope: The Nuclear Imaging Revolution | 8:00 am – 12:00 pm | Room 29A/B | 24 | _ | Level 3 |
| Pharmacy Administration | | | | | |
| Protecting Patients from the Threat of Counterfeit Drugs | 10:00 am - 11:00am | Room 32A/B | 24 | _ | Level 2 |
| Fraud and Abuse: Maintaining Compliance with Federal and State Regulations | 10:00 am - 12:00 pm | Room 30C/D | 25 | _ | Level 1 |
| Establishing a Financially Viable MTM Practice | 1:00 pm – 3:00 pm | Room 31A/B | 26 | MTM | Level 2 |
| Pharmacy Law | | | | | |
| Drug Diversion: The Inside Scoop | 7:30 am - 9:30 am | Room 31A/B | 22 | _ | Level 1 |
| Fraud and Abuse: Maintaining Compliance with Federal and State Regulations | 10:00 am – 12:00 pm | Room 30C/D | 25 | _ | Level 1 |
| Pharmacy Technicians | | | | | |
| Drug Diversion: The Inside Scoop | 7:30 am - 9:30 am | Room 31A/B | 22 | _ | Level 1 |
| Not If, But When: Preparing Pharmacists for an Influenza Pandemic | 7:30 am – 9:30 am | Room 30C/D | 23 | Prevention | Level 2 |
| The Smithsonian's National Pharmacy Collection As a Resource for Pharmacists | 9:00 am – 11:00 am | Room 30E | 24 | _ | Level 1 |
| OSHA Training Course: Maintaining Compliance with the Bloodborne Pathogens Standard | 10:00 am - 11:00am | Room 33A/B | 24 | _ | Level 1 |
| Protecting Patients from the Threat of Counterfeit Drugs | 10:00 am - 11:00am | Room 32A/B | 24 | _ | Level 2 |
| Fraud and Abuse: Maintaining Compliance with Federal and State Regulations | 10:00 am – 12:00 pm | Room 30C/D | 25 | _ | Level 1 |
| Unleashing the Inner Activist: Political Action 101 | 10:00 am – 12:00 pm | Room 30A/B | 26 | Communication | Level 1 |
| Professional Development | | | | | |
| Unleashing the Inner Activist: Political Action 101 | 10:00 am – 12:00 pm | Room 30A/B | 26 | Communication | Level 1 |
| Career Awareness Roundtable | 1:00 pm – 3:00 pm | Room 33A/B | 26 | | Level 1 |
| | | | | | |
| Satellite Symposia | | | | | |

November 14, 2008

6

YOUR TICKET TO A BRIGHTER PHARMACY FUTURE



Friday, March 14

Certificate Training Program

Delivering Medication Therapy Management Services in Your Community

Level 3

7:30 am - 6:00 pm

Convention Center, Room 30B

ACPE# 202-203-07-088-L04 • 1.1 CEU

This certificate training program has been developed as a joint project by APhA and the American Society of Consultant Pharmacists (ASCP) and is intended to enhance pharmacists' clinical expertise in evaluating complicated medication regimens, identifying medication-related problems, and making recommendations to patients, caregivers, and health care professionals. Through self-study modules, case studies, hands-on patient interviews, and assessment practice sessions, pharmacists will obtain the clinical knowledge and skills needed to establish medication therapy management services.

(Ticket required. Preregistered attendees only.)

Speaker(s): Melissa A. Somma McGivney, PharmD, University of Pittsburgh; Jeffrey C. Delafuente, MS, FCCP, FASCP, Virginia Commonwealth University

Certificate Training Program

OTC Advisor: Advancing Patient Self-Care

Level 3

7:30 am - 6:00 pm

Convention Center, Room 30D

ACPE# 202-000-07-100-L04-P • 0.8 CEU

OTC Advisor®: Advancing Patient Self-Care, a National Certificate Training Program for Pharmacists, is an innovative training program that explores the pharmacist's role in providing self-care services to patients and presents cutting-edge information about self-care products and services, as well as a review of nonprescription therapeutics and self-care counseling techniques. The program examines economically viable options for pharmacists interested in providing services to self-treating patients in their communities, and discusses practice implementation strategies.

(Ticket required. Preregistered attendees only.)

Speaker(s): Kelly Brock, PharmD; Bella Mehta, PharmD, The Ohio State University

Supported by an educational grant from Procter & Gamble.



Certificate Training Program

Pharmaceutical Care for Patients with Diabetes

Level 3 7:30 am - 6:00 pm

Convention Center, Room 29C

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ACPE# 202-000-06-114-L01 • 0.8 CEU

Pharmaceutical Care for Patients with Diabetes is designed to foster pharmacists' ability to promote optimal self-management by patients with diabetes. This intensive certificate training program will highlight the pharmacist's vital role as a drug therapy expert on a diabetes health care team. During the course, comprehensive instruction on the pathophysiology of diabetes with acute and long-term complications will be provided, along with an emphasis on patient assessment using strategies for management and monitoring of patients' disease progression. Participants will be evaluated on their blood glucose monitoring, foot exam, and insulin injection techniques. Pharmacists must complete a self-study learning guide and assessment test prior to attending this session. A final exam will be administered at the conclusion of this program.

(Ticket required. Preregistered attendees only.)

Speaker(s): Tommy Johnson, PharmD, CDE, University of Georgia; Staci-Marie Norman, PharmD, CDE, Martin's Pharmacy

Certificate Training Program

Pharmacy-Based Immunization Delivery

Level 3

7:30 am - 6:00 pm

Convention Center, Room 30A



ACPE# 202-000-06-111-L01 • 0.8 CEU

Pharmacy-Based Immunization Delivery will focus on providing pharmacists with the skills and resources necessary to establish and promote successful adult immunization services. Detailed information about routine adult immunizations will be provided in the self-study modules and reinforced during live training using case studies and interactive discussions. Pharmacists will be expected to demonstrate intramuscular and subcutaneous injections on a partner during the seminar and are asked to wear clothing that will allow easy access to the deltoid muscle. Pharmacists also must complete a self-study learning guide and assessment test prior to attending the session. A final exam will be administered at the conclusion of the program.

(Ticket required. Preregistered attendees only.)

Speaker(s): Dennis D. Stanley, RPh, Ukrop's Super Markets Pharmacy; Stephan L. Foster, PharmD, FAPhA, University of Tennessee Supported by an educational grant from VaxServe.



Certificate Training Program

Pharmacy-Based Lipid Management

Level 3

7:30 am - 6:00 pm

Convention Center, Room 29D

ACPE# 202-000-06-112-L01 • 0.8 CEU

Pharmacy-Based Lipid Management is a two-part (self-study and live seminar) certificate training program that enhances pharmacists' current knowledge of the pathophysiology and treatment of dyslipidemias using the Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults guidelines. This innovative program will enable pharmacists to recommend optimal treatment strategies for patients with lipid disorders while working in collaboration with other health care professionals. Emphasis will be placed on practical tools, techniques, and information to assist in establishing a pharmacist-conducted lipid management service. Because the seminar is highly case-based, pharmacists are required to complete the self-study learning guide and assessment test prior to attending this session. Competency in blood sample collection via finger stick will be assessed and a final exam will be administered at the conclusion of this program.

(Ticket required. Preregistered attendees only.)

Speaker(s): Thomas L. Lenz, PharmD, MA, Creighton University; Carrie Foust Koenigsfeld, PharmD, Drake University

Pharmacy Administration; Preceptors

RLS Workshop for Community Practice Residencies (CPRLS)

Level 2

8:00 am - 4:00 pm

Convention Center, Room 30C

ACPE# 204-202-06-091-L04 • 0.8 CEU

Residency program directors and preceptors can use this systematic approach to design and deliver community care pharmacy practice residency training to enhance the quality of existing or start-up programs. Prereadings will prepare attendees to participate in simulation of the design of a program using the American Society of Health-System Pharmacists' Residency Learning System (RLS) Model. The workshop includes hands-on experience in applying direct observation to assess residents' performance. Registrants will be sent study materials in the mail.

(Ticket required. Preregistered attendees only.)

Speaker(s): James A. Owen, PharmD, American Pharmacists Association; William A. Miller, PharmD, University of Iowa; Anne Burns, BPharm, RPh, American Pharmacists Association

Cosponsored by the American Society of Health-System Pharmacists.



Pharmacy Administration

How to Find the Right Partner: Building a High Quality Clinical Services Pharmacy Business Model

Level 1

12:30 pm – 3:00 pm

Convention Center, Room 30E

ACPE# 202-000-08-056-L04-P • 0.25 CEU

This is not a marriage seminar, but it is definitely a pharmacy relationship "mixer" to help you find the right partner to build a high-quality pharmacy program that improves patient safety, enhances experiential education and develop a clinical services business model. This seminar will showcase academic and contract pharmacy partnerships and will be highly interactive to gain insight from all participating pharmacy experts (including you) who have ideas and knowledge to share. Come and find out what pharmacy partnership opportunities await you and discover how you can "work things out!"

Speaker(s): David H. Schwed, BPharm, FACA, FAPhA, Woodruff's Drugs; Todd D. Sorensen, PharmD, University of Minnesota; Kathleen Johnson, PharmD, MPH, PhD, University of Southern California; Krista M. Scardina, PharmD, Health Resources and Services Administration; Jimmy R. Mitchell, RPh, MPH, MS, HRSA Office of Pharmacy Affairs; Tom Renshaw, RPh, 340B Prime Vendor Program/Apexus

Supported by the HRSA Pharmacy Services Support Center.

Preceptors

Creating a Mutually Beneficial IPPE (Introductory Pharmacy Practice Experience)

Level 1

1:00 pm – 3:00 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-022-L04-P • 0.2 CEU

The revised ACPE Accreditation Standards and Guidelines, effective July 2007, places increased emphasis on experiential learning. By applying this learning model, the Introductory Pharmacy Practice Experience (IPPE) has become more defined and standardized. This session will assist practitioners, preceptors, and educators involved with IPPE's to create educationally sound practice experiences for student pharmacists.

Speaker(s): Kathleen Hill-Besinque, PharmD, MSEd, University of Southern California; Susan H. Staggs, PharmD, BCPS, University of Iowa Supported by an educational grant from Merck & Co, Inc.

Pharmacy Administration; Pharmacy Law; Pharmacy Technicians

The Permissible Scope of Compounding by Pharmacists

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 31A/B/C

ACPE# 202-999-08-074-L03-P • 0.2 CEU

ACPE# 202-999-08-074-L03-T • 0.2 CEU

Patient and prescriber demand for pharmacy compounding is increasing every year. The scope of patient-specific compounding raises questions concerning traditional pharmacy practice, appropriate regulatory methods, and the balance between the federal government and the states. A review of how the pharmacy profession, the federal government, and the courts re-



spond to those questions will assist in defining where pharmacy compounding fits into the U.S. health care system. This session will address various degrees to which pharmacists are involved with compounding. It will also review the regulatory and legal issues that affect compounding.

Speaker(s): Tom Murry, PharmD, Esq, Pharmacy Compounding Accreditation Board

Cosponsored by the American Society for Pharmacy Law.

Hospital Practice; Pharmacy Administration

Transitioning the Clinical Pharmacist into an Emergency Medicine Environment

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-077-L04-P • 0.2 CEU

The Joint Commission has recently made recommendations encouraging pharmacists to engage in prospective medication reviews for emergency departments (EDs). Yet fewer than 3% of EDs have full-time clinical pharmacists on staff. This session will explore the activities of pharmacists, residents, and students in the ED. Recommendations will be made for the administrative and logistical process of increasing the presence of pharmacists in the ED. The advantages of pharmacist involvement will also be discussed, including medication reconciliation, cost containment, and decreasing overcrowding.

Speaker(s): Daniel P. Hays, PharmD, BCPS, University of Rochester Medical Center, Strong Memorial Hospital; Wendy Friedig, PharmD, MBA, BCPS, Nebraska Medical Center

Nuclear Pharmacy

Disease States and the Cardiac Kingdom

Level 3

2:00 pm - 5:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-025-L01-P • 0.3 CEU

This program is designed to provide the attendees with an overview and assessment of patients suffering from diabetes and obesity. The complications of diabetes and obesity along with the increase in cardiovascular and metabolic comorbidities are discussed. Since bariatic surgery is growing in popularity and frequency, the safety, utilization of resources, nutritional support, and a review of the latest surgical techniques are presented. Included in this session will be the multitude of imaging resources and radiopharmaceutical agents used in nuclear cardiac imaging studies.

Speaker(s): Darlene Fink-Bennett, MD, William Beaumont Hospital; Stephen L. Heun, AS, CNMT, NCT, Triad Isotopes; Kerstyn C. Zalesin, MD, William Beaumont Hospital Clinical Patient Care

HIV Update 2008 Level 2

3:30 pm – 5:30 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-035-L02-P • 0.2 CEU

Medication resistance, new chemical entities, revised treatment guidelines, and enhanced approaches to patient education continue to initiate change in the management of HIV infection. New modalities for treating HIV infection bring the promise of greater tolerability and enhanced adherence. This session reviews the latest guidelines for prophylaxis and treatment of HIV. Promising new and emerging therapies will be highlighted, along with innovative strategies to improve adherence.

Speaker(s): Betty J. Dong, PharmD, FASHP, FCCP, University of California at San Francisco School of Pharmacy, National HIV/AIDS Clinicians' Consultation Center

Supported by an educational grant from Gilead Sciences, Inc

Clinical Patient Care

New Drugs of 2007

Level 1

3:30 pm – 5:30 pm

Convention Center, Room 31A/B/C

ACPE# 202-000-08-047-L01-P • 0.2 CEU

Be sure to take your seat early for this recurring Annual Meeting favorite! Key information about medications marketed during 2007 will be reviewed, including indications for use, routes of administration, and associated precautions. The new drugs will be compared with established therapeutic options whenever possible. Patient counseling tips and practical monitoring considerations are provided.

This course is also offered on Monday, March 17 at 7:30 am.

Speaker(s): Daniel A. Hussar, PhD, University of the Sciences in Philadelphia

Integrating Science into Practice

Research Methods: Instrumental Variables and Outcome Inferences from Observational Data

Level 3

3:30 pm – 5:30 pm

Convention Center, Room 30E

ACPE# 202-000-08-028-L04-P • 0.2 CEU

As treatment rates expand with new insurance mechanisms, treated patients will less resemble patients in controlled trials and the consequences of treatment for these patients will be uncertain. Policymakers need to evaluate the treatment consequences for these patients to assess whether treatments are over- or underutilized in practice. Observational health care databases contain substantial treatment variation that can be used to assess treatment consequences in practice. However, both treatment selection issues and the heterogeneity of treatment effects across the population limit the inferences that can be made from observational data. Instrumental variable (IV) methods can possibly overcome the treatment selection bias using observational data but researchers must be careful how to interpret IV estimates if treatment effects are heterogeneous across patients. This session will use applied examples to introduce the use of IV methods for researchers working in pharmacy economic, social, and administrative sciences and practice.

Speaker(s): John M. Brooks, PhD, University of Iowa



Clinical Patient Care; Pharmacy Technicians

Colorectal Care: The Pharmacist's Role in Cancer Prevention and Screening

Theme: Prevention

Level 1

4:00 pm - 5:00 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-019-L01-P • 0.1 CEU

ACPE# 202-000-08-019-L01-T • 0.1 CEU

Colorectal cancer is the second leading cause of cancer deaths. Appropriate screening for colorectal cancer can detect the disease in its early stages when treatment is most effective or, in many cases, prevent cancer before it occurs. Pharmacists can play an active role in making sure their patients are actively trying to prevent colorectal cancer and are receiving their recommended screenings. This session will prepare pharmacists to educate patients on risk factors, prevention measures, and the importance of screening for colorectal cancer. It will also provide guidance for counseling patients on the various bowel prep methods for colonoscopies.

Speaker(s): Patrick Medina, PharmD, BCOP, The University of Oklahoma

Saturday, March 15

Satellite Symposium

Counterfeit Drugs: How Pharmacists Can Help Protect the Medication Supply

5:30 am - 8:00 am

Hyatt, Douglas Pavilion D

ACPE# 207-000-08-020-L05-P • 0.2 CEU

Pharmacists play a critical role in preventing counterfeit drugs from entering the distribution system. As the final "gatekeepers" of the drug distribution system, pharmacists are instrumental in protecting the integrity of our medication supply. As vital partners in addressing this growing problem, pharmacists will be essential allies in the efforts undertaken by the FDA, PDMA, and other key organizations in preventing counterfeit drugs from affecting their patients. This symposium features the investigative reporter and author of "Dangerous Doses," who has helped uncover the systemic contamination of our medication supply along with the Associate Executive Director of the National Association of Boards of Pharmacy discussing this national epidemic.

Speaker(s): Katherine Eban, *Dangerous Doses;* Eleni Z. Anagnostiadis, RPh, National Association of Boards of Pharmacy

Conducted by SynerMed Communications and supported by Ortho-McNeil, Inc.



Integrating Science into Practice

APhA-APRS ESAS Research Roundtable Breakfast

Level 3

7:00 am – 8:30 am Convention Center, Room 29C/D

ACPE# 202-000-08-009-L04-P • 0.15 CEU

Attendees will have the opportunity to network with colleagues on various research topics in the economic, social, and administrative sciences. Table topics include:

- Career Development: Sabbaticals. Earlene Lipowski, PhD, University of Florida
- Career Development in Research: Fellowships/Sabbaticals. Gary R. Matzke, PharmD, FCP, FCCP, Virginia Commonwealth University, Medical College of Virginia
- Hot Topics in Research: Medicare Part D. David Mott, PhD, University of Wisconsin
- Hot Topics in Research: Using Patient Registries. Kavita Nair, PhD, University of Colorado Denver
- Hot Topics in Research: MTM. Leticia R. Moczygemba, PharmD, University of Texas at Austin
- **Practical Issues in Research: Grant Writing**. Betty Chewning, PhD, University of Wisconsin in Madison

(Ticket required. Preregistered attendees only.)

Opening General Session

The Economics of Healthcare

8:30 am - 11:00 am

Convention Center, Ballroom 20

ACPE# 202-000-08-050-L04-P • 0.1 CEU

ACPE# 202-000-08-050-L04-T • 0.1 CEU

The featured keynote presentation during the APhA2008 Opening General Session will be delivered by Uwe E. Reinhardt, PhD, professor of economics and public affairs at Princeton University. Dr. Reinhardt has been studying the United States healthcare environment for over two decades. He has addressed the growing threats and the troubling trends in hospital systems, insurance companies, and the pharmaceutical industry for a number of governmental commissions and private companies. Dr. Reinhardt's presentation, "The Economics of Healthcare," will examine the lack of cost-effective consciousness in our healthcare system. He will present ideas for achieving greater cost-effectiveness, especially in the area of drug therapy.

Speaker(s): Uwe E. Reinhardt, PhD, Princeton University Supported by an educational grant from Eli Lilly and Company.



Pharmacy Technicians; Professional Development

Continuing Professional Development: A Systematic Approach to Learning and Professional Development

Level 1

1:00 pm - 2:00 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-021-L04-P • 0.1 CEU

ACPE# 202-000-08-021-L04-T • 0.1 CEU

Continuing professional development (CPD) is a self-directed, ongoing, systematic, and outcomes-focused approach to learning and professional development. CPD has been implemented in a number of countries and is actively being explored for the profession of pharmacy in the United States through a series of state-based pilots. Pharmacists who have engaged in CPD thus far have felt more engaged in their learning and more prepared to meet the challenges of their practice and the pharmacy profession. This session will provide an introduction to the components of CPD and give you objective tools to identify and respond to YOUR professional learning needs.

Speaker(s): Jennifer Moulton, RPh, Iowa Pharmacy Association; Mike Rouse, BPharm (Hons), MPS, Accreditation Council for Pharmacy Education (ACPE); Anna Legreid Dopp, PharmD, University of Wisconsin

Clinical Patient Care; Pharmacy Technicians

Filling Up on Fiber: The Beneficial Health Effects

Themes: Prevention; Cardiovascular Level 1

1:00 pm - 2:00 pm

Convention Center, Room 30E

ACPE# 202-000-08-032-L04-P • 0.1 CEU

ACPE# 202-000-08-032-L04-T • 0.1 CEU

Fiber is not only important for digestive tract health, but it has cardiovascular, endocrine, and metabolic advantages as well. Unfortunately, the majority of Americans consume far less than the recommended daily intake. Convincing patients to consume more fiber can be a challenge for health care providers given the dietary changes that need to be made and the potential for adverse effects. This session will highlight the numerous uses for fiber. Pharmacists will learn about the various sources of fiber based on type, the clinical practice guidelines that include fiber, and dosing recommendations based on patient characteristics and conditions. Emphasis will be placed on the counseling approach and dietary recommendations that pharmacists can communicate to their patients.

Speaker(s): CoraLynn B. Trewet, MS, PharmD, BCPS, University of Iowa, Broadlawns Family Health Center

Clinical Patient Care; Pharmacy Administration; Pharmacy Technicians

Report Cards for Pharmacy Performance: What's Your Grade?

Level 1

1:00 pm – 2:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-059-L04-P • 0.1 CEU

ACPE# 202-000-08-059-L04-T • 0.1 CEU

Improving the quality of health care services delivered to patients, including pharmacy services, is a national priority. PQA, a pharmacy quality alliance, is developing quality measures for pharmacists and pharmacies that will be available in the near future. These measures will be used to generate report cards that analyze pharmacy and pharmacist performance. Come to this session to learn how this will affect your practice.

Speaker(s): Rebecca Chater, RPh, MPH, FAPhA, Kerr Drug, Inc./KDI Clinical Services; Brad Tice, PharmD, PMP, PharmMD Solutions, LLC Supported by an educational grant from Pfizer Inc.

Pharmacy Administration; Preceptors

Implementation of the PGY1 Community Pharmacy Residency Standard: Roundtable Discussion

Level 2

1:00 pm – 2:30 pm

Convention Center, Room 29C/D

ACPE# 202-000-08-060-L04-P • 0.15 CEU

Using a roundtable format, this session is designed to provide a venue for interactive discussion on current community pharmacy residency issues related to the implementation of the PGY1 Community Pharmacy Residency Standard. Attendees of this session will participate in a series of discussion topics that include implementing the new PGY1 Community Residency Accreditation Standard, strategies for successful resident assessment (e.g., Resitrak), preceptor development, medication safety, program marketing, and the residency accreditation process. This program will be of interest to community pharmacy residency program representatives and those interested in learning more about community pharmacy residency training.

The Residency Accreditation Process. Jean-Venable "Kelly" R. Goode, PharmD, BCPS, FAPhA, FCCP, Virginia Commonwealth University

Implementing the New PGY1 Community Residency Accreditation Standard. Jay D. Currie, PharmD, FCCP, FAPhA, The University of Iowa

Medication Safety. Sarah Ray, PharmD, BCPS, Aurora Health Care Preceptor Development. Jaime Montuoro, PharmD, SUPERVALU Pharmacies

Program Marketing. Peggy G. Kuehl, PharmD, FCCP, BCPS, University of Missouri Kansas City

Strategies for Successful Resident Assessment. Jeffrey A. Goad, PharmD, MPH, FCPhA, FCSHP, University of Southern California



Pharmacy Law; Pharmacy Technicians

A Malpractice Primer for Pharmacists

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 31C

ACPE# 202-999-08-001-L03-P • 0.2 CEU

ACPE# 202-999-08-001-L03-T • 0.2 CEU

This program will review the elements of a malpractice action and trace the existence and evolution of various theories of malpractice liability for pharmacists. Particular attention will be focused on the evolving pharmacist duty to warn and the impact various statutes (e.g., OBRA 90 and MedGuide regulations) can have in malpractice cases. The presenters will use numerous recent court decisions to illustrate concepts.

Speaker(s): Jay Campbell, RPh, JD, North Carolina Board of Pharmacy; Edward D. Rickert, RPh, JD, Smith, Rickert & Smith Cosponsored by the American Society for Pharmacy Law.

Integrating Science into Practice

APhA-APRS ESAS Contributed Papers Podium Session I

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 30A/B

ACPE# 202-000-08-006-L04-P • 0.2 CEU

Researchers will make 15-minute presentations of their research findings. A question-and-answer session will follow.

- Thematic analysis for how patients, prescribers, experts, and patient advocates view the process for choosing prescription medications. <u>Schommer J</u>, Worley M, Kjos A, Schondelmeyer S, Pakhomov S, University of Minnesota. (167))
- Controlling for drug dose in systematic review and metaanalysis: A case study of the effect of antidepressant dose. <u>Hansen R</u>, University of North Carolina – Chapel Hill, Moore C, University of Pittsburgh, Dusetzina S, Leinwand B, University of North Carolina – Chapel Hill, Gartlehner G, Danube University/ Ludwig Boltzmann Institute for Health Technology Assessment, Gayns B, University of North Carolina – Chapel Hill. (175)
- Pharmacist-provided extended diabetes care: A randomized controlled trial. <u>Doucette W</u>, Witry M, University of Iowa College of Pharmacy. (205)
- Stimulants and Atomoxetine use in children and adolescents. <u>Aparasu R</u>, University of Houston, College of Pharmacy, Bhatara V, University of South Dakota Sanford School of Medicine. (216)
- Development and construct validation of the pharmacists' care of migraineurs scale. <u>Shah N</u>, West Virginia University, Desselle S, University of Oklahoma, Skomo M, Duquesne University. (179)
- Racial differences in adherence to medications by patients with diabetes. <u>Goodin A</u>, Nau D, University of Kentucky. (210)



Clinical Patient Care

Asthma and COPD: New Treatment and Education Strategies

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 31A/B

ACPE# 202-999-08-011-L01-P • 0.2 CEU

The management of asthma and chronic obstructive pulmonary disease (COPD) continues to be a challenge for both practitioners and patients. Updated guidelines, new research findings, and inhaler device requirements have changed the approach to asthma and COPD management. Pharmacists will learn to apply the new treatment guidelines to assist with treatment selection and reduce exacerbations. Improved patient education strategies will also be reviewed as a critical means to disease control and management.

Speaker(s): Darin Ramsey, PharmD, BCPS, Richard L. Roudebush VA Medical Center, Butler University; Julie M. Koehler, PharmD, Butler University, Clarian Health Partners, IU-Methodist Family Practice Center Cosponsored by the American College of Allergy, Asthma and Immunology. Supported by an educational grant from Schering-Plough.

Clinical Patient Care

Cough and Cold Management for Children: A Patient's Perspective

Theme: Communication Level 1

1:00 pm - 3:00 pm

Convention Center, Room 30C/D

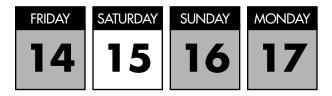
ACPE# 202-000-08-082-L04-P • 0.2 CEU

Safety and efficacy issues, as well as serious adverse events, have prompted debate regarding the use of cough and cold products in children. The FDA has been tasked with reviewing the safety and efficacy data for these products. As a result of such recent discussions, parents and caregivers have been encouraged to take multiple precautions when selecting cough and cold products for children. This session will explore the various ways that pharmacists can influence safe medication use in their pediatric patients who present with a cough or cold. Patient testimonials will be incorporated to depict the challenges faced when selecting products. Safety and efficacy data, regulatory compliance, and education strategies will also be addressed.

Speaker(s): Victoria Tutag Lehr, PharmD, Wayne State University, Children's Hospital of Michigan; R. William Soller, PhD, University of California at San Francisco

Supported by an educational grant from the Consumer Healthcare Products Association.

November 14, 2008



Hospital Practice; Pharmacy Technicians

Joint Commission Pharmacy Update 2008

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-039-L04-P • 0.2 CEU

ACPE# 202-000-08-039-L04-T • 0.2 CEU

This session will review the updates to the Joint Commission accreditation process and the Standards Improvement Initiative. Performance measurement initiatives, problematic medication-related standards, and the 2008 National Patient Safety Goals will be addressed. Pharmacists will also learn performance improvement strategies that can be implemented in their respective workplaces.

Speaker(s): Melinda C. Joyce, PharmD, FAPhA, FACHE, The Medical Center

Clinical Patient Care

Successful Approaches to Initiating Medication **Therapy Changes**

Themes: MTM; Communication Level 2

2:15 pm - 3:15 pm

Convention Center, Room 30E

ACPE# 202-000-08-066-L01-P • 0.1 CEU

You've conducted a comprehensive medication therapy review and identified several medication therapy changes that could be beneficial for the patient. It is now time to implement these changes. This session will assist pharmacists with initiating medication therapy changes. The common classes of chronic medications seen in medication therapy management (MTM) encounters will be reviewed, with an emphasis on, intraclass and interclass conversions. Pharmacists will learn to recognize when initiating therapy change is appropriate. Factors such as optimizing therapy and cost savings will be discussed.

Speaker(s): Marilyn Stebbins, PharmD, University of California, San Francisco, CHW Medical Foundation, Mercy Medical Group Supported by an educational grant from Wyeth.

Clinical Patient Care; Pharmacy Technicians

The Good, the Bad, and the Probiotics

Theme: Prevention

Level 1

2:15 pm - 3:15 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-072-L04-P • 0.1 CEU

ACPE# 202-000-08-072-L04-T • 0.1 CEU

Normal flora in the gut is essential for digestion, protection of the mucosal lining, immunity, and elimination of unwanted microorganisms. Normal flora can be disrupted by various mechanisms (e.g., antibiotic use, alcohol, stress, poor diet). Probiotics are becoming more common in food products and dietary supplements to support normal bacterial growth in the gut. This session will explore the rationale for using probiotics, the importance of probiotics, and the methods to introduce probiotics into the digestive tract.

Speaker(s): Nicholas G. Popovich, PhD, University of Illinois-Chicago

Supported by an educational grant from Amerifit Brands.

November 14, 2008

Nuclear Pharmacy

Homeland Security

Level 3 2:30 pm - 5:30 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-036-L04-P • 0.3 CEU

Radioactive pharmaceuticals play a vital role in the diagnosis and therapy of patients in the U.S. Given the heightened state of homeland security, radioactive pharmaceutical usage must maintain its place in health care. This session will highlight the handling of risk communications involving threats of radioactive materials as well as the drugs for counteracting their effects, the security of radiopharmacies, and the continued availability of radioisotopes.

Speaker(s): Daniel J. Barnett, MD, MPH, Johns Hopkins Center for Public Health Preparedness, Johns Hopkins Bloomsberg School of Public Health; Kevin Nelson, PhD, CHP, Mayo Clinic Jacksonville; Darrell R. Fisher, PhD, Pacific Northwest National Laboratory

Supported by an educational grant from Covidien.

Integrating Science into Practice

Colleagues in Research: Power in Numbers or How to Build Interdisciplinary Relationships to **Advance Pharmacy Practice**

Level 2

3:30 pm - 5:30 pm

Convention Center, Room 30A/B

ACPE# 202-000-08-018-L04-P • 0.2 CEU

The scale and complexity of today's research demand that pharmacists move beyond the confines of their individual disciplines and practice settings to explore new organizational models for intradisciplinary translational research. Whether you are a pharmacist in a community setting or an academic researcher, you will need to develop interdisciplinary relationships to work in the team-oriented environments that characterize today's emerging research efforts. This program will discuss the process of building these essential relationships to creating innovative interdisciplinary research and how to develop research mentoring opportunities. This program is structured for pharmacists at all levels and disciplines.

Speaker(s): David P. Zgarrick, PhD, Drake University; Nathaniel M. Rickles, PharmD, PhD, BCPP, Northeastern University; Earlene Lipowski, PhD, University of Florida; Marsha A. Raebel, PharmD, Kaiser Permanente Colorado Institute for Health Research

Pharmacy Administration; Pharmacy Technicians; Preceptors

Conflict Management for Pharmacists and Preceptors

| Theme: | Communication |
|---------|---------------|
| Level 1 | |

3:30 pm - 5:30 pm

Convention Center, Room 30C/D

ACPE# 202-000-08-020-L04-P • 0.2 CEU

ACPE# 202-000-08-020-L04-T • 0.2 CEU

Conflict is often sparked by differing opinions, values, beliefs, and interests. Excellent conflict managers are those who can anticipate conflict, react appropriately, and intervene with minimal stress and emotional toll for the parties involved. Being able to manage conflict among coworkers, employees, staff, students, and patients is an invaluable skill set for pharmacists, preceptors, and educators. This session will address the various ways in which individuals handle conflict and the best approaches for dealing with those situations.

Speaker(s): Diane Ginsburg, MS, RPh, FASHP, University of Texas at Austin; Lynn Pezzullo, RPh, Quality Partners of Rhode Island

Endorsed by the New Practitioner Network.

Supported by an educational grant from Merck & Co, Inc.



Pharmacy Law

Hot Law Topic Roundtable

Level 1

3:30 pm - 5:30 pm

Convention Center, Room 29C/D

ACPE# 202-999-08-037-L03-P • 0.2 CEU

Using a roundtable format, attendees will have the opportunity to participate in discussions on various timely legal issues facing pharmacists. Table topics will include common regulatory and legal concerns involved in appearing before a Board of Pharmacy, legal matters surrounding FDA-mandated medication guides, legal issues surrounding internet pharmacy practice, legal and patient safety concerns of electronic prescribing, and legal and policy issues stemming from the debate over access to investigational drugs. Experts in each of the topic areas will introduce and facilitate discussion.

- Internet Pharmacy Issues. John C. Kirtley, PharmD, Arkansas State Board of Pharmacy
- E-prescribing Issues. Donna Horn, RPh, DPh, Institute for Safe Medication Practices
- Internet Pharmacy Issues. Michael Burleson, RPh, Kentucky Board of Pharmacy
- Medication Guides. Ilisa B.G. Bernstein, PharmD, JD, US Food and Drug Administration
- Access to Investigational Drugs. Jay Campbell, RPh, JD, North Carolina Board of Pharmacy
- Board of Pharmacy Regulatory Issues. Edward D. Rickert, RPh, JD, Smith, Rickert & Smith

Cosponsored by the American Society for Pharmacy Law.

Clinical Patient Care

Immunization Update 2008

Level 2

3:30 pm - 5:30 pm

Convention Center, Room 30E

ACPE# 202-000-08-038-L01-P • 0.2 CEU

The practice of immunizations is constantly evolving. Vaccine recommendations change routinely, new products are continuously introduced, reimbursement criteria tend to be in flux, and technological advancements continue to be made. This session will bring you up to date on the latest news in immunizations and provide a glimpse of what's on the horizon. Various ways to expand the influenza season will be introduced, with an emphasis on best practice activities. Both experienced and novice pharmacist immunizers are certain to benefit.

Speaker(s): Stephan L. Foster, PharmD, FAPhA, University of Tennessee Memphis; Jeffery A. Goad, PharmD, MPH, FCPhA, FCSHP, University of Southern California

Supported by an educational grant from VaxServe.



Clinical Patient Care

MTM Grand Rounds

Theme: MTM

Level 2 3:30 pm - 5:30 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-046-L04-P • 0.2 CEU

This session will provide actual case-based MTM therapeutic interventions to test pharmacists' skills and enhance their knowledge of clinical applications in pharmacy practice. Learn how the experts handled challenging medication therapy problems and worked with their patients and other health care providers to improve health outcomes. Pharmacists can sharpen their MTM skills by attending this innovative learning session.

Speaker(s): Marialice Bennett, RPh, FAPhA, The Ohio State University; Daniel E. Buffington, PharmD, Clinical Pharmacy Services, Inc.

Clinical Patient Care

Opportunistic Infections and Hepatitis Coinfection in Patients with HIV

Theme: Prevention

Level 2

3:30 pm - 5:30 pm

Convention Center, Room 31A/B

ACPE# 202-999-08-051-L02-P • 0.2 CEU

Because of their weakened immune system, patients with HIV are at an increased risk for opportunistic infections. The type and extent of infection is often associated with the CD4 count and pathogen exposure. Some infections may occur when CD4 counts are high and the patient is relatively healthy, while others tend to appear during the latter stages of the disease when CD4 counts are extremely low. Hepatitis is also common in patients with HIV and can be difficult to manage given the patient's immunocompromised state. This session will review the most commonly encountered HIV-related opportunistic infections and the appropriate treatment of such infections. The management of hepatitis will also be addressed. Pharmacists will be prepared to educate patients regarding risk factors, prevention measures, and screening for hepatitis and opportunistic infections. Emphasis will be placed on medication adherence to maintain a desired CD4 count as well as patient education strategies to reduce their exposure risk.

Speaker(s): Jennifer Cocohoba, PharmD, University of California San Francisco; Ian R. McNicholl, PharmD, BCPS, University of California San Francisco Positive Health Program at San Francisco General Hospital Medical Center Cosponsored by the Society of Infectious Disease Pharmacists.

Clinical Patient Care

Self-Care and Nonprescription Therapy for **Cardiovascular Disease**

Theme: Prevention; Cardiovascular Level 2

3:30 pm - 5:30 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-063-L01-P • 0.2 CEU

Approximately 1 in 3 Americans has at least one form of cardiovascular disease (CVD). CVD claims more lives each year than any other cause of death, including deaths from diabetes, cancer, chronic lower respiratory

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diseases, and accidents combined. Self-care prevention and treatment modalities can have a significant impact on disease progression and mortality. Either as standalone therapy or in conjunction with prescription medications, appropriate use of self-care and nonprescription products can be invaluable to disease management. This session will highlight numerous opportunities for pharmacists to assist patients with the self-care of CVD, including primary and secondary prevention strategies, blood pressure monitoring, and lipid lowering. Empowering patients to better manage CVD will be fundamental components of this session.

Speaker(s): Joseph Saseen, PharmD, FCCP, BCPS, CLS, University of Colorado Denver; Carrie Maffeo, PharmD, BCPS, CDE, Butler University

Clinical Patient Care

The Changing Landscape of Pain Management: New Approaches, Treatments, and Regulations

Level 2

<u>3:30 pm – 5:30 pm</u>

Convention Center, Room 31C

ACPE# 202-000-08-071-L01-P • 0.2 CEU

Pain management specialists routinely deal with the fine line between providing pain relief and preventing abuse. Patient and provider advocacy groups, prescribing restrictions, and new treatment options can both complicate and facilitate adequate pain management. This session will explore how to maximize the benefits of pain management while minimizing the risks. Pharmacists will learn about the recent activities and changes in the practice of pain management. Approaches to dealing with abuse and prescribing restrictions will be emphasized. Advances in treatment options will also be reviewed.

Speaker(s): Kathryn Hahn, PharmD, DAAPM, Oregon State University, Bi-Mart Pharmacy; Lisa Davis, PharmD, FCCP, BCPS, BCOP, University of the Sciences in Philadelphia

Supported by educational grants from Purdue Pharma and Endo.

Satellite Symposium

Treat to Success: The Pharmacist's Role in the Treatment of Patients with Type 2 Diabetes

6:00 pm - 8:30 pm

Hyatt, Douglas Pavilion D ACPE# 456-000-08-006-L01-P • 0.2 CEU

ACPE# 456-000-08-006-L01-T • 0.2 CEU

This symposium will provide practical information on pharmacists' role in improving glycemic control of patients with type 2 diabetes. The goal is to enhance pharmacists' abilities to facilitate patient acceptance, adherence, and optimal use of new treatment paradigms, which encourage the timely addition of advanced therapies (e.g., insulin analogs and incretins). The role of devices such as pens and pumps will also be explored.

Speaker(s): Jerry Meece, RPh, FACA, CDM, CDE, Plaza Pharmacy and Wellness Center; David L. Joffee, BSPharm, CDE, FACA, University of Florida, Sweetbay Pharmacy, DiabetesinControl.com; Scott R. Drab, PharmD, CDE, BC-ADM, University of Pittsburgh, University Diabetes Care Associates

Conducted by Global Directions in Medicine and supported by Novo Nordisk Inc.

Satellite Symposium

Case Studies in Allergic Rhinitis: Focus on Nonprescription Antihistamines

6:00 pm – 9:00 pm

Hyatt, Douglas Pavilion C

ACPE# 202-000-08-106-L01-P • 0.2 CEU

Allergic rhinitis is one of the most common chronic conditions in the United States, and one for which patients frequently seek self-treatment. The increasing nonprescription availability of second-generation antihistamines means that more patients than ever may be able to self-treat their symptoms successfully. Pharmacists can help to ensure successful self-treatment by identifying appropriate patients and assisting with product selection.

Speaker(s): Dennis M. Williams, PharmD, University of North Carolina; Maria Marzella Sulli, PharmD, St. John's University, King Kullen Pharmacy Wellness Place

Conducted by the American Pharmacists Association and supported by McNeil Consumer Healthcare.

Sunday, March 16

Satellite Symposium

Reducing Risk of Coronary Heart Disease in Patients with Hypertriglyceridemia-Associated Mixed Dyslipidemia

5:30 am - 7:30 am

Hyatt, Randle A

ACPE# 073-999-08-018-L01-P • 0.15 CEU

This symposium will review approaches to assessing CHD risk in patients with elevated TG and non–HDL–C, the pharmacologic properties and rationale for selecting agents utilized in the treatment of mixed dyslipidemia, and the application of best evidence when developing clinical care plans for risk reduction in patients with mixed dyslipidemia.

Speaker(s): James M. McKenney, PharmD, National Clinical Research, Virginia Commonwealth University School of Pharmacy; Mathew K. Ito, PharmD, FCCP, CLS, Oregon State University, Oregon Health and Science University; Harold Bays, MD, FACP, L-MARC Research Center, Louisville Endocrinology PSC

Conducted by SciMed, LLC and supported by Reliant Pharmaceuticals

Satellite Symposium

Direct Renin Inhibitors: A Novel Approach to Hypertension Management

5:45 am - 7:30 am

Hyatt, Randle D/E

ACPE# 380-000-08-001-C01-P • 0.2 CEU

The goal of this continuing education activity will be to provide pharmacists with an overview of the role of direct renin inhibition in the management of hypertension. This activity will identify and discuss a new drug class aimed at blocking renin, and examine the differences between these new agents and current treatment. This activity will emphasize the role of the pharmacist in intervening and educating patients to improve medication adherence and patient outcomes.

Speaker(s): Michael A. Weber, MD, State University of New York Downstate College of Medicine; Benjamin J. Epstein, PharmD, BCPS, University of Florida

Conducted by The CE Solution, Inc. and supported by Novartis..



Integrating Science into Practice

2008 Health Policy Forum: Medication Safety **Reform in the U.S. Health Care System**

Level 2 7:00 am - 9:00 am

Convention Center, Room 32A/B

ACPE# 202-000-08-029-L04-P • 0.2 CEU

Issues of medication safety have received considerable attention in the U.S. as reports of adverse effects have prompted prescriber warnings and the withdrawal of several commonly used medications from the market. The 2008 Health Policy Forum will present a panel of experts to discuss medication safety reform in the U.S. health care system from different perspectives. The intent of this session is to review issues confronting the current medication approval process and to learn about potential strategies to ensure the safety of medications in the U.S.

Speaker(s): Trevor Gibbs, MD, GlaxoSmithKline; Bruce M. Psaty, MD, PhD, University of Washington; Paul Seligman, MD, MPH, Food and Drug Administration

Pharmacy Law

Case Law Update

Level 1

7:00 am - 9:00 am

Convention Center, Room 33A/B

ACPE# 202-999-08-014-L03-P • 0.2 CEU

This program will focus on discussion of cases involving pharmacy or the pharmaceutical industry that have been decided over the past 12-month period. The focus will be on understanding the trends in pharmacy case law development. Presenters will explore how these cases may affect the future practice of pharmacy.

Speaker(s): William Stilling, JD, Parsons Behle & Latimer; Laura Carpenter, RPh, JD, Carpenter Law Firm, PLLC

Cosponsored by the American Society for Pharmacy Law.

Clinical Patient Care

Cervical Cancer Prevention Strategies

Themes: Prevention; Women's Health

Level 2

7:00 am - 9:00 am

Convention Center, Room 31A/B

ACPF# 202-000-08-015-101-P • 0.2 CFU

Cervical cancer is the second most common cause of cancer in women and is estimated to cause nearly 4,000 deaths each year in the United States. The primary risk factor for cervical cancer is infection with human papillomavirus (HPV). Other risk factors include smoking, middle to advanced age, multiparity, HIV infection, long-term use of oral contraceptives, infrequent Pap smears, and African American, Hispanic, and Native American ethnicity. Preventive measures can be taken to reduce a woman's risk of developing cervical cancer. This session will provide background information on cervical cancer and highlight the prevention measures that pharmacists can employ when educating patients.

Speaker(s): Kellie L. Jones, PharmD, BCOP, Purdue University; Judith Smith, PharmD, FCCP, BCOP, The University of Texas MD Anderson Cancer Center



Clinical Patient Care

Documenting MTM and Patient Care Activities Theme: MTM

Level 1

7:00 am - 9:00 am

Convention Center, Room 30C/D

ACPE# 202-000-08-026-L04-P • 0.2 CEU

This session will provide the tools and resources to help you document your MTM services effectively and efficiently. Recommended documentation procedures will be discussed, including documentation of the patient care visit, documentation for billing, and documentation for the patient. Documentation systems, both paper and electronic, will be reviewed. Participants will engage in practice documentation exercises using patient cases.

Speaker(s): Holly Divine, PharmD, CGP, CDE, University of Kentucky; Daniel E. Buffington, PharmD, Clinical Pharmacy Services, Inc.

Clinical Patient Care

Parkinson's Disease: Moving Forward with **Treatment Modalities**

Level 1

7:00 am - 9:00 am

Convention Center, Room 30A/B

ACPE# 202-999-08-053-L01-P • 0.2 CEU

Parkinson's disease is one of the most common neurodegenerative disorders, affecting about 1% of people older than 50. The incidence of Parkinson's disease increases with age. Therefore, as the population ages, the number of people diagnosed with Parkinson's disease will simultaneously increase. Currently, there is no cure for the disease; however, symptoms can be managed with appropriate therapy. A number of new and emerging medications and dosage forms are bound to improve outcomes and quality of life for those with this chronic and progressive movement disorder. This session will bring you up to date on the latest advances in the treatment of Parkinson's disease.

Speaker(s): Melody Ryan, PharmD, MPH, University of Kentucky; Bradley R. Williams, PharmD, FASCP, CGP, University of Southern California

Cosponsored by the College of Psychiatric and Neurological Pharmacists. Supported by an educational grant from Teva Neuroscience.

Clinical Patient Care

The Prevention and Management of Diabetes Complications

Themes: Prevention; Cardiovascular

Level 2 7:00 am - 9:00 am

Convention Center, Room 29C/D

ACPE# 202-000-08-075-L01-P • 0.2 CEU

Diabetes affects every organ of the body. If not controlled, a prolonged state of hyperglycemia causes microvascular and macrovascular changes, resulting in a multitude of complications, which are the primary contributors to the morbidity and mortality rates associated with diabetes. This session will explore the preventive measures and medication therapies for complications of this chronic disease, such as neuropathies, erectile dysfunction, gastroparesis, heart disease, kidney disease, and

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retinopathies. Pharmacists will learn how to screen for complications, educate patients regarding their risk for complications, and assist patients and other health care providers with the management of complications.

Speaker(s): Susan Cornell, BS, PharmD, CDE, CDM, Midwestern University Chicago; Tommy Johnson, PharmD, CDE, University of Georgia Supported by an educational grant from GlaxoSmithKline.

Clinical Patient Care

What's New in Cardiovascular Care

Theme: Cardiovascular

Level 2

7:00 am - 9:00 am

Convention Center, Room 29A/B

ACPE# 202-000-08-080-L01-P • 0.2 CEU

Our understanding of the mechanisms of cardiovascular disease and optimal treatment approaches is constantly evolving. Interpreting the results of ongoing and recently concluded clinical trials is important to be able to apply the research to clinical practice. This session will examine how the latest cardiovascular studies are influencing patient care, medication use, and patient safety.

Speaker(s): Joseph Saseen, PharmD, FCCP, BCPS, University of Colorado Denver

Supported by an educational grant from CV Therapeutics, Inc.

Clinical Patient Care; Pharmacy Technicians

When It's Lost, Replace It: Micro- and Macronutrient Supplementation

Level 1

7:00 am - 9:00 am

Convention Center, Room 30E

ACPE# 202-000-08-081-L04-P • 0.2 CEU

ACPE# 202-000-08-081-L04-T • 0.2 CEU

Micronutrients, such as vitamins and minerals, are to be consumed in minute quantities to sustain life. Macronutrients, such as carbohydrates, protein, and fat, are also essential to sustain life but are to be consumed in much larger amounts. A healthy lifestyle and well-balanced diet are often enough to maintain adequate nutrient intake. However, certain diseases, medications, conditions, and inadequate meal consumption can cause nutrient depletion. This session will highlight the various ways in which nutrients can be replaced. Given specific patient populations, medications, and diseases, pharmacists will learn to assess a patient's need for nutrient and dietary supplementation.

Speaker(s): Carol J. Rollins, MS, RD, PharmD, University Medical Center; Alan P. Agins, PhD, Brown Medical School

Supported by an educational grant from Pharmavite.

Second General Session

From Homeless to Harvard: The Unexpected Impact You Can Have to Motivate and Help Others

Level 1 9:00 am - 11:00 am

Convention Center, Ballroom 20

ACPE# 202-000-08-017-L04-P • 0.1 CEU

ACPE# 202-000-08-017-L04-T • 0.1 CEU

The APhA 2008 Annual Meeting & Exposition is an excellent venue for drawing motivation to be the best pharmacist you can be. The Second General Session will feature an awe-inspiring presentation of perseverance under the most dire circumstances yet overcoming those circumstances, and succeeding. The keynote presenter, Liz Murray, will paint the picture of how she personally overcame incredible odds to finish high school in just two years while living on the streets of New York City, then went on to graduating from Harvard on a full scholarship. Liz will describe how individuals along the way helped her in small ways to find opportunities and solutions to the simple and complex problems she faced on her journey to a better life. The session will specifically present parallels to the role pharmacists can play by simply reaching out to their patients in small ways to improve their medication-related outcomes. The issue of pharmacist involvement in encouraging and assisting patients with medication compliance issues will be featured. Interventions such as learning the patient's name, showing concern, and questioning using conversational open-ended questions will be discussed. Pharmacists taking the few minutes to better understand the adversity many of their patients face and ways to lend support will be highlighted.

Speaker(s): Liz Murray, Author, From Homeless to Harvard

Nuclear Pharmacy

Development and Production of PET Radiopharmaceuticals

Level 3

11:00 am - 1:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-024-L04-P • 0.2 CEU

An Overview of the Chemistry Pipeline or, How To Get Them In and How To Get Them Out! As the field of PET imaging grows, pharmacists will need additional insight into the development and production of current and new PET radiopharmaceuticals. The challenges from a chemistry perspective in developing new PET radiopharmaceuticals will be discussed. PET radiopharmaceutical quality control testing is demanding and the processes to validate analytic methods will be discussed.

Speaker(s): Steven S. Zigler, PhD, PETNET Solutions; Robert H. Mach, PhD, Washington University School of Medicine

Meet the Researchers: APhA Contributed Papers Poster Session

12:30 pm - 2:00 pm

Convention Center, Hall F

Attend these sessions to learn about innovative projects and cutting edge research from poster authors and researchers. Authors and researchers will be available at their posters to share in-depth information about their work, answer any questions, and engage in a dialogue about their work.



Pharmacy Administration; Pharmacy Technicians

A Team Approach to Improving Medication Use and Decreasing Medication Errors

Theme: Communication

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-002-L05-P • 0.2 CEU

ACPE# 202-000-08-002-L05-T • 0.2 CEU

Inappropriate medication use and medication errors are often a result of faulty systems, miscommunication, or environmental distractions. Collaborative efforts among pharmacists, pharmacy staff, health care providers, and patients can help to decrease medication errors and improve medication use. This session is designed to discuss how to include all pharmacy staff in the process of reducing medication errors. Each person's role on the pharmacy team will be described with an emphasis on a step-wise, systematic approach to decreasing the risk for errors. Ways to enhance communication with prescribers, other health care providers, and patients will be integral to this session. Environmental issues that contribute to errors and medication misuse will also be addressed.

Speaker(s): Donna Horn, RPh, DPh, Institute for Safe Medication Practices; Matthew Grissinger, RPh, FASCP, Institute for Safe Medication Practices

Endorsed by the New Practitioner Network.

Supported by an educational grant from the Community Pharmacy Foundation..

Pharmacy Law; Pharmacy Technicians

Legislative and Regulatory Update

Level 1

1:00 pm – 3:00 pm

Convention Center, Room 30C/D

ACPE# 202-999-08-040-L03-P • 0.2 CEU

ACPE# 202-999-08-040-L03-T • 0.2 CEU

This program will review the development of laws and regulations over the past year that affect the practice of pharmacy. Topics to be addressed include, but are not limited to, Congressional and federal agency action regarding Medicare Part D, Medicaid payment reform, tamper-resistant prescription pads, pharmacy compounding, prescription drug importation, MedGuides, RiskMAPs, electronic prescribing, a behind-the-counter category of drugs, and FDA reforms..

Speaker(s): Kristina Lunner, American Pharmacists Association; Hrant Jamgochian, Esq., American Pharmacists Association; Marcie Bough, PharmD, American Pharmacists Association

Cosponsored by the American Society for Pharmacy Law.

Supported by an educational grant from Eli Lilly and Company.



Clinical Patient Care

Migraine Management: A Pharmacist's Guide to Improving Outcomes and Quality of Life

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 31A/B

ACPE# 202-000-08-044-L01-P • 0.2 CEU

Nearly 30 million Americans suffer from migraines, many of whom self-medicate. Migraines are often undiagnosed and, therefore, are undertreated. Proper use of abortive and preventive therapies can greatly improve the quality of life for those with migraines. Pharmacists are positioned to routinely interact with these patients and can offer assistance with the self-care and medication management of migraines. This session will provide a detailed review of current management strategies, highlight new and emerging treatment options, and assist pharmacists with patient education and consultation for their patients with migraines.

Speaker(s): Charles F. Lacy, MS, PharmD, FCSHP, University of Southern Nevada; Cindy C. Selzer, PharmD, Indiana University Hospital

Pharmacy Administration; Pharmacy Technicians

Movin' on Up: Advancing the Roles of the Pharmacy Team

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 30E

ACPE# 202-999-08-067-L04-P • 0.2 CEU

ACPE# 202-999-08-067-L04-T • 0.2 CEU

New responsibilities for pharmacy technicians are being identified throughout the profession of pharmacy, transitioning the position of pharmacy technician from a job to a career. Participants will learn how training and certification are the keys to professional advancement. The use of certified pharmacy technicians frees up the pharmacist for patient-focused services. Speakers will highlight the opportunities available for pharmacy technician advancement. A PTCB update for 2008 including accreditation status and consumer perceptions will be presented. Evolution and the future of regulation of pharmacy technicians will be reviewed. The session will discuss the benefits of creating a career path for technicians with a focus on training, recruitment, and retention.

Speaker(s): Melissa Madigan, PharmD, JD, National Association of Boards of Pharmacy; Melissa Murer Corrigan, RPh, Pharmacy Technician Certification Board; Maria Boyle, MS, RPh, National Association of Boards of Pharmacy; Miriam A. Mobley-Smith, PharmD, Chicago State University

Cosponsored by the Pharmacy Technician Certification Board.



Clinical Patient Care; Pharmacy Technicians

Patience with Your Patients: Communication and Interviewing Techniques for Challenging MTM Encounters

Themes: MTM; Communication Level 2

1:00 pm - 3:00 pm

Convention Center, Room 30A/B

ACPE# 202-000-08-054-L04-P • 0.2 CEU

ACPE# 202-000-08-054-L04-T • 0.2 CEU

With the increasing number of patients taking advantage of MTM services, and as more pharmacists begin providing MTM services, the potential for communication barriers also increases. This session will explore how to handle language barriers, literacy challenges, resistance to change, financial restrictions, over-communicators, dementia, behavioral resistance to change, and other obstacles to providing effective MTM services.

Speaker(s): Mary Ann Kliethermes, PharmD, University of Illinois at Chicago; Sandra Leal, PharmD, CDE, Association of Clinicians for the Underserved (ACU), HRSA Pharmacy Services Support Center, El Rio Health Center Supported by an educational grant from Wyeth.

Integrating Science into Practice; Preceptors

Practice-Based Research to Improve Health Outcomes

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 29C/D

ACPE# 202-000-08-055-L04-P • 0.2 CEU

In a health care industry that places a great deal of emphasis on evidenced-based medicine, the medical literature is in constant need of quality research and outcomes reporting. Pharmacists, preceptors, pharmacy residents, and student pharmacists engaged in research activities are prime candidates to contribute to health care outcomes and the medical literature. Pharmacy-based research and publication are excellent means to promote pharmacy practice and the role of the pharmacist in health care. This session will provide guidance for those wanting to be more involved with research and the medical literature. Emphasis will be placed on project development and manuscript preparation.

Speaker(s): Jon Schommer, PhD, University of Minnesota; William Doucette, PhD, University of Iowa

Supported by an educational grant from Merck & Co, Inc.

Clinical Patient Care

Screening for Disease: Risk Assessment and Point-of-Care Testing by Pharmacists

Themes: Prevention; Cardiovascular Level 1

1:00 pm – 3:00 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-062-L04-P • 0.2 CEU

Numerous opportunities exist for pharmacists to identify patients at risk for chronic conditions. Metabolic syndrome, prehypertension, and prediabetes are all examples of criteria typically used to identify patients at high risk of

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developing these respective diseases. Other screening tools and devices are available for conditions such as osteoporosis, dyslipidemia, and obesity. If detected and managed early, patients have a better chance at avoiding disease progression. Pharmacists should be able to recognize high-risk patients and assist them with risk reduction. This session will define the roles of pharmacists in screening for disease and point-of-care testing activities.

Speaker(s): Jennifer L. Rodis, PharmD, The Ohio State University; Kelly Brock, PharmD

AIHP Contributed Papers Podium Session

1:00 pm - 4:00 pm

Hyatt, Edward A

- Drug metabolism in textbooks commonly used in pharmacy schools. <u>Griffith R</u>, West Virginia University School of Pharmacy/ American Institute of the History of Pharmacy. (232))
- Early nineteenth-century physician-apothecaries in Ouachita Parish, Louisiana. <u>Sirmans S</u>, University of Louisiana at Monroe College of Pharmacy/American Institute of the History of Pharmacy. (233)
- Issues in developing a history of public health for pharmacy students. <u>Slack M</u>, University of Arizona. (234)
- Medicine bottles from Deadwood's historic Chinatown. Collison P, University of South Dakota. (235)
- Moral courage among practicing pharmacists: An historical perspective. <u>Gettman D</u>, University of Appalachia College of Pharmacy. (236)
- Morris Bealle, anti-establishment advocate and author of Drug Story. <u>Palmieri A</u>, University of Florida College of Pharmacy/ American Institute of the History of Pharmacy. (237)
- Pharmaceutical practices in Mexico: Spanish Empire period. <u>DeVos P</u>, San Diego State University/American Institute of the History of Pharmacy. (238)
- Sister pharmacists and hospital pharmacy practice from the 1800s to the 1970s. <u>Henderson M</u>, Wright S, American Institute of the History of Pharmacy/Independent Researchers. (239)

Presented by the American Institute of the History of Pharmacy and cosponsored by the American Pharmacists Association.

Nuclear Pharmacy

Regulatory Update

Level 3

2:00 pm - 5:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-058-L03-P • 0.3 CEU

This program is designed to provide an overview and current thinking on two very important regulatory areas of nuclear pharmacy practice: rules and regulations regarding the transportation of radiopharmaceuticals and USP Chapter 797. The appropriate interpretation and adherence to Department of Transportation regulations are vital to the safety and success of nuclear pharmacy practice. The development and implementation of USP Chapter 797 has significant impact on the practice methodology as well as laboratory design and equipment requirements for nuclear pharmacy laboratories and personnel.

Speaker(s): Sam Augustine, PharmD, Creighton University; Timothy M. Quinton, Radiopharmacy, Inc.; S. Duann Vanderslice, RPh, BCNP, FAPhA, IBA Molecular North America



Clinical Patient Care

The Boom in Biologics I: Unique Treatment Options for Chronic Conditions

Level 1

3:30 pm - 4:30 pm

Convention Center, Room 29C/D

ACPE# 202-000-08-069-L01-P • 0.1 CEU

Biologics are unique medications that are derived from human or animal protein and target the immune system. For example, in patients with psoriasis and rheumatoid arthritis, tumor necrosis factor-alpha (TNF-alpha) is overproduced by activated T cells. Biologics stop disease progression by inhibiting the communication between TNF-alpha and T cells. Monoclonal antibodies are used in cancer treatment as a form of passive immunotherapy to illicit an immune response to the cancer cells. Technological advancements for biologic agents continue to give patients new alternatives to manage their diseases. This session will highlight various classes of biologic medications and their intended uses. Pharmacists will learn how they work, appropriate candidates for therapy, and important counseling points with regard to their use.

Speaker(s): Stan Louie, PharmD, University of Southern California Supported by an educational grant from Amgen.

Clinical Patient Care

Advances in the Treatment of Fibromyalgia

Level 1

3:30 pm - 5:30 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-004-L01-P • 0.2 CEU

Fibromyalgia is a chronic disorder that affects as many as 1 in 50 Americans. Fibromyalgia is often misunderstood and may go unrecognized while the patient continues to suffer from significant symptoms. If this condition is not identified and managed appropriately, fibromyalgia can be debilitating, interfering with a patient's ability to function and perform activities of daily living. This session will provide an overview of fibromyalgia and discuss the current treatment options for this disorder. A promising new therapy will be highlighted. Pharmacists will learn how to play a role in the treatment and management of fibromyalgia.

Speaker(s): Linda Krypel, PharmD, FAPhA, Drake University; Raylene M. Rospond, PharmD, FCCP, BCPS, Drake University

Integrating Science into Practice

APhA-APRS ESAS Contributed Papers Podium Session II

Level 2

3:30 pm - 5:30 pm

Convention Center, Room 30E

ACPE# 202-000-08-007-L04-P • 0.2 CEU

Researchers will make 15-minute presentations of their research findings. A question-and-answer session will follow.

- Young consumers' risk perceptions of OTC pain relievers: A randomized experiment examining the effects of product risks and benefits presented on a label. <u>Sangasubana N</u>, Nova Southeastern University, Bentley J, University of Mississippi. (223)
- Use of the Andersen Healthcare Utilization Model to determine factors associated with complementary and alternative November 14, 2008



medicine use in African Americans. Bohman T, <u>Barner J</u>, Brown C, Richards K, University of Texas College of Pharmacy. (222)

- Pharmacists' actions when patients use complementary and alternative therapies with medications in Texas-Mexico border cities. <u>Brown C</u>, Pena A, Resendiz K, University of Texas at Austin. (207)
- Identification and creation of knowledge-based content and validation of a measure to assess pharmacist knowledge of herbal and dietary supplements: Preliminary study. Lin H, Pickard A, Mahady G, Popovich N, University of Illinois at Chicago. (190)

Facilitator: Sujit S. Sansgiry, PhD, University of Houston

Pharmacy Law; Pharmacy Technicians

FDA Update

Level 2

3:30 pm – 5:30 pm

Convention Center, Room 32A/B

ACPE# 202-999-08-030-L03-P • 0.2 CEU

ACPE# 202-999-08-030-L03-T • 0.2 CEU

The program will review FDA initiatives and actions over the past year that affect the practice of pharmacy. Topics to be addressed include drug safety, medication guides, and other patient information, counterfeit drugs, drug importation, unapproved drugs, pharmacy compounding, bar codes, drug approvals, and other recent activities.

Speaker(s): Ilisa B.G. Bernstein, PharmD, JD, US Food and Drug Administration

Cosponsored by the American Society for Pharmacy Law.

Clinical Patient Care; Pharmacy Technicians

Growing in the Wrong Direction: Managing Childhood Obesity

Themes: Prevention; Cardiovascular Level 2

3:30 pm – 5:30 pm

Convention Center, Room 31A/B

ACPE# 202-000-08-034-L01-P • 0.2 CEU

ACPE# 202-000-08-034-L01-T • 0.2 CEU

With the growing prevalence of obesity among adolescents, a significant toll is placed on the American health care system. Projections are now being made for the health care costs and resources necessary to manage these individuals as they advance into their third and fourth decades of life. The long term effects of childhood obesity and the inherent risk for heart disease is profound. There is an urgent need to assist children with healthy weight management. This session will highlight the ways that pharmacists can help obese children and their parents with weight loss efforts. Medication therapy and surgical interventions will be discussed. Statewide and global initiatives to combat childhood obesity will also be addressed.

Speaker(s): Edward A. Bell, PharmD, BCPS, Drake University; Seena L. Haines, PharmD, Palm Beach Atlantic University



Clinical Patient Care

Menopause: The Onset of New Health Care Needs

Theme: Women's Health

Level 1

3:30 pm - 5:30 pm

Convention Center, Room 30A/B

ACPE# 202-000-08-042-L01-P • 0.2 CEU

The physiological and hormonal changes that women experience with menopause bring about the need to address subsequent health care issues. The loss of estrogen leads to unwanted effects such as hot flashes and other vasomotor symptoms, mood swings, and sexual dysfunction, as well as a decrease in bone density. Postmenopausal women are also more prone to heart disease. This session will review the physiological and emotional changes experienced by women going through menopause. New pharmacological entities for postmenopausal health issues will be highlighted. Pharmacists will also learn about prevention measures and selfcare approaches to assist women going through menopause.

Speaker(s): Kathleen Haynes, PharmD, BCPS, VEI/Community Health Network; Laura B. Hansen, PharmD, FCCP, BCPS, University of Colorado Denver

Supported by an educational grant from Wyeth.

Clinical Patient Care; Pharmacy Technicians

Safe Travels: Advice for International Travelers

Theme: Prevention

Level 1

3:30 pm – 5:30 pm

Convention Center, Room 30C/D

ACPE# 202-000-08-061-L04-P • 0.2 CEU

ACPE# 202-000-08-061-L04-T • 0.2 CEU

International travel, although exciting, can raise many concerns for patients during the planning phase and before departure. Vaccine-preventable diseases, gastrointestinal organisms, problematic insects, and first aid issues can make planning for travel a confusing and challenging process. This session will explore the appropriate use of nonprescription products for the prevention and maintenance of travel-related ailments. Vaccination requirements for certain geographic areas will also be addressed. Pharmacists will learn how to identify and counsel patients with travel-related needs so that patients can stay healthy regardless of their destination.

Speaker(s): Jeffery A. Goad, PharmD, MPH, FCPhA, FCSHP, University of Southern California; Dennis D. Stanley, RPh, Ukrop's Super Markets Pharmacy

Supported by an educational grant from VaxServe.

Clinical Patient Care

The Boom in Biologics II: The Emergence of Biosimilar Products

Level 2

4:45 pm – 5:45 pm

Convention Center, Room 29C/D

ACPE# 202-000-08-070-L01-P • 0.1 CEU

Since the introduction of human insulin in 1982, significant advancements in the biologic industry have been made. New chemical entities and delivery methods for biologic agents continue to offer patients disease management alternatives. As patents for biologics approach their expiration dates, follow-on biologics will begin to emerge. This session will highlight the various classes of biologic medications and the implications of the follow-on approval process and use of biosimilar products.

Speaker(s): Joshua W. Devine, PharmD, PhD, DoD Pharmacoeconomic Center

Supported by an educational grant from Amgen.

Satellite Symposium

COPD: Expanding the Key Role of the Pharmacist

6:00 pm - 9:00 pm

Hyatt, Elizabeth Parlor D

ACPE# 202-000-08-108-L04-P • 0.2 CEU

Chronic obstructive pulmonary disease (COPD) has been called "the largest uncontrolled epidemic of disease in the United States today." Although COPD cannot be cured, recent advances in our understanding of the disease process — coupled with the introduction of effective new therapies — provide substantial opportunity for improved patient survival and quality of life. Pharmacists are in a key position to contribute to many important aspects of disease management.

Speaker(s): Karen J. Tietze, PharmD, University of the Sciences in Philadelphia; Dennis M. Williams, PharmD, University of North Carolina

Conducted by the American Pharmacists Association and supported by Boehringer Ingelheim Pharmaceuticals, Inc. and Pfizer Inc.

Satellite Symposium

Setting Expectations with Weight Loss Patients

6:00 pm – 9:00 pm

Hyatt, Elizabeth Parlor E

ACPE# 202-000-08-105-L01-P • 0.2 CEU

Patients who embark on a weight loss program often do so with high hopes and great expectations. But those expectations can be the downfall of even the most committed dieter. Patients often have unrealistic ideas about the amount of weight they will lose and the rate at which they will lose it. They also often are unprepared for the challenges of maintaining a calorie deficit in our "supersized" environment, so they end up relying on willpower instead of "skill power." Pharmacists who have a clear understanding of what is and is not possible in weight management can help patients avoid common traps and set appropriate expectations.

Speaker(s): Regina Mears, BPharm, MA, Life Management, Target Pharmacy; Renee Ahrens, PharmD, MBA, RBT Consulting

Conducted by the American Pharmacists Association and supported by GlaxoSmithKline Consumer Healthcare.



Monday, March 17

Satellite Symposium

Managing the Complexity of Type 2 Diabetes in the Community and Outpatient Environment

5:30 am - 7:30 am

Hyatt, Randle A

ACPE# 221-000-08-003-L01-P • 0.15 CEU

ACPE# 221-000-08-003-L01-T • 0.15 CEU

According to the CDC, 7% of the U.S. population is living with Type 2 diabetes (T2DM) and are at elevated risk of morbidity and mortality. Pharmacists need to work within the health care team to manage T2DM patients to goal. This program will prepare pharmacists to be active team members by discussing treatment strategies, management of combination therapy, cardiovascular risk and monitoring, patient education, and strategies to maximize patient outcomes.

Speaker(s): David W. Bartels, PharmD, BCPS, CDE, FCCP, University of Illinois at Chicago, University of Illinois at Rockford College of Medicine; Anne L. Peters, MD, FACP, CDE, University of Southern California; Curtis Triplitt, PharmD, CDE, Texas Diabetes Institute, University of Texas Health Science Center at San Antonio

Conducted by Pro CE, Inc. and supported by Takeda Pharmaceuticals North America, Inc.

Clinical Patient Care

Advances in the Treatment of Opioid-Induced Constipation

Theme: Prevention

Level 2

7:30 am - 9:30 am

Convention Center, Room 31C

ACPE# 202-000-08-005-L01-P • 0.2 CEU

Opioid-related constipation is one of the most frequent side effects of chronic pain treatment. More than 250,000 terminal cancer patients each year take opioids and more than half experience constipation. The discomfort can be so great that patients may choose to forego taking their medications for pain relief to avoid the constipation effect. Fortunately, there are both preventable measures and treatment options for these patients, and the pharmacist can play a pivotal role in the management of their pain. This session will provide pharmacists with an understanding of the current prevention and treatment strategies, including emerging therapies, for opioid-induced constipation so that they can have a greater impact on patients' treatment success and quality of life.

Speaker(s): Cindy L. O'Bryant, PharmD, BCOP, University of Colorado Denver; Sunny Linnebur, PharmD, FASCP, BCPS, CGP, University of Colorado Denver

Supported by an educational grant from Wyeth.



Integrating Science into Practice

APhA-APRS ESAS Contributed Papers Podium Session III Level 2

7:30 am - 9:30 am

Convention Center, Room 30A/B

ACPE# 202-000-08-008-L04-P • 0.2 CEU

Researchers will make 15-minute presentations of their research findings. A question-and-answer session will follow.

- Norm balance in predicting pharmacists' intention to collaborate with physicians to improve medication therapy. Liu Y, Doucette W, Farris K, University of Iowa. (199)
- Patterns of Osteoporosis Prevention and Therapy Between 1997 and 2004 Using United States National Survey Data. <u>Maneno M</u>, Lee E, Wutoh A, Howard University Center for Minority Health Services Research; Zuckerman I, University of Maryland Baltimore, School of Pharmacy. (202)
- Ask, Advise, and Refer: A Thematic Analysis for Generating Hypotheses to Promote Adoption of a Brief Tobacco Cessation Intervention in Community Pharmacies. <u>Patwardhan</u> P, Chewning B, University of Wisconsin. (171)
- Pharmacist Attitudes Toward Mental Illness and Provision of Pharmacy Services. <u>Rickles N</u>, Northeastern University; Singh R, Montagne M, Massachusetts College of Pharmacy and Health Sciences. (203)
- Community Pharmacy Managers' Role Orientation Does Ownership Matter? <u>Perepelkin J</u>, Dobson R, University of Saskatchewan. (174)
- Key Factors Affecting Pharmacist-Physician Collaboration: The Perspective from Pharmacists. Liu Y, Doucette W, Farris K, University of Iowa. (193)

Clinical Patient Care; Pharmacy Law; Pharmacy Technicians

Drug Diversion: The Inside Scoop

Level 1

7:30 am - 9:30 am

Convention Center, Room 31A/B

ACPE# 202-999-08-027-L03-P • 0.2 CEU

ACPE# 202-999-08-027-L03-T • 0.2 CEU

Drug diversion is the use of prescription drugs for illicit purposes and has taken a toll on both the criminal justice and health care systems. As the prevalence of drug diversion has increased in the United States., the DEA has become more active in developing programs and strategies to combat this activity. Real-life scenarios will be used to illustrate how drug diversion affects the practice of pharmacy. Pharmacists will learn about the drugs most commonly used illicitly, as well as prevention measures and patient education activities.

Speaker(s): Mark W. Caverly, Drug Enforcement Administration

Cosponsored by the American Society for Pharmacy Law.

Supported by an educational grant from Alpharma.



Clinical Patient Care

New Drugs of 2007

Level 1

7:30 am - 9:30 am

Convention Center, Room 32A/B

ACPE# 202-000-08-047-L01-P • 0.2 CEU

Be sure to take your seat early for this recurring Annual Meeting favorite! Key information about medications marketed during 2007 will be reviewed, including indications for use, routes of administration, and associated precautions. The new drugs will be compared with established therapeutic options whenever possible. Patient counseling tips and practical monitoring considerations are provided.

This course is also offered on Friday, March 14 at 3:30 pm.

Speaker(s): Daniel A. Hussar, PhD, University of the Sciences in Philadelphia

Clinical Patient Care; Pharmacy Technicians

Not If, But When: Preparing Pharmacists for an Influenza Pandemic

Theme: Prevention

Level 2

7:30 am - 9:30 am

Convention Center, Room 30C/D ACPE# 202-999-08-049-L01-P • 0.2 CEU

ACPE# 202-999-08-049-L01-T • 0.2 CEU

An influenza pandemic would bring severe illness, death, and a societal burden. As seen in years past, the worldwide death toll can be in the millions. It is likely a matter of time until the next pandemic occurs. Fortunately, there are ongoing preparatory measures led by the U.S. government and the World Health Organization to detect, prevent, and manage influenza outbreaks that could lead to pandemics. This session will explore the roles that pharmacists can play in pandemic preparedness. Emphasis will be placed on planning and response activities, as well as patient education strategies.

Speaker(s): Craig Martin, PharmD, BCPS, University of Kentucky, University of Kentucky Health Care; Michael Klepser, PharmD, Ferris State University Cosponsored by the Society of Infectious Disease Pharmacists.

Supported by an educational grant from VaxServe.

Clinical Patient Care

The Appropriate Treatment and Management of ADHD

Level 1 7:30 am - 9:30 am

Convention Center, Room 33A/B

ACPE# 202-999-08-068-L01-P • 0.2 CEU

An alarming number of children are routinely diagnosed with ADHD, which has increased over the years. Unfortunately, other conditions such as sleep disorders, hearing impairment, autism, and adverse medication effects are commonly mistaken for ADHD. In other instances, children with ADHD go undiagnosed and are alternatively classified as "problem children." To complicate the management of ADHD, patients may have other disorders that commonly accompany the condition, such as anxiety, depression, and bipolar disorder. This session will review the classic signs and symptoms of ADHD, as well as those common disorders that are often misdiagnosed as ADHD or associated with ADHD. Pharmacists will learn appropriate intervention and counseling strategies to better assist parents and caregivers. Appropriate treatment strategies will also be explored.

Speaker(s): Julie A. Dopheide, PharmD, BCCP, University of Southern California; William A. Kehoe, PharmD, MA, FCCP, BCPS, University of the Pacific

Cosponsored by the College of Psychiatric and Neurological Pharmacists.

Supported by an educational grant from McNeil Pediatrics, administered by Ortho-McNeil Janssen Scientific Affairs, LLC.

Clinical Patient Care

Venous Thromboembolism: Prevention and Treatment Strategies

Theme: Prevention; Cardiovascular

Level 1

7:30 am - 9:30 am

Convention Center, Room 29C/D

ACPE# 202-000-08-079-L01-P • 0.2 CEU

Venous thromboembolism (VTE) is often a result of a triad of events including venous stasis, vascular injury, and a hypercoagulable state. Age, history of VTEs, and adverse effects of some medications can also contribute to the development of VTEs. VTE is classified as either a deep vein thrombosis (DVT) or pulmonary embolism, both of which can be life threatening. A DVT is sometimes referred to as "economy-class syndrome," referring to airplane travel that subjects patients to long durations of immobility and low cabin pressure. VTE has received more attention in the past few years, as they strike at any time and affect patients in various age groups, especially women taking oral contraceptives, pregnant women, and those who are otherwise healthy. Many of the acquired risks for VTEs are modifiable. Pharmacists can, therefore, play a role in educating patients about VTE risk reduction and assist with the screening process. This session will highlight key patient populations, screening tools, and the prophylaxis and treatment strategies for VTEs.

Speaker(s): Stuart T. Haines, PharmD, BCPS, University of Maryland; Henry I. Bussey, PharmD, FCCP, FAHA, The University of Texas at Austin, The University of Texas Health Science Center at San Antonio, The Medical Park at Stone Oak, ClotCare.com, ClotFree System

Supported by an educational grant from sanofi-aventis U.S.



Nuclear Pharmacy

Dark Age Magic to New Age Hope: The Nuclear Imaging Revolution Level 3

8:00 am - 12:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-023-L01-P • 0.4 CEU

This program is designed to provide attendees with an overview of significant changes to nuclear pharmacy practice as it merges with the molecular imaging age. Radiopharmaceuticals, instrumentation, and new imaging approaches to disease management will be discussed. The session will highlight the historical development of radiopharmaceuticals and their use in nontraditional uses and explore new MRI, CT, PET, and SPECT molecular imaging technology.

Speaker(s): Ronald J. Callahan, PhD, Massachusetts General Hospital; Vibhu Awashi, PhD, BCNP, University of Oklahoma Health Science; Dee Wu, PhD, Radiological Sciences, The University of Oklahoma Health Sciences Center; Jack Juni, MD, FACNP, CardiArc

Supported by an educational grant from GE Healthcare.

Integrating Science into Practice; Pharmacy Technicians

The Smithsonian's National Pharmacy Collection As a Resource for Pharmacists

Level 1

9:00 am - 11:00 am

Convention Center, Room 30E

ACPE# 202-999-08-076-L04-P • 0.2 CEU

ACPE# 202-999-08-076-L04-T • 0.2 CEU

Artifacts, documents, and other objects related to pharmacy have been collected, studied, and exhibited at the Smithsonian Institution since the establishment of the Section of Materia Medica in the Department of Anthropology of the U.S. National Museum in 1881. Many of the curators of the pharmacy collections were pharmacists, and ties with the pharmacy profession and industry were close. Pharmacists can learn about the practice innovations over the years and extrapolate these to recent changes and future changes. When counseling patients, pharmacists will be able to provide a historical perspective on therapy advancements. This program will feature three Smithsonian curators who will describe these changes and how they affect the national pharmacy collection, especially access to this valuable resource by pharmacists.

Speaker(s): Eric Jentsch, MA, Smithsonian Institution, National Museum of American History; Diane Wendt, BA, Smithsonian Institution, National Museum of American History; Ramunas Kondratas, PhD, Smithsonian Institution, National Museum of American History

Presented by the American Institute of the History of Pharmacy and cosponsored by the American Pharmacists Association.



Clinical Patient Care; Pharmacy Administration; Pharmacy Technicians

Protecting Patients from the Threat of Counterfeit Drugs

Level 2

10:00 am - 11:00 am

Convention Center, Room 32A/B

ACPE# 202-000-08-083-L05-P • 0.1 CEU

ACPE# 202-000-08-083-L05-T • 0.1 CEU

The increased prevalence of counterfeit drugs is a growing public health problem in the United States Counterfeit drugs threaten the integrity of the nation's drug supply and pose a significant risk to the health and safety of patients. This session will describe the growing problem of counterfeit drugs, including factors driving the market for counterfeit drugs. Pharmacists will learn about the methods that are being used to identify counterfeit drugs, how some of the regulations may affect current practice, how to report a counterfeit product and to educate patients about counterfeits.

Speaker(s): Ilisa B.G. Bernstein, PharmD, JD, US Food and Drug Administration Supported by an educational grant from Eli Lilly and Company.

Clinical Patient Care; Pharmacy Technicians

OSHA Training Course: Maintaining Compliance with the Bloodborne Pathogens Standard

Level 1

10:00 am - 11:00 am

Convention Center, Room 33A/B

ACPE# 202-000-08-052-L03-P • 0.1 CEU

ACPE# 202-000-08-052-L03-T • 0.1 CEU

Pharmacists whose job responsibilities include handling diabetes meters, lancets, or syringes or those who are involved with screening activities that require point-of-care testing and specimen analysis need to receive Occupational Safety and Health Administration (OSHA) training on an annual basis. Pharmacists who engage in these activities are at risk of exposure to bloodborne pathogens, including hepatitis, HIV, and other potentially infectious materials. This session is designed to meet the OSHA training requirements for those individuals who do not routinely receive such training. Attendees will learn how to recognize bloodborne pathogen hazards, how to minimize exposure risk, the proper post-exposure response, and recordkeeping requirements.

Speaker(s): Stephan L. Foster, PharmD, FAPhA, University of Tennessee Memphis

Supported by an educational grant from Sharps Compliance.

November 14, 2008



Pharmacy Administration; Pharmacy Law; Pharmacy Technicians

Fraud and Abuse: Maintaining Compliance with Federal and State Regulations

Level 1

10:00 am - 12:00 pm

Convention Center, Room 30C/D

ACPE# 202-999-08-033-L03-P • 0.2 CEU

ACPE# 202-999-08-033-L03-T • 0.2 CEU

Government agencies and health plans have recently imposed significant new fraud and abuse compliance requirements on pharmacists and pharmacies. This session will review the Medicare and Medicaid criteria, including employee training, development of whistleblower and conflict of interest policies, and penalties for hiring persons excluded from Medicare, Medicaid, and other government programs. Additionally, major new audit programs initiated by government agencies and health plans will be reviewed. Critical fraud and abuse compliance laws, such as anti-kickback statutes, will also be addressed.

Speaker(s): Don Bell, II, JD, National Association of Chain Drug Stores Cosponsored by the American Society for Pharmacy Law.

Clinical Patient Care

New Products, Technology, and Treatment Options for Patients with Diabetes

Theme: Cardiovascular Level 2

10:00 am - 12:00 pm

Convention Center, Room 31A/B

ACPE# 202-000-08-048-L01-P • 0.2 CEU

The diabetes care market is constantly evolving. New medications, products, and treatment recommendations are introduced each year. This session explores the therapeutic changes and product innovations seen during the past year. Pharmacists will be better prepared to educate patients and interact with other health care practitioners to improve the diabetes care they provide.

Speaker(s): R. Keith Campbell, RPh, CDE, FAPhA, Washington State University; Amy Nicholas, PharmD, CDE, University of Kentucky Supported by an educational grant from Merck & Co, Inc. Clinical Patient Care

Psychological Issues in Adolescents and Young Adults

Level 2

10:00 am - 12:00 pm

Convention Center, Room 29C/D

ACPE# 202-999-08-057-L01-P • 0.2 CEU

At least one in five adolescents has a mental health disorder, which is often due to environmental or genetic causes. As different sections of the brain mature at different rates, adolescents become more vulnerable to addictive behavior and mental illness. The drastic hormonal changes that adolescents experience can also lead to emotional and behavior problems. Understanding and managing these issues can be extremely challenging, both for parents and health care providers, especially given the safety concerns surrounding the medications used in adolescents with mental illness. This session will review the psychological disorders commonly seen in adolescents and young adults. The warning signs, counseling needs, and therapies for various mental health disorders will be discussed.

Speaker(s): Kara Lee Shirley, PharmD, BCPS, BCPP, Western Psychiatric Institute and Clinic; Jason M. Noel, PharmD, BCCP, University of Maryland

Cosponsored by the College of Psychiatric and Neurological Pharmacists.

Supported by an educational grant from Bristol-Myers Squibb/Otsuka America Pharmaceutical, Inc.

Clinical Patient Care; Integrating Science into Practice

Show Me the Numbers: Simple Approaches to Interpreting Clinical Trials and Patient Safety Data

Level 2

10:00 am – 12:00 pm

Convention Center, Room 31C

ACPE# 202-000-08-065-L05-P • 0.2 CEU

With evidence-based medicine driving therapeutic recommendations, it is important to understand the research methods and statistics that provide the evidence; this is especially true now that patient safety data has become such an important focus when determining the applicability of medications in clinical practice. FDA must take patient safety issues into consideration when approving a new drug, revising package labeling, or deciding to remove a drug from the market. Practitioners need to be able to interpret the research when patient safety concerns are raised. This session will review basic statistics and outcomes measures to provide pharmacists, preceptors, students, and residents with a better understanding of the medical literature and research. Methods to accurately interpret and analyze patient safety data will be emphasized.

Speaker(s): Elaine Chiquette, PharmD, BCPS, Amylin Pharmaceuticals Inc.; Amy Heck Sheehan, PharmD, Purdue University



Pharmacy Technicians; Professional Development

Unleashing the Inner Activist: Political Action 101

Theme: Communication Level 1

10:00 am – 12:00 pm

Convention Center, Room 30A/B

ACPE# 202-000-08-078-L04-P • 0.2 CEU

ACPE# 202-000-08-078-L04-T • 0.2 CEU

This session will describe how pharmacists can get involved in the political process and help bring about change regarding issues that affect them. Presenters will explain how legislation paves the way for change in pharmacy practice and patient care. Examples of ways pharmacists can foster relationships with legislators will be provided.

Speaker(s): Jennifer Fix, RPh, MBA, Medicine Shoppe; Endorsed by the New Practitioner Network.

Clinical Patient Care

Assisted Reproduction: Cycling Through the Treatment Options

Theme: Women's Health

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 31C

ACPE# 202-000-08-010-L01-P • 0.2 CEU

College, careers, and lifestyles have resulted in couples waiting longer to conceive. Infertility is often an unfortunate consequence of attempting to reproduce later in life; it can also be caused by physiologic conditions in both men and women. In vitro fertilization and assisted reproduction therapy are becoming more common as technology and new treatment options are introduced to the marketplace. The session will highlight the treatment options for couples having difficulty with conception.

Speaker(s): Karen M. Gunning, PharmD, University of Utah; Shareen El-Ibiary, PharmD, BCPS, University of California San Francisco

Professional Development

Career Awareness Roundtable

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 33A/B

ACPE# 202-000-08-013-L04-P • 0.2 CEU

Using a roundtable format, this session is designed to provide information and examples that will aid student pharmacists, residents, and transitioning practitioners in making informed decisions on ways to develop a rewarding practice. Participants will begin with a career planning discussion, followed by roundtable presentations that provide an opportunity to interact directly with pharmacists from a variety of practice settings.

- Nuclear Pharmacy. Nicki L. Hilliard, PharmD, MHSA, BCNP, FAPhA, University of Arkansas for Medical Sciences
- Care for the Underserved. Seena L. Haines, PharmD, FAACP, Palm Beach Atlantic University
- Academia. Robert Day, PharmD, University of California, San Francisco



- Federal Pharmacy. Christopher Lynch PharmD, MEd, Naval School of Health Sciences
- Clinical Community Practice. Daniel Forrister, PharmD, University of Georgia
- Drug Information. Candy Tsourounis, PharmD, University of California San Franciisco
- MTM Consulting. Marisa Soto, PharmD, CDE, El Rio Health Center
- Independent Pharmacy. Vincent Hartzell, PharmD, Hartzell's Pharmacy
- Hospital Administration. Christie Robinson, PharmD, BCPS, University of California San Francisco
- Postgraduate Studies and Research. Elliott Sogol, PhD, RPh, FAPhA, American Pharmacists Association

Supported by an educational grant from Healthy Careers.

Clinical Patient Care; Pharmacy Administration

Establishing a Financially Viable MTM Practice Theme: MTM

Level 2

1:00 pm – 3:00 pm

Convention Center, Room 31A/B

ACPE# 202-000-08-064-L04-P • 0.2 CEU

Medication therapy management (MTM) services offer great opportunities and rewards for the future of pharmacy practice, but some pharmacists have said, "Show Me the Money!" before they are willing to get started. As the demand for MTM services continues to rise, the need for financially viable business models is a necessity. This session will show you how to build a successful business model for the provision of MTM in your practice by guiding you through a strategy for promoting MTM services to your patients and other health care providers, identifying payers, and determining how to calculate the return on investment for the services offered. Additional information will be provided about working as an independent contractor for MTM service delivery. Learn how you and your practice can benefit from MTM today!

Speaker(s): Joe E. Heidrick, RPh, PharmD, KDI Health Solutions, LLC; LeAnn Causey Boyd, PharmD, BCPS, CDE, Causey's Pharmacy dba Causey's Rx Solutions

Endorsed by the New Practitioner Network.



Clinical Patient Care

Managing the 3 D's in the Elderly: Depression, Dementia, and Delirium

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 30A/B

ACPE# 202-999-08-041-L01-P • 0.2 CEU

The prevalence of depression seems to increase with age and suicide rates tend to be higher in older adults. Depression commonly occurs in patients with dementia and it is difficult to identify depression in these individuals. Dementia and depression in the elderly often present with similar symptoms and delirium is often mistaken for dementia or vice versa. Therefore, when depression is coupled with dementia or delirium, the management of these coexisting conditions in the elderly can be quite cumbersome. This session will uncover the issues important to pharmacists providing care for individuals with these disorders. The presentation will discuss the differences and similarities, common causes, expected disease progression, and treatment options for depression, dementia, and delirium.

Speaker(s): Patrick R. Finley, PharmD, BCPP, University of California at San Francisco; Ryan Carnahan, PharmD, MS, BCPP, The University of Oklahoma

Cosponsored by the College of Psychiatric and Neurological Pharmacists.

Hospital Practice

Mental Health and Substance Abuse Disorders: From Inpatient to Outpatient

Level 2

1:00 pm - 3:00 pm

Convention Center, Room 30C/D

ACPE# 202-999-08-043-L01-P • 0.2 CEU

Nearly 1 in 4 adults admitted to community hospitals have mental health or substance abuse (MHSA) disorders. This trend accounts for about one-fourth of hospital resources used. To decrease the extensive use of such resources, there is an obvious need for earlier intervention and more aggressive management of MHSA disorders during and after admission. This session presents the latest data surrounding MHSA disorders in community hospitals. Pharmacists will learn management strategies for the inpatient stay and upon discharge.

Speaker(s): Anthony Tommasello, PharmBS, MS, PhD, Office of Substance Abuse Studies, University of Maryland; Darryl Inaba, PharmD, CADC III, University of California, San Francisco

Cosponsored by the College of Psychiatric and Neurological Pharmacists.

Clinical Patient Care

MRSA: A Growing Bug in the Community Theme: Prevention

Level 1

1:00 pm – 3:00 pm

Convention Center, Room 32A/B

ACPE# 202-000-08-045-L01-P • 0.2 CEU

Community-acquired Methicillin-resistant *Staphylococcus aureus* (CA-MRSA) has recently surfaced as a widespread health problem and is becoming increasingly more prevalent. It is now the most common cause of skin and soft tissue infections. Cases have been reported within school systems, and seem to have the most impact on student athletes. All CA-MRSA strains are resistant to beta-lactam antibiotics, complicating the treatment approach. MRSA infections can be fatal, and the death rate from them was higher than that for HIV and AIDS in 2005. This session will highlight the risk factors and treatment options for CA-MRSA. Prevention strategies for health care workers, students, and patients will be reviewed.

Speaker(s): KarenBeth H. Bohan, PharmD, BCPS, Wilkes University Supported by an educational grant from Pfizer Inc.

Clinical Patient Care

The Outpatient Management of Heart Failure

Theme: Cardiovascular

Level 1

1:00 pm - 3:00 pm

Convention Center, Room 29A/B

ACPE# 202-000-08-073-L01-P • 0.2 CEU

Heart failure is responsible for the majority of hospital visits among individuals over the age of 65. As heart failure symptoms worsen, a patient's quality of life is drastically reduced and the limitations on physical activity become more pronounced. Pharmacists are in an ideal situation to assist patients with symptom management and reduce hospital visits. Monitoring therapy, encouraging medication adherence, and tracking symptom severity can be key to improving a patient's quality of life. This session will highlight the latest research regarding heart failure. A casebased approach will be used to illustrate the impact that pharmacists can have on management of the disease and improving outcomes.

Speaker(s): Steven W. Chen, PharmD, FASHP, University of Southern California; Jo Ellen Rodgers, PharmD, BCPS, University of North Carolina

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CONTINUING EDUCATION PARTICIPATION

Online Continuing Education Submission

All continuing education participation will be recorded online for APhA2008. Claiming credit online is quick and simple! You may record your CE in the Cyber Café during the meeting or online at the meeting Web site after the meeting until April 30, 2008. You can print your CE Statement of Credit directly from your computer for your records.

To Claim Credit

You will need your username and password, which were provided to you with your conference registration badge.

From the Cyber Café:

- 1. Click on the CE icon.
- 2. Log in using your pharmacist.com username and password.
- Enter the Voucher Code of the session for which you wish to claim credit. (This will be announced at the beginning of each session.)
- 4. Follow the on-screen instructions to complete session/ speaker evaluations.
- 5. Upon successful completion of the evaluation, your certificate will be available from your "claim credit" history link.
- 6. Print the Statement of Credit and save for your records

From Another Web Site:

- 1. Go to www.aphameeting.org.
- 2. Click the "Education" link and select "Continuing Education Information."
- 3. Login with your pharmacist.com username and password.
- 4. Follow steps 3 6 in the adjacent column.

For Assistance

- If you cannot find your login and password, please contact infocenter@aphanet.org or phone 1-800-237-APhA (2742), ext. 7546 for assistance.
- If you forget your Voucher Code, contact the APhA education department at education@aphanet.org.
- If the survey does not appear on your screen, you may have a Pop-Up Blocker. To bypass this, simply hold down the Control key and click "Begin."

On-site registrants: Please note, you will need to wait 24 hours after registering before recording CE participation.

All CE participation must be recorded by April 30, 2008, 11:59pm EDT.

Use the form on the next page to help you keep track of your CE as you attend courses.

Notes:

Friday, March 14

| □ Sharing Success with Colleagues: Publishing Your Experiences in Journals and Books | | | | |
|---|--------------------|--|--|--|
| · | 9:00 am – 1:30 pm | | | |
| How to Find the Right Partner: Quality Clinical Services Pharm | | | | |
| Creating a Mutually Beneficial I | I | | | |
| Pharmacy Practice Experience) | | | | |
| | 1:00 pm - 3:00 pm | | | |
| The Permissible Scope of Comp Pharmacists | ounding by | | | |
| | 1:00 pm – 3:00 pm | | | |
| Transitioning the Clinical Pharm Emergency Medicine Environme | | | | |
| | 1:00 pm – 3:00 pm | | | |
| 🗌 Federal Pharmacy Forum Air Fo | | | | |
| | 1:30 pm – 3:30 pm | | | |
| Disease States and the Cardiac | | | | |
| | 2:00 pm – 5:00 pm | | | |
| □ HIV Update 2008 | 3:30 pm – 5:30 pm | | | |
| New Drugs of 2007 | | | | |
| 5 | 3:30 pm – 5:30 pm | | | |
| Research Methods: Instrumental Outcome Inferences from Obser | | | | |
| | 3:30 pm — 5:30 pm | | | |
| Colorectal Care: The Pharmacis Prevention and Screening | t's Role in Cancer | | | |
| | 4:00 pm - 5:00 pm | | | |

Saturday, March 15

| APhA-APRS ESAS Researc | h Roundtable Breakfast 7:00 am - 8:30 am | | | | | |
|--|---|--|--|--|--|--|
|] The Economics of Healthcare 8:30 am - 11:00 am | | | | | | |
| A Malpractice Primer for Pharmacists 1:00 pm - 3:00 pm | | | | | | |
| APhA-APRS ESAS Contribu | | | | | | |
| Asthma and COPD: New T Strategies | | | | | | |
| | 1:00 pm – 3:00 pm | | | | | |
| Continuing Professional De Approach to Learning and | evelopment: A Systematic Professional Development 1:00 pm - 2:00 pm | | | | | |
| Cough and Cold Manager A Patient's Perspective | nent for Children: | | | | | |
| | 1:00 pm – 3:00 pm | | | | | |
| □ Filling Up on Fiber: The Be | 1:00 pm – 2:00 pm | | | | | |
| Implementation of the PGY Residency Standard: Round | dtable Discussion | | | | | |
| | 1:00 pm – 2:30 PM | | | | | |
| □ Joint Commission Pharmac | by Update 2008 1:00 pm - 3:00 pm | | | | | |
| Report Cards for Pharmacy Grade? | | | | | | |
| | 1:00 pm – 2:00 pm | | | | | |
| Successful Approaches to I Therapy Changes | nitiating Medication | | | | | |
| | 2:15 pm – 3:15 pm | | | | | |
| □ The Good, the Bad, and th | e Probiotics | | | | | |
| | 2:15 pm – 3:15 pm | | | | | |
| Homeland Security | 2:30 pm – 5:30 pm | | | | | |
| Colleagues in Research: Pc to Build Interdisciplinary Re Pharmacy Practice | elationships to Advance | | | | | |
| | 3:30 pm – 5:30 pm | | | | | |
| Conflict Management for P | harmacists and Preceptors 3:30 pm - 5:30 pm | | | | | |
| ☐ Hot Law Topic Roundtable | 3:30 pm – 5:30 pm | | | | | |
| Immunization Update 200 | 8 | | | | | |
| November 14 | 3:30 pm - 5:30 pm | | | | | |
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- □ MTM Grand Rounds
- 3:30 pm 5:30 pm Opportunistic Infections and Hepatitis Coinfection in Patients with HIV
- 3:30 pm 5:30 pm Self-Care and Nonprescription Therapy for Cardiovascular Disease
- 3:30 pm 5:30 pm The Changing Landscape of Pain Management: New Approaches, Treatments, and Regulations 3:30 pm - 5:30 pm

Sunday, March 16

- □ 2008 Health Policy Forum: Medication Safety Reform in the U.S. Health Care System 7:00 am - 9:00 am
- □ Case Law Update 7:00 am 9:00 am
- Cervical Cancer Prevention Strategies 7:00 am - 9:00 am
- Documenting MTM and Patient Care Activities
 7:00 am 9:00 am
 Parkinson's Disease: Moving Forward with Treatment
 - Modalities 7:00 am - 9:00 am
- The Prevention and Management of Diabetes Complications
- □ What's New in Cardiovascular Care 7:00 am - 9:00 am

7.00 am - 9.00 am

- When It's Lost, Replace It: Micro- and Macronutrient Supplementation 7:00 am - 9:00 am
- ☐ From Homeless to Harvard: The Unexpected Impact You Can Have to Motivate and Help Others 9:00 am − 11:00 am
- Development and Production of PET Radiopharmaceuticals 11:00 am - 1:00 pm
- □ A Team Approach to Improving Medication Use and Decreasing Medication Errors 1:00 pm - 3:00 pm
- □ Legislative and Regulatory Update
- 1:00 pm − 3:00 pm
 Migraine Management: A Pharmacist's Guide to
 Improving Outcomes and Quality of Life
 1:00 pm − 3:00 pm
- Movin' on Up: Advancing the Roles of the Pharmacy Team
- 1:00 pm − 3:00 pm
 Patience with Your Patients: Communication and Interviewing Techniques for Challenging MTM Encounters
 1:00 pm − 3:00 pm
- Practice-Based Research to Improve Health Outcomes
 1:00 pm 3:00 pm
- □ Screening for Disease: Risk Assessment and Point-of-Care Testing by Pharmacists 1:00 pm - 3:00 pm
- Regulatory Update
- 2:00 pm 5:00 pm Advances in the Treatment of Fibromyalgia 3:30 pm - 5:30 pm APhA-APRS ESAS Contributed Papers Podium Session II
- 3:30 pm 5:30 pm FDA Update 3:30 pm - 5:30 pm Growing in the Wrong Direction: Managing Childhood Obesity
- 3:30 pm 5:30 pm Menopause: The Onset of New Health Care Needs 3:30 pm - 5:30 pm Safe Travels: Advice for International Travelers 3:30 pm - 5:30 pm
- ☐ The Boom in Biologics I: Unique Treatment Options for Chronic Conditions 3:30 pm - 4:30 PM

☐ The Boom in Biologics II: The Emergence of Biosimilar Products 4:45 pm - 5:45 pm

Monday, March 17 □ Advances in the Treatment of Opioid-Induced Constipation 7:30 am - 9:30 am APhA-APRS ESAS Contributed Papers Podium Session III 7:30 am - 9:30 am Drug Diversion: The Inside Scoop 7:30 am - 9:30 am □ New Drugs of 2007 7:30 am - 9:30 am □ Not If, But When: Preparing Pharmacists for an Influenza Pandemic 7:30 am - 9:30 am □ The Appropriate Treatment and Management of ADHD 7:30 am - 9:30 am Venous Thromboembolism: Prevention and Treatment Strategies 7:30 am - 9:30 am Dark Age Magic to New Age Hope: The Nuclear Imaging Revolution 8:00 am - 12:00 pm □ The Smithsonian's National Pharmacy Collection As a **Resource for Pharmacists** 9:00 am - 10:00 am □ Fraud and Abuse: Maintaining Compliance with Federal and State Regulations 10:00 am - 12:00 pm □ New Products, Technology, and Treatment Options for Patients with Diabetes 10:00 am - 12:00 pm OSHA Training Course: Maintaining Compliance with the Bloodborne Pathogens Standard 10:00 am - 11:00 am □ Protecting Patients from the Threat of Counterfeit Drugs 10:00 am - 11:00 am Psychological Issues in Adolescents and Young Adults 10:00 am - 12:00 pm □ Show Me the Numbers: Simple Approaches to Interpreting Clinical Trials and Patient Safety Data 10:00 am - 12:00 pm □ Unleashing the Inner Activist: Political Action 101 10:00 am - 12:00 pm □ Assisted Reproduction: Cycling Through the Treatment Options 1:00 pm - 3:00 pm Career Awareness Roundtable 1:00 pm - 3:00 pm Establishing a Financially Viable MTM Practice 1:00 pm – 3:00 pm □ Managing the 3 Ds in the Elderly: Depression, Dementia, and Delirium 1:00 pm - 3:00 pm □ Mental Health and Substance Abuse Disorders: From Inpatient to Outpatient 1:00 pm - 3:00 pm □ MRSA: A Growing Bug in the Community 1:00 pm - 3:00 pm □ The Outpatient Management of Heart Failure 1:00 pm - 3:00 pm Notes

November 14, 2008

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| 32 | YOUR TICKET TO A BRIGHTER PHARMACY FUTURE |

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Notes

Shuttle Schedule • December 7 - 11

Shuttle Service to Orange County Convention Center

TRANSPORATION INFORMATION

HOURS OF OPERATION SUNDAY, December 7, 2008 7:00AM- 7:00PM, Every 15-20 Minutes

MONDAY, December 8, 2008 7:00AM- 6:30PM, Every 15-20 Minutes

Breakfast Symposia Limited Service from 5:30AM-6:30 AM Every 20-30 Minutes

TUESDAY, December 9, 2008

7:00AM- 5:30PM, Every 15-20 Minutes

Breakfast Symposia Limited Service from 5:30AM-6:30 AM Every 20-30 Minutes

WEDNESDSAY, December 10, 2008

7:00AM- 5:30PM, Every 15-20 Minutes

Breakfast Symposia Limited Service from 5:30AM-6:30 AM Every 20-30 Minutes

ASHP's Happenin' Street Party at Universal Studios Florida® Service to/from ALL ASHP Official Hotels 7:00PM- 11:00 PM

THURSDAY. December 11, 2008

8:00AM- 4:30PM, Every 15-20 Minutes

Breakfast Symposia Limited Service from 5:30AM-6:30 AM Every 20-30 Minutes



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Wheelchair accessible transportation is available during hours of operation. Call toll free (888) 283-6225 to

schedule (allow 30 minutes).



Shuttle services managed and operated by Transportation Management Services

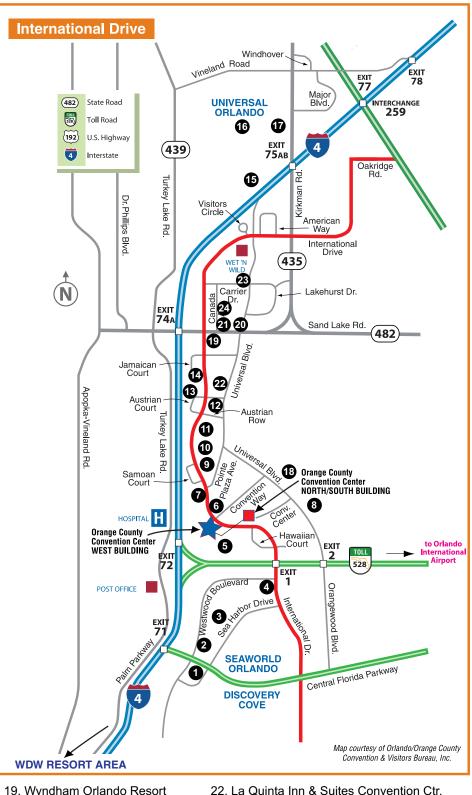
| HOTELS | ROUTE | BOARDING |
|---|-------|---|
| Courtyard by Marriott I-Drive | 4 | Curbside on Austrian Ct. |
| Crowne Plaza Orlando Universal | 6 | Back Entrance of Hotel |
| Doubletree Castle Hotel | 5 | Curbside on Universal |
| Enclave Suites | 6 | Curbside on Carrier |
| Hampton Inn Convention Center | 5 | Curbside on Universal |
| Hawthorne Suites Universal | 6 | Curbside on Canada Ave. |
| Hilton Garden Inn SeaWorld | 2 | Main Lobby |
| Homewood Suites I-Drive | 5 | Curbside on Universal at Hyatt Place |
| Hyatt Place Orlando Convention Center | 5 | Curbside on Universal |
| International Plaza Resort | 2 | Main Lobby outside Porte-cochere |
| La Quinta Inn & Suites Convention Cente | er 5 | Curbside on Universal |
| The Peabody Orlando | W | Walking distance to the Convention Center |
| Renaissance Orlando Resort at SeaWorl | d 2 | Convention Center Entrance |
| Residence Inn by Marriott I-Drive | 6 | Curbside on I-Drive |
| Residence Inn SeaWorld | 2 | Back Entrance of Hotel |
| Rosen Centre Hotel | W | Walking distance to the Convention Center |
| Rosen Plaza Hotel | 4 | Curbside on I-Drive |
| Rosen Shingle Creek Resort | 3 | Bus pavilion right of main entrance |
| Staybridge Suites Orlando | 4 | Corner of I-Drive & Austrian Ct. (Bus Stop 26) |
| Universal's Hard Rock Hotel | 1 | Convention Entrance - Abbey Rd. Bus Stop |
| Universal's Portofino Bay Hotel | 1 | Bus Piazza |
| Universal's Royal Pacific Resort | 1 | Main Lobby outside Porte-cochere |
| Westin Imagine Orlando | 3 | Main Lobby |
| Wyndham Orlando Resort | 6 | Convention Center Entrance |
| | | |

ORLANDO

Orlando/Orange County Convention & Visitors Bureau, Inc

43rd ASHP Midyear Clinical Meeting & Exhibition December 7 - 11, 2008

- 1. Residence Inn SeaWorld \$149.00 single/double
- 2. Hilton Garden Inn SeaWorld \$144.00 single/double
- 3. Renaissance Orlando Resort \$191.00 single/double
- 4. International Plaza Resort \$144.00 single/double
- 5. Rosen Centre Hotel (Co-Headquarter Hotel) \$199.00 single/double
- 6. Peabody Orlando (Headquarter Hotel) \$219.00 single/double
- 7. Rosen Plaza Hotel \$194.00 single/double
- 8. Rosen Shingle Creek Resort \$199.00 single/double
- 9. Hampton Inn Convention Ctr. \$129.00 single/double
- 10. Homewood Suites I-Drive \$139.00 single/double
- 11. Hyatt Place Orlando Convention Ctr. \$149.00 single/double
- 12. Doubletree Castle Hotel \$119.00 single/double
- 13. Courtyard by Marriott I-Drive \$139.00 single/double
- 14. Staybridge Suites Orlando\$129.00 one-bdr. suite, single/double\$149.00 two-bedroom suite
- 15. Universal's Royal Pacific Resort \$174.00 single/double
- 16. Universal's Hard Rock Hotel \$180.00 single/double
- 17. Universal's Portofino Bay \$195.00 single/double
- 18. Westin Imagine Orlando \$199.00 single/double



- 19. Wyndham Orlando Resort \$139.00 single/double
- 20. Crowne Plaza Orlando Universal \$169.00 single/double
- 21. Residence Inn by Marriott I-Dr \$149.00 single/double
- 22. La Quinta Inn & Suites Convention Ctr. \$120.00 single/double
- Enclave Suites
 \$89.00 deluxe studio/\$119.00 one bdr. suite
- 24. Hawthorn Suites \$125.00 one bdr. suite



Ambulatory Care PRN Focus Session— Updates in Vaccine and Immunization Practices Monday, October 15, 2007 Convention Center: Rooms 601 and 603 3:45 p.m. – 5:45 p.m.

Moderator:

Eric J. MacLaughlin, Pharm.D., BCPS Associate Professor and Division Head of Adult Medicine, Department of Pharmacy Practice, Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, Texas

| 3:45 p.m. | New Vaccines and New Indications Jean-Venable Goode, Pharm.D., BCPS Associate Professor of Pharmacy Practice, Virginia Commonwealth University, Richmond, Virginia |
|-----------|---|
| 4:20 p.m. | Vaccine Development: What Is in the Pipeline? Mary Hayney, Pharm.D., FCCP, BCPS Associate Professor, University of Wisconsin School of Pharmacy, Madison, Wisconsin |
| 4:55 p.m. | Pharmacist's Role in Immunization Practice Management Amy Flusche, Pharm.D., BCPS Director of Pharmacy Services, Lincoln County Medical Center, Ruidoso, New Mexico |
| 5:30 p.m. | Questions and Answers |

Faculty Disclosures

Jean-Venable Goode: No conflicts to disclose. *Mary Hayney:* No conflicts to disclose. *Amy Flusche:* No conflicts to disclose.

Learning Objectives

- 1. Describe new vaccines that are currently in development, including malaria, HIV, influenza, and nicotine.
- 2. Understand challenges associated with development of new vaccines for different diseases.
- 3. Describe emerging technologies being researched for vaccine delivery.
- 4. Explain the process, policies and procedures of incorporating immunization services into a pharmacy practice.
- 5. Describe the practice model of a successful clinical pharmacy immunization program.
- 6. Explain methods and challenges of compensation for clinical services.

Self-Assessment Questions

- 1. Which of the following is an obstacle associated with HIV vaccine development?
 - A. The virus cannot be grown in the laboratory.
 - B. The virus never mutates in nature.
 - C. No known naturally occurring immunity to the virus exists.
 - D. CD8+ T cell stimulation is not a useful strategy for vaccine-induced immune responses.
- 2. Which of the following is the main immunologic advantage of the use of DNA vaccines for the prevention of hepatitis C infection?
 - A. They down regulate Th1 responses.
 - B. They generate vigorous cell mediated immune responses.
 - C. They generate high antibody concentrations.
 - D. They vigorously stimulate B cells.
- 3. Which of the following reasons presents an obstacle to stockpiling influenza vaccine in anticipation of an influenza pandemic?
 - A. The pandemic virus cannot be identified prior to the pandemic.
 - B. Avian influenza virus do not induce immune responses in humans.
 - C. Influenza vaccines will not be effective for control of infection during a pandemic.
 - D. Adverse reactions to the vaccine are likely to prevent widespread immunization.
- 4. Which of the following is the main antigen presenting cell in the skin?
 - A. Alveolar macrophage.
 - B. T lymphocyte.
 - C. Keratinocyte.
 - D. Langerhans cell.
- 5. Which of the following roles should every pharmacist fill in immunization?
 - A. Advocate, facilitator, researcher
 - B. Advocate, facilitator, immunizer
 - C. Advocate, researcher, immunizer
 - D. Facilitator, researcher, immunizer
- 6. Which of the following statements about Medicare Part B billing is correct?
 - A. Medicare Part B covers newly FDA approved vaccinations such as Zostavax
 - B. A pharmacy needs nothing more than their store's NPI number to bill Medicare Part B
 - C. Pharmacies can bill Medicare Part B for the administration of Zostavax using a G code.
 - D. A pharmacy must be a DME supplier to become a Part B mass immunization provider.
- 7. Which of the following statements best reflect the changes to Medicare Part D for 2008?
 - A. Medicare Part D will cover all FDA approved vaccinations including flu and pneumonia vaccines.
 - B. Physicians will be able to bill Medicare Part D for the cost and administration of vaccines.
 - C. Pharmacies will have to bill Part D for reimbursement of vaccine cost and bill Part B for administration.
 - D. Pharmacies will be able to submit one claim to Medicare Part D for cost and administration of vaccines.

Answers to Self-Assessment Questions

- 1. C
- 2. B
- 3. A
- 4. D
- 5. B
- 6. C
- 7. D

Ambulatory Care PRN/Pharmacokinetics and Pharmacodynamics PRN Focus Session— The Science and Practice of Pharmacogenetic Guided Warfarin Dosing

Tuesday, October 21 1:15 p.m.–3:15 p.m. Convention Center: Room 108 Program No. 217-000-08-106-L01-P; 2.0 contact hours.

Moderators: Alan J. Zillich, Pharm.D. Assistant Professor Purdue University Indianapolis, Indiana

and

Brian R. Overholser, Pharm.D. Assistant Professor Purdue University Indianapolis, Indiana

Agenda

| 1:15 p.m. | Pharmacogenetics of Warfarin Brian F. Gage, M.D., M.Sc. Associate Professor, Department of Medicine, Washington University, St. Louis, Missouri |
|-----------|---|
| 2:05 p.m. | Statement For: Pharmacogenetic-Guided Warfarin Dosing <i>Gloria R. Grice, Pharm.D., BCPS</i> Assistant Professor, Pharmacy Practice, Barnes-Jewish Hospital Anticoagulation Service, Washington University, St. Louis, Missouri |
| 2:40 p.m. | Statement Against: Pharmacogenetic-guided Warfarin Dosing Ann K. Wittkowsky, Pharm.D., BCPS Clinical Professor, University of Washington School of Pharmacy, Director of Anticoagulation Services, University of Washington Medical Center. University of Washington, Seattle, Washington |

Faculty Conflict of Interest Disclosures

Brian F. Gage: received grant funding/research support from Osmetech, Autogenomics Gloria R. Grice: grant funding/research support from NIH



November 14, 2008

Ann K. Wittkowsky: no conflicts to disclose.

Learning Objectives

- 1. Describe PK/PD issues regarding warfarin use.
- 2. Explain the CYP 2C polymorphisms and influence on the PK of Warfarin and outcomes, including INR.
- 3. Describe the literature supporting the correlation of predicted dose with actual therapeutic dose when using pharmacogenetics plus multiple other clinical variables in warfarin management.
- 4. Explain the known and likely advantages of using patient genotype to initiate and refine warfarin doses.
- 5. Apply genotype appropriately in addition to phenotype to patients beginning warfarin using a free, Web-based dosing nomogram.
- 6. Critically review current literature and science regarding the comparison of geneticbased vs. traditional warfarin dosing, and assess its application to general practice and routine patient management.
- 7. Consider possible drawbacks of over-reliance on genetic testing to inform warfarin dosing.

Self-Assessment Questions

- 1. When using genotype, clinical factors, and the first few INRs, what is the correlation between predicted warfarin dose and actual therapeutic dose in orthopedic patients?
 - A. 22-25%
 - B. 44-48%
 - C. 70-79%
 - D. 95-100%
- 2. When a pharmacogenetic-based approach was compared with a clinical-based approach in randomized trials and open-label cohorts, which of the following outcomes were found?

A. Improved percent time in therapeutic INR range with a pharmacogenetic approach

B. Achieved first therapeutic INR and stable anticoagulation earlier with a pharmacogenetic approach

C. Reduced clinical adverse events (minor bleeding and elevated INRs) with a pharmacogenetic approach

- D. All of the above
- 3. Which of the following statements best describes the role of pharmacogenetics in warfarin management?



A. Genotype is a useful variable to consider along with other clinical variables when selecting the first warfarin dose and refining the first several doses.B. Genotype is most helpful after one week of therapy in patients with low risk of bleeding.

C. Genotype should be considered in patients who have taken warfarin previously.

- D. Genotype should not be considered when initiating and refining warfarin doses.
- 4. Genetic-based initiation of warfarin dosing lowers the risk of major bleeding complications associated with oral anticoagulant therapy.
 - A. True
 - B. False
 - C. Unknown
- 5. What proportion of patients have the *3/*3 expression of CYP2C9, and thus require ultra-low doses of warfarin?
 - A. <1%
 - B. 1-5%
 - C. 5-10%
 - D. 10-20%
- 6. Which of the following recommend genetic testing to inform warfarin dosing?
 - A. The FDA, in the warfarin package insert

B. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines for Antithrombotic and Thrombolytic Therapy (8th Edition)

C. American College of Medical Genetics Working Group on Pharmacogenetic Testing

D. None of the above

Answers to Self-Assessment Questions

- 1. C
- 2. D
- 3. A
- 4. C
- 5. A
- 6. D



Pharmacogenomics in Warfarin Management

Argument For Genomic Testing

Gloria R. Grice, Pharm.D., BCPS Assistant Professor, St. Louis College of Pharmacy Manager, Barnes-Jewish Hospital Anticoagulation Service Washington University Medical Center

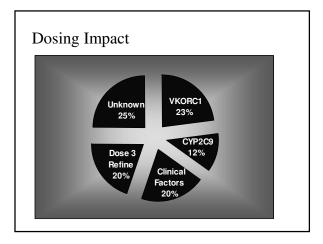
Challenges of Warfarin Management

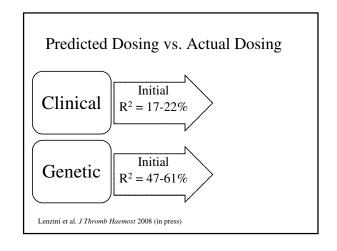
- Narrow therapeutic index
- Adverse effect profile
 - Black box warning for bleeding
 - 2nd highest drug causing adverse events among outpatients
- Wide dose variability
- Long time to achieving therapeutic INR

Advantages to Pharmacogenetic-Guided Anticoagulation

- More Predictable/Less Variability
- Improves Patient Outcomes
- FDA Advisory
- Easier for Clinician Management
 - Fewer surprises
 - Website, dosing algorithms available
 - Additional variable
- Cost Effective?

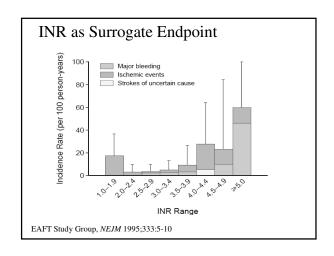
| Incidence of <i>CYP2C9 & VKORC1</i> SNPs (%) | | | | | |
|---|-----------|----------------------|--------|-------|--|
| | Caucasian | African- American | Other | Asian | |
| <i>CYP2C9</i> *2 | 13.1 | 5.2 | 10.4 | 0 | |
| <i>CYP2C9</i> *3 | 6 | 1 | 4.2 | 4 | |
| VKORC1 Group A | 36.6 | 9.5 | 41.7 (| 85 | |
| VKORC1 Group B | 63.4 | 90.5 | 58.3 | 14 | |
| Gage et al. <i>Clin Pharmacol Ther</i> 2008 in press Marsh et al. <i>J Thromb Haemost</i> 2006; 4: 473–4 | | | | | |





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Time to Anticoagulation-Related Outcomes Less Stable More Bleeding 1.0 χ²=6.21; *P*=0.01 v/out Stable Dos χ²=8.30; *P*=0.004 8 0.8 0.8 0.6 **J** 0.6 **e** 0.4 CYP2C9 variant B 0.2 CYP2C9 variant 0.0 2000 2800 360 0 200 300 400 500 600 700 800 900 1000 0 400 1200 Follow-up, d Follow-up, d Variant Wild Type 58 33 17 6 6 3 2 2 2 127 39 19 10 6 3 3 2 2 58 23 16 9 9 6 4 3 127 71 54 34 22 10 6 0 Higashi et al JAMA. 2002;287:1690-1698

Randomized Trials: Anderson et al.

| End Point | PG Group (n=101) | STD Group (n=99) | P-value |
|-------------------------|------------------|------------------|---------|
| Out-of-range INRs (%) | 30.7 | 33.1 | 0.47 |
| # of dosing adjustments | 3.0 | 3.6 | 0.035 |
| # of INRs drawn | 7.2 | 8.1 | 0.06 |
| Total AEs | 34 | 42 | 0.26 |

Genetic-guided doses were more accurate than standard dosing (p<0.001) = Fewer dosing changes and INR monitoring

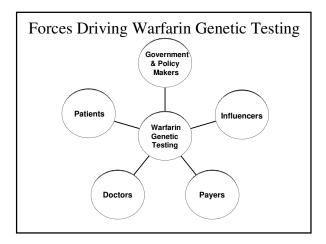
Anderson et al. Circulation 2007;116:2563-70

| End Point | PG Group (n=92) | STD Group (n=93) | P-value |
|---|-----------------|------------------|---------|
| Time to first therapeutic INR (days) | 4.8 | 7.5 | < 0.001 |
| Days below therapeutic range | 2.01 | 8.00 | <0.001 |
| Time in therapeutic range (%) | 80.4 | 63.4 | <0.001 |
| # of INRs drawn | 4.9 | 10.7 | <0.001 |
| Bleeding events (minor) | 3.2 | 12.5 | < 0.02 |

| Outcomes in Orthop | edic I | Patients | |
|---|--------------------|-------------------|-------------------------------------|
| Outcome Variable | Clinical (N=90) | Genetic (N=70) | P-value for cohort difference |
| | | | |
| Mean PTTR in 30 days (SD) | 56% (20.5%) | 62% (19.1%) | 0.066 |
| Frequency INR > (Target INR + 1.5) within 30 days | 17 (19) | 2 (3) | 0.002 |
| Symptomatic adverse events within 30 days (%) | 5 (6) | 3 (4) | 0.51 |

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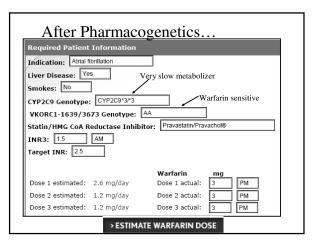


Advantages to Pharmacogenetic-Guided Anticoagulation

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- Improves Patient Outcomes
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 - Additional variable to consider
- Cost Effective?

| Case 1 | |
|--------------------------|--|
| Case I | |
| No genetics | at initiation |
| | Required Patient Information |
| > Warfarin Dosing | Age: 71 Sex: Male Ethnicity: Non-Hispania |
| 1 | Race: White, Caucasian, or Middle Eastern |
| > <u>Hemorrhage Risk</u> | Weight: 180 lbs or 81.8 kgs BSA 2.12 |
| > Patient Education | Height: (6 feet and 4 inches) or (193 cms) |
| | Smokes: No Liver Disease: Yes |
| > Contact Us | Indication: Atrial fibrillation |
| > References | Baseline INR: 1.05 Target INR: 2.5 |
| → Admin | CYP2C9 Genotype: Not available/pending Randomize & Bl |
| Vser: | VKORC1-1639/3673 Genotype: Not available/pending |
| Patient: Version 3.7 | Amiodarone/Cordarone® Dose: 400 mg/day |
| Build : 10 April 2007 | Statin/HMG CoA Reductase Inhibitor: Pravastatin/Pravachol® |
| | Any azole (eg. Fluconazole): No |
| | Sulfamethoxazole/Septra/Bactrim/Cotrim/Sulfatrim: No |
| | ☑ Ascept Terms of Use Estimated Dose 3.5 mg/day |
| www.WarfarinDosing.org | Caution: Liver Disease |

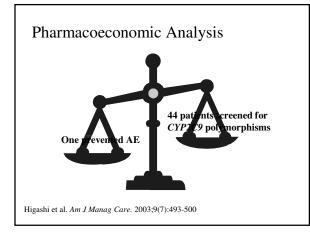
| Case 1 No genetics at | initiation | |
|--------------------------|------------|-----------|
| Days after warfarin | INR | Dose (mg) |
| 0 | 1.05 | 3 |
| 1 | | 3 |
| 2 | | 3 |
| 3 | 1.5 | 3 |
| 4 | 2.3 | ? |
| | 1 | 1 |



| | Case 1 Very slow metal | bolizer; sensitive | ę |
|------|---------------------------|--------------------|-----------|
| | Days after warfarin | INR | Dose (mg) |
| 1 | 0 | 1.05 | 3 |
| | 1 | | 3 |
| | 2 | | 3 |
| | 3 | 1.5 | 3 |
| | 4 | 2.3 | 0 |
| | 5 | | 0 |
| | 6 | | 0.5 |
| | 7 | 2.1 | 1 |
| | 21 | 2.5 | ~0.6/day |
| Gric | e G et al. J Thromb Haema | ost. 2008;6:207-9 | |

Advantages to Pharmacogenetic-Guided Anticoagulation

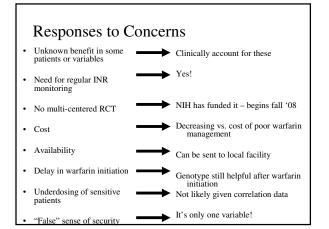
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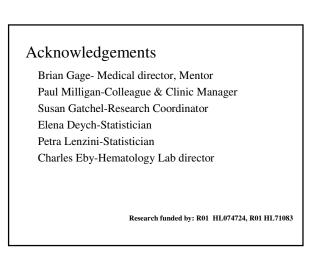


Cost-Effectiveness

- Report from 2007 estimates testing for *CYP2C9* and *VKORC1* could:
 - Decrease healthcare costs by \$1.1 billion
 - Prevent 85,000 serious bleeding events annually
 - Prevent 17,000 strokes annually
- Other factors not assessed:
 - Reduction in hospital length of stay?
 - Reduction in use of low-molecular weight heparin?

McWilliam et al. AEI-Brooking Joint Center for Regulatory Studies Working Paper. 2006





PHARMACOGENOMICS IN ANTITHROMBOTIC THERAPY

Argument Against Genomic Testing

Ann K Wittkowsky Pharm.D., CACP, FASHP, FCCP Clinical Professor University of Washington School of Pharmacy Director, Anticoagulation Services University of Washington Medical Center

RECENT PRESS RELEASES



PGXL Laboratories Provides DNA-Testing For Coumadin Patients

genelee

Days Before Warfarin Label Change, Genelex Debuts Direct-to-Consumer

Nanosphere Announces First FDA Cleared Genetic Test for Warfarin Sensitivity

WARFARIN INITIATION DOSING METHODS

- 1. FLEXIBLE INITIATION
 - a. With nomogram
 - b. Without nomogram empiric dosing
- 2. AVERAGE DAILY DOSING
 - a. With nomogram
 - b. Without nomogram empiric dosing

FLEXIBLE INITIATION OF WARFARIN

- Daily INR determination
- · Daily dosing adjustments based on rate of increase in INR
- · Goal is prediction of eventual maintenance dose
- · most commonly used in inpatient settings
- 10mg and 5mg starting dose algorithms available and compared in various populations

Fennerty et al. Br J Med. 1984; 288:1268-70. Cosh DG et al. Aust NZ J Med. 1989; 19:191-7. Gedge J et al. Age Ageing. 2000; 29:31-4. Roberts GW et al. Ann Pharmacotherapy. 2003; 37:799-803. Roberts GW et al. Aust NZ J Med. 1999; 29:731-6. Crowther MA et al. Arch Intern Med. 1999; 159:46-8. Crowther MA et al. Ann Intern Med. 1997; 127:332-3.

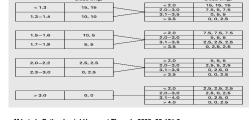
AVERAGE DAILY DOSING METHOD WITH NOMOGRAM

- 1. Pengo: 5mg qd x 4, then INR on day 5 to predict maintenance dose
- 2. Siguret: 4mg qd x 3, then INR on day 4 to predict maintenance dose
- 3. Oates: 2mg qd x 14, then INR on day 15 to predict maintenance dose
- 4. Tait: 5mg qd x4, then INR on day 5 to select doses for days 5-7, then INR on day 8 to predict maintenance dose

Pengo V et al. Am J Cardiol. 2001; 88:1214-6. Siguret V et al. Am J Med. 2005; 118:137-42.57. Oates A et al. Br J Clin Pharmacol. 1998; 46:157-61. Tait RC et al. Br J Haematol. 1998; 101:450-4.

AVERAGE DAILY DOSING METHOD WITH NOMOGRAM 10mg qd x 2, then INR on day 3 to select doses for days 3-4, then INR

On day 5 to select does for days 5-7



Kovacs MJ et al. Pathophysiol Haemost Thromb. 2002; 32:131-3. Kovacs MJ et al. Ann Intern Med. 2003; 138:714-9.

AVERAGE DAILY DOSING METHOD WITHOUT NOMOGRAM

1. Non-Sensitive Patients

- initiate at 4-5mg po qpm
 recheck INR in 3-5 days
 adjust until INR > 2.0, the select maintenance dose

2. Sensitive Patients

- initiate at 1-3mg po qpm
 recheck INR in 3-5 days
 adjust until INR > 2.0, then select maintenance dose

| PATIENT CASE | |
|---------------|---|
| ID | 71 year old male |
| Med Hx | CAD, HTN, mild CHF |
| Social Hx | mild EtOH use non-smoker |
| MEDS | amiodarone 200mg qd furosemide 20mg qd lisinopril 5mg qd ASA 81mg qd |
| BASELINE LABS | PT 13.6 sec HCT 38% Scr 1.2 |
| PLAN | initiate warfarin |

FACTORS LIKELY TO **INCREASE SENSITIVITY TO WARFARIN**

| Age > 75 | Clinical congestive heart failure |
|------------------------|-----------------------------------|
| Elevated baseline INR | Clinical hyperthyroidism |
| Fever | End stage renal failure |
| Diarrhea | Malignancy |
| Known CYP2C9 Variant | Following heart valve replacement |
| Hypoalbuminemia | Hepatic disease |
| Malnutrition | Decreased oral intake |
| | |
| Drug-drug interactions | |

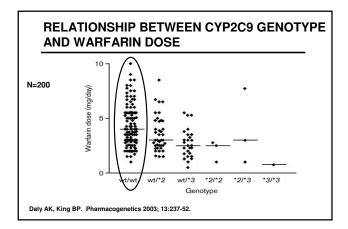
| DATE | INR | WARFARIN | DATE | INR | WARFARIN |
|------|------|----------|------|-----|----------|
| 1 | 1.05 | 2.5mg | 8 | | 1.25mg |
| 2 | | 2.5mg | 9 | | 1.25mg |
| 3 | | 2.5mg | 10 | 3.7 | HOLD |
| 4 | 1.7 | 2.5mg | 11 | | 1mg |
| 5 | | 2.5mg | 12 | | 1mg |
| 6 | | 2.5mg | 13 | 2.8 | 1mg |
| 7 | 4.3 | hold | 14 | | 1mg |

| | | | | OTYPE C | | mg/day |) |
|----------------------------|-----|-------|-------------------|-------------------|-------------------|------------------|------------------|
| | Ν | *1/*1 | *1/*2 | *1/*3 | *2/*2 | *2/*3 | *3/*3 |
| Caucasian Ref 1/1995 | 94 | 4.7mg | 3.8mg (19% ↓) | | | | |
| Caucasian Ref 2/1999 | 52 | 4.2mg | 3.5mg (18% ↓) | 2.5mg (41% ↓) | 3.5mg (18% ↓) | | |
| Caucasian Ref 3/2000 | 180 | 6.7mg | 5.2mg (22% ↓) | 3.8mg (43% ↓) | | 1.8mg (73% ↓) | |
| Caucasian Ref 4/2000 | 561 | 5.0mg | 4.31mg (14% ↓) | 3.97mg (21% ↓) | 3.04mg (39% ↓) | 4.1mg (18% ↓) | |
| Caucasian Ref 5/2002 | 185 | 5.6mg | 4.9mg (13% ↓) | 3.3mg (41% ↓) | 4.07mg (27%↓) | 2.3mg (59%↓) | 1.6mg (71% ↓) |
| Caucasian Ref 6/2002 | 93 | 5.6mg | 3.9mg (30% ↓) | 2.9mg (48% ↓) | 2.9mg (48% ↓) | 2.6mg (43% ↓) | 1.3mg (77%↓) |
| Asian <i>Ref 7/1998</i> | 47 | 3.0mg | | 1.75mg (42% ↓) | | | 0.4mg (87% ↓) |

AVERAGE POPULATION DISTRIBUTION OF CYP2C9 GENOTYPE BY ETHNICITY

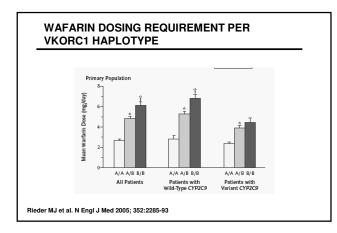
| | *1/*1 | *1/*2 | *1/*3 | *2/*2 | *2/*3 | *3/*3 |
|---------------------------|-------|-------|-------|-------|-------|-------|
| Caucasians (n=1383) | 65.3% | 20.4% | 11.6% | 0.9% | 1.4% | 0.4% |
| Africans (n=250) | 90.8% | 6% | 3.2% | 0 | 0 | 0 |
| Spanish/ Turks (n=656) | 58.8% | 17.5% | 18.8% | 1.2% | 3% | 0.7% |
| Asians (n=1005) | 96.9% | 0 | 3.1% | 0 | 0 | 0 |

Lee CR et al. Pharmacogenetics 2002; 12:251-63.



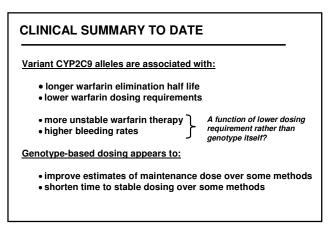
| | White | Black | Other or mixed |
|-----------------|---------|---------|----------------|
| | (n=838) | (n=153) | (n=24) |
| /KORC1 861 C>A | 36.0% | 8.8% | 26.1% |
| VKORC1 3673 G>A | 36.6% | 9.5% | 41.7% |
| /KORC1 5808 T>G | 25.1% | 4.6% | 8.3% |
| /KORC1 6853 G>C | 37.2% | 24.3% | 41/7% |
| /KORC1 9041 G>A | 39.4% | 51.3% | 41.7% |

Gage BF et a. Clin Pharmacol Ther 2008 (epub ahead of print)



| Dose Prediction Method | Equa | ation Compone | ents | R ² | Median absolute prediction error |
|------------------------------|--------------------------|-------------------------------------|----------------------------|----------------|---|
| Genetic | BSA Age Black race | target INR amiodarone smoking | DVT/PE VKORC1 CYP2C9 | 54% | 1.0 mg/day |
| Clinical | BSA Age Black race | target INR amiodarone smoking | DVT/PE | 17% | 1.5mg/day |

| AUTHOR | | COMPONEN | rs | R2 |
|---------------------|---------------|---------------------------------|------------------|-----|
| Bodin et al 2005 | Weight | | CYP2C9 VKORC1 | 54% |
| Sconce et al 2005 | Age Height | | CYP2C9 VKORC1 | 54% |
| Wadelius et al 2005 | Age Weight | Indication Drug interactions | CYP2C9 VKORC1 | 56% |
| Veenstra et al 2005 | Age Gender | | CYP2C9 VKORC1 | 61% |
| Kimura et al 2006 | Age Gender | Weight | CYP2C9 VKORC1 | 33% |

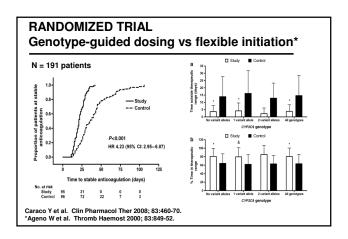


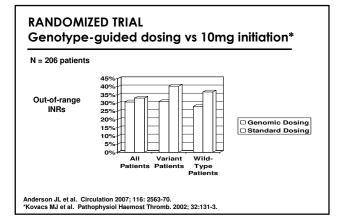
BUT.....

- 1. Genotypes associated with very lower dosing requirements are very rare
- 2. There is still considerable variability in dosing requirements within each genotype, including wild-type
- 3. There is no evidence that genotype-based initiation is:

a. Better than YOUR method of initiation, with INR-based adjustments, to reach a stable maintenance dose

b. Associated with improved clinical outcomes, specifically a reduction in major bleeding complications





BLEEDING OUTCOMES IN RANDOMIZED TRIALS

1. Caraco et al.

"Incidence of bleeding was higher in the control group patients than in the study group patients (12.5% vs 3.2%; p<0.02).'

"Of the 15 bleeding episodes, 14 were minor."

2. Anderson et al.

"Serious clinical events were infrequent (pharmacogenetic=4; standard=5) and were unrelated to out-of-range INRs"

WHAT DOES THE NEW COUMADIN PACKAGE INSERT REALLY SAY?

CLINICAL PHARMACOLOGY

- <u>Pharmacogenomics (new section)</u> a. Patients with *2 or *3 allele demonstrate
 - Increased bleeding risk
 - Decreased dosing requirement Increased risk of over- anticoagulation during initiation
 - b. 55% of variance in warfarin dose can be explained by
 - VKORC1 and CYP2C9 genotype plus age, height, body weight, interacting drugs, indication

DOSING

Initial Dose The lower initiation dose should be considered for patients with certain genetic variations in CYP2C9 and VKORC1 as well as the elderly, debilitated patients, and patients with potential to exhibit great than expected INR responses.

WHAT DO THE GUIDELINES SAY?

Antithrombotic and Thrombolytic Therapy: ACCP Evidence Based Clinical Practice Guidelines (8th Edition)

"...we suggest against the use of pharmacogenetic-based initial dosing to individualize warfarin dosing (Grade 2C)."

Am Coll Med Genetics Working Group on Pharmacogenetic Testing²

...there is insufficient evidence at this time to recommend for or against Routine CYP2C9 and VKORC1 testing.

Ansell J et al. Chest 2008; 133 (suppl 6): 160-198. Flockhart DA et al. Genet Med 2008; 10:139-50. 1. 2.

INFLUENCING FORCES

- 1. FDA initiative to advance personalized medicine
- 2. Manufacturers of CYP2C9/VKORC1 testing systems
- 3. Genomics researchers
- 4. in-the-trenches practitioners
- 5. Health economics

CONCERNS ABOUT GENETIC TESTING

- 1. False sense of complacency about the need for rigorous monitoring by assuming that genotyping will lead to accurate dosing
- 2. Wait time for genotyping results may lead to delay in initiation of therapy, leading to adverse events
- 3. Underdosing (and adverse events) of patients who appear to be sensitive to warfarin based on genomic testing but who in fact have higher dosing requirements
- 4. Significant increase in healthcare costs

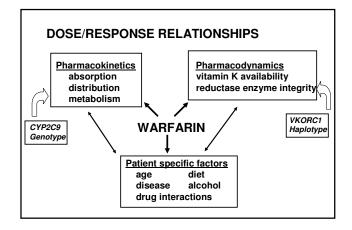
Bussey HI et al. Pharmacotherapy 2008; 28:141-3.

ECONOMIC IMPLICATIONS

\$250-\$500 to test CYP2C9 and VKORC1

- 1. How many episodes of over-anticoagulation would testing prevent?
- 2. How many major bleeding episodes would testing prevent?
- 3. What is the cost-effectiveness of testing all patients?

RANDOMIZED CLINICAL TRIAL OF ROUTINE INITIATION VS GENOMIC-BASED INITIATION IS NECESSARY TO ANSWER THESE QUESTIONS





The Hard Rock Hotel Chicago • Chicago, Illinois June 19–22, 2008

PROGRAM AGENDA

THURSDAY, JUNE 19, 2008

| 7:00 рм-9:00 рм | Registration and Networking Reception | | |
|-----------------|--|--|--|
| | Byrdland/Firebird/Flying V | | |

FRIDAY, JUNE 20, 2008

| 7:00 AM-8:00 AM | Registration and Breakfast Byrdland/Firebird/Flying V/SG |
|-------------------|--|
| 8:00 AM-8:30 AM | Welcome and Introductions Fender Ballroom |
| | Elizabeth A. Cardello, RPh American Pharmacists Association |
| | Rosemary R. Berardi, PharmD, FCCP, FASHP, FAPhA The University of Michigan |
| 8:30 AM-10:30 AM | Assessing Clinical Skills Using Objective Structured Clinical Exams Fender Ballroom |
| | Moderator |
| | Rosemary R. Berardi, PharmD, FCCP, FASHP, FAPhA |
| | The University of Michigan |
| | Speaker |
| | Beth A. Martin, RPh, PhD |
| | University of Wisconsin |
| 10:30 ам-10:45 ам | Break |



| 10:45 ам-12:00 рм | Evaluating and Refining the Self-Care Fender Ballroom | 2 Curriculum |
|-------------------|---|--|
| | Moderator Gail D. Newton, PhD, RPh Purdue University | |
| | Speakers Karl Hess, PharmD, RPh Western University | |
| | Nicholas G. Popovich, PhD University of Illinois at Chicago | |
| 12:00 рм-1:30 рм | Luncheon and Mentoring Activity Byrdland/Firebird/Flying V/SG | |
| 1:30 рм-3:00 рм | Concurrent Therapeutic Breakout Ses | sions |
| | Helping Patients With Chronic Pain Evaluate Claims for Unproven Remedies Fender Ballroom I | Managing Cough and Cold Symptoms in Pediatric Patients— Now What? Fender Ballroom II and III |
| | Moderator Tami L. Remington, PharmD The University of Michigan | Moderator Karen J. Tietze, PharmD University of the Sciences in Philadelphia |
| | Speaker Carla R. Rubingh, PharmD University of Nebraska Medical Center | Speaker Leslie A. Briars, PharmD University of Illinois at Chicago |
| 3:00 рм-3:30 рм | Break | |
| 3:30 рм-5:00 рм | Concurrent Breakout Sessions | |
| | Counseling Self-Treating Patients Quickly and Effectively: A QuEST for the Ideal Process <i>Fender Ballroom I</i> | Integrating Health Literacy Concepts in Self-Care Education: Teaching Patients With Diabetes Fender Ballroom II and III |
| | Moderator Rosemary R. Berardi, PharmD, FCCP, FASHP, FAPhA The University of Michigan | Moderator Lisa A. Kroon, PharmD, CDE University of California–San Francisco |
| | Speaker Shauna M. Buring, PharmD University of Cincinnati | Speaker Sharon L. Youmans, PharmD, MPH University of California–San Francisco |
| 5:00 рм | Adjournment | |
| 6:30 рм | Dinner at the Hard Rock Hotel Chica | 30 |
| E | 6 | |



SATURDAY, JUNE 21, 2008

| 7:00 AM-8:00 AM | Breakfast |
|------------------|---|
| 8:00 AM-9:30 AM | Breaking News and Emerging Self-Care Issues Fender Ballroom |
| | Moderator Karen J. Tietze, PharmD University of the Sciences in Philadelphia |
| | What's in the Bottle? Judy McMeekin, PharmD Food and Drug Administration/Center for Drug Evaluation and Research |
| | The Effects of Regulatory Activity on Self-Care for Cough and Cold Karen Shapiro, PharmD Arcadian Health Plan |
| | Behind-the-Counter: Where Does It Stand? Marcie A. Bough, PharmD American Pharmacists Association |
| 9:30 AM-9:50 AM | Break |
| 9:50 AM-11:50 AM | Roundtables—Educational Best Practices Fender Ballroom |
| | Moderator Anne Lamont Hume, PharmD, FCCP, BCPS University of Rhode Island |
| | Community Pharmacy Practice Experience Target Intervention Programs to Increase Appropriate Use of OTC Calcium and Aspirin Jennifer Cerulli, PharmD, BCPS, AE-C Albany College of Pharmacy |
| | Fostering Learning and Growth Through Innovative Teaching Strategies Nicole M. Gattas, PharmD, BCPS St. Louis College of Pharmacy |
| | Teaching Self-Care Practices in Asthma Management Through Service- Learning Katherine Heller, PharmD Palm Beach Atlantic University |
| | Partners in D: First-Year Pharmacy Students Patient Consultation in Medicare Part D Plan Selection Roger S. Klotz, RPh, BCNSP, FASCP, FACA, FCPhA Western University of Health Sciences |
| | 6 |



| | | Designing Patient-Centered Wellr and Prevent Disease Thomas L. Lenz, PharmD, MA Creighton University | ness Programs That Enhance MTM | | |
|------------------|--|---|---|--|--|
| | | Self-Care and OTC Education for Paul J. Oesterman, PharmD University of Southern Nevada Vicki Chan-Padgett, PA-C, MPAS | | | |
| | | Touro University–Nevada Using Games to Reinforce Learnin Pharmacotherapeutics Case Studi Jeegisha Patel, PharmD Oregon State University/Oregon He | es | | |
| | > | Partner for Promotion—A Longitu Pharmacy Practice Experience Jennifer L. Rodis, PharmD The Ohio State University | udinal Community Advanced | | |
| | > | Teaching Students to Overcome O Use of Conversation Maps Jennifer D. Smith, PharmD, CPP, Campbell University Wilson Community Health Center | Communication Barriers Through the BC-ADM, CDE | | |
| 11:50 ам-1:00 рм | | ncheon and Group Photograph dland/Firebird/Flying V/SG | | | |
| 1:00 рм-2:30 рм | Concurrent Therapeutic Breakout Sessions | | | | |
| | 0 | elf-Care Strategies for Preventing steoporosis ender Ballroom I | Using Monitoring Devices and Diagnostic Products in Medication Therapy Management Fender Ballroom II and III | | |
| | L | oderator eslie A. Shimp, PharmD, MS niversity of Michigan | Moderator Stefanie P. Ferreri, PharmD, CDE, FAPhA University of North Carolina at Chapel Hill | | |
| | L B | Deaker Duise Parent-Stevens, PharmD, CPS he University of Illinois at Chicago | Speaker Megan Wagner, PharmD SUPERVALU Pharmacies | | |

2:30 рм-3:00 рм

Break



| 3:00 рм-5:00 рм | Emerging Clinical Evidence and Practical Implications Fender Ballroom | | |
|-----------------|--|--|--|
| | Moderator Carol J. Rollins, MS, RD, PharmD, BCNSP University of Arizona | | |
| | Emerging Evidence on Vitamin D—Beyond Bone Health Roger S. Klotz, RPh, BCNSP, FASCP, FACA, FCPhA Western University of Health Sciences | | |
| | Evidence for Using Probiotics in the Treatment of Irritable Bowel Syndrome H. Jae Kim, MD, MSc Mayo Clinic College of Medicine | | |
| | Recent Data and New Self-Care Strategies for Improving Eye Health Richard G. Fiscella, MPH, RPh University of Illinois at Chicago | | |
| | Translating Evidence Into Practice: Opportunities Through Practice- Based Research Earlene Lipowski, PhD University of Florida | | |
| 5:00 рм | Adjournment | | |

SUNDAY, JUNE 22, 2008

| 7:30 AM-8:00 AM | Breakfast Byrdland/Firebird/Flying V/SG |
|-----------------|---|
| 8:00 AM-9:00 AM | What's New in the OTC Aisle? Novel Products and Rx-to-OTC Switches Fender Ballroom |
| | Moderator Gail D. Newton, PhD, RPh Purdue University |
| | Speakers R. William Soller, PhD University of California–San Francisco |
| | Sharon B.S. Gatewood, PharmD Virginia Commonwealth University Ukrop's Pharmacy |
| 9:00 ам-9:15 ам | Break |



| 9:15 ам-11:30 ам | Innovative Self-Care Activities in Pharmacy Practice Fender Ballroom |
|-------------------|--|
| | Moderator Tami L. Remington, PharmD The University of Michigan |
| | Expanding Clinical Services Through Collaborative Practice Protocols Nancy Hecox, PharmD, CDP Bi-Mart Pharmacy |
| | Establishment of Academic-Practice Partnerships With a Focus on Self-Care Christopher J. Turner, BPharm, PhD University of Colorado Denver |
| | Self-Care and Medication Therapy Management Services Natasha Michaels, PharmD Kerr Health Care Center |
| | Indian Health Service Pharmacy Practice: Providing Patient-Centered Care and Self-Care Activities CDR Christopher Lamer, PharmD, MHS, BCPS, NCPS, CDE Indian Health Service |
| | A Successful Community Pharmacy–Based Weight Loss Program D. Terry Forshee, DPh, PD, CDE Cherokee Pharmacy and Take Charge Nutrition |
| | Developing Pharmacist-Run Community Health Centers Seena L. Haines, PharmD Palm Beach Atlantic University |
| 11:30 ам-12:00 рм | Closing Remarks and Departures Fender Ballroom |
| | Elizabeth A. Cardello, RPh |

American Pharmacists Association





Reach Higher

June 8-11 - ASHP 2008

Summer Meeting and Exhibition Washington State Convention and Trade Center Seattle, Washington

An Intensive Educational and Skills-Building Experience for Health-System Pharmacy Leaders

ONSITE PROGRAM

<u>Elevate Your Expectation</u>

FULL PAGE AD

C2

Medi-Dose

FULL PAGE AD

Page 1

ASHP Ad

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Reach Higher

June 8-11 - ASHP 2008

Summer Meeting and Exhibition Washington State Convention and Trade Center Seattle, Washington



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Ameri-Dose

General Information

Meeting Location

All ASHP meeting sessions, House of Delegates activities, and exhibits will be held at the beautiful Washington State Convention and Trade Center unless noted otherwise. The Center is a non-smoking facility, conveniently located in the heart of downtown Seattle, with onsite parking, business services, and eateries—and all within steps of the official ASHP Summer Meeting hotels.

Registration

Registration is located in Exhibition Hall 4C, Level 4.

Self-Registration with Scan & Go Speed Pass

Pre-registrants can scan the bar codes found on their confirmation letters for even faster service. This confirmation will get you through the *fast lane* of **Scan & Go Registration**, so be sure to bring your confirmation with you. You must present photo identification. Kiosks can be used for badge and ticket pick-up by pre-registered attendees and exhibitors, and for onsite attendee registration.

HOURS

| Saturday | 1:00 PM - 5:30 PM |
|------------------|-------------------|
| Sunday | 7:30 AM – 5:30 PM |
| Monday — Tuesday | 7:30 PM – 4:00 PM |
| Wednesday | 7:30 AM - 1:00 PM |

Staffed Registration

Assistance will be available if you choose to register onsite and not use the Self-Registration Kiosks.

HOURS

| Saturday | 1:00 PM - 5:30 PM |
|----------------|--------------------|
| Sunday | 9:00 AM - 5:30 PM |
| Monday-Tuesday | 7:30 AM – 2:00 PM |
| Wednesday | 7:30 AM - 12:00 PN |

Badges

Badges should be worn at all times, preferably on your right side where they are easier to read. Your badge is your admission pass for all meeting sessions, exhibits, and the Welcome Reception.

Badges are color-coded as follows:

| Green | Full-Time Registrant |
|--------|----------------------|
| Red | Part-Time Registrant |
| Blue | Exhibitor |
| Yellow | Guest |

Lost Badges

Should you lose you badge while attending the meeting, please check with the ASHP Summer Meeting Information Center to see if it has been turned in. Lost badges can be replaced at Staffed Registration for a \$25 replacement fee.

Badge Ribbons

Wear your membership ribbon proudly! Come by the ASHP Membership Information Center and pick up a ribbon showing your years of ASHP membership. New ASHP members, Fellows, Section Members, and Poster Reviewers can also pick up their badge ribbons at this location. Presenters of educational programs will receive their ribbons in the meeting rooms prior to the start of the sessions. Poster Presenters will pick up their ribbons during poster set-up.

Electronic Business Card

All full- and part-time registrants should find an electronic business card with their registration materials. The card is encoded with your registration information. Because all cards look alike, it's important to print your name on the back of your card as soon as you receive it. Exhibitors have the option of renting a card reader for their booth. Using your card when visiting these booths will save you time in completing surveys, forms, and when requesting additional information.

Download Multimedia Sessions of the ASHP 2008 Summer Meeting

Catch the educational sessions you miss. After the meeting, we'll be offering Web access to all available audio-synched presentations. Order all the sessions onsite for \$99 or for \$199 when you get home.

Guest Program

Guests of registered Summer Meeting attendees are welcome to attend the 2008 Summer Meeting and Exhibition. Pre-registered Guest Program participants may attend the specially planned tours, "Blues n' Brews" Welcome Reception, Exhibit Program, and lunch on Wednesday in the Exhibit Hall. Tickets for the daily tours can be purchased at the Tour Desk the day of the tour, based on availability, and on a first-come, first-served basis. The Tour Desk opens thirty (30) minutes prior to the scheduled time of departure. The per person daily tour prices are listed below. Tours will depart from the Convention Place Tunnel which is located on Level 1 of the Convention & Trade Center behind the escalators. (see pg 8 for tour descriptions).

Guest Daily Tour Pricing

Monday, June 9 9:45 AM – 2:45 PM **Tastes of the Pike Place Market and Seattle Highlights** \$130.00

Tuesday, June 10 10:30 AM - 2:30 PM Glassblowing and Lakes Cruise \$95.00

Housing Questions

If you have a housing question the hotel is unable to answer, a Housing Bureau representative will be available on Sunday from 9:00 AM - 4:30 PM and Monday from 7:30 AM - 4:30 PM. Please visit the ASHP Headquarters Office in Room 310 (Level 3) and the receptionist will be able to assist you with contacting the Housing Bureau. You may also contact the Housing Bureau directly by calling 888-877-0255 or 206-461-5881.

FULL PAGE AD

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Ortho McNeil

General Meeting Information

Remember to Bring a Book

Our keynote speaker, Sir Ken Robinson, is a pioneer in the crusade to create an education system that not only teaches our children - but also embraces and encourages their creative minds. In an effort to support this wonderful pursuit, ASHP is partnering with BooksFirst!, a non-profit organization that collects and distributes high-quality books to under-resourced classrooms. Please join us in this cause by bringing one children's literature book to donate in the registration area. We ask that the books be new or used but in good condition; and please, no textbooks. Thank you for your continuing support of ASHP and the ever-growing learning community.

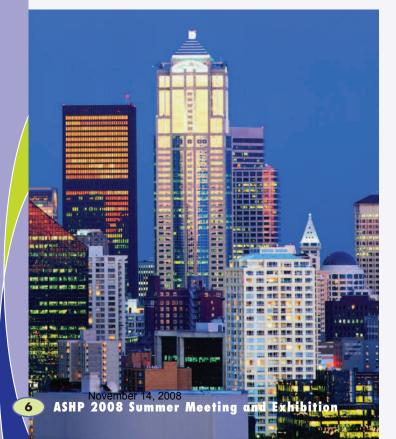
Children

For health and safety considerations, children under the age of 16 years will not be admitted to the Exhibit Hall or educational sessions.

Consumption of Alcoholic Beverages Policy

Attendees of the meeting should take note of the policy approved by the ASHP House of Delegates regarding the consumption of alcoholic beverages:

"That alcohol is a drug and should be used with the respect and concern afforded to any drug; that pharmacists should extend their professional obligations and responsibilities to alcohol use by individuals and themselves; that pharmacists have an obligation to ensure that, if consumed, alcohol is used only responsibly; that pharmacists, by example in their personal conduct, should foster awareness of the nature of alcohol and responsible use of alcohol by those who choose to use alcohol; and that ASHP and its members continue to support and foster impaired-pharmacists programs as a means of providing opportunities for such individuals to rehabilitate themselves."



KEY LOCATIONS ASHP Headquarters Office

Room 310, Level 3

Registrants may contact ASHP staff and make general inquires about the meeting through the ASHP Headquarters office.

Exhibition Program

Exhibition Hall 4A/B, South Lobby, Level 4

Network with industry representatives and learn about the latest in pharmaceutical products and technology in the Exhibit Hall. Make sure you allow time in your busy schedule for this one-of-akind experience!

HOURS

| Monday—Tuesday | 11:00 AM-2:00 PM |
|----------------|------------------|
| Wednesday | 11:00 AM-1:00 PM |

Don't Miss Out! On Wednesday, ASHP is hosting lunch in the Exhibit Hall. A ticket, included in the full-time registration fee, one-day Wednesday registration fee, and Guest Program price, is required to receive lunch. Tickets are valid on Wednesday only.

ASHP Summer Meeting Information Center

Room 454, Level 4 (South Galleria)

Do you have questions specifically about the ASHP Summer Meeting & Exhibition? For answers, stop by the ASHP Summer Meeting Information Center, located in Room 454 (Level 4, adjacent to the South Galleria).

| H | 0 | U | R | S | |
|---|---|---|---|---|--|
| H | 0 | U | R | S | |

| Saturday | 10:30 AM - 5:30 PM |
|-----------|--------------------|
| Sunday | 7:30 AM - 6:00 PM |
| Monday | 7:30 AM – 5:15 PM |
| Tuesday | 7:30 AM – 5:15 PM |
| Wednesday | 7:30 AM – 3:00 PM |
| | |

ASHP Membership Information Center

South Lobby, Level 4

The Membership Information Center will have resources available for all new members, current members, and those who would like to join ASHP. Stop by to learn about the many benefits and opportunities for involvement. Take Control of Your Future...Become Involved Today!

HOURS

| Sunday | 9:00 AM - 4:30 PM |
|----------------|-------------------|
| Monday-Tuesday | 7:30 AM - 5:00 PM |
| Wednesday | 7:30 AM – 2:00 PM |

ASHP Bookstore

South Lobby, Level 4

Visit the ASHP Bookstore where you'll find the latest resources designed to meet your professional and clinical needs. Purchase our newest reference books and software or see a demonstration of our latest electronic products. Be sure to take advantage of our free shipping, offered exclusively at the ASHP Bookstore.

HOURS Sı

| Sunday | 9:00 AM - 4:30 PM |
|----------------|---------------------------|
| Monday-Tuesday | 7:30 AM - 5:00 PMpage 688 |
| Wednesday | 7:30 AM – 2:00 PM |

FULL PAGE AD

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NuAire

General Meeting Information

NEW! Networking Lounge

South Lobby, Level 4

Need a location to meet up with colleagues and friends or just a place to sit down and take a break? If so, ASHP has created this comfortable spot for all our Summer Meeting participants to join up with each other, relax between sessions, or just grab a light bite to eat.

ASHP Network Connections

South Lobby, Level 4

Located within the Networking Lounge, ASHP Network Connections allow you to send and receive email messages without leaving the Convention and Trade Center. This service features individual computer workstations where you can send, retrieve, and print your emails. You can also use the Network Connections to submit your CE Request and Meeting Evaluations online. As of Tuesday morning, stations will also be available in the Registration Area (Exhibition Hall 4C).

HOURS

| Sunday | 9:00 AM - 5:30 PM |
|-----------|-------------------|
| Monday | 7:30 AM - 5:30 PM |
| Tuesday | 7:30 AM - 5:30 PM |
| Wednesday | 7:30 AM – 3:00 PM |

ASHP Press Office

Room 304, Level 3

ASHP staff are available to assist members of the media. Meeting attendees can visit the Press Office for a preview of the promotional materials available for this year's observance of National Hospital & Health-System Pharmacy Week or to arrange for hometown publicity of their presentation at the Summer Meeting.

HOURS

| Sunday: | 10:00 AM - 2:00 PM |
|-------------------|--------------------|
| Monday — Tuesday: | 8:00 AM - 4:00 PM |
| Wednesday: | 9:00 AM - 12:00 PM |

ASHP Audio-Visual Preview Room

Room 308, Level 3

Computers will be available for speakers to preview their slides from 7:00 AM to 6:00 PM daily.



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ASHP Summer Meeting News & Views

Stands with abundant supplies of the latest ASHP Summer Meeting news are located throughout the Convention and Trade Center.

Business Services

Level 1

FedEx Kinko's is a full-service business center, offering FedEx shipping, high-speed duplication, binding, posters, signs, banners, fax service, instant passport photos, lamination, Mac and PC rentals, Internet access and free pick-up and delivery. E-mail your documentation preparation requests right from your PC. E-mail: usa5161@fedexkinkos.com Phone: 206-467-1767

HOURS

| Saturday and Sunday | 9:00 AM - 6:00 PM |
|---------------------|--------------------|
| Monday | 7:00 AM — Midnight |
| Tuesday — Thursday | Open 24 hours |
| Friday | Midnight – 9:00 PM |

Coat and Baggage Check

South Lobby, Level 4

| HOURS | |
|----------------|-------------------|
| Monday-Tuesday | 7:30 AM - 6:00 PM |
| Wednesday | 7:30 AM - 3:00 PM |

First Aid Station

In the event of a medical emergency, contact the Convention and Trade Center's *Security Control* immediately by dialing 5127 or 206-694-5127 from any house phone located in the facility. In addition, red "hot line" phones are located around the facility; these ring directly into the Security Control Office. The Convention and Trade Center requests that our clients and guests *not* contact 911 directly.

Lost and Found

Security Control Office

Lost and found items should be turned into and claimed at the Convention and Trade Center's Security Control Office. Security can be reached by dialing extension 5127 on any house phone or 206-694-5127 in the Convention and Trade Center.

Restaurant Reservations / Concierge Services

Level 1

Seattle's Convention and Visitors Bureau is proud to offer the Seattle Visitor Center / Concierge Services. Stop by or make Visitor Information inquiries by calling 206-461-5840. Friendly staff can find and book all kinds of services, such as:

- Restaurant reservations: insider's access and knowledge to find the right place to match your wishes.
- Ground transportation of all kinds: taxis, towncars, vans, limos, with the best-informed drivers in town.
- Personal services: babysitting, flowers, spas and salons, massage.

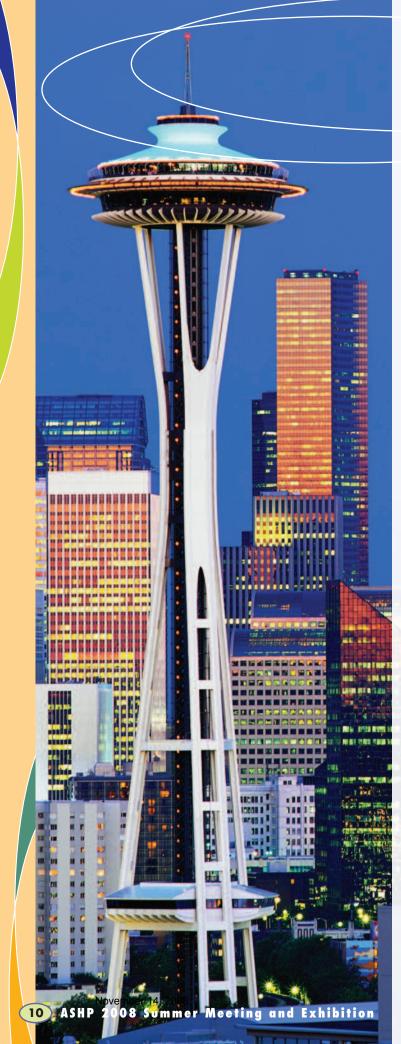
HOURS

9:00 AM - 5:00 PM daily.

FULL PAGE AD

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Advantage



State Affiliate Networking Roundtables

Saturday, 12:30 PM – 2:15 PM Willow A, Level 2 Sheraton Seattle Hotel

All state affiliate volunteer leaders (officers, staff, committee chairs, committee members, etc.) are invited to participate. Networking Roundtables are where those participating can share their challenges and offer best practices. Potential topics include non-dues revenue, membership recruitment and retention, leadership development, student and new practitioner involvement, approaches to strategic planning, advocacy initiatives, and others.

ASHP-PAC Breakfast - Countdown to November

Sunday, 7:00 AM – 8:30 AM Sheraton Seattle Hotel

Willow A, Level 2

The 2008 elections are heating up. In November, the White House, and control of the Congress will be hotly contested. ASHP's political action committee, ASHP-PAC, is gearing up to support candidates who are "pharmacy-friendly." Attend the PAC breakfast and learn how to get involved in ASHP's political advocacy. For more information or to support the ASHP-PAC, contact gad@ashp.org

National Hospital & Health-System Pharmacy Week Open House

Sunday, 11:30 AM – 1:00 PM

Room 304, Level 3

Get tips on planning your pharmacy department's observance of National Hospital & Health-System Pharmacy Week (October 19-25). Preview the promotional items available for this year's observance and get tips for "telling your story" from ASHP's Public Relations staff.

"Blues n' Brews" Welcome Reception

Sunday, 5:00 PM - 6:30 PM

South Lobby and Plaza, Level 4

Whether you'll be spending the day traveling to Seattle, participating in the House of Delegates, or setting up your booth in the Exhibit Hall, we invite you to join us Sunday evening for a welcoming celebration like no other! Light hors d'oeuvres and a sampling of some of the Northwest's best micro-brewed beers will be available for your taste buds to explore, all while enjoying sounds from local "Blues" musicians in the company of your colleagues and friends. What better way to kick off this year's Summer Meeting & Exhibition!

Tickets for the reception are included in the full-time paid registration fee and Guest Program price. New this year, registered exhibitors will also receive a ticket. Additional tickets can be purchased in Staffed Registration for \$25.00. Tickets are non-refundable.

> Special Events continued on page 12

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GUEST PROGRAM TOURS

Tours will depart from the Convention Place Tunnel located behind the escalators on Level 1 of the Convention and Trade Center. Based upon availability, tickets for the daily tours can be purchased at the Tour Desk the day of the tour on a first-come, first-served basis. The Tour Desk opens thirty (30) minutes prior to the scheduled time of departure.

Tastes of the Pike Place Market and Seattle Highlights

Monday, 9:45 AM - 2:45 PM

This tour will highlight Seattle's most memorable and historic areas. The first stop on the tour will be Pike Place Market. A century after its founding, the Market remains a vital part of Seattle's social and economic fabric. While at the Market, eat your way through Seattle's most celebrated culinary landmark and experience some of the most sought-after market stops and interesting local creations.

After spending time at Pike Place Market, get ready to view Seattle from the perspective of a local. You will be escorted around town by a friendly and informative Seattleite who will provide historical background of the area, point out interesting landmarks, as well as give insider tips on special shopping and sightseeing areas.

This portion of the tour will begin with a stop by Seattle's waterfront the Hiram Chittenden Locks. A stop at the Locks will show how the area's fresh and salt waters meet. Following the Locks, your coach will embark on a scenic drive through Seattle's best neighborhoods on the way to the Space Needle. You then will have the opportunity to ascend 605 ft. to the top of Seattle's most recognizable landmark and enjoy views of Puget Sound, Mount Rainier, the Cascade and Olympic mountain ranges and, of course, the beautiful city of Seattle!

Note: A light jacket and comfortable shoes are recommended.

Glassblowing and Lakes Cruise

Tuesday, 10:30 AM – 2:30 PM

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Head to historic Pioneer Square for a live glass blowing demonstration and tour. Seattle has become internationally recognized as a center for glass art in the world, second only to Venice, Italy. There will be a private glassblowing demonstration at Glasshouse Studio during your visit. Be amazed as glass artists form masterful pieces right before your eyes.

While in Pioneer Square, you will also visit Foster White Gallery. Since its inception in 1968, the gallery has become one of the premier galleries on the West Coast exhibiting a wide range of contemporary paintings, sculptures and glass pieces. The gallery has represented internationally renowned artist Dale Chihuly since 1978 and continues to represent the best and brightest glass artists. A boxed lunch is included during your visit to Pioneer Square.

The final component of the tour will be a two-hour lakes cruise, which will treat you to spectacular glimpses of Seattle's unique inner-city shoreline. The cruise starts in Lake Union where guests will pass kayakers, sailors and the famous houseboat from Sleepless in Seattle. You will cruise into Lake Washington and pass the University of Washington's football stadium and Seattle's famous floating bridge. As you cruise in Lake Washington you will see million-dollar mansions including Bill Gate's, Kenny G's, the Nordstrom family's, and Steve Miller's, as well as more handcrafted houseboats.

Note: A light jacket and comfortable shoes are recommended.

POSTER AWARDS

Those posters describing research or projects that are related to 2008 Summer Meeting educational programming will be eligible to receive special recognition. "Educational programming" topics include those offered during the Learning Community, Series, and Hot Topics.

These posters will be presented on Monday and will be judged based on the following criteria:

- Project design: clearly-defined objectives, sound methodology, appropriate analysis of data, conclusions consistent with objectives and results, etc.
- Significance of project to the general body of knowledge
- Overall clarity and organization of poster

Judging will be performed onsite. Authors will receive special recognition onsite, and award-winning posters will be designated as such. Certificates will be mailed to winners following conclusion of the Summer Meeting.

OPENING SESSION

Monday, 10:10 AM – 11:00 AM Ballroom 6A/B, Level 6

Presidential Address



Janet A. Silvester, MBA, FASHP, Director of Pharmacy

Services, Martha Jefferson Hospital, Charlottesville, VA

Acknowledgement of 2008 Harvey A. K. Whitney Award Recipient



Philip J. Schneider, M.S., FASHP

Acknowledgement of the Donald E. Francke Medal Recipient



Toshitaka Nabeshima, Ph.D.

Keynote Address: Sir Ken Robinson, Ph.D.



As a pharmacy leader, how are you responding to your most urgent day-to-day issues?

- Making sound decisions for your patients despite the challenges resources, regulatory standards, personnel issues
- Convincing colleagues and superiors of the value of pharmacy services
- Implementing and sustaining best practices in quality, efficiency, safety
- Fluctuations in culture, workflow, morale in this ever-changing environment
- Shortage of pharmacists, nurses
- Balancing personal life and career

Are your responses creative? Innovative? In our Opening Session, Sir Ken Robinson will identify the major myths about creativity that hold organizations back and the proven strategies for innovation that drive the great ones forward. Voted Best Speaker of the Year by more than 200 global and European companies, Sir Ken delivers core ideas and techniques that have the power to make **innovation** an organizational habit.

Knighted by Queen Elizabeth II in 2003 for his outstanding achievements as a leading expert on human resources, Sir Ken has advised international governments, Global 500 companies, not-for-profit corporations and some of the world's leading cultural organizations.

A powerful storyteller with personal warmth, intellectual clarity, and the timing of a stand-up comedian, Sir Ken was born in Liverpool in 1950. He earned a Ph.D. from the University of London in 1981, and until 2001 was a Professor of Education at Warwick University in the UK; he is now a Professor Emeritus. Author of several books, his most recent, "Out of Our Minds: Learning to be Creative," is described by *Director* magazine as "a truly mind-opening analysis of why we don't get the best out of people at a time of punishing change." In 2005, Sir Ken was named as one of Time/Fortune/CNN's "Principal Voices," and is facilitating the project *Catalyzing Creativity*, a forum for the discussion and exchange of ideas on innovation and creativity in business.

In his provocative, inspiring, and uniquely funny presentations, Sir Ken draws from worldwide practical experience and cutting-edge research in science, business, and the arts to unlock the kind of thinking that solves problems and sustains innovation.

THE INAUGURAL AND AWARDSTuesday, 10:10 AM - 11:00 AMBallroom 6A/B, Level 6

Welcoming Remarks from the ASHP President:



Janet A. Silvester, MBA, FASHP

Janet A. Silvester, MBA, FASHP, Director of Pharmacy Services, Martha Jefferson Hospital, Charlottesville, VA

Presentation of the 2008 Practitioner Recognition Awards

The ASHP Practitioner Recognition Program recognizes excellence in pharmacy practice and grants recognition and promotes public awareness of pharmacists who have distinguished themselves in pharmacy practice. Individuals who have achieved FASHP status have successfully demonstrated sustained practice excellence in health-system pharmacy practice for 10 years or greater, contributed to the total body of knowledge in pharmacy practice, demonstrated active involvement and leadership in professional activities, and have actively been involved in and committed to educating practitioners and the public.

Dennis G. Brierton, PharmD, BCPS Brian D. Buck, PharmD Richard M. Cadle, PharmD, BCPS Michele A. Danish, PharmD Mark Donaldson, BS, PharmD Patricia Pecora Fulco, BS, PharmD, BCPS Mary M. Hess, PharmD Jon D. Horton, BS, PharmD William N. Jones, MS Thomas D. Keith, MS, PharmD Michael G. Kendrach, PharmD Laura K. Mark, MS, PharmD Teresa A. Miller, PharmD, FCSHP Natasha C. Nicol, PharmD Jennifer G. Reddan, PharmD Michael P. Rivey, MS, BCPS Armen I. Simonian, PharmD Susan J. Skledar, RPh, MPH Fei Wang, MSc, PharmD, BCPS Patricia M. Wegner, PharmD

ASHP Board of Directors Awards Presentation

Honorary Membership:



Charles M. King, Jr., BSPharm, MS

Charles (Chuck) M. King, Jr. has been director of pharmacy services in several hospitals and has served on the faculty of the Samford University, College of Pharmacy, and the University of Alabama, School of Health

Services Administration. Additionally, King was director of pharmacy at the University of Minnesota Hospitals and director of graduate studies in hospital pharmacy there. In 1987 he joined the ASHP Research and Education Foundation as its Executive Vice President and Chief Executive Officer.

Under his leadership at the ASHP Foundation, the organization expanded its program offerings significantly while building a strong financial base. In the mid-nineties, King led a major capital campaign to ensure that the ASHP Foundation was positioned to fund important programs into the future through the creation of an endowment program named in honor of former ASHP CEO, Joseph A. Oddis. The net assets of the ASHP Foundation grew from less than \$1 million in 1987 to more than \$10 million upon his retirement in 2000.

King received his BS in Pharmacy from the University of Toledo, College of Pharmacy, and his MS in Pharmacy from the Philadelphia College of Pharmacy.

Honorary Membership:



David Zilz, RPh, MS, FASHP

David Zilz is Senior Consultant, Corporate Pharmacy Programs UW Health Systems and Hospital & Clinics, Clinical Professor Emeritus- UW School of Pharmacy -Madison, Wisconsin, and maintains an active independent consulting practice.

At UW Hospital and Clinics, Zilz was devoted to identifying and implementing innovative contemporary pharmacy practices services, training of pharmacy residents, and developing new hospital administrative services. In addition to serving as the Director of Pharmacy Services for more than two decades, Zilz was instrumental in establishing a number of key hospital programs including: Home Care and Infusion Services, a UWHC Technology Identification and Assessment organization, and the Office of Clinical Research for the UW Medical School capacity.

His organization and association leadership roles have included two three-year terms as Treasurer of ASHP, Chair of Novation Pharmacy Executive Committee, Member of Steering Committee of Pharmacy Executive Committee -University Health Systems Consortium, and Coordinator of programs for the Directors of Pharmacy of the Wisconsin HMO Association, Chair Wisconsin Pharmacy Forum (Triad of PSW, UW School of Pharmacy, State Examining Board) Board of Visitors UW School of Pharmacy.

A past president of ASHP, Zilz is a recipient of the Harvey A.K. Whitney Lecture Award, the ASHP Award for Distinguished Leadership in Health-System Pharmacy Practice, the John Webb Visiting Lecture Award, the Donald C. Brodie Pan Pacific Award, a John McKesson Inaugural Fellow, and was named twice as the WSHP Pharmacist of the Year. He has an extensive list of publications related to pharmacy, hospital administrative, and other health-related topics. He continues to lecture in the United States and internationally on trends that impact the research, production, distribution, and utilization and management implications of pharmaceuticals in the United States.

Award of Excellence:



Daniel E. Buffington, PharmD, MBA

President and CEO of Clinical Pharmacology Services (CPS) in Tampa, Florida, **Dan Buffington** maintains membership in numerous pharmacy and medical organizations at local, state, and national levels, serving on committees, involving himself in legislative

initiatives, and holding elected offices. CPS, which he created in 1991, emulates a medical specialty practice model, providing patient care services and also serves as a clinical research center and training site for medical and pharmacy students. The practice has grown to include 7 pharmacists, 2 physicians, and more than 25 employees.

An active participant in several collaborative national efforts between various pharmacy organizations on reimbursement issues, including the current Pharmacist Services Technical Advisory Coalition (PSTAC), Buffington was appointed to the American Medical Associations (AMAs) Current Procedural Terminology (CPT) Panel in 2004. He represents the pharmacy profession on the CPT's Allied Health Committee, and has played an active role in the development of professional relationships and ultimately the approval of the new permanent Medication Therapy Management (MTM) CPT codes that are pharmacist-specific.

Buffington routinely serves as a pharmacy expert for the media, including television, radio, and newspaper interviews on clinical issues and issues surrounding drug therapy topics and has testified for House and Senate subcommittees on pharmacy issues. Having accepted a full-time faculty position in Internal Medicine at the University of South Florida (USF) College of Medicine early in his career, Buffington helped develop the University's Division of Clinical Pharmacology, and still serves as clinical faculty with the USF College of Medicine.

The author of many articles and textbook chapters on both clinical and pharmacy management topics, Buffington's devotion to advancing pharmacist clinical services is evident in this passion for medication safety, pharmacy practice models, and the pursuit of reimbursement for pharmacist services.

Inaugural Address



Kevin J. Colgan, MA, RPh, FASHP, PharmD, MBA

Incoming ASHP President **Kevin J. Colgan, MA, RPh, FASHP,** Senior Vice President of Health Economics and Outcomes Research, EPI-Q, Inc., Oakbrook, IL

The Inaugural Reception follows the session.

HARVEY A.K. WHITNEY LECTURE AWARD RECEPTION AND DINNER

Tuesday, 7:00 PM - 10:00 PM

Metropolitan Ballroom, Level 3, Sheraton Seattle Hotel



Enjoy an elegant evening as we honor the Harvey A.K. Whitney Lecture Award recipient, **Philip J. Schneider, MS. FASHP**

The Harvey A.K. Whitney Lecture Award is the most prestigious honor awarded in health-system pharmacy – is presented annually

to an individual who has made an outstanding contribution to health-system pharmacy practice. Tickets are \$80

and nonrefundable. Order tickets when you register or at the meeting in the Registration Area. Seating is reserved and table selection must be made at the Member Services Desk by 2:00 PM on Monday, June 9. Attire is evening formal, black tie optional.

Philip J. Schneider, MS, FASHP, is a clinical professor and director of the Latiolais Leadership Program at The Ohio State University College of Pharmacy. His current teaching and research are focused on improving the medication-use process and improving medicationuse safety. He developed a nationally recognized program for the reporting and analysis of adverse drug events that led to improvements in the medication-use process at the Ohio State University Medical Center. The severity scale developed as part of this program is widely used in the health care industry, including serving as the basis for the system used by the United States Pharmacopeia.

Schneider is a past president of ASHP and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). He is also a widelypublished author who has written more than 100 articles and abstracts in professional and scientific journals, ten book chapters, and edited seven books. He is a sought-after speaker and has made numerous presentations to both domestic and international audiences.

Long active in the international arena, Mr. Schneider was the 2006 recipient of ASHP's Donald E. Francke Medal, which honors individuals who have made significant contributions to international pharmacy practice. He is past Secretary and newsletter editor of the Hospital Pharmacy Section of the International Pharmaceutical Federation (FIP), served as chair of the Congress Planning Committee, and was a member of the FIP Board of Pharmacy Practice and Executive Committee.

Special Events > ASHP House of Delegates

The House of Delegates is the major policymaking body of ASHP. The 60th Meeting of the ASHP House of Delegates will convene at the Washington State Convention and Trade Center during the Summer Meeting. Meetings are scheduled so that all attendees may observe the House in action. The Open Forum on Saturday is your opportunity to share your views with ASHP officers, board members, and Policy Committee chairs about Society activities or services issues, or other matters of professional concern to practitioners.

House of Delegates Registration

Saturday, 1:00 PM – 5:30 PM

Exhibition Hall 4C, Level 4

Sunday, 7:30 AM – 12:00 PM (After Sunday, register in the Executive Office)

House of Delegates Caucuses Facilitated by the Chair of the House

Sunday, 8:00 AM – 10:00 AM Room 619, Level 6 Tuesday, 11:00 AM – 1:00 PM



Open Forum for Members

Saturday, 2:30 PM – 4:30 PM Ballroom 6C, Level 6

This session is the "Open Hearing of the House of Delegates." Items scheduled for action by the House may be discussed as well as any matter of concern to ASHP members related to pharmacy practice in hospitals and health systems. Discussion will be facilitated by the Chair of the House of Delegates, and the session will be attended by ASHP officers, members of the Board of Directors, and ASHP staff. The Open Forum is an excellent opportunity for practitioners to bring emerging issues to the attention of ASHP leaders.

Delegate Primer on HOD Processes

(Previously known as the "Delegate Orientation")

Saturday, 4:30 PM – 5:30 PM Room 619, Level 6

Open to new and current delegates, this session is designed to review and familiarize members of the House of Delegates with parliamentary procedures used during the meetings.

House of Delegates First Meeting

Sunday, 2:00 PM – 4:30 PM

Meet the Candidates - Candidates for ASHP Offices to Go On-the-Record

Monday, 12:00 PM – 1:30 PM Room 619, Level 6 Hear what each nominee for ASHP President, Board of Directors, and House of Delegates Chair has to offer the membership at the "Meet the Candidates" session starting at noon. Afterward, the candidates will answer members' questions until 1:30 PM.

Election of the 2009–10 ASHP President and 2009–12 members of the Board of Directors will occur during the annual balloting in August. An audio recording of the "Meet the Candidates" session will be available from the ASHP Web site in time for the annual balloting.

The new Chair of the House of Delegates will be elected and installed Tuesday, June 10 during the House's Second Meeting, which starts at 4:30 PM.

Delegate Reception

Monday, 5:30 PM - 6:30 PM

Princessa Ballroom First Floor, Grand Hyatt Seattle

Ballroom 6E, Level 6

Open to delegates and alternate delegates.

House of Delegates Second Meeting

Tuesday, 4:30 PM – 6:00 PM

Ballroom 6E, Level 6

Find House of Delegates Agenda on page 17 Page 698

16) ASHP 2008 Summer Meeting and Exhibition

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House of Delegates Agenda > Special Events

Sunday, June 8 2:00 PM – 4:30 PM

2:00 PM – 4:30 PM

Ballroom 6E, Level 6

House of Delegates First Meeting

Presiding: Teresa J. Hudson Chair, House of Delegates

- 1. Call to Order
- 2. Invocation
- 3. Roll Call of Delegates
- 4. Report of Previous Session
- 5. Committees of The House
 - a. Report on Resolutions
 - b. Report of Committee on Nominations
- 6. Report of Officers
 - a. President and Chair of the Board Janet A. Silvester
 - b. Treasurer Paul W. Abramowitz
 - c. Executive Vice President Henri R. Manasse, Jr.
- 7. Recommendations of Delegates
- 8. Board of Directors Reports on Councils
 - a. Council on Pharmacy Management Stanley S. Kent, Board Liaison
 - b. Council on Pharmacy Practice James G. Stevenson, Board Liaison

- c. Council on Public Policy Sheila L. Mitchell, Board Liaison
- d. Council on Therapeutics Lynnae M. Mahaney, Board Liaison
- e. Council on Education and Workforce Development Diane B. Ginsburg, Board Liaison
- 9. Statements of Candidates, House of Delegates Chair
- 10. Announcements
- 11. Adjournment of First Meeting

Tuesday, June 10, 2008 4:30 PM – 6:00 PM Ballroom 6E, Level 6

House of Delegates Second Meeting

Presiding: Teresa J. Hudson Chair, House of Delegates

- 1. Call to Order
- 2. Quorum Call
- 3. Election of Chair of The House of Delegates
- 4. Committees of The House
 - a. Report on Resolutions
- 5. Unfinished and New Business
- 6. Recommendations of Delegates
- 7. Installation of Officers and Directors
- 8. Announcements
- 9. Adjournment of Session

SAVE THE DATE!

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Education Sessions

The ASHP 2008 Summer Meeting and Exhibition is designed for maximum flexibility, choice, and convenience. Choose whatever combination of programming is best for you!

LEARNING COMMUNITY

Build skills by participating in this year's Learning Community. The Learning Community is comprised of six sessions for 14 hours of practical, results-driven training.

The Business of Pharmacy Learning Community

When faced with escalating financial responsibility and seemingly out-of-control costs and bottom line pressure, hospital administrators sometimes question the ability of their pharmacy directors to manage the business equivalent of a multi-million dollar business. Underlying this concern are lack of understanding of the complexities of managing pharmacy operations, exception processes that make pharmacy so different from other clinical and operational departments, and the uniqueness that makes pharmacy both a clinical and operational function. All too often, issues surface only after critical incidents trigger doubts regarding the controls in place to manage specific functions, often with painful and disruptive results. These six sessions will address proactive financial and business strategies for health-system pharmacy success and effective integration with organization-wide strategy and communication.

Pharmacy through the C-Suite Prism Monday. 8:00 AM - 10:00 AM

Dollars & Sense: Building a Strong Financial Base Monday, 2:00 PM - 5:00 PM

Stewardship of Resources, Part 1: People Tuesday, 8:00 AM - 10:00 AM

Stewardship of Resources, Part 2: Services Tuesday, 2:00 PM - 4:30 PM

Innovating for the Future Wednesday, 8:00 AM - 11:00 AM

The Business of Pharmacy: Putting It All Together Wednesday, 1:00 PM - 2:30 PM

SERIES PROGRAMMING

Series programming offers the right level of detail by focusing on key aspects of a single topic. From basic to advanced, choose one or more stand-alone sessions in a series to meet your needs.

Quality Standards in Clinical Practice Series



Pharmacists are an integral spoke in the quality wheel, and we're the best equipped to be making key decisions about a patient's drug regimen. In this series, explore how new models can be used in implementing emergency pharmacy services; understand the need for pharmacy involvement and the various protocols used in glycemic control of patients; get up to speed on anemia management associated with renal disease; unearth what happens with medications in the ICU and behind the double-doors of the OR; and more, in this sixpart series. This series was planned in cooperation with the *ASHP Quality Improvement Initiative*.

Quality Standards in Emergency Pharmacy Monday, 8:00 AM - 10:00 AM

Achieving Optimal Glycemic Control Monday, 2:00 PM - 5:00 PM

Implementation of an Anemia Management Program Tuesday, 8:00 AM - 10:00 AM

How to Better Detect and Prevent Adverse Events and Medication Errors in Your ICU Tuesday, 2:00 PM - 4:30 PM

Anesthesia, OR, and PACU: Medication Use Behind the Double Doors Wednesday, 8:00 AM - 11:00 AM

Are Quality Standards Possible in Antibiotic Resistance? Wednesday, 1:00 PM - 2:30 PM

Anticoagulation Series

How can pharmacists be a part of the process of improving safe use of anticoagulants in both the inpatient and outpatient settings and at the patient and health-system level? Delve into the nitty-gritty, which will focus on a range of ways pharmacists can make a difference. The afternoon session will include breakout sessions.

Implementing the New National Patient Safety Goals on Anticoagulation Monday, 8:00 AM - 10:00 AM

Improving Safe Use of Anticoagulants Monday, 2:00 PM - 5:00 PM

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Education Sessions

Informatics Series

The information technology revolution has fueled the demand in hospitals and health systems for accomplished experts who can select, implement and maintain CPOE, BCMA, EHR and other systems. Are you keeping up with this revolution? Have all the information you need to be the project leader for BCMA or CDSS? In this series, wire-in on information technology's latest and greatest, and explore best practices – and pitfalls – in the evaluation, implementation, and monitoring of IT solutions.

An audience response system will be used in these sessions. Participation is limited, so please arrive early.

Where Do You Stand? Comparing Your Institution to the ASHP 2007 Informatics Survey Results Monday. 8:00 AM - 10:00 AM

Robotic IV Automation: Human Intelligence Combined with Robotic Accuracy Monday, 2:00 PM - 5:00 PM

It Is a Revolutionary Change: How to Prepare For and Carry Out a Successful CPOE Implementation Tuesday, 8:00 AM - 10:00 AM

Linear, 2-D Stacked, 2-D Matrix, Oh My! Navigating the Complexities of Barcode Medication Administration Tuesday, 2:00 PM - 4:30 PM

Managing Knowledge Management Systems: Optimizing CDSS Wednesday, 8:00 AM - 11:00 AM

Formulary Management in an Integrated Information System Environment: Challenges and Successes Wednesday, 1:00 PM - 2:30 PM

Hot Topics

Timely as always, these popular sessions cover top issues in health-system pharmacy. Topics include updates from The Joint Commission, USP <797>, new drugs in primary care, 340B, legislative issues, and more.

The Joint Commission Hospital Update 2008 Sunday, 10:30 AM - 12:00 PM

New Drugs in Primary Care 2008 Monday, 8:30 AM - 10:00 AM

The 340B Drug Pricing Program - An Update Monday, 2:00 PM - 5:00 PM

Implementing Evidence-Based Interventions to Improve the Treatment of Severe Sepsis:

The ASHP Research and Education Foundation Award for Excellence in Medication-Use Safety Winner Tuesday, 8:00 AM - 10:00 AM

USP <797> Update 2008 and Personnel-Related Environmental Sampling Tuesday, 8:00 AM - 10:00 AM

Current Legislative and Regulatory Issues in Pharmacy 2008 Tuesday, 2:00 PM - 4:30 PM

Complying with USP <797>: Hoods, Isolators, and Cleanrooms Tuesday, 2:00 PM - 4:30 PM

Prescription for Confusion: Health Literacy and the Rx Label Wednesday, 8:00 AM - 9:30 AM



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Educational Information

Educational Objectives

2008 ASHP Summer Meeting educational programs are developed to maintain and enhance the knowledge, skills, and abilities of pharmacists and associated personnel in health-care systems through instruction on important issues relevant to contemporary pharmacy practice. The educational goal of this meeting is to provide information and instruction on a variety of topics to enable pharmacy practitioners to provide quality patient care.

Target Audience

Programs at the 2008 ASHP Summer Meeting are intended to meet the needs of pharmacy managers and their staff, clinical pharmacists, clinical coordinators, and pharmacy technicians, and well as the pharmaceutical industry and academia.

Continuing Professional Development (CPD)*

ASHP offers a wide variety of continuing education programs to help you increase your knowledge and skills. As you identify your own professional needs and create your individualized CPD plan, ASHP can be a vital partner in helping you achieve your professional goals. At the 2008 Summer Meeting you won't just be getting CE; you'll be immersing yourself in the kind of meaningful learning that can truly improve patient care. Dialog and network with your peers. Experience the very best in live continuing education with ASHP.

*CPD definition:

Continuing Professional Development is the lifelong process of active participation in learning activities that assists individuals in developing and maintaining continuing competence, enhancing their professional practice, and supporting achievement of their career goals.

Poster Presentations

Poster sessions encourage registrants to informally discuss projects in pharmacy practice with colleagues. This is your opportunity to pick up ideas from successful programs that have worked in other healthcare systems. Due to ACPE regulations, CE is not offered for poster sessions.

There are three broad poster designations. The final letter in the poster presentation number indicates its designation. The designations are as follows:

Evaluative Studies (E): Completed original research including new ideas or services in pharmacy practice.

Descriptive Reports (D): Describes new, improved, or innovative roles or services in pharmacy practice or unusual clinical cases that have not been formally evaluated but are of such importance that they must be brought to the attention of practitioners.

Research-in-Progress (R): Uncompleted evaluative studies that were in progress when the papers were submitted for presentation.

Poster Awards

Posters best describing research or projects that are related to educational topics will receive special recognition. Posters will be judged on:

- Project design (clearly defined objectives, sound methodology, appropriate analysis of data, conclusions consistent with objectives and results, etc.)
- > Significance of project to the general body of knowledge.
- Overall clarity and organization of posters.

Awards will be issued onsite.

CONTINUING EDUCATION CREDIT

Pharmacists

All educational sessions will be offered for CE credit. ASHP determines the number of contact hours for each session. Registrants may earn up to 15.5 contact hours (1.55 CEUs) at the 2008 ASHP Summer Meeting. All attendees must submit their CE on-line at the CE Request Center or obtain a paper CE Request form from the ASHP Summer Meeting Information Center at the meeting. To receive ACPE Credit, you must obtain a CE Session Code for each CE session you attend. The codes are announced only during the live sessions.

Pharmacy Technicians

The 2008 ASHP Summer Meeting educational sessions are a Pharmacy Technician Certification Board (PTCB) acceptable method for Certified Pharmacy Technicians to obtain continuing education credit. Programs identified as most suitable for pharmacy technicians are designated with a "T" following the ACPE number.

Special Requirements

Some states have special continuing education requirements for program content. Please check with your state to determine if such requirements exist and to determine if these programs meet those requirements.

Florida Licensed Pharmacists and Technicians: Please selfreport your CE to CE Broker. No Consultant Pharmacist CE offered.



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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How to Request Continuing Pharmacy Education Credit for Attending ASHP Meetings

To receive CE credit, you must obtain a *CE Session Code* for each CE session you attend. The codes are announced only during the live sessions by the moderators; ASHP staff members serving as room monitors will also have this information. *CE Session Codes are not printed in the Program Book.*

Requesting CE Credit Online – Three Steps:

STEP 1: Keep Track of Your CE Session Codes

Use the form "Sessions I Attended at the ASHP Summer Meeting in Seattle" (between pages 16 and 17 in this Program Book) to record the Session Code, the Session Name, *and* the number of hours you attended for each session. *Keep this form for your own tracking purposes; it is not valid for CE.*

STEP 2: Submit Your CE Request Online

Go to the *ASHP CE Request Center* either by using a terminal at Network Connections or use your own computer and go to www.ashp.org/meetings/cerequest/index.cfm.

- If you use your own computer, you will need your 8-digit ASHP Customer/Membership ID number to log into the CE Request Center.
- If you don't know your number, please call Customer Service at 866-279-0681 (U.S. and Canada) or 01-240-646-7082 (International).
- Sessions are not accessible on the CE Request Center until the day they occur.
- If you registered for the meeting onsite, you cannot submit CE Requests online until August 1, 2008.
- Warning: If you plan to record CE daily, DON'T click on "Submit ALL CE" until after you have recorded all meeting CE information.
- Once you click on "Submit ALL CE," you cannot go back to record additional CE for this meeting or make changes.
- If you submit a CE request without the number of hours filled in, your CE request will be invalid.

STEP 3: Print Your CE Statement

After you have submitted your CE Request online, you have the option to immediately print your CE statement or to send it to your email address. We strongly recommend sending it to your email address because access to printers in at Network Connections is limited.

Paper CE Request Form Option

If you don't want to submit your CE request online, pick up a *CE Request Form* at the ASHP Summer Meeting Information Center.

- Submit your completed form at the ASHP Summer Meeting Information Center.
- The "Sessions I Attended" forms are not accepted in lieu of CE Request Forms.
- Your CE Statement will be mailed to you approximately eight to ten weeks following the meeting.

You may submit your CE request anytime after the meeting. Per ACPE requirements, these programs are valid only for three years.

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Schedule at a Glance

SATURDAY, JUNE 7

12:30 PM - 2:15 PM Networking Roundtables for Affiliate Volunteers

1:00 PM — 5:30 PM House of Delegates Registration

2:30 PM – 4:30 PM Open Forum for Members

4:30 PM – 5:30 PM **Delegate Primer on HOD Processes** (Previously known as the "Delegate Orientation")

SUNDAY, JUNE 8

7:00 AM — 8:30 AM ASHP-PAC Breakfast - Countdown to November

7:30 AM — 12:00 PM House of Delegates Registration

8:00 AM — 10:00 AM House of Delegates Caucus

10:30 AM - 12:00 PM The Joint Commission Hospital Update 2008

11:30 AM — 1:00 PM National Hospital & Health-System Pharmacy Week Open House

12:30 PM — 1:45 PM ASHP Section of Pharmacy Practice Managers — Networking Session

2:00 PM — 4:30 PM First House of Delegates Meeting

5:00 PM - 6:30 PM "Blues n' Brews" Welcome Reception

MONDAY, JUNE 9

7:30 AM — 5:00 PM **Posters**

8:00 AM - 10:00 AM Pharmacy through the C-Suite Prism

8:00 AM - 10:00 AM Quality Standards in Emergency Pharmacy

8:00 AM - 10:00 AM Implementing the New National Patient Safety Goals on Anticoagulation

8:00 AM - 10:00 AM Where Do You Stand? Comparing Your Institution to the ASHP 2007 Informatics Survey Results

8:30 AM - 10:00 AM New Drugs in Primary Care 2008

10:10 AM -11:00 AM **Opening Session**

11:00 AM -2:00 PM Exhibit Program

 $12{:}00\ \text{PM}-1{:}30\ \text{PM}$ House of Delegates - Meet the Candidates

12:30 PM - 1:30 PM ASHP Section of Home, Ambulatory, and Chronic Care Practitioners - Networking Session

2:00 PM - 5:00 PM Dollars & Sense: Building a Strong Financial Base

2:00 PM - 5:00 PM Improving Safe Use of Anticoagulants

2:00 PM - 5:00 PM Achieving Optimal Glycemic Control

2:00 PM - 5:00 PM Robotic IV Automation: Human Intelligence Combined with Robotic Accuracy

2:00 PM - 5:00 PM The 340B Drug Pricing Program - An Update

5:15 PM — 6:15 PM ASHP Section of Pharmacy Informatics and Technology — Networking Session 5:15 PM — 6:15 PM ASHP Section of Clinical Specialists and Scientists — Networking Session

5:30 PM - 6:30 PM House of Delegates Reception

TUESDAY, JUNE 10

7:30 AM - 5:00 PM **Posters**

8:00 AM - 10:00 AM Implementation of an Anemia Management Program

8:00 AM - 10:00 AM It Is a Revolutionary Change: How to Prepare For and Carry Out a Successful CPOE Implementation

8:00 AM - 10:00 AM

Implementing Evidence-Based Interventions to Improve the Treatment of Severe Sepsis: The ASHP Research and Education Foundation Award Winner for Excellence in Medication-Use Safety Winner

8:00 AM - 10:00 AM USP <797> Update 2008 and Personnel-Related Environmental Sampling

8:00 AM - 10:00 AM Stewardship of Resources, Part 1: People

10:10 AM -11:00 AM The Inaugural and Awards

11:00 AM — 12:00 PM House of Delegates Caucus

11:00 AM -2:00 PM Exhibit Program

12:30 PM – 1:30 PM ASHP Section of Inpatient Care Practitioners – Networking Session

 $\begin{array}{l} 12:30 \ \text{PM}-1:30 \ \text{PM} \\ \textbf{HRSA Networking Session} \end{array}$

2:00 PM - 4:30 PM Stewardship of Resources, Part 2: Services

November 14, 2008

2:00 PM - 4:30 PM How to Better Detect and Prevent Adverse Events and Medication Errors in Your ICU Schedule at a Glance

2:00 PM - 4:30 PM Linear, 2-D Stacked, 2-D Matrix, Oh My! Navigating the Complexities of Barcode Medication Administration

2:00 PM - 4:30 PM Current Legislative and Regulatory Issues in Pharmacy 2008

2:00 PM - 4:30 PM Complying with USP <797>: Hoods, Isolators, and Cleanrooms

4:30 PM - 6:00 PM Second House of Delegates Meeting

 $7{:}00\ \text{PM}-10{:}00\ \text{PM}$ Harvey A.K. Whitney Lecture Award Reception and Dinner

WEDNESDAY, JUNE 11

8:00 AM - 9:30 AM Prescription for Confusion: Health Literacy and the Rx Label

8:00 AM - 11:00 AM Innovating for the Future

8:00 AM - 11:00 AM Managing Knowledge Management Systems: Optimizing CDSS

8:00 AM - 11:00 AM Anesthesia, OR, and PACU: Medication Use Behind the Double Doors

11:00 AM - 1:00 PM Exhibit Program and Lunch in the Exhibit Hall

1:00 PM - 2:30 PM The Business of Pharmacy: Putting It All Together

1:00 PM - 2:30 PM Formulary Management in an Integrated Information System Environment: Challenges and Successes

1:00 PM - 2:30 PM Are Quality Standards Possible in Antibiotic Resistance?

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Daily Programs > Saturday, June 7 & Sunday, June 8

SATURDAY, JUNE 7

12:30 PM - 2:15 PM Willow A, Level 2, Sheraton Seattle Hotel Networking Roundtables for Affiliate Volunteers

1:00 PM - 5:30 PM Exhibition hall 4C, Level 4 House of Delegates Registration

2:30 PM – 4:30 PM Ballroom 6C, Level 6 Open Forum for Members

This session is the "Open Hearing of the House of Delegates," during which items scheduled for action by the House may be discussed. It is also a time for discussion of any matter of concern to ASHP members related to pharmacy practice in hospitals and health systems. Discussion will be facilitated by the Chair of the House of Delegates, and the session will be attended by ASHP officers, members of the Board of Directors, and ASHP staff. The Open Forum is an excellent opportunity for practitioners to bring emerging issues to the attention of ASHP leaders.

4:30 PM - 5:30 PM Room 619, Level 6 Delegate Primer on HOD Processes

(Previously known as the "Delegate Orientation" - for all delegates and alternate delegates)

SUNDAY, JUNE 8

7:00 AM - 8:30 AM

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Willow A, Level 2, Sheraton Seattle Hotel

ASHP PAC Breakfast – Countdown to November

7:30 AM – 12:00 PM Exhibition Hall 4C, Level 4

House of Delegates Registration

(After Sunday morning, delegates can register in the Executive Office)

8:00 AM - 10:00 AM Room 619, Level 6 House of Delegates Caucus

A caucus session on policy proposals facilitated by the Chair of the House.

10:30 AM - 12:00 PM Ballroom 6C, Level 6 The Joint Commission Hospital Update 2008

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Program #204-000-08-101-L03P (1.5 Contact Hours)

Speaker: Darryl S. Rich, PharmD, MBA, FASHP, Surveyor, The Joint Commission, Oakbrook Terrace, IL

Description: Get the latest on Joint Commission hot topics. Find out what the most common medication-related standards scored non-compliant are and why, as well as 2008's National Patient Safety Goals and medication-related standards. Learn about Joint Commission's perspective on the new Anticoagulation Management requirements.

Learning Objectives:

- Describe the most common Joint Commission medicationrelated standards scored non-compliant on hospital surveys, and the reasons why.
- Explain Joint Commission's new National Patient Safety Goals for 2008.
- Discuss new requirements for Joint Commission medicationrelated standards in 2008-2009.
- Summarize Joint Commission's perspective on the new Anticoagulation Management requirements.

10:30 AM - 10:35 AM

Announcements

10:35 AM - 11:45 AM

The Joint Commission Hospital Pharmacy Update for 2008

11:45 AM - 12:00 PM

Questions, Answers, and Discussion

11:30 AM – 1:00 PM Room 304, Level 3 National Hospital & Health-System Pharmacy Week Open House

Get ideas for planning your pharmacy department's observance of National Hospital & Health-System Pharmacy Week (October 19-25). Preview the promotional items available for this year's observance and get pointers for "telling your story" from ASHP's Public Relations staff.

12:30 PM - 1:45 PM

Willow A, Level 2, Sheraton Seattle Hotel

ASHP Section of Pharmacy Practice Managers

Medication Reconciliation Pearls and Pitfalls: Networking Session

The Section of Pharmacy Practice Managers will facilitate brief pearls presentations from a panel of experts on timely and relevant topics related to medication reconciliation. These presentations will be followed by Q&A to assist with sharing of ideas among peers.

Monday, June 9 > Daily Programs

Topics to be discussed include:

- successful implementation of pharmacist-led and interdisciplinary approaches to medication reconciliation in inpatient and outpatient settings
- utilizing pharmacy students, technicians and nurses to maximize the success of your program
- developing a business case to obtain additional pharmacist resources
- overcoming challenges in implementing manual and software-driven approaches to medication reconciliation

Facilitator: Steve Rough, MS, Director of Pharmacy, University of Wisconsin Hospitals and Clinics, Madison, WI

2:00 PM - 4:30 PM Ballroom 6E, Level 6 First House of Delegates Meeting

5:00 PM - 6:30 PM South Lobby and Plaza, Level 4 "Blues n' Brews" Welcome Reception

MONDAY, JUNE 9

7:30 AM - 5:00 PM Posters Ballroom 6A/B Foyer, Level 6

8:00 AM - 10:00 AM Room 607, Level 6 Pharmacy through the C-Suite Prism

The Business of Pharmacy Learning Community

Program #204-000-08-102-L04P (2.0 Contact Hours)

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: Following an introduction that sets the stage for the Learning Community, you will examine six key financial questions required of successful pharmacy leaders, with emphasis on communicating with the C-Suite and how the COO and CFO view the pharmacy department. Attendees will participate in an interactive dialog with hospital business experts.

Learning Objectives:

- Describe the pivotal position of pharmacy business operations within health systems and its impact on organizational financial metrics and success.
- Apply strategies for improving communication with the C-Suite and other key departments.
- Explain key financial questions pharmacy leaders must address to proactively support overall organizational goals, aligned with effective pharmacy management.

8:00 AM - 8:10 AM Welcome and Announcements

8:10 AM - 9:30 AM

Pharmacy through the C-Suite Prism

Susan Teil Boyer, MS, RPh, FASHP, Vice President, Pharmacy and Laboratory Services, MultiCare Health System, Tacoma, WA; and Vice President, Professional Services, Good Samaritan Hospital, a part of MultiCare Health System, Puyallup, WA George J. Brown, BA, MD, Chief Operating Officer, MultiCare Health System, Tacoma, WA

9:30 AM - 10:00 AM

Interactive Dialogue with Audience: How to Communicate Effectively with C-Suite Members

8:00 AM - 10:00 AM Room 603, Level 6 Quality Standards in Emergency Pharmacy

Quality Standards in Clinical Practice Series

Program #204-000-08-103-L01P (2.0 Contact Hours)

Moderator: Daniel P. Hays, PharmD, BCPS, Clinical Pharmacy Specialist, University of Rochester Medical Center, Rochester, NY

Description: More and more institutions every day are warming up to the idea that pharmacy services in the emergency department can improve safety and outcomes. In this session, experts will share new information about emergency pharmacy services, as well as new models that can be implemented in even the most resource-strapped institutions. This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- Describe key aspects of quality standards related to emergency pharmacy.
- Explain the impact of these quality standards on your practice.
- Explain how to operationalize relevant quality standards in your practice.
- Describe how pharmacists need to approach the emergency department to practice effectively.

8:00 AM - 8:05 AM Announcements

8:05 AM - 8:45 AM

How to Approach the E.D. for Effective Practice

Nicole M. Acquisto, PharmD, Emergency Medicine/Critical Care Pharmacy Specialty Resident, University of Rochester, Rochester, NY

Daily Programs > Monday, June 9

8:45 AM - 9:25 AM

Quality Standards: Key Aspects and Implementation into Your Practice

Daniel P. Hays

9:25 AM - 10:00 AM Impact of Standards on Practice

Rollin (Terry) J. Fairbanks, MD, MS, Assistant Professor, University of Rochester, School of Medicine, Rochester, NY

8:00 AM - 10:00 AM Ballroom 6C, Level 6 Implementing the New National Patient Safety Goals on Anticoagulation

Anticoagulation Series

Program #204-000-08-104-L05P (2.0 Contact Hours)

Moderator: William E. Dager, PharmD, FCSHP, Pharmacist Specialist, University of California, Davis Medical Center, Sacramento, CA

Description: The benefits of anticoagulation therapy continue to be recognized, with their use continually expanding. Anticoagulants, however, have fairly narrow therapeutic windows, and numerous variables exist that can influence responses to therapy and approaches to their use. As such, anticoagulants have been identified as a class of agents frequently associated with adverse medication events. The presence of dedicated individuals familiar with implementing and monitoring anticoagulation therapy, either in the in patient or outpatient setting, has been shown to improve outcomes related to anticoagulation therapy. To reduce potential mishaps, The Joint Commission has added national patient safety goals for anticoagulation therapy, seeking implementation by institutions by the end of 2008. This program will explore approaches for administrators and clinical staff to recognize and successfully prepare to implement the national patient safety goals.

Learning Objectives:

- Describe key aspects of the new National Patient Safety Goals (NPSG) on anticoagulation.
- Describe examples of ways that have been successfully used to improve the safe use of anticoagulants.
- Explain roles that pharmacists can play in improving the safe use of anticoagulants.
- Identify challenges and strategies for resolving them to fulfill new requirements.

8:00 AM - 8:05 AM

Announcements

8:05 AM - 8:25 AM Overview and Description of NPSG

Edith A. Nutescu, PharmD, FCCP, Clinical Associate Professor and Director, Antithrombosis Center, University of Illinois at Chicago, College of Pharmacy, Chicago.

8:25 AM - 8:50 AM

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Minimizing Distribution-Related Adverse Events of Anticoagulants

Steve Meisel, PharmD, Director of Medication Safety, Fairview Health Services, Minneapolis, MN November 14, 2008

8:50 AM - 9:20 AM

Integrating the New Joint Commission Guidelines When Managing Anticoagulation Therapy

Ann K. Wittkowsky, PharmD, Director, Anticoagulation Services, University of Washington Medical Center, Seattle

9:20 AM - 9:40 AM

Practical Practice Pearls When Monitoring Anticoagulation

William E. Dager

9:40 AM - 9:50 AM

Which: a Protocol, Guideline, Other, or All of the Above?

Michael P. Gulseth, PharmD, BCPS, Assistant Professor, University of Minnesota College of Pharmacy, Duluth; and Clinical Pharmacy Specialist, St. Mary's Medical Center, Duluth

9:50 AM - 10:00 AM

Questions, Answers, and Panel Discussion

8:00 AM - 10:00 AM Room 613, Level 6

Where Do You Stand? Comparing Your Institution to the ASHP 2007 Informatics Survey Results

INFORMATICS SERIES

Program #204-000-08-105-L04P #204-000-08-105-L04T

(2.0 Contact Hours)

Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: How do you compare to your peers when it comes to embracing and implementing IT solutions? In Part I of this session, experts will share the results from the ASHP 2007 Informatics Survey, which explored how hospitals, health systems, their leaders, and their staff use technology to safely and efficiently care for patients. Part II explores the unintended consequences often encountered when implementing medication management systems and how the Pharmacy Informaticist can help mitigate known and unknown risks.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Learning Objectives:

- Compare and contrast your institution's success at IT solutions with comparable hospitals and health-systems from around the country.
- Identify and discuss common risks and/or unintended consequences encountered when implementing medication management supporting systems.
- Describe strategies for mitigating unknown or known risks when deploying medication management system solutions.

ASHP 2008 Summer Meeting and Exhibition

Monday, June 9 > Daily Programs

8:00 AM - 8:10 AM Announcements and Welcome

8:10 AM - 9:15 AM

Compare Yourself with the ASHP 2007 Informatics Survey

Karl F. Gumpper, RPh, BCPS, FASHP, Director, Section of Pharmacy Informatics & Technology, American Society of Health-System Pharmacists, Bethesda, MD Craig A. Pedersen, RPh, PhD, Associate Professor, College of Pharmacy, The Ohio State University, Columbus

9:15 AM - 9:45 AM

Pharmacy Informatics and Risk Management: Minimizing Negative Events and its Consequences

Mark H. Siska, RPh, MBA/TM, Assistant Director Pharmacy Informatics & Technology, Mayo Clinic, Rochester, MN

9:45 AM - 10:00 AM Questions, Answers, and Panel Discussion

8:30 AM - 10:00 AM Room 615, Level 6 New Drugs in Primary Care 2008 HOT TOPIC

Program #204-000-08-106-L01P (1.5 Contact Hours)

Speaker: J. Thomas Frank, PharmD, Associate Professor, Pharmacy Practice, Family and Community Medicine, Area Health Education Center NE, University of Arkansas for Medical Sciences, Jonesboro

Description: As drug therapy experts, pharmacists are often called upon for facts and opinions about recently introduced drugs. New drugs are introduced at a rate that exceeds the reading time of many busy practitioners. This presentation is intended to provide a broad-based discussion and objective information about new drug options.

Learning Objectives:

- Assess new trends in drug development.
- Explain indications, pharmacology, adverse effects and dosing of the products discussed.
- Determine the role these products will play in the participant's practice.
- Evaluate the economic implications of these choices.
- Examine products in the short-term pipeline that will be important to the practice of the participants.

8:30 AM - 8:35 AM Announcements

8:35 AM - 9:50 AM

New Drugs in Primary Care 2008

9:50 AM - 10:00 AM

Questions, Answers, and Discussion

10:10 AM -11:00 AM Ballroom 6A/B, Level 6 Opening Session - see page 13 for details



Presidential Address: Janet A. Silvester, MBA, FASHP, Director of Pharmacy Services, Martha Jefferson Hospital, Charlottesville, VA



Acknowledgement of the 2008 Recipient of the Harvey A.K. Whitney Lecture Award: Philip J. Schneider



Acknowledgement of the 2008 Recipient of the Donald E. Francke Medal: Toshitaka Nabeshima, PhD, MS, FASHP



Keynote Address: Leading A Culture of Innovation

Sir Ken Robinson, PhD, one of Time/Fortune/CNN's "Principal Voices," and facilitator of the Catalyzing Creativity project, a forum for the discussion and exchange of ideas on innovation and creativity.

11:00 AM - 2:00 PM Exhibit Program Exhibition Hall 4A/B, Level 4

12:00 PM - 1:30 PM Room 619, Level 6 House of Delegates - Meet the Candidates

12:30 PM - 1:30 PM Room 615, Level 6 ASHP Section of Home, Ambulatory, and Chronic Care Practitioners Reimbursement for Clinical Services:

Networking Session

This networking session will provide an opportunity for participants to discuss their successes and challenges in obtaining reimbursement for clinical services. Topics that will be covered include facility billing versus MTM CPT codes, opportunities to expand revenue, and challenges in daily practice.

Facilitator: Timothy Brown, PharmD, Director of Clinical Pharmacotherapy, Akron General's Center for Family Medicine, Akron

November 14, 2008

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Daily Programs > Monday, June 9

2:00 PM - 5:00 PM Room 607, Level 6 Dollars & Sense: Building a Strong Financial Base

The Business of Pharmacy Learning CommunityProgram #204-000-08-107-L04P(3.0 Contact Hours)

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: Charge systems, the revenues cycle, and related controls are the backbone of health-system financial management that require constant focus and attention, often missing in many pharmacy management structures. You'll get the basics of business plans, cost/benefit analysis, and return on investment. You'll also examine budgeting, variance analysis and other controls, as well as the effective use of dashboards for monitoring performance.

Learning Objectives:

- Explain the challenges and problems of charge systems, the revenue cycle, and related controls.
- Identify and explain selected business tools and resources for strategic management and operational controls.
- Identify and explain selected strategies, resources and organizational capabilities for achieving departmental and organizational results.

2:00 PM - 2:10 PM Welcome and Announcements

2:10 PM - 3:00 PM

Dollars and Sense: Building a Strong Financial Base for Pharmacy Services – The Basics

William H. Puckett, MS, MBA, FASHP, Principal, WHP-Rx Consulting, LLC, Windermere, FL; and Pharmacy Consultant, Ernst & Young, LLP, Dallas, TX

3:00 PM - 3:50 PM TBD

3:50 PM - 4:30 PM TBD

4:30 PM - 5:00 PM Interactive Dialogue with Audience: How to Build a Strong Financial Base

2:00 PM - 5:00 PM Ballroom 6C, Level 6 Improving Safe Use of Anticoagulants

Anticoagulation Series Program #204-000-08-108-L05P

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(3.0 Contact Hours)

Moderator: William E. Dager, PharmD, FCSHP, Pharmacist Specialist, University of California, Davis Medical Center, Sacramento

Description: How can pharmacists be a part of the process of improving safe use of anticoagulants in both the inpatient and outpatient settings and at the patient and health-system level? Delve into the nitty-gritty in this session, which will focus on a range of ways to make a difference.

November 14, 2008 ASHP 2008 Summer Meeting and Exhibition

Learning Objectives:

- Explain steps that you can take to ensure compliance with the new standards in your setting.
- Identify strategies that you can apply in your setting for improving the safe use of anticoagulants.

2:00 PM - 2:05 PM

Announcements

2:05 PM - 2:30 PM

Strategies for Implementing an Inpatient Program to Meet the NPSG

Michael P. Gulseth, PharmD, BCPS, Assistant Professor, University of Minnesota College of Pharmacy, Duluth; and Clinical Pharmacy Specialist, St. Mary's Medical Center, Duluth Laura Marie Traynor, PharmD, BCPS, Assistant Professor, University of Minnesota College of Pharmacy, Duluth; and Pharmacist, Mercy Hospital and Healthcare Center, Moose Lake, MN

2:30 PM - 2:50 PM

Strategies for Implementing an Outpatient Program to Meet NPSG

Edith A. Nutescu, PharmD, FCCP, Clinical Associate Professor and Director, Antithrombosis Center, University of Illinois at Chicago, College of Pharmacy, Chicago

2:50 PM - 3:10 PM

Considerations for Prophylaxis for Treatment of Patients with Arterial Disease

Sarah A. Spinler, PharmD, BCPS, Professor of Clinical Pharmacy, University of the Sciences in Philadelphia, Philadelphia, PA

3:10 PM - 3:30 PM What's the Deal with Genetic Testing?

Ann K. Wittkowsky, PharmD, Director, Anticoagulation Services, University of Washington Medical Center, Seattle

3:30 PM - 3:50 PM

Financial Benefits of Pharmacy-Based Anticoagulation Services

John Grubbs, MS, RPH, Director of Pharmacy, UC Davis Medical Center, Sacramento, CA; and Assistant Dean of Clinical Pharmacy, UCSF School of Pharmacy, San Francisco

3:50 PM - 4:00 PM Questions, Answers, and Discussion

4:00 PM - 4:15 PM Break

Monday, June 9 > Daily Programs

4:15 PM - 5:00 PM Breakout Roundtables

Exploring Anticogulation in the Inpatient Setting *Room 619, Level 6* William E. Dager Michael P. Gulseth

Sarah A. Spinler

Exploring Anticoagulation in the Transitional and Outpatient Settings *Room 401, Level 4* Edith A. Nutescu Ann K. Wittkowsky

Managing the Implementation of the NPSG into Your Hospital Ballroom 6C, Level 6 Steve Meisel, PharmD, Director of Medication Safety, Fairview Health Services, Minneapolis, MN Laura Marie Traynor John Grubbs

2:00 PM - 5:00 PM Room 603, Level 6 Achieving Optimal Glycemic Control

Quality Standards in Clinical Practice Series

Program #204-000-08-109-L01P (3.0 Contact Hours)

Moderator: Stuart T. Haines, PharmD, BCPS, FASHP, Professor and Vice Chair for Education, University of Maryland School of Pharmacy, Baltimore; and Clinical Specialist, Joslin Diabetes Center at University of Maryland Medicine, Baltimore

Description: Patients, practitioners, and health care systems are struggling to achieve tight glycemic control, but where does the pharmacist fit in? Many new anti-diabetic medications and monitoring devices have emerged in the past five years and practitioners in a variety of settings have developed protocols to address this growing problem. Find out the latest medications, technologies, and strategies that have been developed to address the needs of patients who have diabetes, pre-diabetes, or transient hyper-glycemia. This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- Recommend effective medication regimens for patients who have not yet achieved optimal glycemic control.
- Explain how to apply quality standards to develop systemwide medication use policies that will help achieve optimal glycemic control.
- Describe how to monitor therapeutic plans and drug use policies to achieve optimal glycemic control for individual patients and populations of patients.

2:00 PM - 2:15 PM Announcements and Welcome

2:15 PM - 2:35 PM Hot Issues in Medications for Hyperglycemia

Stuart T. Haines

2:35 PM - 2:50 PM Small Group Discussion

2:50 PM - 3:05 PM Large Group Debrief

3:05 PM - 3:25 PM Best Practices in Institutions — Achieving Optimal Glycemic Control

Paul M. Szumita, PharmD, BCPS, Clinical Pharmacy Practice Manager, Brigham and Women's Hospital, Boston, MA; and Adjunct Assistant Professor of Pharmacy, Critical Care, Adjunct appointment from Northeastern University, Boston, MA

3:25 PM - 3:35 PM Break

> 3:35 PM - 3:50 PM Small Group Discussion

3:50 PM - 4:05 PM Large Group Debrief

4:05 PM - 4:25 PM Measuring Glycemic Control

Dawn C. Fuke, PharmD, BCPS, Clinical Pharmacy Specialist, Primary Care, Providence Physician Division, Portland, OR; and Affiliate Faculty, Oregon State University/Oregon Health & Science University, Portland

4:25 PM - 4:40 PM Small Group Discussion

4:40 PM - 4:55 PM Large Group Debrief

4:55 PM - 5:00 PM Concluding Remarks, Questions and Answers

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Daily Programs > Monday, June 9

2:00 PM - 5:00 PM Room 613, Level 6 Robotic IV Automation: Human Intelligence Combined with Robotic Accuracy

Informatics Series

Program #204-000-08-110-L04P (3.0 Contact Hours)

Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: The next innovative technology to facilitate closing the medication-use process loop, improve patient and employee safety is the automation of the IV compounding practice utilizing robotic compounders. In the past decade, hospital systems have been transforming into a virtual electronic system with CPOE, e-MAR, BCMA, enhanced with high technology equipment to improve patient safety and increase pharmacy efficiencies with oral dosage forms. The developments of robotic intravenous compounding technology have been incomplete over this time period due to the complexity of the compounding arena that will improve patient and employee safety, and increase pharmacy efficiencies. This session will cover the various components utilized, regulatory considerations and their role in medication safety.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Learning Objectives:

- Describe the current state of robotic IV automation and how it facilitates closing the med-use process loop, the types of medication compounded, and final preparations dispensed.
- > Describe the safety features with robotic IV automation.
- Identify the benefits and challenges of the various robotic IV automated products discussed.
- Explain the regulatory environment requirements with robotic IV automation.
- Compare and contrast the medication safety features of robotic IV automation versus a manual IV compounding process.

2:00 PM - 2:10 PM

Welcome and Announcements

2:10 PM - 2:55 PM

Overview of Robotic IV Automation

Michael W. Culligan, RPh, Assistant Director, Saint Francis Hospital & Medical Center, Hartford, CT Luci A. Power, BS, MS, Senior Pharmacy Consultant, Power Enterprises, San Francisco, CA

2:55 PM - 3:05 PM

Audience Participation: Electronic Submission of Questions via Digital Pens

3:05 PM - 3:45 PM

Regulations Impacting Robotic IV Automation

Michael Culligan Luci A. Power

3:45 PM - 3:55 PM Audience Votes on Questions

3:55 PM - 4:35 PM

Medication Safety Features of Robotic IV Automation

Michael W. Culligan Luci A. Power

4:35 PM - 5:00 PM

Questions, Answers, and Panel Discussion

2:00 PM - 5:00 PM Room 615, Level 6

The 340B Drug Pricing Program -An Update

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Program #204-000-08-111-L04P (3.0 Contact Hours)

Moderator: Christopher A. Hatwig, MS, RPh, FASHP, Senior Director, Apexus, Irving, TX

Description: Walk through a typical hospital evaluation process and discover appropriate implementation strategies to ensure compliance with regulatory requirements while optimizing program savings. Learn about the voluntary Prime Vendor Program's role in negotiating sub-340B discounts on pharmaceuticals and discounts on other products and services. Hear various examples of hospitals' experience with the 340B Drug Pricing, highlighting unique challenges and benefits of the program including its impact on improving access to affordable pharmaceuticals for their patient populations.

Learning Objectives:

- Explain key changes to federal register notices and their importance to overall program integrity.
- Describe best practices for optimizing savings while ensuring program compliance in complex health-system settings.
- Describe recent changes with the PSSC and Prime Vendor Program designed to address disproportionate share hospitals' needs.

2:00 PM - 2:05 PM Announcements

2:05 PM - 2:40 PM

HRSA's Updates and New Patient Safety Collaborative

Jimmy R. Mitchell, RPh, MPH, Director, Office of Pharmacy Affairs, HRSA/Healthcare Systems Bureau, Rockville, MD Krista Scardina, PharmD, Program Management Officer, HRSA/Healthcare System Bureau, Rockville, MD

Monday, June 9 > Daily Programs

2:40 PM - 3:10 PM

Hospital Eligibility, Enrollment and Implementation to Ensure Compliance

Melinda Joyce, PharmD, FAPhA, Corporate Director of Pharmacy, The Medical Center, Bowling Green, KY

3:10 PM - 3:35 PM

340(b) Compliance: Notes from the Field

Andrew L. Wilson, BS, PharmD, FASHP, Senior Manager, Ernst & Young, LLP, Richmond, VA

3:35 PM - 3:40 PM Break

3:40 PM - 4:10 PM

340B Prime Vendor Program — Adding Value

Christopher A. Hatwig

4:10 PM - 4:40 PM 340B Legislative Update

William H. von Oehsen III, AB, MTS, JD, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access, Washington, DC; and Principal, Powers Pyles Sutter & Verville, P.C., Washington, DC

4:40 PM - 4:55 PM

Questions, Answers, and Panel Discussion

4:55 PM - 5:00 PM Conclusion

5:15 PM - 6:15 PM Room 613, Level 6 ASHP Section of Pharmacy Informatics and Technology - Networking Session

This session is for pharmacists who are interested in informatics, computerized provider order entry (CPOE), clinical decision support, e-prescribing, barcode point-of-care, and other issues related to technology. Members of the ASHP Section of Pharmacy Informatics and Technology will facilitate a dialogue on timely and relevant topics relating to the patient-safety enhancing technologies. Topics for the discussions include issues associated with implementing these systems along with the application of information technology standards and regulations. This Networking Session will also provide attendees an opportunity to discuss what they have learned in the "Informatics Series" during the course of the meeting.

Facilitator: Dennis A. Tribble, PharmD, Chief Technology Officer, ForHealth Technologies, Inc., Daytona Beach, FL

5:15 PM - 6:15 PM Ballroom 6C, Level 6 ASHP Section of Clinical Specialists and Scientists

The New National Patient Safety Goal on Anticoagulation: Networking Session

This networking session will provide an opportunity for participants to discuss and review NPSG standards and implementation requirements while also incorporating the lessons learned from the anticoagulation educational sessions at the 2008 Summer Meeting. The discussion will also cover practical approaches/tools in anticoagulation management, challenges to implementing the standard, and successful implementation strategies.

Facilitator: Michael P. Gulseth, PharmD, BCPS, Assistant Professor, University of Minnesota College of Pharmacy, Duluth; Clinical Pharmacy Specialist, St. Mary's Medical Center, Duluth, MN

5:30 PM – 6:30 PM

Princessa Ballroom, First Floor, Grand Hyatt Seattle

House of Delegates Reception

(for delegates and alternate delegates)

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Daily Programs > Tuesday, June 10

TUESDAY, JUNE 10

7:30 AM - 5:00 PM Posters Ballroom 6A/B Foyer, Level 6

8:00 AM - 10:00 AM Room 603, Level 6 Implementation of an Anemia Management Program

Quality Standards in Clinical Practice Series

Program #204-000-08-113-L01P (2.0 Contact Hours)

Moderator: Chanel F. Agness, PharmD, BCPS, Assistant Professor, University of Maryland School of Pharmacy, Department of Pharmacy Practice and Science, Baltimore

Description: In this interactive session, clinical pharmacy managers and services coordinators, pharmacy administrators, clinical pharmacists and residents can explore the process of implementing an outpatient anemia management program. This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- Explain the clinical implications of establishing an anemia management program.
- Describe the process of clinical privileging and developing a scope of practice.
- Identify key quality standards related to anemia management and describe how to incorporate them into your practice.

8:00 AM - 8:05 AM

Announcements

8:05 AM - 8:25 AM Clinical Implications of Anemia Management

Chanel F. Agness

8:25 AM - 9:00 AM Small Group Activity: Defining a Scope of Practice

9:00 AM - 9:35 AM Clinical Privileging and Quality Standards

Jannet M. Carmichael, PharmD, BCPS, VISN 21 Pharmacy Executive, VA Sierra Pacific Network, Reno, NV

9:35 AM - 9:55 AM Small Group Activity: Assessing Process Outcomes

9:55 AM - 10:00 AM Concluding Remarks, Questions and Answers

8:00 AM - 10:00 AM Room 613, Level 6

It Is a Revolutionary Change: How to Prepare For and Carry Out a Successful CPOE Implementation

Informatics Series

Program #204-000-08-114-L04P #204-000-08-114-L04T

(2.0 Contact Hours)

Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: Evidence supports the impact of CPOE as a way to improve patient care. Academic medical centers are leading the way, but the vast majority of hospitals have not yet implemented CPOE. Where does your institution stand? Open dialogue between pharmacists, physicians, and nurses is critical to success. But what are the other important factors? This session will address the critical success factors to a successful CPOE implementation.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Learning Objectives:

- Describe specific factors impacting an efficient and effective CPOE implementation in your setting.
- Identify the features of a CPOE system that are critical to clinician adoption at your institution.
- Describe the type of implementation team needed to help your institution successfully implement CPOE.

8:00 AM - 8:10 AM

Welcome and Announcements

8:10 AM - 8:20 AM

Audience Participation: Electronic Submission of Questions via Digital Pens

8:20 AM - 8:50 AM Implementation of CPOE

 Anne M. Bobb, BSPharm, Clinical Informatics Pharmacist, Northwestern Memorial Hospital, Chicago, IL
 Lynn A. Boecler, PharmD, MS, Senior Director, Pharmacy Services, Evanston Northwestern Healthcare, Evanston. IL

8:50 AM - 9:05 AM

Audience Votes on Questions

9:05 AM - 9:40 AM

Optimization and Maintenance

Anne M. Bobb Lynn A. Boecler

9:40 AM - 10:00 AM Questions, Answers, and Panel Discussion

Tuesday, June 10 > Daily Programs

8:00 AM - 10:00 AM Room 615, Level 6

Implementing Evidence-Based Interventions to Improve the Treatment of Severe Sepsis:

The ASHP Research and Education Foundation Award for Excellence in Medication-Use **Safety Winner**

ΗΟΤ ΤΟΡΙC

Program #204-000-08-115-L05P

(2.0 Contact Hours) Moderator: Cynthia LaCivita, PharmD, Director, Education and

Special Programs, ASHP Research & Education Foundation, Bethesda, MD

Description: Worldwide 1.400 people die daily from severe sepsis. That number is expected to grow by 1.5% each year. Find out how Barnes-Jewish Hospital (BJH) effectively tackled their severe sepsis rates and mortality. By creating BJH-specific severe sepsis order sets, a framework that functioned as a lever for change was clearly articulated. Get the details of this award-winning program during this session.

Learning Objectives:

- Describe an effective process for significantly reducing incidence and mortality of sepsis.
- Explain benefits of implementing this process.
- Identify challenges to implementing steps for the reduction of severe sepsis and how to effectively handle them.

8:00 AM - 8:05 AM

Announcements

8:05 AM - 8:55 AM

Learn It, Measure It, Improve It -The Pharmacist's Role in Surviving Sepsis 2008

Scott Micek, PharmD, BCPS, Critical Care Pharmacist, Barnes-Jewish Hospital, St Louis, MO

8:55 AM - 9:00 AM

Questions, Answers, and Discussion

9:00 AM - 9:50 AM

Sustaining "It" - The Required Vigilance in Improving Sepsis Care

Craig A. McCammon, PharmD, BCPS, Clinical Pharmacist, Emergency Medicine, Barnes-Jewish Hospital, St. Louis, MO

9:50 AM - 10:00 AM Questions, Answers, and Discussion

8:00 AM - 10:00 AM **Ballroom 6C, Level 6** USP <797> Update 2008 and Personnel-**Related Environmental Sampling**

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Program # 204-000-08-116-L03P #204-000-08-116-L03T (2.0 Contact Hours)

Moderator: Eric S. Kastango, MBA, RPh, FASHP, President/CEO, Clinical IQ, LLC, Florham Park, NJ

Description: Get the latest on USP <797>. Learn strategies on how to comply with the new personnel-related activities in the USP chapter and how to comply with competency assessment and glove-fingertip and surface sampling requirements.

Learning Objectives:

- Discuss the changes of the revised UPS Chapter <797>.
- Explain the personnel-related sections of the revised chapter and implement strategies on how to comply with the competency assessment and glove fingertip sampling requirements and seamlessly integrate them into your pharmacy operations.

8:00 AM - 8:15 AM Welcome and Announcements

8:15 AM - 9:00 AM **Discussion: The Revised Changes**

Lawrence A. Trissel, FASHP, Research Consultant, Self-Employed, Cashiers, NC

9:00 AM - 9:30 AM **Understanding the Personnel-Related** Changes

Eric S. Kastango

9:30 AM - 10:00 AM

Questions, Answers, and **Panel Discussion**

8:00 AM - 10:00 AM Room 607, Level 6 Stewardship of Resources, Part 1: People

The Business of Pharmacy Learning Community

Program #204-000-08-112-L04P #204-000-08-112-L04T

(2.0 Contact Hours)

(33

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: In this session, you'll explore critical issues that surround organizational structure, staffing profiles, organizational capability, individual competencies, and succession planning as essential building blocks for the productive stewardship of the people we call "resources."

Daily Programs > Tuesday, June 10

Learning Objectives:

- Describe how to apply strategies for building individual capability.
- > Explain strategies for building organizational capacity.
- Describe how to apply strategies for recognizing high-potential and emerging leaders.
- Discuss the creative options and alternatives for managing the human resource pipeline.

8:00 AM - 8:10 AM

Welcome and Announcements

8:10 AM - 8:50 AM

Developing the Optimal Practice Model for the Future

Philip E. Johnson, MS, RPh, FASHP, Director of Pharmacy, Moffitt Cancer Center, Tampa, FL

8:50 AM - 9:30 AM

Developing the Renaissance Pharmacist and Leaders for the Future

Sara J. White, MS, Pharmacy Leadership Coach, Mountain View, CA

9:30 AM - 10:00 AM

Interactive Dialogue with Audience: How to Build Stewardship of Resources

10:10 AM - 11:00 AM Ballroom 6A/B, Level 6

The Inaugural and Awards

Welcoming Remarks from the ASHP President

Janet A. Silvester, MBA, FASHP, Director of Pharmacy Services, Martha Jefferson Hospital, Charlottesville, VA

Presentation of the 2008 ASHP Practitioner Recognition Awards

ASHP Board of Directors Awards Presentation

Honorary Membership: Charles M. King, Jr. and David A. Zilz, RPh, MS, FASHP

Award of Excellence: Daniel E. Buffington, PharmD, MBA

(See pages 12 and 13 for bios.)

Inaugural Address

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Incoming ASHP President: Kevin J. Colgan, MA, RPh, FASHP, Senior Vice President of Health Economics and Outcomes Research, EPI-Q, Inc., Oakbrook, IL

The Inaugural Reception follows the session.

11:00 AM - 12:00 PM Room 619, Level 6 House of Delegates Caucus

11:00 AM - 2:00 PM Exhibition Hall 4A/B, Level 4 Exhibit Program

12:30 PM - 1:30 PM Room 601, Level 6 HRSA Networking Session

The Patient Safety and Pharmacy Collaborative

Interested in learning from pharmacists who significantly improved outcomes for their patients? Join an exciting informational session to learn about HRSA's collaborative on Patient Safety and Pharmacy. Hear high-performing pharmacists in frontline positions talk about their insights, experiences, and share their expertise in achieving high levels of safety and quality at their practice sites. HRSA representatives will facilitate a discussion on the Collaborative and how your organization can become involved.

Facilitator: Krista M. Scardina, PharmD, LCDR, USPHS, Health Systems Bureau, Health Resources and Services Administration, Rockville, MD

12:30 PM – 1:30 PM Room 603, Level 6 ASHP Section of Inpatient Care Practitioners - Medication Safety -General Networking Session

Members of the ASHP Section Advisory Group on Medication Safety will facilitate a dialogue on timely and relevant topics related to medication safety, such as efforts focused on national patient safety goals and progress on medication reconciliation. The agenda is highly flexible and may change based upon audience interests. Members interested in hearing more about these topics are invited to participate in discussions and to share ideas with their peers.

Facilitator: Deb Saine, MS, Medication Safety Coordinator, Winchester Medical Center

2:00 PM - 4:30 PM Room 607, Level 6 Stewardship of Resources, Part 2: Services

The Business of Pharmacy Learning Community

Program #204-000-08-117-L04P (2.5 Contact Hours)

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: Too often, pharmacy leaders view their role in narrow terms, focused on the integrity of the department's clinical and operational day-to-day function, with little attention to the influence pharmacy must exert in the larger organization. In this session, explore the relationships of internal services, the balancing of cost management with clinical service quality, and the connections between patient safety and risk management, both internal to departmental function and externally within the larger organization.

Learning Objectives:

- Identify and explain strategies, tactics and messaging for drug-cost management.
- Explain the relationship between risk management, patient safety, and service, and its critical importance to the overall organizational and patient care goals.
- Explain how to effectively use tools for monitoring and reporting return on investment, fiscal responsibility and patient care management.

Tuesday, June 10 > Daily Programs

2:00 PM - 2:10 PM Welcome and Announcements

2:10 PM - 2:50 PM

Strategies to Resource Management Excellence, or "How to be a Huntin' Dog and not a Porch Dog"

Ronald H. Small, MBA, FASHP, Chief Pharmacy Officer, Wake Forest University Baptist Medical Center, Winston-Salem, NC; and Vice President Healthcare Research and Quality

2:50 PM - 3:30 PM

Organizing the Organization for **Optimal Medication Use**

Timothy S. Lesar, PharmD, Director of Clinical Pharmacy Services, Albany Medical Center, Albany, NY

3:30 PM - 4:10 PM

Implications of Sub-Optimal **Medication Use**

Agatha L. Nolen, MS, FASHP, Director, OPPS, HCA (Hospital Corporation of America), Nashville, TN

4:10 PM - 4:30 PM

Interactive Dialogue with Audience: How to Build Stewardship of Resources

2:00 PM - 4:30 PM

Room 603, Level 6 How to Better Detect and Prevent

Adverse Events and Medication Errors in Your ICU

Quality Standards in Clinical Practice Series

Program #204-000-08-118-L05P

(2.5 Contact Hours)

Moderator: Brian L. Erstad, PharmD, FASHP, Professor, University of Arizona, Tucson

Description: The majority of studies that have investigated ADEs and medication errors in patients in the ICU involve chart reviews and voluntary incident reporting techniques. Direct observation is another method that has been used to detect ADEs and medication errors in hospitalized patients. However, until recently, there were no investigations that used a continuous observation approach to look at the overall medication-use process that leads to medication errors and preventable ADEs in the ICU setting. This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- List two limitations of traditional approaches to detecting adverse drug events and medication errors in the ICU setting.
- Compare the advantages and disadvantages of chart review and incident reporting techniques for detecting adverse drug events and medication errors compared to a direct observation approach.
- Discuss options for decreasing adverse drug events and medication errors based on their stage of occurrence.

2:00 PM - 2:05 PM Announcements

2:05 PM - 2:15 PM Scenario 1: Hospital ICU Brian L. Erstad

2:15 PM - 2:55 PM **Small Group Exercise: Methods**

for Improving Event Reporting and Detection

Brian L. Erstad Brian J. Kopp, PharmD, BCPS, Clinical Pharmacist, University Medical Center, Tucson, AZ; and Clinical Assistant Professor, The University of Arizona, College of Pharmacy, Tucson

2:55 PM - 3:15 PM

Scenario 2: Patient Safety and Methods of Event Detection

Brian L. Erstad

3:15 PM - 3:55 PM

Small Group Exercise: A Focus on System Changes that Decrease Events

Brian L. Erstad Brian J. Kopp

3:55 PM - 4:15 PM

Methods to Decrease Events Brian J. Kopp

4:15 PM - 4:20 PM

Conclusions

4:20 PM - 4:30 PM

Questions, Answers, and Discussion

2:00 PM - 4:30 PM Room 613, Level 6

Linear, 2-D Stacked, 2-D Matrix, Oh My! Navigating the Complexities of Barcode **Medication Administration**

Informatics Series

Program #204-000-08-119-L04P

(2.5 Contact Hours)

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Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: What should a medication barcode include? What shouldn't it? With a lack of a standardized national system, institutions are grappling with the implementation of a barcoding system that meets their needs. In this session, get the scoop on implementing and maintaining an effective program in this session.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Daily Programs > Tuesday, June 10

Learning Objectives:

- Describe a process for selecting vendors that includes an evaluation of functionality considerations, operational costs, and training/go-live support.
- Name key considerations in the planning phases, such as space and staffing requirements, workflow implications, and special packaging needs.
- Describe how to develop a stepwise roll-out implementation plan for your institution which validates a system's technical capabilities.
- Explain a comprehensive data management plan which monitors the success of a barcode medication administration system.

2:00 PM - 2:10 PM Welcome and Announcements

2:10 PM - 2:20 PM

Audience Participation: Electronic Submission of Questions via Digital Pens

2:20 PM - 2:55 PM

Selecting the Vendor: Features, Functionality, Strategy and Negotiations

Christopher R. Fortier, PharmD, Manager, Pharmacy Support Services, Medical University of South Carolina, Charleston

2:55 PM - 3:00 PM Audience Votes on Questions

3:00 PM - 3:45 PM

Implementing BCMA: Assessing Readiness, Designing Project Plans, and Managing Change

Christopher R. Fortier

3:45 PM - 4:15 PM

Measuring Impact: Data Collection, Analysis, Monitoring, and Response

Michael E. Sura, PharmD, Director of Clinical Informatics, Froedtert Hospital, Milwaukee, WI

4:15 PM - 4:30 PM Questions, Answers, and Discussion

2:00 PM - 4:30 PM Room 615, Level 6 Current Legislative and Regulatory Issues in Pharmacy 2008

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Program #204-000-08-120-L03P (2.5 Contact Hours)

Moderator: Brian M. Meyer, MBA, Director, Government Affairs Division, ASHP, Bethesda, MD

Description: Find out the latest legislative and regulatory issues affecting hospital and health-system pharmacy. Learn about issues being considered by Congress, the Centers for Medicare and Medicaid Services, Food and Drug Administration and state legislators and regulators. Apply this information to your practice, no matter what your setting.

Learning Objectives:

- Identify current regulatory and legislative issues impacting health-system pharmacists in a variety of practice settings.
- Apply the regulatory and legislative information to a range of practice topics.

2:00 PM - 2:05 PM Announcements

2:05 PM - 2:25 PM Update on the Hospital Outpatient Prospective Payment System for 2009

Justine Coffey, JD, LLM, Director, Federal Regulatory Affairs, ASHP, Bethesda, MD

2:25 PM - 2:45 PM

Recognition and Payment for Pharmacist Clinical Services

Joseph M. Hill, III, MA, Director, Federal Legislative Affairs, ASHP, Bethesda, MD

2:45 PM - 3:05 PM

Education, Certification and Registration of Pharmacy Technicians

Geralyn M. Trujillo, MPP, Director, State Government Affairs, ASHP, Bethesda, MD

3:05 PM - 3:10 PM Questions, Answers, and Discussion

3:10 PM - 3:30 PM Other Current Federal Legislative Issues Joseph M. Hill, III

3:30 PM - 3:50 PM Other Current Federal Regulatory Issues Justine Coffey

3:50 PM - 4:10 PM Other State Legislative and Regulatory Issues Geralyn M. Trujillo

4:10 PM - 4:30 PM Questions, Answers, and Discussion

Tuesday, June 10 & Wednesday, June 11 > Daily Programs

2:00 PM - 4:30 PM Ballroom 6C, Level 6 Complying with USP <797>: Hoods, Isolators, and Cleanrooms

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Program #204-000-08-121-L03P #204-000-08-121-L03T

#204-000-08-121-L03T (2.5 Contact Hours) **Moderator: Eric S. Kastango, MBA, RPh, FASHP,** President/CEO, Clinical IQ, LLC, Florham Park, NJ

Description: Standards and regulations give guidance for accomplishing a necessary task but still leave enough room flexibility to accommodate different operations. In the case of USP chapter <797>, this flexibility has resulted in different interpretations and those interpretations have led to good and bad sterile compounding facilities. This presentation will share experiences from early attempts to design and build compliant sterile compounding facilities.

Learning Objectives:

- Explain the meaning behind the facility requirements in USP Chapter <797>.
- Develop strategies for compliance based on both positive and negative experiences of past projects.
- Explain how to communicate effectively with the project architects and engineers.

2:00 PM - 2:10 PM Welcome and Announcements

2:10 PM - 3:00 PM

Understanding the Behind-the-Facility Requirements and Developing Strategies for Compliance

James T. Wagner, President, Controlled Environment Consulting, Bethlehem, PA

3:00 PM - 3:50 PM

Developing Strategies for Compliance and Effectively Communicating with Project Architechts

Karl M. Kilgore, AIA, NCARB, President, The CPI Group, Englewood, CO; and Medical Facility Planning Specialist

3:50 PM - 4:30 PM Questions, Answers, and Panel Discussion

4:30 PM - 6:00 PM Ballroom 6E, Level 6 Second House of Delegates Meeting

7:00 PM – 10:00 PM Metropolitan Ballroom, Level 3, Sheraton Seattle Hotel

Harvey A.K. Whitney Lecture Award Reception and Dinner

Advance ticket purchase required. See page 15 for details.

WEDNESDAY, JUNE 11

8:00 AM - 9:30 AM Room 615, Level 6

Prescription for Confusion: Health Literacy and the Rx Label

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Program #204-000-08-129-L05P (1.5 Contact Hours)

Speaker: Michael S. Wolf, PhD, MPH, Assistant Professor and Director, Northwestern University, Chicago, IL

Description: "1 tab PO QD" just isn't cutting it anymore. Health literacy is increasingly viewed as a patient safety issue and has been shown to contribute to medication errors. A common mistake involves the word "once" — as in "once daily" — which Spanish-speaking patients have misinterpreted as "eleven" times. Individuals with limited health literacy have less health knowledge, worse self-management skills, lower use of preventive services, and higher hospitalization rates. In this session, learn more about the scope and details of this important issue and what can be done about it.

Learning Objectives:

- Describe issues and problems related to patients' misunderstanding common dosage instructions on prescription drug container labels.
- Describe common causes for misunderstanding prescription drug warning labels among adults with low literacy.
- Explain the relationship between low health literacy levels and overall and cause-specific mortality.
- Determine the usefulness of consumer-directed, FDA-approved Medication Guides to patients with limited literacy.
- Identify steps that can be taken to design prescription drug labels that are clear to patients with low health literacy levels

8:00 AM - 8:05 AM Announcements

8:05 AM - 8:15 AM Health Literacy: Definition and Epidemiology

8:15 AM - 8:35 AM

The Problem with Prescription Drug Labeling: The Institute of Medicine Report

8:35 AM - 8:50 AM

Improving Consumer Medication Information: Best Practices for Dispensing

8:50 AM - 9:05 AM

Improving Drug Instructions: From Prescribing to Dispensing

Daily Programs > Wednesday, June 11

9:05 AM - 9:20 AM A Policy Road Map for Better Rx Labelings

9:20 AM - 9:30 AM Questions, Answers, and Discussion

8:00 AM - 11:00 AM Room 607, Level 6

Innovating for the Future

The Business of Pharmacy Learning Community

Program #204-000-08-122-L04P #204-000-08-122-L04T (3.0 Contact Hours)

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: Find out how to build the capacity for creativity and innovation. Learn from entrepreneurial leaders who will share their insights on challenging traditional thinking, strategies for change management, and capitalizing on new service opportunities.

Learning Objectives:

- > Apply strategies for change management.
- Explain tactics for fostering creativity and developing entrepreneurship.
- Describe characteristics of risk assessment and mitigation to support effective decision making.

8:00 AM - 8:10 AM Welcome and Announcements

8:10 AM - 8:45 AM

Creating Change and Innovating for Success

James A. Jorgenson, RPh MS, FASHP, Director of Pharmacy Services, University of Utah Hospitals and Clinics, Salt Lake City; and Associate Dean for Pharmacy, University of Utah College of Pharmacy, Salt Lake City

8:45 AM - 9:25 AM

Redesigning Medication Use Systems and Pharmacist Practice Models to Support Organizational Strategic Initiatives

James A. Jorgenson

9:25 AM - 10:00 AM Maximizing your Medicare Part-D

Opportunity

Douglas E. Miller, BS, PharmD, Pharmacy Consultant, Douglas E. Miller, LLC, Norcross, GA

10:00 AM - 10:35 AM

Future of Pharmacy: Doom or Gloom?

Robert (Bob) F. Carta, Assistant Vice President/Corporate Pharmacy Services, Carolinas HealthCare System, Charlotte, NC

10:35 AM - 11:00 AM

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Interactive Dialogue with Audience: How to Innovate for the Future November 14, 2008 ASHP 2008 Summer Meeting and Exhibition

8:00 AM - 11:00 AM Room 613, Level 6

Managing Knowledge Management Systems: Optimizing CDSS

Informatics Series

Program #204-000-08-123-L04P #204-000-08-123-L04T

(3.0 Contact Hours)

Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: With the many commercial knowledge bases available, how can you determine which is the right one for your institution? What is the right level of alerts to set for pharmacists vs. physicians vs. nurses? Learn how to best use clinical decision support systems to support your staff and peers, and how to take a leadership role in your institution in managing these systems.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Learning Objectives:

- Compare the use of a commercial knowledge base with a custom set of rules developed at a hospital.
- Compare and contrast the advantages and disadvantages of utilizing order sets and protocols.
- Describe roles and skills needed to effectively manage your evaluation of available clinical decision support systems, implementation of such systems, and post-implementation measurement of success.

8:00 AM - 8:10 AM

Welcome and Announcements

8:10 AM - 8:20 AM

Audience Participation: Electronic Submission of Questions via Digital Pens

8:20 AM - 8:55 AM

Commercial Knowledge Bases versus Custom Rule Sets

Thomas H. Payne, MD, Medical Director, IT Services, UW Medicine, University of Washington, Seattle, WA; and Clinical Associate Professor, Departments of Medicine, Health Services and Medical Education & Biomedical Informatics Dean F. Sittig, PhD, Director, Applied Research in Medical Informatics, Northwest Permanente, Portland, OR

8:55 AM - 9:05 AM Audience Votes on Questions

9:05 AM - 9:40 AM

Order Sets versus Protocols Thomas H. Pavne

9:40 AM - 10:00 AM Results of Audience Vote

Wednesday, June 11 > Daily Programs

10:00 AM - 10:35 AM

Effective CDSS Management — Skills and Roles for Pharmacists

Dean F. Sittig

10:35 AM - 11:00 AM Questions, Answers, and Panel Discussion

8:00 AM - 11:00 AM Room 603, Level 6 Anesthesia, OR, and PACU: Medication Use Behind the Double Doors

Quality Standards in Clinical Practice Series

Program #204-000-08-124-L01P (3.0 Contact Hours)

Moderator: Julie A. Golembiewski, PharmD, Clinical Associate Professor, University of Illinois at Chicago

Description: More often than not, pharmacists are left in the cold when it comes to medication use in the OR, in the Cath Lab, and by Anesthesia. What really happens? How can pharmacy services be best utilized in these unique settings? Find this out and more in this session that will look into the future of pharmacy services.

This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- Describe key aspects of quality standards related to use of anesthesia and practice in the OR and PACU.
- Explain the impact of these quality standards to your practice.
- Explain how to operationalize relevant quality standards in your practice.

8:00 AM - 8:10 AM

Announcements

8:10 AM - 9:00 AM

Medication Safety in the Operating Room – What's Different?

Eric L. Chernin, BSPharm, Pharmaceutical Care Specialist-OR Pharmacy, Sarasota Memorial Hospital, Sarasota, FL

9:00 AM - 9:50 AM

Ensuring a Safe Environment — Spotlight on Process Improvement

Deborah S. Wagner, BS, PharmD, Associate Clinical Professor of Pharmacy, and Assistant Clinical Professor of Anesthesiology, University of Michigan Health Systems, Ann Arbor

9:50 AM - 10:00 AM Break

10:00 AM - 10:50 AM

Interventional and Perioperative Imaging — Pearls for Pharmacists

Peggy S. Bickham, PharmD, Assistant Director, Specialty and Support Services, University of Illinois Medical Center, Chicago; and Clinical Assistant Professor, University of Illinois College of Pharmacy

10:50 AM - 11:00 AM Questions, Answers, and Discussion

11:00 AM – 1:00 PM Exhibition Hall 4A/B, Level 4 Exhibit Program and Lunch in the Exhibit Hall

1:00 PM - 2:30 PM Room 607, Level 6 The Business of Pharmacy: Putting It All Together

The Business of Pharmacy Learning Community

Program #204-000-08-126-L04P 204-000-08-126-L04T

(1.5 Contact Hours)

Moderator: Sharon M. Enright, MBA, BSPharm, Senior Manager, Ernst & Young LLP, Richmond, VA

Description: A panel will review proactive pharmacy financial management perspectives, strategies, tactics and skills for building integration, organizational alignment and departmental growth.

Learning Objectives:

- Identify strategies for positioning your pharmacy department operations within the business function of your organization.
- Explain the advantages of proactive financial management strategies.
- Describe how effective pharmacy business management supports common organizational, departmental, and patient care goals.

1:00 PM - 1:10 PM Welcome and Announcements

1:10 PM - 1:45 PM

The Business of Pharmacy: Putting it All Together

Keith Hanchey, Pharmacist, Executive Director, Ernst & Young, Dallas, TX

1:45 PM - 2:30 PM

Panel Discussion between Audience and Business of Pharmacy Faculty

Billy W. Woodward, BS, RPh, Clinical Associate Professor, University of Texas College of Pharmacy, Austin; and President, Renaissance Pharmacy Services, Ltd., Temple, TX Keith Hanchey Sharon M. Enright

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Daily Programs > Wednesday, June 11

1:00 PM - 2:30 PM Room 613, Level 6

Formulary Management in an Integrated Information System Environment: Challenges and Successes

Informatics Series

Program #204-000-08-127-L04P #204-000-08-127-L04T

(1.5 Contact Hours)

Moderator: Brent I. Fox, PharmD, PhD, Assistant to the Dean for Educational Technology, Auburn University, Harrison School of Pharmacy, Auburn, AL

Description: To say that managing a hospital's formulary is challenging is often an understatement. And to say that formulary integration across multiple clinical information systems is difficult is an even larger understatement. Further integration of a charging process that complies with the formulary and is 100% accurate is an additional layer of complexity. In this session, learn tips for managing your institution's formulary within a multi-information system healthcare environment.

An audience response system will be used in this session. Participation is limited, so please arrive early.

Learning Objectives:

- Identify challenges you may face when integrating a formulary across multiple information systems.
- Define your barriers to implementing a charging process that is consistent with the formulary.
- Describe methods and processes that have been used to successfully integrate formulary and charging information across information systems.
- Explain ways that your pharmacy department can take leadership in, and informatics personnel can facilitate, an accurate formulary and charging process.

1:00 PM - 1:10 PM

Announcements and Welcome

1:10 PM - 1:25 PM

The Pharmacist's Role in Formulary Management: The I.S. Change Control Process and Managing Clinician Expectations

Brian L. Pinto, BS, PharmD, Clinical Specialist, Drug Information, The Johns Hopkins Hospital, Baltimore, MD

1:25 PM - 1:35 PM

Audience Participation: Electronic Submission of Questions via Digital Pens

1:35 PM - 1:50 PM

Obstacles to Formulary Management: So Many New Drugs, So Little Time and Issues with Non-Formulary Items

Brian L. Pinto

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1:50 PM - 2:00 PM Audience Votes on Questions

2:00 PM - 2:15 PM

Tools to Facilitate Formulary Management: Forecasting, Monograph Services, and Electronic Tools

Brian L. Pinto

2:15 PM - 2:30 PM Questions, Answers, and Discussion

1:00 PM - 2:30 PM Room 603, Level 6 Are Quality Standards Possible in Antibiotic Resistance?

Quality Standards in Clinical Practice Series

Program #204-000-08-128-L01P (1.5 Contact Hours)

Note: Bring your own antibiogram to this session.

Moderator: Robert P. Rapp, PharmD, FCCP, Professor of Pharmacy, College of Pharmacy, University of Kentucky, Lexington; and Associate Director, Department of Pharmacy Services, University of Kentucky Hospital, Lexington

Description: What quality standards will best help curb antimicrobial resistance in your institution? Discuss the issues with an expert and your fellow participants. Learn to identify appropriate infection control targets for hand hygiene and barrier precaution compliance and discuss the potential goals for antimicrobial resistance rates in specific bacteria. Bring your own antibiogram or review one provided in the session. Discover new and effective ways to improve infection control procedures. Should the pharmacist serve on the infection control committee and if so, what should be pharmacist bring to the table? Discuss and define antimicrobial resistance/susceptibility rates for MRSA, VRE, ESBLs, ampC stable derepression, C. difficile-associated disease, and carbapenem resistance. Discuss and define the practice guidelines for antimicrobial stewardship. Learn to work with Microbiology to best serve your patients.

This session was planned in cooperation with the ASHP Quality Improvement Initiative.

Learning Objectives:

- Identify appropriate infection control issues that require improvement.
- Define and discuss rates of antimicrobial-resistant Gram-positive and Gram-negative bacteria.
- Analyze your hospital antibiogram.
- Discuss the role of the infectious disease trained pharmacist on the antimicrobial stewardship team.

1:00 PM - 1:05 PM Announcements

Wednesday, June 11 > Daily Programs

1:05 PM - 1:30 PM

Quality Assurance Issues for Resistance in Gram-Positive Bacteria

Craig Martin, PharmD, Clinical Pharmacy Specialist-Infectious Diseases, UK HealthCare, University of Kentucky, Lexington; and Associate Professor, Adjunct, University of Kentucky College of Pharmacy, Lexington

1:30 PM - 2:00 PM

Quality Assurance Issues for Resistance in Gram-Negative Bacteria Robert P. Rapp

2:00 PM - 2:30 PM Antibiogram Activity and Analysis

Speaker Disclosures

ASHP Presenter Disclosures

In accordance with ACPE guidelines, ASHP requires all speakers in sessions offering continuing education credit to disclose financial conflicts of interest. All potential conflicts are resolved before a speaker's participation is confirmed. The following speakers have disclosure(s) for their presentations:

Sharon M. Enright Employee: Ernst & Young, LLP

J. Thomas Frank Speaker's Bureau: Novartis, Novo Nordisk, B-I, Pfizer

Stuart T. Haines Advisory/Review Board: Amylin Pharmaceuticals; Consultant: Merck & Co.; AstraZeneca; sanofi-aventis; Financial Holdings: Merck & Co.

Keith Hanchey Employee: Ernst & Young, LLP

Christopher A. Hatwig Employee: Provista

Melinda Joyce Consultant: Pharmacy Services Support Center (PSSC)

Eric S. Kastango Employee: Clinical IQ, LLC

Karl M. Kilgore Employee: The CPI Group

Craig Martin

Advisory/Review Board: Ortho McNeil; Clinical Investigator: Ortho McNeil; Speaker's Bureau: Wyeth, Cubist, Ortho McNeil

Luci A. Power

Advisory/Review Board: Intelligent Hospital Systems; Consultant: Cardinal Health; Speaker's Bureau: Carmel Pharma, Teva/Sicor; Financial Agreement: Covidien Health Care

William H. Puckett Employee: Ernst & Young, LLP, WHP-Rx Consulting, LLC; Contractor: Hospira

November 14, 2008

Robert P. Rapp

Advisory/Review Board: Ortho McNeil, Wyeth; Consultant: Ortho McNeil, Wyeth; Speaker's Bureau: Ortho McNeil, AstraZeneca, Wyeth

Darryl S. Rich Employee: The Joint Commission

Sarah A. Spinler Consultant: GlaxoSmithKline, The Medicines Company; Speaker's Bureau: sanofi aventis

Michael E. Sura Employee: Eli Lilly

Paul M. Szumita Speaker's Bureau: sanofi aventis

Lawrence A. Trissel Employee: TriPharma Research

William von Oehsen, III Employee: Powers, Pyles, Sutter, & Verville, P.C.

Deborah Wagner Advisory/Review Board: Organon; Consultant: Abraxis; Speaker's Bureau: Merck; Financial Support: Abbott

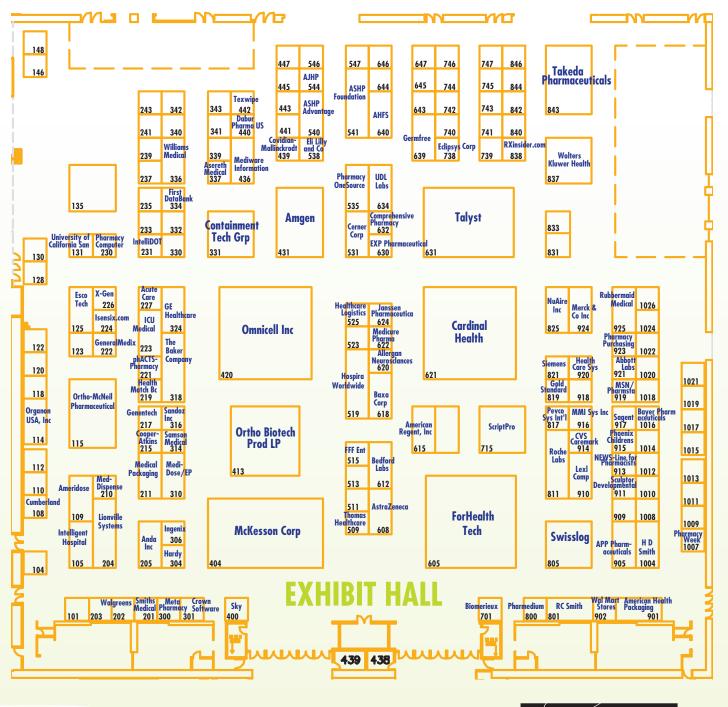
James T. Wagner Employee: Controlled Environment Consulting

Andrew L. Wilson Employee: Ernst & Young, LLP

Billy W. Woodward Employee: Renaissance Pharmacy Services, Ltd.

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Exhibit Hall Floor Plan





Summer Meeting and Exhibition Washington State Convention and Trade Center Seattle, Washingfor 26



Exhibitor List by Name

| Exhibitor | Booth | Exhibitor | Booth |
|--|-----------|---|--------------|
| 340B Pharmacy Center 125 E. John Carpenter Freeway, Floor 14 Irving, TX 75062-2709 | Booth 123 | Apotex Corporation | Booth 237 |
| Abbott Laboratories 200 Abbott Park Road Abbott Park, IL 60064-3537 | Booth 921 | Artromick 4800 Hilton Corporate Drive Columbus, OH 43232-4150 | Booth 714 |
| Abraxis Pharmaceutical Products 1501 E. Woodfield Road, Suite 300E Schaumburg, IL 60173-6029 | Booth 905 | Asereth Medical Services Inc 257 S. Fair Oaks Avenue, Suite 100 Pasadena, CA 91105-2050 | Booth 337 |
| Acute Care Pharmaceuticals 12225 World Trade Drive, Suite F San Diego, CA 92128-3768 | Booth 227 | ASHP Advantage 7272 Wisconsin Avenue Bethesda, MD 20814 | Booth540 |
| AHFS 7272 Wisconsin Avenue Bethesda, MD 20814 AJHP | | ASHP Research and Education Foundation 7272 Wisconsin Avenue Bethesda, MD 20814 | Booth 541 |
| 7272 Wisconsin Avenue Bethesda, MD 20814 | | Astellas Pharma US Inc | Booth 441 |
| Allergan 2525 Dupont Drive Irvine, CA 92612-1599 American Health Packaging | | AstraZeneca 1800 Concord Pike P.O. Box 15437 Wilmington, DE 19950-5437 | Booth 608 |
| 2550 John Glenn Avenue, Suite A Columbus, OH 43217-1188 American Regent, Inc One Luitpold Drive | Booth 625 | The Baker Company 161 Gatehouse Road P.O. Box Drawer E Sanford, ME 04073-1338 | Booth 318 |
| P.O. Box 9001 Shirley, NY 11967-4709 Ameridose | Booth 109 | Baxa Corporation 14445 Grasslands Drive Englewood, CO 80112-7062 | Booth 618 |
| Framingham, MA 01702-8212 Amgen One Amgen Center Drive | Booth 431 | Bayer Pharmaceuticals Corporation 6 W Belt Wayne, NJ 07470-6945 | . Booth 1016 |
| Thousand Oaks, CA 91320-1799 Amphastar Pharmaceuticals | Booth 643 | Bedford Laboratories | Booth 612 |
| 11570 6th Street Rancho Cucamonga, CA 91730 Anda Inc. | Rooth 205 | bioMerieux 100 Rodolphe Street Durbam NC 27712 9402 | Booth 701 |
| 2915 Weston Road Weston, FL 33331-3627 November 14, 2008 | BUUIN 203 | Durham, NC 27712-9402 ASHP 2008 Summer Meeting a | Page 727 |

ASHP 2008 Summer Meeting and Exhibition (43)

Exhibitor List by Name

| | Board of Pharmaceutical Specialties 1100 15th Street NW, Suite 400 Washington, DC 20005-1707 | . Booth 644 |
|------|---|--------------|
| | Cardinal Health 3750 Torrey View Court San Diego, CA 92130-2622 | . Booth 621 |
| | Carmel Pharma Inc. 7029 Huntley Road, Suite O Columbus, OH 43229-1059 | . Booth 330 |
| | Cerner Corporation 2800 Rockcreek Parkway Kansas City, MO 64117-2521 | . Booth 531 |
| | Comprehensive Pharmacy Services 6409 N. Quail Hollow Road Memphis, TN 38120-1414 | Booth 632 |
| | Containment Technologies Group, Inc. 5460 Victory Drive, Suite 300 Indianapolis, IN 46203-5970 | Booth 331 |
| | Cooper-Atkins Corporation 33 Reeds Gap Road Middlefield, CT 06455-1138 | Booth 215 |
| | Craneware 7301 W 129th Street, Suite 210 Overland Park, KS 66213 | . Booth 1008 |
| | Crown Software Inc. 186 Lonely Oaks Lane Killeen, TX 76542-5654 | Booth 301 |
| | Cumberland Pharmaceuticals 707 Walcott Way, Suite 950 Cary, NC 27519 | Booth 108 |
| | CVS Carmark One CVS Drive Woonsocket, RI 02895 | . Booth 914 |
| | Dabur Pharma US, Inc. 200 S. Andrews Avenue, Suite 702 Fort Lauderdale, FL 33301-1864 | . Booth 440 |
| | Eclipsys Corporation | Booth 738 |
| | Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285-0001 November 14, 2008 | Booth 538 |
| 4 | 4 ASHP 2008 Summer Meeting and | Exhibition |

| Esco Technologies Inc. 2940 Turnpike, Suite 15-16 Hatboro, PA 19040-4229 | Booth 125 |
|--|--------------|
| EXP Pharmaceutical Services Corporation | Booth 630 |
| FDA's Center for Drug Evaluation & Research 10903 New Hampshire Avenue, W051-2201 Silver Spring, MD 20993 | Booth 645 |
| FFF Enterprises 41093 County Center Drive Temecula, CA 92591-6025 | Booth 513 |
| First DataBank Inc. 1111 Bayhill Drive San Bruno, CA 94066-3027 | Booth 334 |
| ForHealth Technologies Inc | Booth 605 |
| GE Healthcare 540 W. Northwest Highway Barrington, IL 60010-3051 | Booth 324 |
| GEM Refigerator Company | Booth 740 |
| Genentech Inc. 1 DNA Way South San Francisco, CA 94080-4990 | Booth 217 |
| Germfree | Booth 639 |
| GlaxoSmithKline 1600 Vine Street Philadelphia, PA 19102 | . Booth 1015 |
| Gold Standard Inc | Booth 819 |
| Hardy Diagnostics | Booth 304 |
| | |

H.D. Smith Booth 1004 3063 Fiat Avenue Springfield, IL 62703-5930

Hospira Booth 519 275 N Field Drive D97J, Bldg. H1 Lake Forest, IL 60045-2510

Johnson and Johnson Wound

November 14, 2008

Exhibitor List by Name

Lionville Systems Inc. Booth 204 501 Gunnard Carlson Drive Coatesville, PA 19320-1691 Mallinckrodt Pharmaceuticals/ Covidien Booth 439 675 McDonnell Boulevard St Louis, MO 63042 **One Post Street** San Francisco, CA 94104 98 Elm Street, Suite 2 Cheshire, CT 06410 6250 Shiloh Road, Suite 240 Alpharetta, GA 30005-8400 70 Industrial Drive lvyland, PA 18974-1433 470 Route 31 P.O. Box 500 Ringoes, NJ 08551-1409 200 Cottontail Lane Somerset, NJ 08873-1231 Mediware Information Systems Inc. . . . Booth 436 11711 W. 79th Street Lenexa, KS 66214-1497 Merck & CompanyBooth 924 351 N. Sumnevtown Pike North Wales, PA 19454-2536 199 Jericho Turnpike, LL2 Floral Park, NY 11001-2100 123 E Georgetown Street Crystal Springs, MS 39059-2777 3740 Paris Street

ASHP 2008 Summer Meeting and Exhibition

Denver, CO 80239

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Exhibitor List by Name

4525 Weaver Parkway, Suite 310 Warrenville, IL 60555-0317 661 Moore Road, Suite 100 King Of Prussia, PA 19406-1317 201 Waverly Street Framingham, MA 01702-7129 661 Moore Road, Suite 100 King of Prussia, PA 19406 2100 Fernbrook Lane North Plymouth, MN 55447-4722 1201 Charleston Road Mountain View, CA 94043-1337 56 Livingston Avenue Roseland, NJ 07068-1775 430 Route 22 Bridgewater, NJ 08807-2463 1000 Route 202 Raritan, NJ 08869-1425 Oztech SystemsBooth 104 P.O. Box 1856 Burlingame, CA 94011-1856 14201 SE Petrovitsky Road. #A-3175 Renton, WA 98058-8986 Pevco Systems International Inc. Booth 817 10001 Franklin Square Drive Baltimore, MD 21236-4911 1023 NE 43rd Street Seattle, WA 98105-4611

Pharmacy Computer Services, Inc. Booth 230 129 NW E Street Grants Pass. OR 97526-2009 3535 Factoria Boulevard SE, Suite 440 Bellevue, WA 98006-1209 211 1st Street Ho Ho Kus, NJ 07423-1533 7780 Elmwood Avenue, Suite 210 Middleton, WI 53562-5407 2 Conway Park 150 North Field Drive, Ste 350 Lake Forest, IL 60045 1919 E Thomas Road Phoenix, AZ 85016-7710 Two Perimeter Park South, Suite 230 Birmingham, Alabama 35243 R.C. Smith Company Booth 801 14200 Southcross Drive W Burnsville, MN 55306-6973 1007 Whitehead Road Ext Trenton, NJ 08638-2405 340 Kingsland Street Nutley, NJ 07110 16905 Northcross Drive Huntersville, NC 28078-5012 1300 Division Road, Suite 103A West Warwick, RI 02893-7558 1901 N Roselle Road. Suite 700 Schaumburg, IL 60195-3194

Sandoz Inc. Booth 316 & ES1 111 Ramblewood Road Moorestown, NJ 08057-2627

Sculptor Developmental

Takeda Pharmaceuticals

November 14, 2008

Exhibitor List by Name

Talyst Booth 631 13555 SE 36th Street, Suite 150 Bellevue, WA 98006-1457 675 N. Field Drive Lake Forest, IL 60045 300B Route 17 South Mahwah, NJ 07430 6200 S Syracuse Way, Suite 300 Greenwood Village, CO 80111-4740 UDL Laboratories Inc. 1718 Northrock Court Rockford, IL 61103-1201 NEW University of California 2233 Post Street San Francisco, CA 94115-3470 102 Wilmot Road, #1220 Deerfield, IL 60015-5143 508 SW 8th Street Bentonville, AR 72716-0001 360 Mt. Kemble Avenue Morristown, NJ 07962 Williams Medical Company Booth 336 1150 South Las Brisas Place Placentia. CA 92870-6643 800 Washington Avenue N Minneapolis, MN 55401-1183 300 Daniel Zenker Drive Horseheads, NY 14845-1014

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Exhibitor List by Category = Sponsors (IEV) = New Exhibitors



| EXILIBITO | DUUII |
|-------------------------------|-----------|
| Automation | |
| 340B Pharmacy Resource Center | Booth 123 |
| Baxa Corporation | Booth 618 |
| Cardinal Health | Booth 621 |
| Cooper-Atkins Corporation | Booth 215 |
| ForHealth Technologies Inc | Booth 605 |
| Insensix Inc | Booth 224 |
| Intelligent Hospital Systems | Booth 105 |
| Medacist Solutions Group | Booth 840 |
| McKesson Corporation | Booth 404 |
| Omnicell | Booth 420 |
| Pacific-id | Booth 513 |
| PhACTS | Booth 221 |
| Rees Scientific Corporation | Booth 110 |
| Samson Medical Technologies | Booth 314 |
| ScriptPro | Booth 715 |
| Swisslog Healthcare Solutions | Booth 805 |
| Talyst | Booth 631 |

Biotechnology

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| Amgen | Booth 431 |
|------------------------------------|-----------|
| Johnson & Johnson Wound Management | Booth 128 |
| Medicura Pharma Inc | Booth 622 |

Brand Name Pharmaceuticals

| 340B Pharmacy Resource Center | Booth 123 |
|----------------------------------|--------------|
| Abbott Laboratories | Booth 921 |
| Acute Care Pharmaceuticals | Booth 227 |
| Allergan | Booth 620 |
| American Regent, Inc | Booth 615 |
| Amphastar Pharmaceuticals | Booth 643 |
| Astellas Pharma US Inc | Booth 441 |
| AstraZeneca | Booth 608 |
| Bayer Healthcare Pharmaceuticals | . Booth 1016 |
| Cumberland Pharmaceuticals Inc. | Booth 108 |
| Eli Lilly and Company | Booth 538 |
| Genentech | Booth 217 |
| GlaxoSmithKline | . Booth 1015 |
| | |

| Exhibitor | Booth |
|--------------------------------------|------------|
| H D Smith | Booth 1004 |
| Hospira Worldwide Inc | Booth 519 |
| Janssen | Booth 624 |
| Medicura Pharma Inc | Booth 622 |
| Merck & Company Inc | Booth 924 |
| Organon USA | Booth 114 |
| Ortho-McNeil Inc. | Booth 115 |
| Roche | Booth 811 |
| sanofi aventis | Booth 235 |
| Scios | Booth 511 |
| Takeda Pharmaceuticals North America | Booth 843 |
| TAP Pharmaceuticals | Booth 846 |
| Watson Pharmaceutical | Booth 831 |

Computer Systems/Software

| Baxa Corporation | Booth 618 |
|----------------------------------|------------|
| bioMerieux | Booth 701 |
| Cardinal Health | Booth 621 |
| Cerner Corporation | Booth 531 |
| Cooper-Atkins Corporation | Booth 215 |
| Craneware | Booth 1008 |
| Crown Software Inc | Booth 301 |
| Eclipsys Corporation | Booth 738 |
| ForHealth Technologies Inc | Booth 605 |
| GE Healthcare | Booth 324 |
| Gold Standard | Booth 819 |
| H. D. Smith | Booth 1004 |
| Health Care Systems | Booth 920 |
| Ingenix | Booth 306 |
| Insensix Inc | Booth 224 |
| Lexi-Comp Inc | Booth 910 |
| Lionville Systems Inc | Booth 204 |
| Medacist Solutions Group | Booth 840 |
| McKesson Corporation Booth 404 | |
| Mediware Information Systems Inc | Booth 436 |
| Meta Pharmacy Systems | Booth 300 |
| Omnicell | Booth 420 |
| Oztech Systems | Booth 104 |
| Pacific-id | Booth 513 |
| | |

| Pharmacy Computer Services, Inc. | Booth 230 |
|-----------------------------------|-----------|
| Pharmacy OneSource, Inc. | Booth 535 |
| RXinsider.com | Booth 838 |
| Rees Scientific Corporation | Booth 110 |
| Sculptor Developmental Technology | Booth 911 |
| Siemens | Booth 821 |
| Smiths Medical MD Inc | Booth 201 |
| Standing Stone Inc. | Booth 909 |
| Talyst | Booth 631 |
| Wolters Kluwer Health | Booth 837 |
| | |

Dispensing

| 340B Pharmacy Resource Center | Booth 123 |
|-------------------------------|-----------|
| Baxa Corporation | Booth 618 |
| Cardinal Health | Booth 621 |
| Cerner Corporation | Booth 531 |
| Health Care Logistics | Booth 525 |
| Medacist Solutions Group | Booth 840 |
| McKesson Corporation | Booth 404 |
| Med-DISPENSE | Booth 210 |
| Medi-Dose/EPS Inc. | Booth 310 |
| Medical Packaging Inc | Booth 211 |
| Omnicell | Booth 420 |
| PhACTS | Booth 221 |
| Rubbermaid Medical Solutions | Booth 925 |
| ScriptPro | Booth 715 |
| Swisslog Healthcare Solutions | Booth 805 |
| Talyst | Booth 631 |
| Williams Medical Company | Booth 336 |

Drug Administration Devices

| Baxa Corporation | Booth 618 |
|------------------------------|-----------|
| Carmel Pharma Inc | Booth 330 |
| Health Care Logistics | Booth 525 |
| Hospira Worldwide, Inc | Booth 519 |
| ICU Medical Inc | Booth 223 |
| Intelligent Hospital Systems | Booth 105 |
| Mckesson Corporation | Booth 404 |
| Medi-Dose/EPS Inc. | Booth 310 |
| Mediware | Booth 436 |

Exhibitor List by Category

| Sculptor Developmental Technology | Booth 911 |
|-----------------------------------|-----------|
| Smiths Medical MD Inc | Booth 201 |
| Swisslog Healthcare Solutions | Booth 805 |

Employers/Employment Agencies

| Comprehensive Pharmacy Services | Booth 632 |
|--|-----------|
| Health Match BC | Booth 219 |
| MSN/Pharmstaff | Booth 919 |
| Phoenix Children's Hospital | Booth 915 |
| NEW The University of California, San Francisco | |
| Medical Center | Booth 131 |

Facility Design/Fixtures

| Health Care Logistics | Booth 525 |
|------------------------|-----------|
| Insensix Inc | Booth 224 |
| Lionville Systems Inc. | Booth 204 |
| MMI Systems, Inc | Booth 916 |
| PhACTS | Booth 221 |
| R. C. Smith Company | Booth 801 |

Generic Pharmaceuticals

| 340B Pharmacy Resource Center | Booth 123 |
|----------------------------------|------------|
| Abraxis Pharmaceutical | Booth 905 |
| American Health Packaging | Booth 901 |
| American Regent, Inc | Booth 615 |
| Amphastar Pharmaceuticals | Booth 643 |
| Anda | Booth 205 |
| Apotex Corp | Booth 237 |
| Bedford Laboratories | Booth 612 |
| Dabur Pharma US Inc | Booth 440 |
| GeneraMedix Inc. | Booth 222 |
| H. D. Smith | Booth 1004 |
| Hospira Worldwide, Inc | Booth 519 |
| Mallinckrodt Pharm./Covidien | Booth 439 |
| Mediware Information Systems Inc | Booth 436 |
| Sagent Pharmaceuticals | Booth 917 |
| Samson Medical Technologies | Booth 314 |
| Sandoz | Booth 316 |
| UDL Laboratories Inc | Booth 634 |
| X-Gen Pharmaceuticals | Booth 226 |

Exhibitor List by Category

Government Agency

| 340B Pharmacy Resource Center | Booth 123 |
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| FDA's Center for Drug Evaluation and Research . | Booth 645 |

Heatlh Care Institution

| The University of California San Francisco | |
|--|-----------|
| Medical Center | Booth 131 |

Home Health Care Provider

| H.D. Smith | . Booth 1004 |
|------------------------|--------------|
| Health Care Logistics | Booth 525 |
| Hospira Worldwide, Inc | Booth 519 |
| Smiths Medical MD Inc | Booth 201 |

Hoods, Safety Cabinets

| The Baker Company | Booth 318 |
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| Containment Technologies Group | Booth 331 |
| Esco Technologies Inc | Booth 125 |
| Germfree | Booth 639 |
| NuAire Inc | Booth 825 |

Market Research

| PhACTS | ••• | Booth 221 |
|---------------|-----|-----------|
| RXinsider.com | | Booth 838 |

Parenterals

| Sagent Pharmaceuticals . | | Booth 917 |
|--------------------------|--|-----------|
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Packaging Equipment/Systems

| Cardinal Health | Booth 621 |
|-------------------------------|-----------|
| Medical Packaging Inc | Booth 211 |
| McKesson Corporation | Booth 404 |
| Omnicell | Booth 420 |
| PhACTS | Booth 221 |
| Samson Medical Technologies | Booth 314 |
| Swisslog Healthcare Solutions | Booth 805 |
| Talyst | Booth 631 |

Pharmacy Management Services

| Asereth Medical Services Inc | Booth 337 |
|----------------------------------|-----------|
| Cardinal Health | Booth 621 |
| Comprehensive Pharmacy Services | Booth 632 |
| EXP Pharmaceutical Services Corp | Booth 630 |
| Gold Standard | Booth 819 |
| Medacist Solutions Group | Booth 840 |
| McKesson Corporation | Booth 404 |
| Principle Pharmacy Group, Inc | Booth 118 |
| Rubbermaid Medical Solutions | Booth 925 |
| Smiths Medical MD Inc | Booth 201 |
| Standing Stone Inc | Booth 909 |
| Stericycle | Booth 122 |

Profession or Trade Association

| RXinsider.com Booth 838 |
|-------------------------|
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Publications

| NEWS-LINE for Pharmacists | Booth 913 |
|--------------------------------|------------|
| Pharmacy Purchasing & Products | Booth 923 |
| Pharmacy Week | Booth 1007 |

Refrigeration

| Gem Refrigerator Company | Booth 740 |
|-------------------------------|-----------|
| Health Care Logistics | Booth 525 |
| Insensix Inc | Booth 224 |
| NuAire Inc | Booth 825 |
| RXinsider.com | Booth 838 |
| Swisslog Healthcare Solutions | Booth 805 |
| Talyst | Booth 631 |

Wholesale Distributors

| Acute Care Pharmaceuticals | Booth 227 |
|----------------------------|------------|
| Anda | Booth 205 |
| H.D. Smith | Booth 1004 |
| Medi-Dose/EPS Inc | Booth 310 |
| McKesson Corporation | Booth 404 |
| Williams Medical Company | Booth 336 |

Pharmaceutical Industry-Supported Symposia

The following pharmaceutical industry-supported education programs have been scheduled in conjunction with the ASHP Summer Meeting. These symposia will be held throughout the week at official Meeting hotels. Check the assigned hotel's reader board onsite for meeting room locations. The CE provider is responsible for continuing education credits and content. Interested individuals should call the contact listed below for more information.

SUNDAY, JUNE 8

7:30 AM - 12:10 PM **Sheraton Seattle**

Overcoming Challenges with Anticoagulant Therapy: Complex Cases in Venous Thromboembolism

Sponsored by sanofi-aventis U.S.

Contact Kim Cackowski, ASHP Advantage, 301-664-8830 CE Provider: ASHP Advantage

MONDAY, JUNE 9

5:30 PM - 7:30 PM

Sheraton Seattle

Emerging Approaches in Neuromuscular Blockade and Reversal

Sponsored by Organon/Schering

Contact Mary Minobe, Grant/Downing Education; 303-407-3411 x105 CE Provider: Grant/Downing Education

5:45 AM - 7:45 AM **Sheraton Seattle**

Respiratory Syncytial Virus: Strategies for Identification, **Prevention, and Management**

Sponsored by Medimmune

Contact Claudia Alsina, Rockpointe Corporation; 904-375-2373 CE Provider: Potomac Center for Medical Education-PCME

6:00 AM - 7:45 AM **Sheraton Seattle**

Measuring the Financial Benefits of **Barcode-Based Automation on Patient** Safety, Inventory Management, and **Pharmacist Productivity**

Sponsored by McKessen Corporation Contact Kathleen Theiss. McKesson. 724-741-8382 CE Provider: Inquisit

6:15 AM - 7:45 AM **Sheraton Seattle**

Improving Outcomes of Anticoagulant Therapy in Patients with Non-ST-Elevation Acute Coronary Syndrome: 2008 Update

Sponsored by sanofi-aventis U.S. Contact Kim Cackowski, ASHP Advantage, 301-664-8830 **CE Provider: ASHP Advantage** November 14, 2008

TUESDAY, JUNE 10

6:00 AM - 7:00 AM **Sheraton Seattle**

Meeting the Needs of Patients with Acute Severe Hypertension: Current Practices, **Future Directions**

Sponsored by The Medicines Company Contact Kim Law-Atland, BioCentric, Inc., 856-854-3500 CE Provider: Postgraduate Institute for Medicine

6:00 AM - 7:45 AM **Sheraton Seattle**

Safe Use of Automated Dispensina **Cabinets: Choosing Safety over** Convenience

Sponsored by McKesson Corporation Contact Kathleen Theiss, McKesson; 724-741-8382 **CE Provider: Inquisit**

6:15 AM - 7:45 AM **Sheraton Seattle**

Improving Quality of Antithrombotic Therapy through the Use of **National Performance Measures**

Sponsored by sanofi-aventis U.S.

Contact Kim Cackowski, ASHP Advantage, 301-664-8830 CE Provider: ASHP Advantage

Posters > Monday, June 9

Posters will be presented all day from 7:30 AM to 5:00 PM. Authors will be attending their posters between 12:30 PM and 2:00 PM to answer questions.

Poster Awards

The posters presented on Monday are eligible for special recognition; they are related to ASHP 2008 Summer Meeting educational programming in the following areas:

- Hot Topics: The Joint Commission Update, Health Disparities, and Medication Reconciliation
- The Business of Pharmacy: Administrative Practice, Financial Management, and Medication Reconciliation
- Quality Standards in Clinical Practice: Antibiotic Therapy/Infectious Diseases, Anesthesia/OR/PACU,
- Anemia Management, Glycemic Control, Emergency Care
- Anticoagulation

MONDAY, JUNE 9

Related to "HOT TOPICS" Programming

The Joint Commission Update, Health Disparities, and Medication Reconciliation

- **Board 1** Initiation of a patient discharge counseling service in an ethnically diverse patient population, Jessica Song, Dong Bi, Catherine Hill, Margaret Meute, Phoebe Li (P1R)
- Board 2 Assessing the medication reconciliation process: Identifying nursing education needs, Huzefa H. Master (P2D)
- **Board 3** Use of simulation to provide safe, more efficient and less intimidating early training experiences to compounded sterile preparation (CSP) technicians, Kevin D. Berg, Andrea Billings, William Weiss, Kevin Kleist, (P3D)

Related to "Business of Pharmacy" Learning Community

Administrative Practice, Financial Management, and Human Resources

- **Board 4** Interhospital comparison of programs and services related to antimicrobial expenditures, Ahuva Lustig, Gabriella Naftali, Eyal Schwartzberg (P4D)
- **Board 5** Use of lean management and leader standard work to support lean improvements, Dorothy L. Hancock, Susan Schneider, Christine Swyres (P5D)
- **Board 6** Improving turn-around-time for compounded sterile preparations using lean tools, Dorothy L. Hancock, Trenia Spiller, Susan Schneider, Jonathan Leesman (P6D)
- **Board 7** Creating and maintaining greater organizational efficiency and safety through 5S, Winson Soo-Hoo, Walter Proch, Lynne Goldstein, Greg Bauer, Saeeda King (P7D)

- **Board 8** Decreasing medication turn around time by improving order quality, Christine Swyers, Debbi Hendricks (P8D)
- **Board 9** Use of lean production management tools to improve pediatric oral medication preparation and 24 hour cart fill processes, Lynne Goldstein, Winson Soo-Hoo, Walter Proch, Jeannine Hipp, Saeeda King (P9D)
- Board 10 Sustaining 5-S visual organization in the hospital pharmacy, Anne M. Bournay, Rose Velikanje, Renee Freitag (P10D)
- **Board 11** Kanban: standardized visual control system to manage pharmacy inventory, Barbara Marquardt, Anne Bournay, Steven Wanaka, Judy Whiteman (P11D)
- **Board 12** Reducing parenteral medication wastage in a pediatric teaching hospital through lean process improvement methods, Steven D. Wanaka, Anne Bournay, Mark Murphy, Gretchen Linggi (P12D)
- **Board 13** Creating future leaders in health-system pharmacy: what can an administrative internship do for you?, Niesha Griffith, Elizabeth Van Sant, Erin Hendrick (P13D)

Related to "Quality Standards in Clinical Practice" Series

Antibiotic Therapy / Infectious Diseases, Anesthesia / OR / PACU, Anemia Management, Glycemic Control, Emergency Care

- **Board 15** Good use of neuromuscular-blocking drugs in anaesthesia and reanimation:Guidelines of Anaesthesia and Reanimation Department of University Hospital of Bordeaux, Francoise Petiteau-Moreau, Pierre Maurette, Marie-Claude Saux (P15R)
- Board 16 Successful use of a pharmacist evaluation service to ensure appropriate use of drotrecogin alfa, Thomas J. Johnson, Glenn D. Voss, Aris Assimacopoulos, Jace Knutson, Michael Schaub (P16E)

- Board 17 Comparison of levofloxacin 750mg daily vs. ceftriaxone 1g plus azithromycin 500mg daily for the empiric treatment of hospitalized community-acquired pneumonia (CAP) patients, Christopher R. Frei, Theresa Jaso, Christine U. Oramasionwu, Eric M. Mortensen, Marcos Restrepo (P17E)
- **Board 18** Assessment of clinical quality measures in patients with diabetes treated in a large group practice, Yeshewaneh Beyene, Holly Cleney, Terra Wonsettler (P18E)
- **Board 19** Neuromuscular blockade, reversal agent use, and operating room time: an analysis of US hospital data, Bin Zhang, David Hepner , Mary Helen Tran , Jonathan R. Korn , Joseph Menzin (P19D)
- **Board 20** Assessment of cardiovascular risk factors and management of diabetes at a small group practice: a comparison with statewide averages, Shawn M. Leland, Yeshewaneh Beyene, James Leyhane, Rommel Tolentino, Leonard Leonidas (P20E)
- **Board 21** Epidemiology and treatment of candidemia at a tertiary-care institution, Monica Shah, Robert Adamson, Lea Eslava, Eliahu Bishburg (P21E)
- **Board 22** Evaluation of post-operative vancomycin prophylaxis following implantation of left ventricular assist devices, Simona O. Butler, Paul Walker, Daryl DePestel, Rachel Eyler, Preeti Malani (P22E)
- **Board 23** Estimating the economic impact of a half-day reduction in length of hospital stay among patients with community acquired pnuemonia, Monika K. Raut, Jeff Schein, Richard Grant, Carmela Benson, William Olson (P23E)
- **Board 24** Implementation of an interactive education tool in antibiotherapy for the new prescribers in a group of three geriatric hospitals, Francois X. Chedhomme, Claire Gautreau, Valéry Gautier, Helène Poupet, Alain Chevallier (P24D)
- **Board 25** Survey and clinical interventions of emergency department pharmacy services in a non-academic community hospital, Ira Andrew Schatten, Carol Raschke (P25D)
- Board 26 Hospital quality performance: pharmacy's central role, Christine A. Pierce, Judith Baker, Cynthia McClard (P26D)
- Board 27 Maltose cross-reactivity with blood glucose monitoring devices, Jerry Siegel, Erica Nelson, William Hayton (P27E)

Related to "Informatics" Series

Board 28 Reducing drug packing errors using bar code technology and visual aids, Priscilla Chua (P28D)

Monday, June 9 > Posters

- Board 29 Antidote information program for Pocket PC, Jaime Serna, Rosario Pintor, Teresa Bermejo (P29D)
- **Board 30** Impact of robotic technology on the accuracy and quality of a centralized cart fill process, Jane S. Scott, Kristy Fitzgerald, Earl Sampson, Thuy Doan, Kevin Garrett (P30D)
- **Board 31** Clinical decision support systems: customization of a drug interaction database to avoid alert fatigue, John Horn, Philip Hansten, Jacqueline Osborn, Shabir Somani, Pamela Wareham (P31D)
- **Board 32** Using informatics to coordinate and optimize a large outpatient anticoagulation service in a Veterans Affairs (VA) population, Margaret Gordon, Monica Wells (P32D)
- **Board 33** Implementation of an automated patient-specific medication storage and management solution, Joshua C. Mount, Kyle Lewis, Kimberly Mason, Sherri Ramsey, James Hinkle (P33D)
- **Board 34** Validating the appropriateness of using automated systems to quantify the intravenous admixture wastage in a hospital, Alex C. Lin, Craig Froehle, John Hingl, Dave Mayhaus, Jack Horn (P34R)
- Board 35 Effects of using an intravenous robot system on admixture operations, Alex C. Lin, Jingjing Qian, Jack Horn, John Hingl, Dave Mayhaus (P35E)
- **Board 36** Appropriateness of using a computer simulation approach in evaluating the efficiency of an unit dose drug distribution system, Alex C. Lin, Shih-Feng Chiu, John Hingl, Dave Mayhaus, Jack Horn (P36R)

Related to "Anticoagulation" Series

- **Board 37** Pharmacist versus nursing protocol managed warfarin therapy, Karmen R. Kemmerer, Gedeon Laplante, Adam Porath, Jim Franckum, Alex Rassuchine (P37R)
- **Board 38** Quality of the prescriptions of anticoagulants practices in a geriatric hospital and impact of the diffusion of two new learning tools, Francois X. Chedhomme, Claire Gautreau, Tania Joucdar, Sylvie Haulon, Alain Chevallier (P38E)
- **Board 39** Integration of a pharmacy based anticoagulation parameter into a medical group quality scorecard, Angela Aldrich, Michael Nelson (P39D)
- **Board 40** A retrospective study to assess the use of vitamin K for warfarin reversal, Ellyn K. Schill, Carl Dominguez, Norman Hamada (P40R)
- **Board 53** Prescribing pattern of antihypertensive drugs in essential hypertension in South India, Nair Sreedharan, Ravi Shankar, NR Rau, Padma GM Rao (P53R)

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Posters > Tuesday, June 10

Posters will be presented all day from 7:30 AM to 5:00 PM. Authors will be attending their posters between 12:30 PM and 2:00 PM to answer questions.

Tuesday Poster Categories:

- Administrative Practice / Financial Management / H
- Financial Management / Human Resources Chronic Care / Managed Care
- Chronic Care / Managed Care
 Clinical Services Management
- Cillical Services Managerr
 Drug Use Evaluation
- Drug-Use Evaluation
- General Clinical Practice
- Geriatrics
- Home Care

- Infectious Diseases
- Investigational Drugs
- Outcomes Research
- Pain Management
- Pediatrics
- Pharmacokinetics
- Quality Assurance / Medication-Use Safety

TUESDAY, JUNE 10

Administrative Practice / Financial Management / Human Resources

Board 41 Survey of interviewing techniques used to evaluate potential residency candidates, Sarah Kemink, Tracey Mersfelder, Ryan J. Bickel (P41E)

Ambulatory Care

- **Board 42** Analysis of prescriptions filling labor in community pharmacy, Alex C. Lin, Samuel Huang, Yan Chen (P42E)
- **Board 43** Correlates of blood pressure control in an interdisciplinary hypertension referral center, Deborah Minor, Kenneth Butler, Virginia Wallace, Jennifer Fowler, Sharon Wyatt (P43E)

Cardiology

Board 44 Pharmacist's role in decreasing heart failure (HF) readmissions via the optimization of compliance and patient understanding upon discharge, Julie Cromer, Simona Peker, David Hoffman, Joseph Aprile (P44R)

Chronic Care / Managed Care

Board 45 Effect of rosiglitazone on insulin resistance and body com position in nondiabetic patients undergoing continuous ambulatory peritoneal dialysis, Pornanong Aramwit, Ouppatham Supasyndh, Panipat Bunmee (P45E)

Clinical Services Management

- **Board 46** Evaluation of a palm-based kinetics program, KineticsPro to promote consistency in vancomycin dosing, S. Lena Kang-Birken, Helen Jun (P46D)
- **Board 47** Impact of a collaborative drug practice agreement on pneumococcal vaccine rates in a small community hospital, Sara Tsang, Huzefa Master (P47E)
- **Board 48** Implementation of a medication therapy management service at a teaching county hospital with a younger and diverse patient population, Jennifer Leung, Jessica Song, Phoebe Li, Jen Huang, Geary Wong (P48R)
- **Board 49** Pharmacy led multidisciplinary approach to implementing community acquired pneumonia guidelines, Blane Schilling (P49D)

Drug-Use Evaluation

- **Board 50** Analysis on the status of polypharmacy in elderly patients in Seoul Veteran's Hospital, Haesuk Kwon, Soyoung Back, Hyungsoon Lee, Jaegon Ryu (P50E)
- Board 51 Meropenem and valproate interaction, Manuel Vélez Diaz-Pallarés, Eva Delgado, Ana Alvarez, Covadonga Pérez-Menendez, Teresa Bermejo (P51D)
- **Board 52** Post transplant therapy using human immunoglobulin (intravenous gammaglobulin) to control acute humoral rejection in renal, cardiac or lung allograft recipients, Emmanuelle Roc, Anne-Cécile Gérout, Elodie Reichstadt, Sophie Caillard-Ohlmann, Eric Epailly (P52D)
- **Board 54** Stability of ceftobiprole for injection (500 mg) in representative infusion fluids and containers, Dilip J. Gole, Jimidar Ilias, Hans Vermeersch, Magali B. Hickey, Arjen Tinke (P54E)

Board 55 Stability of high and low concentrations of doripenem (500mg) for injection in representative infusion fluids and containers, Petros Psathas, Timothy P. Gilmor, Daniel E. Schaufelberger, Kaori Ikeda, Kyoko Nagao (P55E)

General Clinical Practice

Board 56 Long-term abstinence from smoking is enhanced by immediate and delayed quitting with varenicline vs bupropion or placebo, David Gonzales, Douglas Jorenby, Carmen Arteaga, Theodore Lee (P56D)

Geriatrics

Board 57 Are psychotropic agents responsible of an increase of falls in gerontologic unit care?, Francois X. Chedhomme, Emmanuelle Giraud, Claire Gautreau, Pierre Bert, Alain Chevallier (P57E)

Home Care

Board 58 Impact of the implementation of a health network of multidisciplinary care for patients with chronic heart failure: analysis of the benefits after 5 years, Renee Lauribe, Philippe Matis, Philippe Lauribe, Helene Benchimol, Alain Chevallier (P58D)

Infectious Diseases

- **Board 59** Budget impact of adding doripenem to a hospital formulary, Thitima Kongnakorn, Sanjay Merchant, Kasem S. Akhras, Mike Ingham, Samir Mody (P59E)
- Board 60 Implementing an automated dispensing machine fomite reduction program, Robin E. Hannan, Diane Funk, Curtis Hannan, Pamela Carsten (P60D)

Investigational Drugs

Board 61 Reduction in intravenous immunoglobulin (IVIG or Anti D) use in patients with chronic immune thrombocytopenic purpura (ITP) receiving romiplostim (AMG 531) in two, phase III, randomized, placebo-controlled trials, Todd Gadberry, Mark Nelson, Alfred Chin, Scott Drugan, John Isitt (P61E)

Tuesday, June 10 > Posters

Outcomes Research

- **Board 62** Transfusion and hospitalization outcomes in erythropoiesis stimulating agent (ESA)-treated cancer chemotherapy patients based on achieved hemoglobin (Hb) levels, Kay Larholt, Tanya Burton, David Hoaglin, Chris Pashos, Brahim Bookhart (P62E)
- **Board 63** Variation in antibiotic prescribing for diabetes patients with cellulitis of the foot, Donald R. Miller, Benjamin G. Fincke, Cindy Christiansen, Robin Turpin (P63D)

Pain Management

Board 64 Practical compounding guidelines for ziconotide, Anthony Buchta (P64D)

Pediatrics

Board 66 Effectiveness of protease inhibitors-based regimen in HIV-infected children, Prapapuck Silapachote, Sujitra Yingyong, Nawaporn Vimolsarawong (P66E)

Pharmacokinetics

Board 67 Association between pharmacokinetic and pharmacogenomic properties of efavirenz and sleep quality in an understudied ethnic minority group, Tristan A. Lindfelt, John O'Brien, Jessica Song, Dean Winslow (P67R)

Quality Assurance / Medication-Use Safety

- **Board 68** Collaborative development and implementation of a universal medication list (UML), Jeanne R. Ezell, Baeteena Black (P68D)
- Board 69 Comparison of one or two strategies to improve pneumonia vaccination rates, Huzefa H. Master, Cynthia Standish, Nancy Sixto (P69E)
- **Board 70** Developing a medication reconciliation process in a restructured hospital in Singapore, Carol Puhaindran, Jonathan Seah, Hai Hong Wong, Joanna Wong, David Ong (P70D)
- **Board 71** Use of kaizen blitz to improve the safety and efficiency of intravenous (IV) admixture services, Margaret A. Huwar, Curt Niekamp, Hugo Chocano, Tammy Young (P71D)

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ASHP Practitioner Recognition Program

The ASHP Practitioner Recognition Program recognizes excellence in pharmacy practice and grants recognition and promotes public awareness of pharmacists who have distinguished themselves in pharmacy practice. Individuals who have achieved FASHP status have successfully demonstrated sustained practice excellence in health system pharmacy practice for 10 years or greater, contributed to the total body of knowledge in pharmacy practice, demonstrated active involvement and leadership in professional activities, and have actively been involved in and committed to educating practitioners and the public. Following are Fellows of ASHP through 2007.

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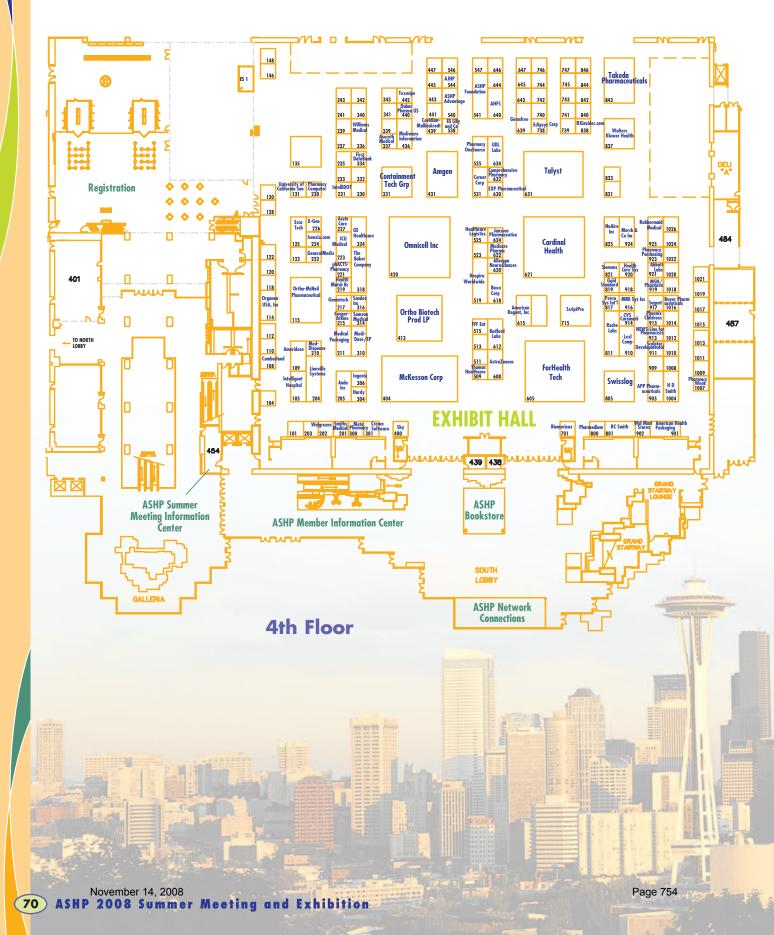
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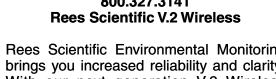


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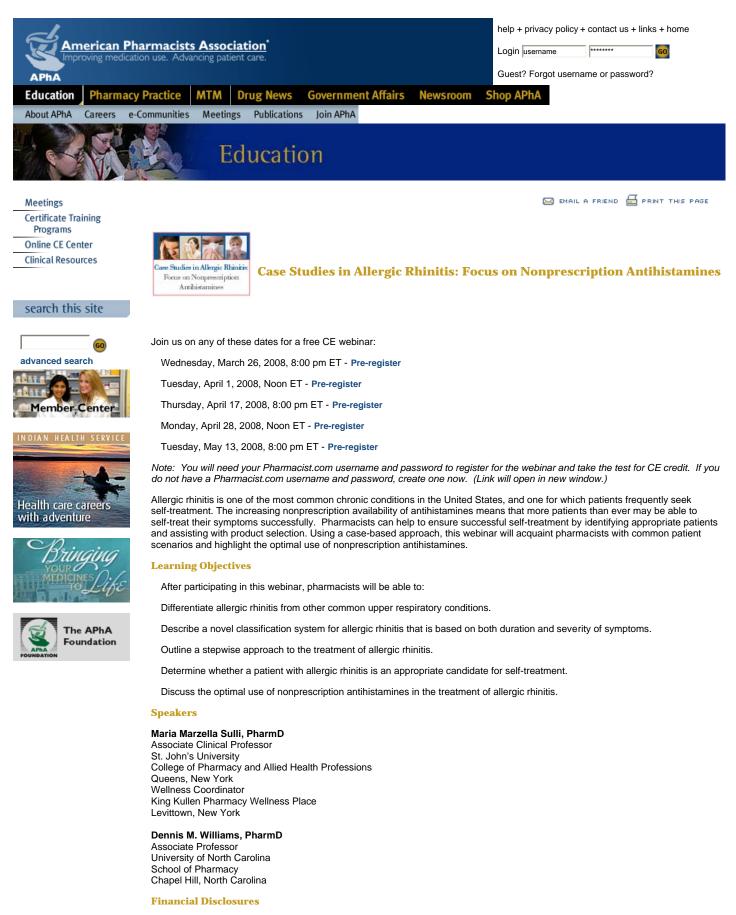
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Maria Marzella Sulli, PharmD, has served as a consultant for GlaxoSmithKline and has been a grant recipient from GlaxoSmithKline and Procter & Gamble.

Dennis M. Williams, PharmD, has served on an advisory board for sanofi-aventis.

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Initial Release Date: March 15, 2008

This webinar was developed by the American Pharmacists Association and supported through an educational grant from McNeil Consumer Healthcare.



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Initial Release Date: March 16, 2008

This webinar was developed by the American Pharmacists Association and supported through an educational grant from Boehringer Ingelheim and Pfizer.



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Managing Osteoporosis in Ambulatory Patients: **Role of the Pharmacist**

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Supported by an educational grant from: *The Alliance for Better Bone Health*

(Proctor & Gamble Pharmaceuticals and sanofi-aventis)



This monograph was developed by ASHP Advantage.



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Mary Beth O'Connell declares that she has served on the speakers bureau for PRIME and has received a research grant from Merck.

Sheryl F. Vondracek declares that she owns stock in Proctor and Gamble.

Catherine N. Klein declares that she has no relationships pertinent to this activity.

Managing Osteoporosis in Ambulatory Patients: Role of the Pharmacist

Mary Beth O'Connell, Pharm.D., BCPS, FASHP, FCCP and Sheryl F. Vondracek, Pharm.D., FCCP, BCPS

Learning Objectives

After studying this monograph, the reader should be able to:

- Discuss the epidemiology and clinical and economic consequences of osteoporosis.
- Name three risk factors for the disease.
- Describe the process of normal bone remodeling and the pathogenesis of osteoporosis.
- Identify a test used to screen for osteoporosis and the gold standard test for diagnosing the disease, interpret the findings of these tests, and explain the basis for determining which patients to treat.
- Counsel a patient about the importance of each component of a bone healthy lifestyle.
- Advise a patient with or at risk for osteoporosis about achieving adequate intakes of calcium and vitamin D through dietary sources and/or recommend a supplement if dietary sources are insufficient.
- Compare and contrast the pharmacology, efficacy on bone mineral density and fractures, and adverse effects of various approved and investigational osteoporosis drug therapies.
- Characterize the role of the pharmacist in improving bone health in ambulatory patients with or at risk for osteoporosis.

steoporosis is a systemic skeletal disorder characterized by low bone mineral density (BMD) and compromised bone strength that predisposes to fractures.¹ Although the bones at certain sites (e.g., the spine, hip, and wrists) are particularly susceptible to the effects of the disease, fractures can occur in nearly any part of the skeleton because osteoporosis is a systemic disease.²

Epidemiology

Osteoporosis is a major public health threat. An estimated 44 million Americans—55% of the U.S. population 50 years of age and older—have osteoporosis or osteopenia (low BMD that is less severe than that associated with osteoporosis).² The numbers of Americans with osteoporosis and osteoporosis-related fractures are expected to increase in the coming years because of the aging of society.

In 2005, osteoporosis was responsible for more than 2 million fractures in the U.S., including nearly 550,000 vertebral fractures, 400,000 wrist fractures, and 300,000 hip fractures.² The number of fractures due to osteoporosis is expected to exceed 3 million by 2025.² Each year more than 500,000 hospitalizations, 800,000 emergency department visits, 2.6 million physician office visits, and 180,000 nursing home placements are attributed to osteoporosis.³ In 2005, the costs of osteoporosis-related fractures amounted to approximately \$19 billion.² Hip fractures accounted for the largest percentage (72%) of these costs compared with other types of fractures.⁴ The costs of osteoporosis-related fractures are expected to increase to more than \$25 billion by 2025.²

Osteoporosis and osteopenia often are thought of as diseases of women but they also affect men. Roughly 20% of Americans with osteoporosis are men.²

Approximately one in two women and one in four men over the age of 50 will have an osteoporosisrelated fracture in their remaining lifetime.²

Osteoporosis and osteopenia affect all races and ethnic groups, with the highest prevalence in non-Hispanic Caucasians and Asians and a lower prevalence among Hispanics and non-Hispanic Blacks.² The risk of osteoporosis is increasing most rapidly among Hispanic women.²

The weakening of bones caused by osteoporosis is initially asymptomatic, often progressing undetected until a fracture occurs. Osteoporotic fractures are called "fragility" or "low-trauma" fractures because they occur with little or no trauma or as a result of a fall from standing height or less.⁵ Osteoporosisrelated fractures can be devastating. One in four patients 50 years of age or older with a hip fracture dies and one in five patients is placed in a nursing home within 1 year after the fracture.^{2,3} Only 15% of patients can walk across a room without assistance 6 months after a hip fracture.² The 1-year mortality rate after a hip fracture is nearly twice as high in men as in women.²

Osteoporosis-related fractures adversely affect quality of life. Many patients with hip fractures are depressed because of a loss of mobility and independence, and patients may be fearful of another fall.³ The risk of another fracture is increased fourfold in women with a hip fracture compared with women who never had a fracture.²

Two thirds of vertebral fractures are asymptomatic or cause only mild pain, but other vertebral fractures can cause acute or chronic back pain, kyphosis (stooped posture), and loss of height.^{6,7} The ability to perform the activities of daily living may be impaired.⁶ Vertebral fractures in the thoracic region can impair pulmonary function, and fractures in the lumbar region can affect the abdominal anatomy leading to abdominal pain, distention, and constipation.^{6,7} Possible psychological sequellae include loss of selfesteem because of physical deformity. The presence of a vertebral fracture increases the risk of another fracture fivefold within one year.⁸ Vertebral fractures also are associated with increased mortality.²

Normal Bone Remodeling

Bone undergoes continuous remodeling to adapt to mechanical stresses, repair damage from fatigue, and provide access to mineral stores. In each small area of bone that is undergoing remodeling there is a coordinated team of cells known as the basic multicellular units (BMUs). There are two main types of cells that make up the BMUs: the osteoclasts, which are bone-resorbing cells that remove old or damaged bone, and the osteoblasts, which are bone-forming cells that build new bone.

Bone remodeling involves various cytokines, growth factors, and hormones. Although the process is not completely understood, remodeling appears to be initiated by signals from osteocytes (bone communication cells) and lining cells (e.g., cells that line the bone surface) that are triggered by stress, microfractures, or other stimuli (e.g., certain diseases, exposure to certain medications).^{5,9} These signals cause the osteoblast precursor cells to release a cytokine ligand known as the receptor for activator of nuclear factor κ B ligand (RANKL). Interactions of RANKL with the receptor for activator of nuclear factor κ B (RANK) causes osteoclast precursor cells to differentiate and mature to activated osteoclasts (Figure 1).¹⁰

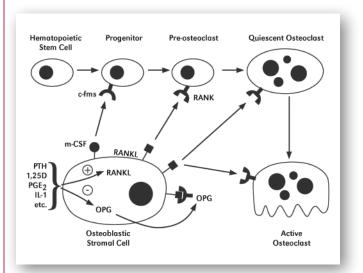


Figure 1. How Osteoclasts Are Formed¹⁰

 $\begin{array}{l} 1,25D=1,25\text{-}dihydroxyvitamin D; \text{IL-1}=\text{interleukin-1}; \text{ m-CSF}=\text{mac-rophage colony stimulating factor}; OPG=\text{osteoprotegerin}; PGE_2=\text{prosta-glandin E}_2; \text{PTH}=\text{parathyroid hormone}; \text{RANK}=\text{receptor for activator of nuclear factor κB; RANKL=\text{receptor for activator of nuclear factor κB} igand \end{array}$

Mature osteoclasts have a ruffled border that forms a tight seal with the resorptive surface of bone. Adhesion of mature osteoclasts to bone is mediated by $\alpha V \beta_3$ integrins. A proton pump expressed on the plasma membrane of osteoclasts secretes hydrogen ions, a process that involves vacuolar H⁺-adenosine triphosphatase (H+-ATPase) enzymes, and the acid that is produced demineralizes hydroxyapatite, the major crystalline salt in bone matrix. The protein matrix, which is made up primarily of type I collagen, is degraded by cathepsin K and other lysosomal proteases. The bone resorption process requires approximately three weeks and is terminated by the release of growth factors from the bone resorption site that stimulate the maturation and activation of osteoblasts. Mature osteoblasts produce osteoprotegerin, a soluble decoy protein that binds to RANK, thereby preventing RANKL from binding to its receptor. Bone resorption ceases, and mature osteoclasts undergo apoptosis (programmed death) or move to another remodeling site.

Mature osteoblasts form bone through a two-step process involving the deposition of type I collagen and other specialized matrix proteins known as osteoid in the resorption cavity and mineralization with calcium, phosphorous, and magnesium.^{5,9} The bone formation process takes three to four months.¹⁰ After bone formation is complete, mature osteoblasts undergo apoptosis or become osteocytes or lining cells. The bone at this site is then in what is referred to as quiescence (a resting phase) until another remodeling cycle begins.

Pathophysiology

The development of osteoporosis and osteoporosisrelated fractures is multifactorial, including skeletal factors (e.g., low BMD and poor bone quality) and non-skeletal factors (e.g., falls).⁵ Bone mass (i.e., BMD) increases throughout childhood, adolescence, and early adulthood. Up to 90% of bone mass is acquired by the age of 18 years in girls and 20 years in boys, with the peak bone mass achieved at the age of 25–30 years.^{7,11} The peak bone mass achieved in men tends to be higher than that in women.¹¹ Genetics accounts for up to 80% of the variability in peak bone mass.¹²⁻¹⁴ Sex hormone deficiency, certain diseases and medications, and lifestyle factors, including poor nutrition (especially dietary calcium and vitamin D intake), inadequate exercise, and cigarette smoking, can account for the remaining variability in the peak bone mass achieved in early adulthood and subsequent rate of bone loss.^{5,15}

Loss of bone mass occurs when bone resorption exceeds bone formation. High turnover bone loss is the result of increased osteoclast activity, with a rate of bone formation that is inadequate to compensate for a large number of deep resorption sites. By contrast, low turnover bone loss is the result of a decrease in osteoblast activity and inadequate filling of normal resorption sites. High turnover bone loss is more common than low turnover bone loss, and it is the type typically observed in postmenopausal women because of a reduction in ovarian estrogen production.

Loss of bone mass usually begins in mid-life in both men and women because of a slight reduction in bone formation.¹⁶ Women experience an accelerated rate of bone loss during perimenopause and the early postmenopausal period because an increased rate of bone resorption accompanies the loss of estrogen. Women can lose up to 20% of their bone mass in the first 5–7 years after menopause.² Estrogen inhibits accelerated bone resorption by decreasing the production of RANKL, suppressing osteoclast proliferation and differentiation, increasing osteoclast apoptosis, decreasing the production of interleukin-1 (IL-1) and other cytokines that stimulate osteoclasts, and increasing the production of osteoprotegerin.⁵ Elderly persons of both sexes lose bone mass at a steady rate as a result of accelerated bone remodeling and reduced bone formation.⁵

Bone strength reflects the integration of bone density and bone quality. Alterations in the bone turnover rate, bone structure/architecture, and bone mineral properties can result in poor bone quality, and, independent of bone density, reduce bone strength and increase the risk for fracture. For example, an accelerated turnover rate in trabecular bone (i.e., the interior porous bone), which is commonly seen in postmenopausal women, results in the formation of deep resorption sites to the point of perforation in some instances. If perforations occur in the horizontal trabecular plates, the vertical trabecular plates will no longer have the same cross-linking support



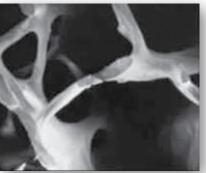


Figure 2. Normal vs. Osteoporotic Bone

and will be at risk for buckling (i.e., fracturing) (Figure 2). This poor quality bone is weak and susceptible to fracture regardless of the BMD. Fractures in younger postmenopausal women usually involve the vertebrae or wrist.^{17,18}

Most osteoporosis-related fractures are the result of falls, especially hip fractures in seniors.^{7,19} Muscle weakness and impairments in vision, gait, balance, or cognition contribute to falls in seniors.⁷ Benzodiazepines, antidepressants, antipsychotic agents, sedative hypnotics, opioid analgesics, and other central nervous system medications increase the risk of falls. The risk of hip fracture is high in seniors because they tend to fall backwards or to the side instead of forward.⁵ Forward falls are likely to cause wrist fractures because of efforts to break the fall using the arms.

Classification

Osteoporosis may be classified as primary or secondary. Primary osteoporosis includes postmenopausal, age-related, and idiopathic osteoporosis. Secondary osteoporosis usually is caused by diseases or medications. Idiopathic osteoporosis typically affects men.

Age-related osteoporosis is caused by vitamin D deficiency and diminished gastrointestinal (GI) calcium absorption, sex hormone production, and osteoblast activity, resulting in a combination of high and low turnover bone loss. It affects women and men in a 2:1 ratio.¹⁷ Bone loss typically involves both trabecular and cortical (i.e., outer) bone, causing fractures of the hip, vertebrae, and wrist.¹⁷

Osteoporosis and osteoporosis-related fractures are less common in men than in women because men achieve a higher peak bone mass, have bones that are larger and stronger, do not undergo a period of accelerated bone loss analogous to menopause, and have a lower propensity to fall than women. The mortality rate after osteoporosis-related fracture, however, is higher in men than in women.^{2,20} The incidence of hip and vertebral

fractures in men does not increase until around the age of 65 years after which time it increases dramatically.¹⁸ Men have a shorter life expectancy than women, which makes them less likely than women to incur fractures in their senior years.²¹ The incidence of wrist and vertebral fractures increases at a younger age in women (around 50 years) than in men, although the age at which the incidence of hip fractures increases in women is similar to that in men.¹⁸

A secondary cause of osteoporosis (Table 1) is identified in at least two in three men, one in two premenopausal and perimenopausal women, and one in three postmenopausal women.²² Glucocorticoids are the most common medication-related cause of osteoporosis.⁵

Risk Assessment

The high risk of fracture recurrence underscores the need for detection of osteoporosis before fractures occur.^{2,8} The goal of initial osteoporosis risk assessment is to identify patients at high risk for low BMD who would benefit from further evaluation. Evaluation of risk factors for osteoporosis or falls, identification of possible signs and symptoms of the disease, detection of secondary causes of the disease, and BMD testing (bone densitometry) are part of this assessment.

Table 2 lists selected risk factors for osteoporosis, falls, and osteoporosis-related factures. Major risk factors are those that increase the risk of osteoporosis independent of an effect on BMD and falling and are included in the World Health Organization fracture risk assessment tool (FRAX) (www.shef. ac.uk/FRAX/). For example, the risk for osteoporosis in women increases as BMD decreases at all ages, but the risk is higher in older women than in younger

Table 1

Selected Secondary Causes of Osteoporosis^{5,7,12,22,23}

Medications

- Glucocorticoids
- Anticonvulsants
 - phenytoin
 - phenobarbital
- Gonadotropin releasing hormone analogs
- Cancer chemotherapy drugs
- Aromatase inhibitors
- Excessive thyroid supplementation
- Chronic heparin use
- Medroxyprogesterone acetate implant
- Proton pump inhibitors?^a
- Selective serotonin reuptake inhibitors?

Diseases

- Chronic obstructive pulmonary disease
- Hyperparathyroidism
- Lymphoma/leukemia
- Rheumatoid arthritis
- Thyrotoxicosis
- Liver disease
- Kidney disease
- Inflammatory bowel disease
- Celiac disease
- Organ transplantation
- Hypogonadism
- Anorexia nervosa
- Stroke
- Multiple sclerosis
- Type 1 diabetes mellitus
- Vitamin D deficiency
- ^a Additional information required before confirmation.

women with the same BMD (i.e., advanced age is an independent risk factor for osteoporosis). $^{\mbox{\tiny 28}}$

Possible signs and symptoms of osteoporosis include low back pain, kyphosis or other curvature of the spine, and a loss of height exceeding 1.5 inches, although none of these symptoms need to be present.⁵ Evidence of fractures or low BMD can be identified on routine X-ray. However, extensive disease is needed before an X-ray can visualize low BMD.

Table 2

Risk Factors for Osteoporosis, Falls and Osteoporosis-Related Fractures^{7,12,23-27}

- Low bone mineral density^a
- Female sex
- Advanced age^a
- Low body weight or body mass index^a
- Caucasian or Asian race
- History of low trauma fracture as an adult^a
- History of osteoporosis-related fracture in firstdegree relative (especially parent with hip fracture)^a
- Current cigarette smoking^a
- Alcohol intake ≥3 drinks/day^a
- Oral glucocorticoid therapy^a
- Secondary causes of osteoporosis (especially rheumatoid arthritis)^a
- Low calcium intake
- Inadequate physical activity
- Vitamin D deficiency/minimal sun exposure
- Recent fall
 - Muscle weakness/frailty
 - Poor vision
 - Cognitive impairment
 - ^a Included in FRAX, the World Health Organization, risk assessment tool.

Most diseases that are secondary causes of osteoporosis can be detected by routine physical exam and laboratory tests, including a complete blood count, liver function tests, blood urea nitrogen, serum creatinine, calcium, phosphorous, alkaline phosphatase, albumin, thyroid-stimulating hormone, free testosterone, 25-hydroxyvitamin D, and 24-hour urine concentrations of calcium and phosphorous.⁵ The medication profile should be reviewed to identify potential medication-related causes of osteoporosis.

An assessment of osteoporosis risk factors, possible signs and symptoms, and laboratory test results for secondary causes of the disease influence whether BMD testing is performed. The Simple Calculated Osteoporosis Risk Estimation, a decision tool commonly referred to as SCORE, may be used by clinicians to identify women in whom bone densitometry is warranted based on age, race, weight, estrogen use, and the presence of rheumatoid arthritis or hip, wrist, or spine fractures from a fall or minor accident.²⁹

Peripheral bone densitometry may be used to screen patients to determine the need for central bone densitometry. Central bone densitometry is required for osteoporosis diagnosis and can be used for monitoring osteoporosis disease progression and response to medications. Quantitative ultrasound of the heel, the most commonly used peripheral bone densitometry technique, provides an estimate of BMD at this peripheral site and predicts fracture risk in postmenopausal women and men 65 years of age and older.⁷ The equipment is portable and easy to use. The test avoids exposing the patient to radiation and is less expensive than central dual energy X-ray absorptiometry (DXA).

Peripheral DXA of the finger, forearm, or heel may be performed, but it exposes the patient to radiation. Users of the equipment must be certified in most states, making this test less useful in a community setting. Peripheral bone densitometry cannot be used to diagnose or monitor osteoporosis.

Consensus guidelines to identify which patients to screen using peripheral bone densitometry are not available. All postmenopausal women and men 65 years of age or older are candidates because of the value of testing for predicting fracture risk, although fewer data are available for men than women.7 Testing might be warranted for perimenopausal women, especially if they have at least one major risk factor for osteoporosis. Peripheral bone densitometry screening currently is not recommended for premenopausal women and younger men because of the lack of data. Osteoporosis in these populations usually is related to a secondary cause warranting central DXA testing.² Peripheral bone densitometry serves no purpose in patients already diagnosed with osteopenia or osteoporosis. Minimal data are available in children and adolescents and thus screening of them is also not recommended in these populations.

Diagnosis

Central DXA is the gold standard for measuring BMD, diagnosing osteoporosis, and monitoring bone loss and response to medication.⁷ Measurements usually are taken at the lumbar spine and proximal femur or total hip, with the lowest BMD value used for diagnosis.⁵ Bone mineral density at the hip and spine is the best predictor of fracture risk at those sites.⁷ Patients usually are recumbent and fully clothed during the procedure, scanning times are short (approximately 10 minutes), and exposure to radiation is minimal (less than that associated with a standard chest X-ray).^{5,7} Indications for central DXA testing are listed in Table 3.

Central DXA reports include a BMD, T-Score, and Zscore. The BMD is expressed as the number of grams of mineral (calcium hydroxyapatite) per square centimeter of the scanned area. The percentage change in BMD is used for serial monitoring of the response to treatment. Measurements are typically repeated after one to two years and must be taken using the same machine to be valid. The T-score is the difference between the patient's BMD and the expected value for a "young, normal" (20–29 years old) Caucasian adult of the same sex, expressed as the number

Table 3 Indications for Central Dual Energy X-ray Absorptiometry^{7,30}

- Women \geq 65 years of age
- Postmenopausal women < 65 years of age with risk factors for fracture
- Perimenopausal women with clinical risk factors for fracture (e.g., low body weight, prior fracture, or high-risk medication use)
- Men ≥70 years of age
- Men 50–70 years with clinical risk factors for fracture
- Adults with a fragility fracture
- Adults with a suspected secondary cause (e.g., patients receiving glucocorticoids)
- Anyone being considered for pharmacologic therapy for osteoporosis

of standard deviations below or above the mean.^{7,31} The Z-score reflects the difference between the patient's BMD and the expected value for a Caucasian person the same age and sex as the patient. A low Z-score (-2.0 or lower) suggests osteoporosis from a secondary cause.²³

A diagnosis of osteoporosis may be made based on the BMD T-score or based on the presence of fragility fractures alone, although bone densitometry is recommended to provide a baseline for assessment of response to treatment and future fracture risk.²³ A T-score of -1.0 or higher (i.e., a BMD within 1 standard deviation lower than that expected for a young, normal adult of the same sex) is considered normal.²³ A T-score of -1.0 to -2.4 is considered osteopenia, and a T-score of -2.5 or lower (i.e., 2.5 or more standard deviations below the expected BMD) is considered osteoporosis. Patients with a T-score of -2.5 or lower and a fragility fracture have severe osteoporosis.⁷

Peripheral bone densitometry results are reported as an estimated BMD, T-score, and Z-score. These T-scores are not equivalent to those measured by central DXA and cannot be used for diagnosis.⁷ A heel quantitative ultrasound T-score of -1.0 has a sensitivity of 75% and a specificity of 66% in identifying patients with a central DXA T-score in the osteoporotic range (-2.5 or less).³² Therefore a peripheral T-score of -1.0 is frequently used as a cutoff value below which further evaluation using central DXA is indicated.

The National Osteoporosis Foundation (NOF) recommends treatment of postmenopausal women and men 50 years of age or older with (1) a hip or vertebral fracture, (2) a femoral neck, total hip, or spine T-score of -2.5 or less measured by central DXA, or (3) a T-score of -1.0 to -2.5 measured by central DXA (i.e., osteopenia) and a secondary cause associated with a high risk of fractures, a 10-year hip fracture probability of 3% or higher, or a 10-year probability of major osteoporosis-related fracture of 20% or higher.⁷ These probabilities are calculated using the online World Health Organization FRAX based on age, sex, weight, height, history of fractures, history of hip fracture in a parent, current smoking, glucocorticoid use, the presence of rheumatoid arthritis or secondary osteoporosis, an intake of 3 or more alcohol units daily, and femoral neck BMD expressed as a T-score or Z-score.²⁴⁻²⁷ Four versions of this tool are available specifically for Asians, Caucasians, Blacks, and Hispanics residing in the United States. This tool is also available in six other countries, including the United Kingdom, Japan, and Sweden, to name a few.

Goals of Interventions

The goals of interventions to improve bone health are based on a knowledge of the epidemiology and pathophysiology of osteoporosis and depend on age, sex, and menopausal status.³³ In male and female children and adolescents, the goal is to maximize the peak bone mass achieved in early adulthood, decreasing the likelihood of developing osteoporosis and fractures in the future. Maintaining bone mass is the goal during adulthood in both sexes. Attenuating the accelerated loss of perimenopause and the early postmenopausal period is the primary goal in women during this 5- to 10-year period. In the late postmenopausal period in women and in older men, preventing further bone loss is the goal. Preventing falls and fractures is an additional goal in elderly women and men.

In patients with osteopenia or osteoporosis, the goals are to maintain or improve bone mass and strength and prevent fractures. In patients with fractures, preventing subsequent fractures, reducing pain and deformity, and improving functional capacity and quality of life are therapeutic objectives.

Prevention and Treatment Strategies

A bone healthy lifestyle that includes weight-bearing, resistance, and muscle-strengthening exercise and efforts to improve balance and prevent falls and fractures (e.g., elimination of environmental hazards and fall-inducing medications) plays an integral role in managing osteoporosis.⁵ Increases in BMD and improvements in agility, strength, balance, and posture, which can reduce the risk of falls and fractures, are associated with weight-bearing, resistance, and muscle-strengthening exercise.⁷ Weight-bearing exercise includes such activities as walking, jogging, climbing stairs, and playing tennis. All patients who are medically fit should be encouraged to perform a moderate intensity weight-bearing

activity for at least 30 minutes most days of the week and a resistance activity at least 2 times a week for 20–30 minutes.³⁴ Examples of resistance and muscle-strengthening exercise include the use of free weights, weight machines, elastic resistance bands, and Tai Chi.

Fall prevention strategies include keeping floors clear of tripping hazards (e.g., telephone and electric cords, throw rugs), using adequate lighting, installing or securing loose hand rails in stairways, wearing supportive footwear with non-skid soles, using a non-slip rubber mat in bathtubs and shower stalls, and storing items within easy reach to avoid the use of step stools.³⁵ A patient's medication profile should also be reviewed to eliminate or minimize medications known to cause falls.

Avoidance or cessation of smoking, minimizing alcohol and caffeine intake, and ensuring proper nutrition with an adequate intake of vitamins and minerals, particularly calcium and vitamin D, are other components of this bone healthy lifestyle. Cigarette smoking is a major risk factor for osteoporosis and fractures. Multiple adverse effects on bone have been documented, such as decreased sex hormone concentrations, reduced intestinal calcium absorption, a direct toxic effect on osteoblasts, and detrimental effects on neurovascular function. Alcohol consumption in moderation has not been associated with an increased risk of osteoporosis or fractures. Excessive alcohol intake (three or more drinks daily) can increase risk due to poor nutrition, impaired calcium and vitamin D metabolism, and an increased risk for falls. According to the 2005 dietary guidelines, alcohol consumption should not exceed one drink per day for women and two drinks per day for men.³⁴ Caffeine consumption has been associated with increased urinary calcium excretion. Patients who consume large amounts of caffeine may need to consume higher amounts of calcium. Caffeine consumption at approximately two servings per day is considered acceptable for bone health.

Agents that Reduce Bone Resorption

Calcium. An adequate dietary intake of calcium is essential for bone formation. Calcium requirements are highest between 9 and 18 years of age (Table 4).³⁷ Only about 25% of boys and 10% of girls in this age group have an adequate calcium intake, largely because of a high intake of low-calcium beverages (e.g., soda pop) instead of milk.³⁷ Senior citizens older than 70 years of age also have high calcium requirements, with up to 1500 mg/day recommended by some clinicians.³⁷ However, only 50–60% of seniors meet these requirements.³⁷ The average dietary intake of calcium in men and women 50 years of age and older is approximately 600–700 mg/day.⁷

The diet is the preferred source of calcium, and dairy products tend to have the highest amounts of elemental calcium.⁷ Dairy products are a good source of calcium (Table 5), although their use may not be advisable for patients with dyslipidemia who need to limit their cholesterol intake. Calciumfortified beverages and food products (e.g., orange

Table 4Institute of Medicine DietaryAdequate Intakes of Calcium36

| Age | Calcium (mg/day) |
|-------------------------|------------------|
| Birth to 6 months | 210 |
| 7–12 months | 270 |
| 1–3 years | 500 |
| 4–8 years | 800 |
| 9–13 years | 1300 |
| 14–18 years | 1300 |
| 19–30 years | 1000 |
| 31–50 years | 1000 |
| 51–70 years | 1200 |
| >70 years | 1200 |
| Pregnancy and Lactation | |
| ≤18 years | 1300 |
| 19–50 years | 1000 |

juice, breakfast cereal) might be good alternatives to dairy products. The calcium content of calciumfortified products varies.^{7,23}

The Nutrition Facts label on food products provides information about the calcium content of a serving.⁴² The calcium content is expressed as a percentage of a 1000-mg/day intake of calcium, and the amount of

elemental calcium in a serving can be calculated by multiplying the percentage figure by a factor of 10. For example, a serving of low-fat milk with a 30% calcium content contains 300 mg of elemental calcium.

Most people with or at risk for osteoporosis do not obtain adequate calcium from the diet and require calcium supplementation.³⁷ The elemental calcium

| Table 5 | | | | | | |
|--|--------------|----------------------|--|--|--|--|
| FOOD OR BEVERAGE Serving Size Calcium Content (m | | | | | | |
| Dairy Products | Serving Size | Calcium Content (mg) | | | | |
| Ricotta cheese (part skim milk) | 1 cup | 669 | | | | |
| Yogurt (plain, low-fat) | 8 oz | 415 | | | | |
| Milk (skim, 1%, 2%, or whole) | 1 cup | 290–300 | | | | |
| Milk, lactose-reduced | 1 cup | 285–302 | | | | |
| Cheese, Swiss | 1 oz | 224 | | | | |
| Cottage cheese, low-fat 1% | 1 cup | 138 | | | | |
| Cheese, low-fat cheddar or colby | 1 oz | 118 | | | | |
| lce cream | 1/2 cup | 90–100 | | | | |
| Calcium-Fortified Products | | | | | | |
| Soy beverage, calcium-fortified | 1 cup | 368 | | | | |
| Orange juice, calcium-fortified | 8 oz | 350 | | | | |
| Cereals, fortified, ready-to-eat | 3/4 cup | 236–1043 | | | | |
| Oatmeal, plain and flavored, instant, fortified | 1 packet | 99–110 | | | | |
| Other Products | | | | | | |
| Sardines (Atlantic, canned in oil, drained) | 3 oz | 325 | | | | |
| Salmon, pink, canned with bones | 3 oz | 181 | | | | |
| Soybeans, green, cooked, boiled, drained, without salt | 1 cup | 261 | | | | |
| Tofu, firm, prepared with calcium sulfate and magnesium chloride (nigari |) 1⁄2 cup | 253 | | | | |
| Spinach, cooked, boiled, drained, without salt | 1 cup | 245 | | | | |
| Turnip greens, cooked, boiled, drained, without salt | 1 cup | 197 | | | | |
| Collards, cooked, boiled, drained, without salt | 1 cup | 266 | | | | |
| Kale, cooked, boiled, drained, without salt | 1 cup | 94 | | | | |
| Broccoli, raw | 1 cup | 41 | | | | |

MANAGING OSTEOPOROSIS IN AMBULATORY PATIENTS **11**

content varies among the calcium salts available as supplements (Table 6).⁴³ The absorption of calcium is limited, and single doses should not exceed 600 mg of elemental calcium.⁵ Larger doses do not result in increased calcium absorption, and they may lead to constipation.

Calcium carbonate and calcium citrate are the most commonly used calcium supplements. Calcium carbonate is preferred over calcium citrate because it has a higher calcium content, is less expensive, and comes in a greater variety of formulations.⁵ Most calcium citrate tablets are large and may be difficult to swallow, although newer chewable formulations of calcium citrate have been introduced. Many calcium carbonate products are available as chewable tablets or liquids. The calcium content of these products varies, which may cause confusion for patients. Combination products with vitamin D are preferred.

The disintegration and dissolution of calcium carbonate are acid-dependent, so it is best taken with food, which promotes gastric acid secretion.⁵ The disintegration and dissolution of calcium citrate are not acid-dependent, so it can be taken with or without food. The absorption of calcium from calcium carbonate may be reduced by concomitant use of proton pump inhibitors or histamine H₂-receptor antagonists, so calcium citrate or larger calcium carbonate doses are suggested to be used in patients receiving these acid-suppressing therapies.⁵ Patients with lactose intolerance, a common condition in Asian and Black Americans,may not be able to reach their calcium goals through diet alone because of avoidance of dairy products.⁴¹ Calcium supplementation can be beneficial for these patients.

Controlled studies show that calcium supplementation increases BMD to a greater extent than placebo (bone loss is associated with placebo) but to a lesser extent than osteoporosis medications that decrease bone resorption or promote bone formation.^{5,44} However, calcium supplementation alone has little impact on fracture risk.⁵

Vitamin D. Vitamin D plays a vital role in promoting GI absorption of calcium.⁴⁵ Exposure of the skin to ultraviolet B light converts 7-dehydrocholesterol in the skin to cholecalciferol (vitamin D_3), which is converted to 25-hydroxycholecalciferol (25-hydroxyvitamin D_3) in the liver and then to 1,25-dihydroxycholecalciferol (also known as calcitriol), the active form, in the kidneys. Ergocalciferol (vitamin D₂) in the diet is converted to cholecalciferol. Vitamin D supplements containing vitamin D_2 or vitamin D₃ are another source. Because hydroxylation is required to activate vitamin D, patients with severe hepatic or renal disease might need to take calcitriol as a supplement to compensate for the inability to synthesize the active form of vitamin D. Endogenous parathyroid hormone (PTH) signals the activation of vitamin D in response to low calcium concentrations.

| Table 6Approximate Elemental Calcium Content of Selected Calcium Supplements43 | | | | | |
|--|----------------------------------|--|--|--|--|
| Calcium Salt | Elemental Calcium Content (%) | Elemental Calcium Content per Tablet or Capsule (mg) | Number of Tablets or Capsules Required to Obtain 1000 mg per Day | | |
| Calcium carbonate | 40 | 200–600 | 2–5 | | |
| Calcium citrate | 21 | 200, 250, or 315 | 2, 3, or 5 | | |
| Calcium gluconate | 9 | 45, 58.5, or 90 | 11, 17, or 22 | | |
| Calcium lactate | 13 | 42.25 or 84.5 | 12 or 24 | | |
| Calcium phosphate tribasic | 40 | 600 | 2 | | |

| Salmon, cooked | 3.5 oz | 360 |
|---|---------|--------|
| Mackerel, cooked | 3.5 oz | 345 |
| Sardines, canned in oil, drained | 1.75 oz | 250 |
| Tuna fish, canned in oil | 3.5 oz | 200 |
| Vitamin D-fortified orange and other fruit juices | 8 oz | 100 |
| Milk, nonfat, reduced fat, and whole, vitamin D-fortified | 8 oz | 100 |
| Ready-to-eat cereal, vitamin D-fortified | Varied | 40–140 |
| Yogurt, low-fat and non-fat , vitamin D-fortified | Varied | 40–80 |

Table 7 Selected Dietary Sources of Vitamin D48,49

The Institute of Medicine recommends a daily vitamin D intake of 200 units (5 μ g) for both sexes up to the age of 50 years, including pregnant and breastfeeding women.⁴⁵ A daily intake of 400 units (10 μ g) is recommended for men and women 51–70 years of age.⁴⁵ Seniors more than 70 years of age of both sexes should receive 600 units/day (15 μ g/day).⁴⁵ However, other organizations recommend larger amounts (e.g., 800–1000 units/day for adults more than 50 years of age).^{7,23}

Vitamin D is a fat-soluble vitamin with the potential to cause toxicity if excessive amounts are consumed. A safe upper limit of at least 2000 units/day (50 μ g/day) has been suggested for adults more than 18 years of age, and there is evidence that higher intakes are safe and might be required for bone health.^{7,45,46}

Research is under way to clarify vitamin D requirements, and new guidelines are in development that probably will increase the recommended daily intake of vitamin D, especially for seniors. Vitamin D deficiency has been linked with cancer, diabetes, and cardiovascular disease, and protective effects of vitamin D supplementation against these diseases and multiple sclerosis have been suggested, although these benefits remain to be further demonstrated.^{46,47} It would be ideal if Vitamin D could be adequately obtained from the diet (Table 7), but most beverages and food products contain little vitamin D. Fortification of food products is limited by law because of concerns about toxicity from excessive intake.⁴⁹

The Nutrition Facts label on food products provides information about the vitamin D content of a serving. The vitamin D content is expressed as a percentage of a 400-units/day intake of vitamin D (an amount that is inadequate for seniors). The amount of vitamin D in a serving can be calculated by multiplying the percentage figure by a factor of 4. For example, a serving of low-fat milk with a 25% vitamin D content contains 100 units of vitamin D.

Most Americans with or at risk for osteoporosis do not obtain an adequate amount of vitamin D from dietary sources or sunlight exposure and require supplementation, especially during the winter for those who live in northern regions where exposure to sunlight is limited.⁴⁸ Measuring serum 25-hydroxyvitamin D concentrations can help detect and prevent vitamin D deficiency. A 25-hydroxyvitamin D deficiency should be considered in people with limited exposure to sunlight, seniors (the ability to synthesize vitamin D is impaired in the skin and kidneys in this age group), people with dark skin (the ability to produce vitamin D from sunlight exposure is lower with the pigment melanin), and people with intestinal fat malabsorption associated with various medical conditions (e.g., Crohn's disease, sprue).⁴⁸ The importance of serum 25-hydroxyvitamin D monitoring was underscored by the findings of only 35% of patients achieving a therapeutic vitamin D concentration (defined as > 75 nmol/mL) after 6 months of 1000 units vitamin D daily, thus suggesting the need for individualized vitamin D supplementation.⁵⁰ A target serum 25-hydroxyvitamin D concentration of 30 ng/mL (75 nmol/L) or higher should be used; with a concentration of 30–100 ng/mL considered normal, 12–29 ng/mL considered insufficient, 11 ng/mL or less considered deficient.⁴⁸

The amount of vitamin D supplementation depends on the deficit. In patients with vitamin D deficiency, large oral doses of vitamin D_2 (ergocalciferol 50,000 units) have been used once or twice a week for at least 8 weeks to aggressively correct the problem.^{5,22} Vitamin D_3 (cholecalciferol) is preferred over vitamin D_2 because it is more effective for raising and maintaining serum 25-hydroxyvitamin D concentrations.⁴⁸ At least 1000 units/day of vitamin D_3 is given to patients with vitamin D insufficiency.⁵ Various tablet or capsule formulations containing vitamin D_3 200–1000 units alone or 100–400 units in combination with calcium salts or multiple vitamins are available for use as supplements. Vitamin D_2 50,000 units orally once or twice a month is an alternative to vitamin $D_3.⁵$

A meta-analysis of 12 double-blind, randomized controlled trials found that vitamin D_3 700–800 units/day with or without calcium supplementation reduced the relative risk of hip fracture by 26% and nonvertebral fracture by 23% compared with calcium supplementation alone and placebo in persons 60 years of age or older.⁵¹ No significant benefit was provided by 400 units/day of vitamin D_3 .

Current study data provide confirming and conflicting data to the meta analysis and emphasize the importance of dosage requirements and adherence relative to efficacy. Data from the Women's Health Initiative confirmed the overall inadequacy of a 400 units/day dosage of vitamin D_3 plus 1000 mg of elemental calcium in postmenopausal women 50 to 79 years of age.⁵² Supplementation reduced the risk of hip fracture by 12%, which was not significant, despite a significant increase in hip BMD. However, when analyzing those women who maintained 80% plus adherence to vitamin D throughout the study, hip fractures decreased by 29%, a significant reduction. Potential reasons for the difference are inadequate serum 25-hydroxyvitamin D concentrations or poor adherence. Adherence decreased to 59% after an average follow up of 7 years. The efficacy of vitamin D₃ 800 units/day, elemental calcium 1000 mg/ day, and a combination of vitamin D_3 and calcium for secondary fracture prevention in patients 70 years of age or older with a history of non-traumatic fracture was evaluated over a 24- to 62-month period in a randomized, placebo-controlled trial.⁵³ No secondary fracture risk reduction was seen within any group. After 2 years, adherence to therapy in this study was also low at 55%. Gastrointestinal symptoms were a cause of nonadherence to calcium therapy. Currently, most clinicians recommend a combination of vitamin D and calcium supplementation in patients with or at risk for osteoporosis.^{48,54,55} Serum 25-hydroxyvitamin D concentrations can be monitored using a goal of at least 30 ng/mL to detect and circumvent problems with nonadherence to vitamin D therapy.

Various so-called bone designer vitamins have been introduced containing calcium, vitamin D, and other substances that might play a role in bone metabolism (e.g., magnesium, boron, vitamin K, phytoestrogens).⁵⁶ The labeling on many of these products is confusing, making it difficult for patients to determine the proper dose.⁵ Bone designer vitamins tend to be costly, and none of the products has been shown to reduce the incidence of bone fractures. Products containing vitamin K (e.g., Viactiv) should be used with caution in patients taking anticoagulants because of the risk of an interaction.

Thiazide diuretics decrease urinary calcium excretion, which might be beneficial for patients with or at risk for osteoporosis who require a diuretic, especially those with calcium losses caused by glucocorticoid therapy.⁵ A meta-analysis of 18 observational studies of current and long-term thiazide use found a 20% reduction in fracture risk.⁵⁷ The beneficial effect does not persist after thiazide diuretic therapy is discontinued.

| | FDA-Approved Indication and Usual Dosage ^a | | Evidence Available for Reduced Fracture Risk | | |
|-------------------------|--|---|---|--------------|-----|
| DRUG OR DRUG CLASS | Prevention | Treatment | Vertebral | Nonvertebral | Hip |
| isphosphonates | | | | | |
| Alendronate | 35 mg/week or 5 mg/day | 70 mg/week or 10 mg/day | ~ | ~ | ~ |
| Ibandronate | 2.5 mg/day or 150 mg/month | 2.5 mg/day or 150 mg/month or 3 mg i.v. every 3 months | V | ~ | |
| Risedronate | 5 mg/day or 35 mg/week | 5 mg/day, 35 mg/week, 75 mg on 2 consecutive days/month, or 150 mg/month | ~ | ~ | ~ |
| Zoledronic acid | N/A | 5 mg i.v. once yearly | ~ | ✓ | ~ |
| ther Antiresorptive Age | nts | | | | |
| Raloxifene | 60 mg/day | 60 mg/day | ~ | | |
| Calcitonin salmon | N/A | 200 units intranasally daily alternating nostrils | ~ | | |
| Estrogen therapy | 0.625 mg/day conjugated estrogens | N/A | ~ | ~ | ~ |
| one Formation Agent | | | | | |
| Teriparatide | N/A | 20 μ g s.c. once daily | ~ | ~ | |

Table 8

FDA = Food and Drug Administration; i.v. = intravenously; N/A = not applicable; s.c. = subcutaneously

Bisphosphonates. Various prescription drug therapies that decrease bone resorption by osteoclasts or increase bone formation by osteoblasts are used for osteoporosis prevention, treatment, or both (Table 8). Bisphosphonates are the primary intervention for managing the disease.⁵⁸ Alendronate was the first bisphosphonate introduced in 1995, so more long-term data are available for this agent than for others in the same class. The other currently available bisphosphonates are second- and thirdgeneration agents with greater potency than alendronate, a first-generation agent. The newest bisphosphonate, zoledronic acid, currently is approved by the Food and Drug Administration (FDA) only for the treatment (not prevention) of osteoporosis. The other three bisphosphonates are approved for both prevention and treatment of postmenopausal osteoporosis. Alendronate and risedronate also are approved to increase bone mass in men with osteoporosis and for the treatment of glucocorticoid-induced osteoporosis in men and women (risedronate is approved to prevent, as well as treat, glucocorticoid-induced osteoporosis). Bisphosphonates with long dosing intervals (e.g., oral forms for weekly or monthly administration, injectable forms for quarterly or annual administration by a healthcare professional) are available to provide patient convenience and promote adherence. Alendronate is available in combination with vitamin D_3 , and risedronate is available in a dose pack with six days of calcium carbonate for patient convenience. Alendronate is the only bisphosphonate available as an oral liquid.

Bisphosphonates are selectively taken up and adsorbed to mineral surfaces in bone subsequently being internalized by osteoclasts or eliminated. Bisphosphonates impair the recruitment, maturation, activity, and survival of osteoclasts by inhibiting key regulatory proteins.⁸⁴ Decreases in both bone turnover and bone loss result.

The biological half-life of bisphosphonates in bone is as long as 10 years, making long-term effects a potential concern.⁵ In theory, increases in mineralization could make bone stiff and vulnerable to cracking. However, whether drug encapsulated in bone is active on a long-term basis is not known but current long-term safety data for risedronate⁸⁵ and alendronate⁸⁶ did not show an increased fracture rate after 7 and 10 years of use, respectively.

Currently available bisphosphonates differ in their binding affinities and persistence in bone.⁸⁴ Alendronate and zoledronic acid have a high affinity for and rate of uptake by bone, low rate of desorption (i.e., release) from bone, high rate of reattachment to bone after desorption, low rate of diffusion in bone, and long persistence in bone. Conversely, risedronate and ibandronate have a low affinity for and rate of uptake by bone, high rate of desorption from bone, low rate of reattachment to bone after desorption, high rate of diffusion in bone, and short persistence in bone. The impact of these pharmacologic differences is unknown.

In clinical trials of bisphosphonates, participants received calcium and vitamin D supplementation, so adequate intake of calcium and vitamin D should be provided to patients using bisphosphonate therapy. Concomitant treatment with bisphosphonates and other antiresorptive therapy is usually not warranted because such dual therapy provides little added benefit.⁵ No fracture data are available with dual antiresorption combination therapy.

Bisphosphonates have the greatest antiresorptive efficacy among antiresorptive agents, with increases in BMD of up to 8%.⁸⁷ Increases in BMD occur in the vertebrae, hip, and other nonvertebral sites, with the greatest increases in the vertebrae and smaller increases at the wrist. Oral products taken weekly or monthly are at least as effective for increasing BMD as those taken daily.^{88,91} Monthly oral ibandronate therapy and ibandronate injections every 3 months are more effective for increasing BMD than daily oral ibandronate therapy in postmenopausal women.^{92,93}

Reductions in the risk of fractures have been demonstrated with all bisphosphonates at vertebral, nonvertebral, and hip sites, with the exception of ibandronate, which has not been shown to reduce hip fractures potentially due to inadequate sample size.^{69–77} The greatest reductions in fracture risk from bisphosphonate therapy are observed in patients with low initial BMD values or large changes from baseline in BMD during therapy.⁸⁷

Hip fractures are the outcomes of greatest interest to clinicians because of the substantial morbidity and mortality associated with these fractures.^{2,3} In one of the three pivotal trials, a randomized, double-blind, placebo-controlled study of alendronate 5 mg/day orally for 24 months followed by 10 mg/day orally for up to 12 additional months in 1946 women with vertebral fractures, the incidence of hip fractures was 1.1% in the alendronate-treated group and 2.2% in the placebo group.⁷⁰ This difference reflects an absolute reduction of 1.1% yielding a 51% reduction in the risk of hip fractures from the use of alendronate.

In a randomized, placebo-controlled study of 5445 women 70–79 years of age with osteoporosis known as the Hip Intervention Program study, oral risedronate 2.5 mg/day or 5 mg/day for 3 years significantly reduced the risk of hip fracture by 40% from 3.2% in the placebo group to 1.9% in the risedronate group with similar benefit from the two risedronate dosages.⁷⁵ The absolute risk and risk reduction are similar to alendronate. In this study, fracture prevention was not seen in the arm with women 80 years and older enrolled into the study without baseline BMD data or previous fracture, which was thought to be a healthier cohort.

In a randomized, double-blind, placebo-controlled, parallel-group study of 2946 postmenopausal women with osteoporosis, the incidence of hip fracture after 3 years was 0.8% with oral ibandronate 2.5 mg daily or 20 mg every other day for 12 doses every 3 months, and 0.6% with placebo, a difference that is not significant.⁷² These findings may reflect flaws in the study methodology that made it under powered to detect an effect from drug therapy (i.e., the low fracture rate in the placebo group may reflect an unusually healthy patient population).⁷³

In a 3-year, randomized, double-blind, placebo-controlled study of 3889 women with postmenopausal osteoporosis known as the Horizon Pivotal Fracture trial, three annual 5-mg injections of zoledronic acid significantly reduced the risk of hip fracture by 41% (absolute change 1.1%) from 2.5% in the placebo group to 1.4% in the zoledronic acid group.⁷⁷

Alendronate, risedronate, and ibandronate reduce the risk of new vertebral fractures by approximately 50% and the risk of nonvertebral fractures by about 20% (31% for ibandronate).^{70,72,75,76} Vertebral and nonvertebral fractures were reduced by 70% and 25%, respectively in patients on zoledronic acid therapy.⁷⁷

Zoledronic acid is the only bisphosphonate evaluated for secondary prevention after hip fracture.⁹⁴ In a randomized, double-blind, placebo-controlled study, 2127 men and postmenopausal women received intravenous (i.v.) zoledronic acid 5 mg or placebo i.v. once annually beginning within 90 days after surgical repair of a hip fracture and were followed for a median time of 1.9 years. Significant reductions in the rate of new vertebral fractures by 46%, nonvertebral fractures by 27%, and death by 28% were associated with zoledronic acid treatment compared with placebo. The rate of hip fracture was reduced by 30%, but the difference was not significant.

The effect of alendronate (and presumably other bisphosphonates) on lumbar spine BMD increases progressively over a 10-year period, but its effect on hip BMD reaches a plateau after 1–3 years.⁸⁶ After discontinuation of bisphosphonate therapy, the BMD is maintained or decreases slowly at a rate similar to that associated with aging.⁹⁵ The BMD in such patients typically is higher than in patients who never received bisphosphonate therapy. The feasibility of temporarily interrupting bisphosphonate therapy (i.e., taking a "drug holiday") and using biochemical markers of bone turnover to monitor for the need to resume therapy is under investigation in women with postmenopausal osteoporosis.⁹⁶

Ideally, clinical studies comparing the effects of various bisphosphonates on fracture rates should be conducted, but large numbers of patients (e.g., 100,000) would need to be enrolled to demonstrate a significant difference.⁹⁷ Comparative studies of the effects of bisphosphonates on BMD and biochemical markers of bone turnover have been conducted, although the use of these surrogate markers has limitations. In 833 postmenopausal women with low BMD who participated in a 1-year randomized, double-blind, extension of a 1-year study comparing alendronate 70 mg orally once weekly with risedronate 35 mg orally once weekly, alendronate produced significantly greater increases from baseline in BMD after 2 years of treatment compared with risedronate.98 Patients treated with alendronate had significantly greater reductions in biochemical markers of bone turnover than patients treated with risedronate. No differences in fractures were reported, but the study had inadequate power to determine this as an efficacy outcome.

In a 12-month, randomized, double-blind, doubledummy, parallel-group, non-inferiority study comparing ibandronate 150 mg orally once monthly with alendronate 70 mg orally once weekly in women with postmenopausal osteoporosis, similar increases in lumbar spine and total hip BMD were observed with the two treatments.⁹⁹

Pharmacoepidemiologic data may provide guidance for the selection among bisphosphonates in the absence of data from comparative clinical trials. Analysis of data from a large managed care database of persons 65 years of age or older found that the incidence of nonvertebral fractures (i.e., hip, humerus, radius, or ulna) within 12 months after initiating treatment was similar with alendronate and risedronate.¹⁰⁰ Most of the efficacy data for bisphosphonates are from studies of women, but some BMD and fracture data are available from the use of these agents in men with osteoporosis. In a 2-year, randomized, double-blind, placebo-controlled study of 241 men 31 to 87 years of age with osteoporosis, alendronate 10 mg/day produced significant increases from baseline in BMD at the lumbar spine by 7.1% and hip by 3.1%.¹⁰¹ The incidence of vertebral fractures was 0.8% in the alendronate group and 7.1% in the placebo group, a difference that is significant.

In a 1-year, prospective, open-label, randomized study of 316 men with primary or secondary osteoporosis, significantly greater increases in lumbar spine BMD were observed in a group receiving risedronate 5 mg/day plus calcium and vitamin D supplements (4.7%) than in a control group receiving supplementation with calcium and vitamin D (1.0%).¹⁰² Significant increases in femoral neck and total hip BMD also were observed in risedronatetreated patients compared with the control group. The incidence of new vertebral fractures was 60% lower (absolute reduction of 8.6%) in the risedronate group than in the control group, a difference that is significant. Compared with the control group, the risk of nonvertebral fractures was reduced by 42% (absolute reduction of 4.5%) in the risedronate group, but the difference was not significant. These data suggest that bisphosphonates provide vertebral fracture prevention and BMD increases similarly in men and women with osteoporosis; however, no hip and nonvertebral fracture prevention has yet been documented in men.

A substantial percentage of patients (10–33%) experience bisphosphonate failure based on changes from baseline in BMD after 1 or 2 years of treatment.^{92,93,98,103,104} In the past, this failure was not detected sooner because of limitations with bone densitometry assessments. The use of biochemical markers of bone turnover, which can be measured and documents changes within one to three months after initiating treatment, to monitor response to bisphosphonates and other antiresorptive agents might increase in the future, which could facilitate the early detection of therapeutic failure.

Bisphosphonates should be used with caution in patients with esophageal disorders because the drugs can cause local irritation of the upper GI mucosa.^{60,61,63} Oral bisphosphonates are contraindicated in patients who are unable to stand or sit upright for at least 30 minutes (60 minutes for ibandronate).^{60,61,63}

The drugs are contraindicated in patients with uncorrected hypocalcemia. Bisphosphonates are not recommended for patients with severe renal impairment (creatinine clearance <30 mL/min).^{60,61,63,64} However, analysis of pooled data from nine randomized, double-blind, placebo-controlled phase III trials with oral risedronate therapy suggested that bisphosphonates might be safely used in patients with creatinine clearance values as low as 15 mL/min.¹⁰⁵

Gastrointestinal adverse effects (e.g., dyspepsia, abdominal pain) are the greatest concern during use of oral bisphosphonates. These effects can be minimized by taking the medication properly (i.e., in an upright sitting or standing position with the recommended amount of water).^{60,61,63} The incidence of GI adverse effects appears similar among the bisphosphonates, although the risk of serious GI effects (perforation, ulceration, GI bleeding) appears to be lower with formulations taken weekly or monthly than those taken daily.⁵ In the 1-year extension study comparing alendronate 70 mg once weekly with risedronate 35 mg once weekly in 833 postmenopausal women with low BMD, the incidence of upper GI adverse effects was similar with the two treatments.⁹⁷ Switching to a different bisphosphonate sometimes resolves the problem. In clinical trials, the incidence of GI adverse effects was slightly lower with the injectable form of ibandronate than with the oral form of the drug, so switching to an injectable bisphosphonate is an option if GI adverse effects are problematic despite efforts to take oral forms as directed.⁶²

Musculoskeletal pain has been reported one day to several months after initiating bisphosphonate therapy.^{60,61,63} Switching to a different bisphosphonate might be tried, although symptoms can recur and discontinuation of therapy might be required. Osteonecrosis of the jaw is an uncommon adverse effect of bisphosphonates seen primarily in patients with cancer undergoing dental procedures and receiving i.v. bisphosphonates, although the problem has occurred rarely in women with postmenopausal osteoporosis receiving oral bisphosphonates.⁶² Risk factors include a diagnosis of cancer, tooth extraction, trauma, surgery, concomitant therapy (e.g., chemotherapy, radiation therapy, corticosteroids), and comorbid conditions (e.g., infection, anemia).⁶² Osteonecrosis has been attributed primarily to excessive suppression of bone turnover.¹⁰⁶ Good oral hygiene is always recommended. Dental evaluation and completion of needed dental work, and treatment of oral infection are recommended before initiating bisphosphonate therapy to reduce the risk for osteonecrosis.¹⁰⁶

Patient nonadherence to bisphosphonate therapy is a potential problem. In a retrospective cohort study using pharmacy and medical claims data for nearly 18,000 patients initiating bisphosphonate therapy, adherence, which was defined as taking 80-100% of prescribed doses, was observed after 1 year, 2 years, and 3 years in only 43%, 35%, and 31% of patients, respectively.¹⁰⁷ In another cohort of more than 35,000 patients taking bisphosphonates, the relative risk reductions of vertebral, nonvertebral, and hip fractures were significantly greater in adherent patients than in nonadherent patients, with the relative risk reduction differences being 20–45%.¹⁰⁸ Adherence to bisphosphonates is associated with significant savings in prescription drug and inpatient and outpatient costs.107

Bisphosphonate dosing regimens with long dosing intervals have been developed to promote adherence. Patient preference for once-weekly and oncedaily oral alendronate therapy was evaluated in a randomized, open-label, crossover study of 272 postmenopausal women with osteoporosis who received 4 weeks of treatment with each regimen.¹⁰⁹ Significantly more women preferred once-weekly treatment (86%) than once-daily treatment (9%), primarily because of greater convenience and anticipated ease in adhering to therapy on a long-term basis. Similarly, in a 6-month, randomized, open-label, crossover study of 342 postmenopausal women with osteoporosis, significantly more patients preferred ibandronate 150 mg orally once monthly (66%) over alendronate 70 mg orally once weekly (27%), largely because of greater convenience and ease in adhering to treatment on a long-term basis.¹¹⁰

Patient education is needed to minimize adverse effects from and promote adherence to bisphosphonate therapy. Education should be repeated periodically because of the progressive reduction in adherence over time that typically occurs during bisphosphonate therapy.¹⁰⁷ Patients should be advised to take oral bisphosphonates with a full glass (6-8 oz) of plain water (not mineral water, coffee, tea, juice, soda pop, or milk) at least 30 minutes (60 minutes for ibandronate) before the first food or drink of the day.^{60,61,63} Patients also should be warned to avoid lying down for at least 30 minutes (60 minutes for ibandronate) after taking an oral dose.^{60,61,63} Patients should be counseled to report to their healthcare provider any GI problems. Calcium-, magnesium-, aluminum-, and iron-containing medications can interfere with the absorption of bisphosphonates, so patients should be advised to take these medications at different times of day.^{61,63} Specific instructions for what to do if a bisphosphonate dose is missed should be provided to patients; skip the dose if daily, take the dose the same or next day with a full five days between subsequent doses, if weekly and allow at least seven days to elapse between doses intended for monthly administration.^{60,61,63}

Ibandronate injection is provided in a kit with a prefilled clear glass syringe containing a single 3-mg/3mL dose, a 23-gauge, 3/4-inch needle with wings, needle-stick protection device, 3-inch plastic tubing, and alcohol swabs.⁶² Refrigerated storage and reconstitution are not required. The drug is administered i.v. over 15–30 seconds. Hypocalcemia should be corrected before administration of ibandronate.

Zoledronic acid is provided in bottles containing a ready-to-use 5-mg/100-mL solution that does not require refrigeration.⁶² The drug is administered by i.v. infusion over at least 15 minutes. Hypocalcemia should be corrected before administration. Adequate hydration should be provided before administration of zoledronic acid because renal impairment has been observed after administration of the drug to dehydrated patients. Acute phase reactions (e.g., influenza-like illness, fever, myalgia, arthralgias) have been reported after zoledronic acid administration. Acetaminophen or ibuprofen can be used to minimize these reactions. The likelihood of these reactions decreases with repeated administration of the drug. There was evidence of a higher incidence of serious atrial fibrillation in zoledronic acid-treated patients (1.3%) than in placebo-treated patients (0.5%) in the Horizon pivotal fracture trial that was not corroborated in the study of zoledronic acid for the secondary prevention of fractures.^{77,94} If there is an increased risk for atrial fibrillation, it probably is a bisphosphonate class effect because an increased risk has been observed in alendronate-treated patients.¹¹¹ However, the data linking bisphosphonates and atrial fibrillation are mixed, with no evidence of an increased risk in a population based case-control study.¹¹² The FDA is investigating the risk of atrial fibrillation from bisphosphonate use but state that no changes in prescribing habits are needed at this time.

Reimbursement for part or all of the infusion and facility charges is provided by Medicare part B and some insurance companies for i.v. bisphosphonates.

The manufacturers of bisphosphonate products provide a variety of patient education materials about the pathophysiology of, risk factors for, and diagnosis, prevention, and treatment of osteoporosis. Many of these materials are available on the internet in multiple languages and include osteoporosis risk-assessment tools. Patient-assistance programs are available from manufacturers to help patients with financial concerns. Adherence programs with reminders sent electronically or by the U.S. mail are available for ibandronate.

Estrogen Agonist-Antagonists

Tamoxifen. The first-generation estrogen agonistantagonist (formerly referred to as a selective estrogen receptor modulator), tamoxifen, has beneficial effects on BMD and fracture prevention. However, tamoxifen can cause endometrial hyperplasia and carcinoma, venous thromboembolism (VTE), and stroke, and thus is not used or approved by FDA for osteoporosis.¹¹³ Raloxifene. Raloxifene is a second-generation estrogen agonist-antagonist with agonist activity in bone and on lipids and antagonist activity in breast and uterine tissues.⁵⁸ Raloxifene is approved by FDA for the prevention and treatment of osteoporosis in postmenopausal women (it is not approved for use in men with osteoporosis).65 Raloxifene increases BMD at the spine and hip, but the increase is smaller than that from bisphosphonates.¹¹¹ Raloxifene reduces the risk of vertebral fractures by 30-50% in women with postmenopausal osteoporosis; this reduction is greater than expected based on the BMD changes, suggesting a disconnect between the effects of the drug on BMD and fractures.78,79 Raloxifene has no effect on the rate of nonvertebral or hip fractures.⁷⁹ Adding raloxifene to alendronate is no more effective for increasing BMD than alendronate alone, although the combination is more effective than raloxifene alone.¹¹⁴

Raloxifene reduces total and low-density lipoprotein (LDL) cholesterol concentrations, but it has no effect on high-density lipoprotein cholesterol levels.¹¹⁵ Raloxifene decreases the risk of invasive breast cancer, and the drug recently was approved by FDA to reduce the risk of invasive breast cancer in postmenopausal women with osteoporosis or at high risk for invasive breast cancer.^{65,116} Raloxifene does not cause endometrial hyperplasia.¹¹⁵ However, it increases the risk for VTE as much as threefold.^{116,117} Therefore, the drug should not be taken by women with a history of or current VTE. An increased risk for fatal stroke was associated with raloxifene use in a placebo-controlled study of postmenopausal women with coronary heart disease (CHD) or multiple risk factors for CHD, but the risk was low (1.2% versus 0.8% with placebo).¹¹⁶

Raloxifene usually is taken as a single daily oral 60-mg dose. Common adverse effects include hot flushes, leg cramps, and peripheral edema.⁶⁵ Al-though the hot flushes usually occur primarily during the first six months of therapy, this adverse effect might cause some women to discontinue therapy.

Calcitonin Salmon

Calcitonin salmon is a synthetic form of a natural polypeptide hormone secreted by the thyroid gland that decreases bone resorption. It is approved by FDA for the treatment (not prevention) of postmenopausal osteoporosis only in women who are more than 5 years beyond menopause.^{66,118} Calcitonin salmon is available as an injection for subcutaneous (s.c.) or intramuscular administration and a nasal spray, but the nasal spray is used more widely because of greater convenience and minimal adverse effects. Rhinitis, epistaxis, and nasal irritation are the most common adverse effects from intranasal calcitonin salmon.⁶⁶

In a 5-year, double-blind, randomized, dose ranging, placebo-controlled study of 1255 postmenopausal women with osteoporosis, intranasal calcitonin salmon 200 units/day produced significant increases from baseline in lumbar spine BMD and a significant reduction in the risk of new vertebral fractures by 33% compared with placebo.⁸⁰ A high dropout rate was reported in the study with only 55% of the women completing at least three years of the trial. However in this group, new vertebral fractures were still significantly reduced by 34%. Data demonstrating an impact on nonvertebral and hip fracture rates are not available.

Calcitonin salmon 200 units/day intranasally or 100 units/day s.c. decreases bone pain from osteoporotic vertebral compression fractures, with an onset of effect within 1 week.^{119,120} The analgesic effects could be mediated directly through stimulation of calcitonin receptors or indirectly by endorphins, prostaglandin inhibition, or another mechanism.^{119,121}

Intranasal calcitonin salmon is administered as a single daily 200-unit dose, alternating nostrils daily.⁶⁶ The drug is provided in a 3.7-mL clear class bottle with a screw-on pump that delivers a 200-unit/0.09-mL dose when activated. The pump should be primed before the first dose, but priming is not necessary before each subsequent dose. The bottles should be stored under refrigeration until opened, but the bottle in use should be stored at room temperature in an upright position. Patients using calcitonin salmon nasal spray should be counseled about the proper priming, storage, and administration techniques.

Hormone Therapy

In the past, hormone therapy (HT) comprising estrogen (ET) alone for women who have undergone a hysterectomy or estrogen plus a progestin (EPT) for women with an intact uterus was widely used to increase BMD and reduce the risk for hip, vertebral, and nonvertebral fractures in postmenopausal women with or at risk for osteoporosis.^{81,82,122,123} However, increased risk for stroke with long-term ET and increased risk for CHD and stroke and concerns about breast cancer with long-term EPT was discovered during the Women's Health Initiative trials.^{119,120} In most women with or at risk for osteoporosis, the risks outweigh the bone benefits of HT. Therefore, HT is no longer recommended for the prevention or treatment of osteoporosis, although it is approved by FDA for the prevention (not treatment) of postmenopausal osteoporosis.^{7,23,67,124} When HT is used solely for the prevention of postmenopausal osteoporosis, such use should only be for women who are at substantial risk for osteoporosis for whom non-estrogen therapy is inappropriate or not tolerated. Estrogen therapy continues to be used for the treatment of moderate to severe vasomotor symptoms and vulvar and vaginal atrophy due to menopause.¹²⁴ The lowest effective dosage should be used for the shortest duration required in these women. Contraindications to the use of HT include known or suspected breast cancer, estrogen-dependent neoplasia, or pregnancy; undiagnosed abnormal genital bleeding; and current or history of thromboembolic disease.²³

Estrogens and Progestins. Estrogens are administered orally or transdermally for osteoporosis. Increases in BMD are associated with both products.²³

Progestins prevent estrogen-induced endometrial hyperplasia and carcinoma.²³ Various progestins are available. The most commonly used progestin, medroxyprogesterone acetate, usually is administered orally as a daily 2.5-mg or 5-mg dose or cyclically as a 5-mg/day dose for 12–14 days of a 28–31 day cycle.¹²⁵

In the past, the estrogen content of oral contraceptives was higher than that in the low-dose preparations used today, and use of the older preparations was associated with slightly higher BMD measurements compared with oral contraceptive non users.¹²⁶ However, modern oral contraceptives are not expected to have a favorable effect on BMD but will sometimes be used for women with anorexia nervosa to decrease the risk of osteoporosis.

Testosterone. Increases in BMD have been observed in men receiving testosterone-replacement therapy for hypogonadism, but fracture data are not available.¹²⁷ Testosterone-replacement therapy is not approved by FDA for the prevention or treatment of osteoporosis. Other therapies (e.g., bisphosphonates, teriparatide) are preferred for men with osteoporosis.⁵ The use of testosterone or methyltestosterone in women with or at risk for osteoporosis is not recommended because insufficient BMD and no fracture data are available.¹²⁸

Bioidentical Hormone Products. Some patients prefer bioidentical hormone products that are the same as the natural estrogen, progesterone, and androgens produced by the human body, although many prescription products are derived from natural sources. Bioidentical hormone products are compounded for oral, topical, vaginal, and other routes of administration. However, BMD and fracture data are not available for bioidentical hormone products.¹²⁹ Most formulations compounded in pharmacies are not subject to FDA oversight for content, purity, safety, or efficacy.¹²⁹ If these products are used, they should be obtained from a reputable source. FDA has taken action against some pharmacies that compound bioidentical hormone products that have made unproven health claims (e.g., superior safety and efficacy) about such products compared with prescription products.¹³⁰

Phytoestogens. Isoflavones (a type of phytoestrogen) are estrogen agonist–antagonists commonly obtained from dietary soy products or dietary supplements.¹³¹ Mixed results have been obtained from studies of the effect of soy isoflavones on BMD.¹³² A reduced risk for bone fracture has been observed in postmenopausal women with a high consumption of soy isoflavones, particularly in the early postmenopausal period.¹³³ Isoflavones are considered relatively safe.¹³¹ Additional research is needed to evaluate the bone benefits from soy isoflavones and to determine the optimal dietary intake. Insufficient evidence exists to recommend their safe use in women with current or past breast cancer and osteoporosis.

Investigational Antiresorptive Therapies

Third-generation estrogen agonist-antagonists have been developed to improve on the efficacy and safety of raloxifene in women with or at risk for postmenopausal osteoporosis, although few comparative studies have been conducted. Oral bazedoxifene has been shown to increase BMD and reduce the risk of vertebral fractures in women with postmenopausal osteoporosis.134 Beneficial effects on bone and improvement in menopausal vasomotor symptoms have been demonstrated from the use of bazedoxifene in combination with conjugated estrogens in postmenopausal women without osteoporosis.¹³⁴ In a 24-month, randomized, double-blind, placebocontrolled study of 1434 healthy postmenopausal women who were at risk for osteoporosis, bazedoxifene 20 mg/day and 40 mg/day and raloxifene 60 mg/day produced similar increases from baseline in lumbar spine BMD.¹³⁵ Bazedoxifene does not appear to stimulate endometrial or breast tissues.

In a 2-year, randomized, double-blind, placebocontrolled study of 410 postmenopausal women, lasofoxifene 0.25 mg/day and 1.0 mg/day were significantly more effective than raloxifene 60 mg/ day in increasing lumbar spine BMD, and the three treatments were comparable in increasing total hip BMD.¹³⁶ Lasofoxifene was significantly more effective than raloxifene in reducing LDL cholesterol concentrations. Additional research is needed to determine the potential usefulness of third-generation estrogen agonist-antagonists in the prevention and treatment of postmenopausal osteoporosis.

Medications that interfere with RANK or its ligand (RANKL) thereby inhibiting osteoclast activation and bone resorption are under investigation. Decreasing RANKL production, blocking RANKL binding to RANK, or enhancing endogenous osteoprotegerin are potential therapeutic approaches.

Denosumab is a fully human monoclonal antibody that binds specifically to RANKL preventing it from binding to RANK (Figure 3). In a 2-year, randomized, placebo-controlled study of 412 postmenopausal women with low BMD, denosumab 30 mg s.c. every 3 months and 60, 100, and 210 mg s.c. every 6 months produced increases from baseline in lumbar spine BMD that were similar to or greater than those produced by alendronate 70 mg orally once weekly and significantly greater than those associated with placebo.¹³⁷ Increases from baseline in hip BMD produced by denosumab and alendronate were similar and significantly greater than those observed with placebo.

Various other strategies for inhibiting bone resorption are under exploration. Antagonists of the receptor for $\alpha V\beta_3$ integrins that play an important role in attaching activated osteoclasts to bone have been developed to inhibit this process and bone resorption.¹³⁸ Odanacatib and balicatib are investigational inhibitors of the protease cathepsin K, which dissolves bone.¹³⁹ Osteoclast-selective inhibitors of the H⁺-ATPase enzymes that result in acid formation by the proton pump expressed on the plasma membrane of osteoclasts causing bone dissolution have been developed.¹⁴⁰ Antagonism of IL-1 is another focus of research because osteoclast recruitment in postmenopausal women appears to be mediated in part by IL-1 production by T cells.¹⁴¹

Agents that Promote Bone Formation

Parathyroid Hormone. Parathyroid hormone (PTH) regulates calcium and phosphate metabolism in the bones, tubular reabsorption of calcium and phosphate by the kidneys, and GI calcium absorption. It increases BMD by stimulating bone formation. A recombinant human form of the 84-amino acid protein is approved in some European countries, but not in the United States, for the treatment of osteoporosis in women.⁷ In an 18-month, randomized, double-blind, placebo-controlled, parallel-group study of 2532 postmenopausal women with low hip or lumbar spine BMD, recombinant human PTH 100 mg/day s.c. significantly reduced the risk for new or worsened vertebral fractures.¹⁴²

Teriparatide. Teriparatide is a recombinant product that contains the 34 amino acids of the biologically active region of and has the same physiologic effects as human PTH.⁶⁸ In a randomized, placebo controlled study of 1637 postmenopausal women with a history of vertebral fractures, teriparatide 20 mg/day and 40 mg/day s.c. produced significant dose-

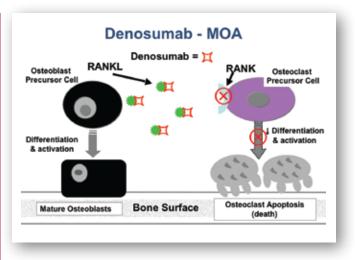


Figure 3. Denosumab Mechanism of Action

 $\label{eq:RANK} \begin{array}{l} \mbox{RANK} = \mbox{receptor for activator of nuclear factor κB} \\ \mbox{RANKL} = \mbox{receptor for activator of nuclear factor κB} \\ \mbox{ ligand } \\ \mbox{ (\aleph)} = \mbox{downstream effects from no RANKL binding to RANK} \end{array}$

dependent increases from baseline in spine and hip BMD after a median of 21 months.⁸³ The risk of new vertebral fractures in the 20-mg/day and 40-mg/day groups was reduced by 65% and 69%, respectively, and the risk of nonvertebral fractures was reduced by 53% and 54%, respectively, compared with placebo.

Significant increases from baseline in spine and hip BMD were observed in 437 men with osteoporosis after 11 months of treatment with teriparatide 20 mg/day and 40 mg/day compared with placebo.¹⁴³ A nonsignificant 51% reduction in the risk of vertebral fracture was associated with 12 months of treatment using the same dosages of teriparatide in another placebocontrolled study of 355 men with osteoporosis.¹⁴⁴

Teriparatide is approved by the FDA for the treatment of osteoporosis in women and men.⁶⁸ It usually is reserved for patients with more severe osteoporosis (e.g., patients with a history of osteoporotic fracture or multiple risk factors for fracture) or a contraindication to, inability to tolerate, or inadequate response to bisphosphonates because of the s.c. route of administration and high cost of teriparatide.⁵ The increase in BMD from teriparatide is greater than that produced by bisphosphonates.¹⁴⁵ In theory, combining the bone forming agent teriparatide with an antiresorptive agent should have improved clinical outcomes. However, the use of alendronate with PTH appeared to blunt the effect of PTH on lumbar spine and femoral neck BMD in men with osteoporosis.¹⁴⁶ Therefore, bisphosphonates are best used before or after teriparatide.⁵

Teriparatide should not be used by patients who are at increased risk for osteosarcoma due to open epiphyses (i.e., pediatric patients and young adults with open epiphyses), Paget's disease of the bone, unexplained elevations in alkaline phosphatase, or a history of external beam or implant radiation therapy involving the skeleton because the drug increased the risk for osteosarcoma in animal studies.⁶⁸ Teriparatide should not be used in patients with bone malignancy, metabolic bone disease other than osteoporosis, or hypercalcemia or in women who are pregnant or breastfeeding.⁶⁸

Teriparatide can cause dizziness, leg cramps, arthralgias, orthostatic hypotension, palpitations, and transient hypercalcemia.⁶⁸ Adverse effects from the drug usually are mild and generally do not require pretreatment.

Teriparatide is provided in a 3-mL prefilled pen containing a clear colorless liquid that should be stored under refrigeration and discarded 28 days after the first use.⁶⁸ The drug is administered by s.c. injection into the thigh or abdominal wall as a single daily dose for up to two years. The needle should be replaced before each use, and the pen should be capped after each use. Patients should be given instructions for how to use the pen, including proper administration technique and syring disposal.

Investigational Formation Therapies

New therapeutic approaches to increasing bone formation in patients with or at risk for osteoporosis are the subject of current research and development. Recombinant human insulin-like growth factor-I (IGF-I) has been studied because insulin-like growth factors regulate the differentiation of osteoblasts and osteoclasts, IGF-I is thought to play an important role in bone mineralization, and targeted deletion of the IGF-I or IGF-I receptor genes is associated with low BMD in animal studies.¹⁴⁷

Therapeutic Choices

Bisphosphonates are the drugs of first choice for the management of osteoporosis, unless it is severe.⁵ Teriparatide should be used in severe cases. Raloxifene and calcitonin salmon are second- or third-line agents used when patients cannot tolerate, fail to respond to, or have contraindications to bisphosphonates. Bisphosphonates and raloxifene can be used for both prevention and treatment of osteoporosis, but calcitonin salmon and teriparatide are reserved for treatment. Raloxifene may be particularly useful for postmenopausal women who cannot take or tolerate bisphosphonates or are at high risk for breast cancer.⁵⁸ Calcitonin salmon may be particularly useful for treating postmenopausal women with acute vertebral fractures and bone pain.⁵⁸

Although hormone therapy has an FDA-approved indication for the prevention of osteoporosis, better alternatives are available for the management of osteoporosis.¹²⁴

The Pharmacist's Role in Therapy

Pharmacists can play an important role in improving bone health in patients with or at risk for osteoporosis by promoting a bone healthy lifestyle with weight-bearing, resistance, muscle-strengthening, and balance exercises; adequate calcium and vitamin D intake from the diet and supplements; smoking cessation; alcohol and caffeine moderation; and fall-prevention strategies. Identifying patients at risk for osteoporosis and referring them to a healthcare provider for a diagnostic work up as appropriate is among the possible contributions of pharmacists.¹⁴⁸ Community pharmacy-based osteoporosis screening services using peripheral BMD measurements have been shown to be effective in identifying patients at risk for osteoporosis, and these services are financially sustainable.¹⁴⁹⁻¹⁵¹ Compensation of pharmacists for these services might be available from some third-party payers and patients themselves.¹⁵¹

The pharmacist might evaluate patient medication lists for agents that can cause or contribute to osteoporosis or impair senses, cognition, or balance increasing the risk for falls. Pharmacists also can collaborate with the patient, his or her physician,

Table 9

Internet-Based Resources for Osteoporosis Information and Patient Education Materials

Centers for Disease Control and Prevention

www.cdc.gov/ncipc/duip/fallsmaterial.htm#Brochures

Brochures in English, Spanish, and Chinese for patients on how to prevent falls and assess the home for safety

Foundation for Osteoporosis Research and Education

www.fore.org/

- Information for patients about osteoporosis, osteopenia, prevention, diagnosis, and treatment
- Online 10-year fracture risk calculator (http://riskcalculator.fore.org/)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

NIH Osteoporosis and Related Bone Diseases-National Resource Center

Bone Resource Page

www.niams.nih.gov/Health_Info/Bone/

- Information for patients about bone health and osteoporosis
- Links to other web-based osteoporosis information resources

National Osteoporosis Foundation

www.nof.org/

- Information for patients about osteoporosis prevalence, prevention, risk factors, symptoms, diagnosis, treatment, and costs
- Osteoporosis risk factor questionnaire (www.nof.org/osteoporosis/Risk_Factor_Card.pdf)
- Clinician's Guide to Prevention and Treatment of Osteoporosis

North American Menopause Society

www.menopause.org/

- Position statements for healthcare professionals about management of osteoporosis in postmenopausal women (2006), role of calcium in perimenopausal and postmenopausal women (2006), role of testosterone therapy in postmenopausal women (2005), role of isoflavones in menopausal health (2000), and other topics
- Information for patients about menopause, hormone therapy, and bioidentical hormones

U.S. Department of Health and Human Services

www.hhs.gov/surgeongeneral/library/bonehealth/

- Fact sheets for patients about bone disease, myths and realities of bone health, and tips to improve bone health
- Fact sheet for healthcare professionals about how to improve bone health (www.hhs.gov/surgeongeneral/library/ bonehealth/factsheet4.htm)
- Bone Health and Osteoporosis: A Report of the Surgeon General (executive summary and full report both available online for healthcare professionals)

U.S. Department of Health and Human Services Office on Women's Health

www.4women.gov/owh/

- The National Bone Health Campaign
- Powerful Girls Have Powerful Bones (www.girlshealth.gov/bones/)

World Health Organization

- Fracture risk assessment tool (www.shef.ac.uk/FRAX/)
- Separate tools for various ages, races, genders, and countries

and other healthcare providers in establishing individualized therapeutic goals and developing a therapeutic plan for preventing or treating osteoporosis. Patients often require assistance with calcium and vitamin D supplement selection. If bisphosphonates are used, the pharmacist might recommend a product with a long dosing interval for patient convenience and to promote and monitor adherence, or an injectable product for patients with difficulty tolerating or adhering to oral bisphosphonate therapy.

Because nonadherence to osteoporosis therapies is a potential problem, repeated patient counseling is particularly important for patients with or at risk for this disease. A wide variety of patient education resources are available on the internet (Table 9). Patient counseling should address a bone healthy lifestyle as well as proper medication use and potential adverse effects. Patient education should empower the patient to assume responsibility for her or his bone health and promote adherence to the therapeutic plan. Myths about osteoporosis (Table 10) should be dispelled. The pharmacist can measure a patient's height correctly, which can reflect bone loss since a younger age, and explain to the patient how to interpret bone densitometry results including any increases in BMD over time as a result of treatment. Changes in height and BMD can serve as powerful motivators for patient adherence to treatment. Pharmacists also can help resolve medicationrelated problems that might have detrimental effects on adherence, the response to drug therapy, and patient outcomes. A pharmacist-managed specialty clinic designed to ensure the safe and effective use of teriparatide in patients with osteoporosis was shown to increase BMD.^{153,154}

Pharmacists also can participate in osteoporosis education programs in the community or work place to advise people about a bone healthy lifestyle and prevention and treatment strategies. Some pharmacists contribute to efforts at managed care and phar-

Table 10

Myths About Osteoporosis¹⁵²

- Osteoporosis is an inevitable part of aging.
- Osteoporosis cannot be prevented.
- Only older white women get osteoporosis.
- Osteoporosis is not very common.
- Osteoporosis is not a serious or deadly condition.
- Osteoporosis has no physical or emotional consequences.
- The medical costs of osteoporosis are not high.
- If you had osteoporosis, you would know it.
- Diagnosing osteoporosis is a long, painful process.
- Once you have osteoporosis, nothing can be done about it.
- Bone fractures from falling have nothing to do with osteoporosis.

macy benefit plans to establish quality indicators, increase the screening for osteoporosis, improve the prescribing of rational therapy to prevent or treat the disease, and monitor and improve osteoporosis disease management services. Examples of screening efforts include chart reviews to identify patients with non-traumatic fractures, establishing registries of patients at risk for osteoporosis, and contacting physicians and other healthcare providers about the need to monitor for osteoporosis in high-risk patients.

Conclusion

Osteoporosis is an increasingly common and potentially devastating disease in the United States. Both non-pharmacologic methods and medications and supplements exist to prevent and treat osteoporosis. Pharmacists can make a considerable contribution to improving bone health and therapeutic outcomes from drug therapy in ambulatory patients with or at risk for the disease.

Self-Assessment Questions

Pharmacists. The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This monograph provides 2.0 hours (0.2 CEUs) of continuing pharmacy education credit (program number 204-000-08-446-H01P). This program is provided free of charge. Pharmacists who complete the program and complete the CE test with a passing grade of 70% may print their CE statement at the ASHP Advantage Testing Center (http://onlinece.ashpadvantage.com/osteo08/monograph). The release date of this program is 7-30-08 and the expiration date is 7-29-09.

Nurse Practitioners. This program has been approved for 2.0 contact hours of continuing education (which includes 0.5 hours of pharmacology) by the American Academy of Nurse Practitioners. Program ID 0907317. The release date of this program is 7-30-08 and the expiration date is 7-29-09.

1. Which of the following statements about sex differences in the incidence of and mortality from osteoporosis is correct?

- a. The incidence of osteoporosis and mortality rate after an osteoporosis-related fracture are higher in women than in men.
- b. The incidence of osteoporosis is higher in women than in men, but the mortality rate after an osteoporosis-related fracture is higher in men than in women.
- c. The incidence of osteoporosis is higher in women than in men, but the mortality rate after an osteoporosis-related fracture is the same in women and men.
- d. The incidence of osteoporosis is the same in women and men, but the mortality rate after an osteoporosis-related fracture is higher in women than in men.
- 2. Which of the following types of bone fractures accounts for the largest percentage of osteoporosis fracture-related costs?
 - a. Hip. c. Vertebrae.
 - b. Pelvis. d. Wrist.
- 3. Which of the following is a risk factor for osteoporosis?
 - a. Cigarette smoking.
 - b. Hispanic African American.
 - c. Obesity.
 - d. Use of estrogens.
- 4. In the normal bone remodeling process, which of the following promotes osteoclast differentiation, activation, and maturation?
 - a. $\alpha V\beta_3$ integrins.
 - b. Cathepsin K.
 - c. Osteoprotegerin.
 - d. Receptor for activator of nuclear factor kB ligand (RANKL).

5. Which of the following is a consequence of the reduction in ovarian estrogen production at menopause?

- a. High turnover bone loss due to decreased osteoblast activity.
- b. Low turnover bone loss due to decreased osteoblast activity.
- c. High turnover bone loss due to increased osteoclast activity.
- d. Low turnover bone loss due to increased osteoclast activity.
- 6. Which of the following is the most common medication-related cause of osteoporosis?
 - a. Gonadotropin releasing hormone analogs.
 - b. Glucocorticoids.
 - c. Heparin.
 - d. Thyroid supplements.
- 7. Which of the following is the gold standard test for diagnosing osteoporosis?
 - a. Peripheral quantitative ultrasound of the heel.
 - b. Peripheral dual energy X-ray absorptiometry (DXA) of the finger, forearm, or heel.
 - c. Central DXA of the spine or hip.
 - d. Central or peripheral DXA at any site.
- 8. Which of the following diagnoses applies to a spine or hip T-score of -2.2 obtained using central DXA?
 - a. Normal. c. Osteoporosis.
 - b. Osteopenia. d. Severe osteoporosis.
- 9. Peak bone mass is achieved during:
 - a. Childhood. c. Early adulthood.
 - b. Adolescence. d. Perimenopause.

- 10. Which of the following is the primary goal of osteoporosis-related interventions in the early postmenopausal years?
 - a. Increasing bone mass.
 - b. Maximizing the peak bone mass.
 - c. Attenuating the accelerated rate of bone loss.
 - d. Preventing falls and fractures.
- 11. Which of the following is a component of a bone healthy lifestyle?
 - a. A diet low in saturated fats and cholesterol.
 - b. Weight loss if overweight or obese.
 - c. Adequate calcium and vitamin D intake.
 - d. A diet low in sodium and high in fiber.
- 12. Which of the following groups of patients has the highest calcium requirements?
 - a. Male and female infants less than 12 months of age.
 - b. Boys and girls 9–18 years.
 - c. Pregnant women 19-50 years of age.
 - d. Men and women more than 50 years of age.

13. Which of the following statements about the dietary calcium and vitamin D intake in most Americans with or at risk for osteoporosis is correct?

- a. Dietary intake of calcium and vitamin D is adequate.
- b. Dietary intake of calcium is adequate, but intake of vitamin D is inadequate.
- c. Dietary intake of calcium is inadequate, but intake of vitamin D is adequate.
- d. Dietary intake of calcium and vitamin D is inadequate.
- 14. Which of the following is an appropriate target for 25-hydroxyvitamin D level to ensure bone health?

| a. ≥20 ng/mL. | c. ≥50 ng/mL. |
|---------------|----------------|
| b. ≥30 ng/mL. | d. ≥100 ng/mL. |

- 15. Which of the following is an advantage of calcium citrate over calcium carbonate for use as a supplement in patients with or at risk for osteoporosis?
 - a. Lower cost.
 - b. Higher calcium content.
 - c. Administration without regard for food intake.
 - d. Greater ease of swallowing of most dosage forms.

- 16. Which of the following forms of vitamin D is recommended for patients with severe hepatic or renal disease who require a supplement?
 - a. Calcitriol.
 - b. Cholecalciferol.
 - c. Ergocalciferol.
 - d. 25-hydroxycholecalciferol.
- 17. Which of the following is the drug of first choice for managing osteoporosis unless it is severe and the drug is contraindicated?
 - a. Bisphosphonates. c. Raloxifene.
 - b. Calcitonin salmon. d. Teriparatide.
- 18. Which of the following bisphosphonates have a low affinity for and rate of uptake by bone, high rate of desorption from bone, low rate of reat-tachment to bone after desorption, high rate of diffusion in bone, and short persistence in bone?
 - a. Alendronate and risedronate.
 - b. Alendronate and zoledronic acid.
 - c. Ibandronate and zoledronic acid.
 - d. Risedronate and ibandronate.
- 19. Which of the following bisphosphonates are approved by the Food and Drug Administration to increase bone mass in men with osteoporosis?
 - a. Alendronate and risedronate.
 - b. Alendronate and zoledronic acid.
 - c. Ibandronate and zoledronic acid.
 - d. Risedronate and ibandronate.
- 20. Which of the following adverse effects is the greatest concern during oral bisphosphonate therapy?
 - a. Dyspepsia and abdominal pain.
 - b. Hypercalcemia.
 - c. Osteosarcoma.
 - d. Venous thromboembolism.
- 21. Which of the following adverse effects has been associated with raloxifene?
 - a. Dyspepsia and abdominal pain.
 - b. Endometrial hyperplasia.
 - c. Osteonecrosis of the jaw.
 - d. Venous thromboembolism.

- 22. Which of the following osteoporosis medications might be particularly useful for a postmenopausal woman with osteoporosis who cannot tolerate bisphosphonates and is at high risk for invasive breast cancer?
 - a. Calcitonin salmon.
 - b. Raloxifene.
 - c. Estrogen and progestin therapy.
 - d. Teriparatide.
- 23. Which of the following osteoporosis medications could be particularly useful for a postmenopausal woman with painful vertebral fractures who cannot tolerate bisphosphonates?
 - a. Calcitonin salmon. c. Estrogen therapy.
 - b. Raloxifene. d. Teriparatide.
- 24. Which of the following osteoporosis medications is recommended for patients with severe osteoporosis?
 - a. Calcitonin salmon.
 - b. Raloxifene.
 - c. Estrogen and progestin therapy.
 - d. Teriparatide.
- 25. Which of the following statements about the use of bisphosphonates in patients treated with teriparatide is correct?
 - a. They provide additive increases in BMD when used with teriparatide.
 - b. They provide little added benefit beyond what is achieved with teriparatide alone.
 - c. They can blunt the effect of teriparatide on BMD, so they are best used before or after teriparatide.
 - d. They might increase the risk for osteosarcoma from teriparatide.

- 26. Which of the following is an investigational antiresorptive agent that binds specifically to RANKL preventing it from binding to the receptor for activator of nuclear factor kB?
 - a. Bazedoxifene.
 - b. Denosumab.
 - c. Odanacatib.
 - d. Recombinant human insulin-like growth factor-I.
- 27. Which of the following bone densitometry tests is feasible for a community pharmacist to perform?
 - a. Central DXA of the spine.
 - b. Central DXA of the hip.
 - c. Peripheral DXA of the finger.
 - d. Peripheral quantitative ultrasound of the heel.
- 28. Which of the following statements about community pharmacy-based osteoporosis screening services is correct?
 - a. They are effective but cost-prohibitive because of a lack of compensation from third-party payers.
 - b. They are effective but cost-prohibitive despite compensation from third-party payers.
 - c. They are effective and financially sustainable only if compensation is available from patients.
 - d. They are effective and financially sustainable because of compensation from third-party payers or patients.

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Medication Adherence

Module 7

MEDICATION THERAPY MANAGEMENT SERVICES

Identifying and Addressing Medication Adherence Issues



Professional education monograph series for pharmacists from APhA



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DISCLOSURES

Randy McDonough, PharmD, CGP, BCPS, and Mary Ann Kliethermes, PharmD, declare no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

APhA's editorial staff declares no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

This publication was prepared by Judy Crespi-Lofton, MS, of JCL Communications on behalf of the American Pharmacists Association.



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Learning Objectives

After reading this monograph, the pharmacist will be able to:

- Explain the medication therapy review process, as described in version 2.0 of the core elements service model of medication therapy management (MTM).
- Describe effective strategies for identifying patients with suspected adherence problems.
- Explain the role of the Pharmacy Quality Alliance adherence quality measures.
- Discuss the appropriate use of selected adherence screening tools in MTM and overall patient care.
- Identify common causes of poor adherence and develop strategies for addressing adherence problems in diverse patient populations.

Introduction

Adherence has been defined as the extent to which a patient's behavior including medication use, diet, exercise, and other lifestyle factors—coincides with medical or health-related advice.¹ Medication adherence refers specifically to the degree of a patient's use of medications. The term persistence is also sometimes used to describe a patient's long-term adherence to a medication regimen. Poor medication adherence and persistence have been linked to a number of adverse outcomes, including unnecessary disease progression, disease complications, reduced functional abilities, lower quality of life, and premature death as well as increased physician's office visits, hospitalizations, and nursing home admissions.²

Adherence to prescribed medication regimens may benefit health outcomes but can be very challenging for patients, and low adherence is very common. In the United States, only an estimated 50% of patients with chronic conditions are adherent to their medication regimens.² (Taking at least 80% of all scheduled dosages—i.e., having an adherence rate of 80% is often considered the threshold for good adherence.³) Increasing costs, complexity, and duration of treatment are associated with decreased adherence rates.¹ Adherence rates are suboptimal even among health care providers, who presumably are knowledgeable about the benefits of appropriate medication use.⁴

Numerous strategies have been used in attempts to improve patient medication adherence rates. One meta-analysis of the efficacy of various strategies to improve adherence found that one-to-one counseling was the most effective method for addressing adherence, whereas provision of written and/or audiovisual educational materials designed to improve adherence was the least effective.⁵ Therefore, medication therapy management (MTM) services provided by pharmacists and the resulting interventions and interactions between a patient and pharmacist may provide ideal opportunities to assess and manage patient adherence.

Assessing Medication Adherence

Patients generally do not volunteer reports of poor adherence without prompting. Pharmacists must be proactive about assessing patients' adherence, and may wish to use a combination of several methods both during individual MTM visits and on a population basis to identify patients who might benefit from an MTM intervention.

Population methods, such as a review of prescription records or claims data to detect gaps in therapy or increased intervals between refills, may help to identify patients with suboptimal adherence to chronic-use medications. Pharmacists may contact patients who are identified in this manner to discuss the issue, or invite such patients to schedule an MTM visit with the pharmacist.

Patient self-reports of adherence are inexpensive and easy to obtain during MTM visits. However, keep in mind that the patient's memory may not be perfect, and the patient may give socially desirable answers (i.e., exaggerate adherence). A selection of forms that may be useful to obtain the patient's self-report of adherence are listed in Table 1.

Adherence screening tools can be used on a routine basis, and may be incorporated into the paperwork that patients are asked to complete at MTM visits. Numerous screening tools are available. One of the most commonly used tools is the Morisky scale, which asks patients to answer "yes" or "no" to the following questions⁶:

- Do you ever forget to take your medications?
- Are you careless at times about taking your medications?
- When you feel better, do you sometimes stop taking your medications?
- Sometimes if you feel worse when you take your medications, do you stop taking them?

An Updated Core Elements Service Model for Medication Therapy Management

In a consensus definition, the pharmacy profession has defined medication therapy management (MTM) to be a distinct group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product. Services may be provided either via face-toface interactions or telephonically by a pharmacist or other qualified health care professional.⁷

Building on this definition, the American Pharmacists Association and the National Association of Chain Drug Stores Foundation developed a model framework for implementing effective MTM services in a community pharmacy setting. As MTM services continued to evolve and emerge in pharmacy practice, the need for a revised version of the core elements service model for MTM became apparent. A revised version 2.0 has been developed and was released in March 2008.⁸

The service model is designed to help pharmacists establish a process in which they can enable patients to better manage their medications by increasing understanding of appropriate drug use, improving adherence, and detecting and/or preventing adverse drug events. In addition to focusing on the identification and resolution of known or suspected medication-related problems, the updated version discusses patients in diverse care settings and increases the emphasis on patient health care transitions, physician collaboration, and patient empowerment.

The MTM process outlined in the core elements model includes performance of a medication therapy review, development of a personal medication record (PMR) and a medication-related action plan (MAP), intervention and/or referral, and documentation and follow-up. Medication-related problems, such as suboptimal adherence, may be identified during the medication therapy review and addressed during the remainder of the process. The PMR and MAP are tools that may assist patients in taking a more active role in managing their medication regimens and addressing identified medication-related problems. As specified in the core elements service model, these documents should be provided to patients during the MTM encounter. In version 2.0, the sample forms provided are designed to be more patientfriendly and more effective tools.

The more "yes" answers the patient provides, the greater the risk for poor adherence. Several variations of this tool exist, including asking patients to rate their responses to the questions on a 5-point scale or a visual analog scale. (Rating adherence on a continuous scale, rather than a dichotomous one, may provide a better picture of the patient's medication use patterns.) Other screening tools ask patients to list the percentage of prescribed doses that they have taken.

Other strategies to assess adherence include counting the patient's pills, measuring patient blood levels of medications, or using an electronic monitoring device that records when the medication bottle is opened. However, these strategies are more intrusive, often more expensive, and may be difficult to implement in a community pharmacy setting.

Finally, incorporating a discussion of adherence as a routine part of the medication therapy review may

Table 1. Selected Tools for Assessing Adherence

| Tool | Web Site/Journal Article |
|--|--|
| Adherence Self-Assessment Instrument | http://www.aids-ed.org/aidsetc?page=cm-302_adhere#S10X |
| Florida/Caribbean AIDS Education and Training Center Charting Tools (several forms available in English and Spanish) | http://www.faetc.org/Chart_Tools/ |
| Medication Adherence Rating Scale (MARS) | Thompson K, Kulkarni J, Sergejew AA. Reliability and validity of a new Medication Adherence Rating Scale (MARS) for the psychoses. <i>Schizophr</i> <i>Res.</i> 2000;42:241–7. |
| Medication Adherence Self-Efficacy Scale | Ogedegbe G, Mancuso CA, Allegrante JP, Charlson ME. Development and evaluation of a medication adherence self-efficacy scale in hyperten- sive African-American patients. J Clin Epidemiol. 2003;56:520–9. |
| Medication Adherence Self-Report Inventory | Walsh JC, Mandalia S, Gazzard BG. Responses to a 1 month self-report on adherence to antiretroviral therapy are consistent with electronic data and virological treatment outcome. <i>AIDS</i> . 2002;16:269–77. |
| Medication Nonadherence Risk Assessment | http://www.ascp.com/education/meetings/2006/annual/upload/ Shelton_Med_adherence_handout.pdf |

be helpful. Pharmacists should ask patients openended nonjudgmental questions (i.e., those that cannot be answered with "yes" or "no"). Such questions should be asked for each individual medication and may include:

- How do you use this medication?
- How often do you miss a dose of this medication?
- How many doses of this medication have you missed in the past week?
- What have you experienced after taking this medication?

Addressing Adherence During MTM Sessions

There are many barriers to adherence that may be present to various degrees, and may exist independently or in combination. Once an adherence problem is identified during the medication therapy review, it is important to work with the patient to determine the underlying cause(s) of the problem and develop appropriate interventions. For example, if a patient misses a large percentage of doses because he or she struggles to afford the medication, then providing the patient with a pillbox to organize the medication is unlikely to resolve the issue.

Interventions with action steps that are within the pharmacist's scope of practice can be offered directly to the patient and incorporated in the MAP. If the recommended intervention requires physician approval prior to initiating the change, the pharmacist may obtain the information necessary from the patient to develop a recommendation that will be communicated to the patient's physician.

In MTM sessions, the pharmacist should ask caring, open-ended questions to determine the factors that impede each patient's adherence, and to keep in mind that different factors may be present within the same patient. (For example, the patient may skip one medication because of cost, but not take another because of an adverse event.) In addition, it is best to work with patients to individually tailor solutions: patients are more likely to embrace a new plan of action if they are involved, to the best of their cognitive ability, in developing it.

Keep in mind the possibility that multiple medication-related problems may be identified during a medication therapy review. It may be confusing or overwhelming for the patient to attempt to completely resolve all problems within the context of a single MTM visit. Pharmacists should aim to prioritize the importance of each medication-related problem to the patient's health and outcomes, including consideration of the patient's perception of importance. Pharmacists can then work to address the most critical issues first, while postponing less critical issues for follow-up MTM visits. Ongoing monitoring and fine tuning of the treatment plan at follow-up visits is also important because adherence support will be an ongoing coaching activity.

Improving medication adherence often requires the pharmacist to encourage the patient to change his or her behavior. The transtheoretical model of behavior change may be applied to medication-taking behavior, possibly in conjunction with motivational interviewing. In the transtheoretical model, the patient's readiness to begin medication-taking behavior is categorized by stages of readiness: precontemplation, contemplation, preparation, action, or maintenance. Motivational interviewing involves the use of specific techniques designed to support the patient's intrinsic motivation to make healthful changes, thus empowering the patient.

In motivational interviewing, patients are encouraged to develop the motivation to make the change themselves, rather than being told what they must do by an authoritarian figure (i.e., the health care provider). Motivational interviewing may be an effective technique, but requires a substantial amount of training to perform correctly.⁹ However, with appropriate training, pharmacists can use motivational interviewing techniques to support medication adherence and promote the adoption of other healthful behaviors (e.g., tobacco cessation, exercise, healthful diet). Motivational interviewing is congruent with the goals of MTM—to make patients empowered consumers of health care.

Regardless of the causes of nonadherence and strategies initiated by the pharmacist during the MTM visit (either directly with the patient or in collaboration with other health care providers), pharmacists should inform prescribers when poor adherence is identified and work to support a team approach to address the patient's health care needs. If the patient has multiple prescribers, the pharmacist can help coordinate all of their prescribed regimens. In addition, patients should be encouraged to share their PMR with all of their health care providers.

Strategies to Address Specific Adherence Barriers

A review of common underlying causes of poor adherence and some suggested interventions are presented here. Table 2 summarizes a number of common barriers to adherence and potential strategies to address them.^{10,11}

Table 2. Strategies to Address Selected Barriers to Adherence

| Barrier to Adherence | Selected Strategies for Intervention | | | | | |
|--|--|--|--|--|--|--|
| Impaired vision | Use large print on written materials. Suggest that the patient use a magnifying glass to read medication labels. Provide a pillbox organizer with large type, color coding, or that "talks." | | | | | |
| Impaired hearing | Use written aids to support patient education interventions, and advise the patient to request written materials whenever possible. | | | | | |
| Impaired motor skills | Provide non-childproof medication bottles, if young children will not have access to the medications. | | | | | |
| Forgetfulness | Use an adherence aid (e.g., a pillbox), possibly in conjunction with a calendar for recording when medication is taken. Help the patient tailor the medication regimen to daily habits (e.g., placing medications next to a toothbrush or coffeemaker). Involve family members or other caregivers in supporting adherence. Provide regular refill reminders. | | | | | |
| Regimen complexity | Use an adherence aid. Pair medication use to specific activities. Provide prepackaged medication units, if possible. Review the regimen to determine whether there are any therapeutically appropriate options to simplify it. | | | | | |
| Multiple physicians | Instruct patient to share the personal medication record with all prescribing physicians. Advise the patient to obtain all medications from the same pharmacy. | | | | | |
| Adverse events | Determine if there are appropriate therapeutic alternatives. Develop strategies to manage the adverse event. Emphasize importance of medication to patient's health. | | | | | |
| Health literacy | Ask the patient to explain back information received to assess patient understanding and clarify any misunderstandings. | | | | | |
| Poor knowledge about medication use | Provide thorough education during the patient's medication therapy management visit. Frequently ask the patient to explain the information back to the pharmacist and clarify any misunderstandings. | | | | | |
| Psychological barriers | Provide referrals to other health care providers as needed. Direct patients to appropriate support groups. Encourage the patient to seek support from family and/or friends to help with medication adherence as well as other issues. | | | | | |
| Beliefs about medications | Assess the patient's beliefs so that misinformation can be identified and countered. Provide accurate information about both the medication's potential benefits and risks. Educate the patient about how the medication works to address the medical problem. | | | | | |
| Cost of medications | Direct the patient to medication assistance programs and/or other discount drug programs. Explore less expensive therapeutic options, if appropriate. Educate the patient about the importance of ensuring that he or she obtains medications from a reliable source to guard against the use of counterfeit or adulterated medications. | | | | | |
| Source: References 10 and 1 | _ | | | | | |

Source: References 10 and 11.

Forgetfulness

One of the most common reasons for poor adherence is forgetfulness. The likelihood that this problem will occur increases with increasing regimen complexity. In addition, patients with cognitive impairments may be more prone to confuse their medication schedules or forget them altogether. Pharmacists can employ multiple strategies to help patients remember their medications. One of the most common strategies is to recommend a pillbox organizer and assist the patient with selecting one. A variety of organizers are available in day, week, or month sizes, with optional features such as different compartments for multiple times of day, color coding, or alarms that sound when it is time for the next dose (Table 3). Such adherence aids may be particularly helpful if the patient has difficulty remembering whether a dose was taken.

Understandably, patients who use several medications, each with a different schedule, may be confused or overwhelmed by the complexity. To assist such patients, pharmacists can review the medication regimen to determine whether there are any options to simplify it. For example, if the patient is using a med-

Table 3.Examples of OnlineMerchants ofAdherence Aids

Adherence aids, such as pill organizers, electronic medication reminders, medication packaging supplies, and related accessories, are available from a variety of online sellers, including:

- www.epill.com
- www.forgettingthepill.com
- www.onnencompany.com
- www.rxsystems.com

ication that must be dosed three or four times daily, the pharmacist can assess whether a medication that has once or twice daily dosing could be appropriate or if the use of combination products is warranted, and then discuss such options with the patient's prescriber(s). Reviewing the patient's dosing schedule to see which medications can be taken concurrently also can simplify the regimen. Additionally, providing the patient with an adherence aid, such as a pillbox, may be helpful. As an added service, pharmacists can offer adherence packaging services, in which the adherence aid is filled at the pharmacy for a fee.

Health Literacy

Health literacy describes a patient's ability to comprehend and act upon health-related information. Low health literacy is very common in the United States, and may affect patients who have good general literacy. A beneficial strategy to address health literacy in MTM visits is to ask the patient to explain back the information they just received. This strategy allows the pharmacist to assess the patient's understanding of the information and immediately clarify any misunderstandings.

Access to Medications

Patients may have poor adherence as a result of problems obtaining the medications. Financial and logistical barriers may impede access. When difficulty affording medications is a concern, pharmacists can work with patients and their prescribers to determine eligibility for any medication assistance programs and/or determine whether there are appropriate treatment options with lower out-of-pocket costs for the patient. During the MTM visit, the pharmacist can include a review of information about the patient's insurance coverage and tiered co-pays to help assess whether the medications that the patient receives are both clinically appropriate and cost effective.

Pharmacists can work together with patients to brainstorm solutions to logistical barriers. For exam-

ple, patients who cannot drive to the pharmacy might be able to enroll in a delivery service or seek out community resources that offer rides.

Consider that patients may have physical impairments that create barriers to medication use. For example, a patient with poor eyesight may not be able to read the medication labels correctly, or a patient with arthritis may find it painful to open the bottle. Such patients may be helped by a pillbox organizer, particularly if it can be filled for the patient. For patients who have difficulty swallowing the medication, alternative dosage forms can be investigated, and/or the pharmacist can determine whether the medication can be mixed in with liquid or food.

Adverse Events

Adverse events often impede adherence to medications. Pharmacists should always assess whether patients have experienced adverse events during MTM visits, and review the patient's entire medication regimen with the goal of preventing the development of any future adverse reactions or drug interactions.

If patients experience adverse events that are affecting their adherence to prescribed medications, the pharmacist should contact the prescriber to discuss therapeutic alternatives and/or determine if an adjunctive therapy can ameliorate the adverse event. For example, if patients experience dry mouth as a side effect, the use of sugarless chewing gum, a salivary substitute, or other treatments may make the adverse event tolerable. In general, it is better to avoid treating an adverse event with another medication, but in some cases this may be necessary (e.g., the use of a laxative in patients receiving chronic opioid therapy). If continuance of the medication despite experiencing adverse events is essential to the patient's health (e.g., a course of antiviral therapy for hepatitis C), the patient should be educated about the long-term health benefits of the medication, and ongoing support should be provided.

Beliefs About Medication

A patient's beliefs and attitudes about medications and illness may have an important influence on adherence. Beliefs and attitudes are often complex and can vary among conditions and medications. For example, some patients may not grasp the seriousness of a chronic condition, some may have difficulty coming to terms with a diagnosis of a chronic disease and accepting the need to take daily medication, while others may be fatalistic about the diagnosis of a chronic disease and believe that they have no control over their health outcomes. Patients' understanding of illness may be influenced by many factors including health literacy and cultural beliefs.

Measuring the Impact of Adherence Interventions

The Pharmacy Quality Alliance (PQA) was established in 2006 in a collaborative effort by pharmacy associations, health insurers, physician and consumer groups, and government. PQA aims to develop a strategy for measuring the performance of pharmacists and pharmacies, and has already made substantial progress toward this goal. Adherence issues have been well-represented in PQA's initial starter set of quality measures.³ These measures provide disease-specific assessments of patient adherence and persistence based on pharmacy claims data. Such measures include the percentage of patients who took medication at least 80% of the time, as well as the percentage of medication users who had a gap in therapy of at least 30 days.

In the future, PQA plans to provide public reports of pharmacists' and pharmacies' performance on such measures. Additionally, these measures may be implemented into a variety of third-party payer programs, such as those used by the Centers for Medicare and Medicaid Services to evaluate Medicare Part D plan performance.

Performance on measures of adherence and other indicators of quality may eventually be used to inform a variety of decisions by patients, payers, and other stakeholders. It is likely that as our health care system aims to shift toward paying for quality rather than quantity, the use of such performance measures will continue to gain in importance for guiding health care purchasing decisions.

Although much work remains to be done before such a plan is implemented on a national scale, it remains likely that in the future, pharmacists' performance will be assessed according to quality measurement of patient care outcomes, of which adherence performance will be a component. Pharmacists who implement effective adherence interventions in medication therapy management services may perform better on such quality measures.

The pharmacist should attempt to gain an understanding of the patient's beliefs about medications during the MTM visit. Thoughtful, open-ended questions can lead to an honest discussion about the patient's beliefs about their medications and diseases, and can help guide the pharmacist's educational interventions.

If the patient does not understand the potential health benefits of the medication, providing educational interventions about the disease and the role of medication may help motivate the patient to use the medication correctly. On the other hand, if the patient is in denial about the seriousness of the medical condition, a discussion about what the illness means to the patient and personal feelings about it, along with provision of information about support groups and other resources, may be more productive.

Patients from different cultures may have very different beliefs about medications, and may not embrace the Western model of health care or trust the health care system. To support such patients, the pharmacist should seek to learn about their culture and beliefs and treat them with respect. Provide factual information about the current medical understanding of their condition and recommended treatment. Undergoing cultural competence training also may assist pharmacists in addressing adherence issues in patients with different belief systems.

Psychological Barriers

Although some psychological and behavioral issues may be too complex to address within an MTM

visit, pharmacists can help to identify the possible presence of such issues and refer the patient to other health care providers accordingly. Mental illness, such as depression, can negatively impact a patient's self-care behaviors including medication adherence. If the patient's resistance to medication usage appears to stem from such issues, the patient should be referred to his or her primary care physician or a mental health professional for further evaluation. The pharmacist can concurrently work to help brainstorm practical solutions to adherence problems, such as the provision of an adherence aid.

Case Vignettes

Case 1

P.L. is a 45-year old woman who was diagnosed with asthma 2 months ago. At the time of diagnosis, her asthma was classified as mild-persistent. Her primary care physician initially prescribed a low-dose inhaled corticosteroid and a short-acting β_2 -agonist. After 1 month of treatment, P.L.'s forced expiratory volume in the first second of expiration (FEV₁) and peak expiratory flow rate (PEFR) had not changed, and she was reporting frequent use of the short-acting β_2 -agonist. Her physician doubled the dosage of the inhaled corticosteroid. After another month of treatment, P.L.'s condition remained unchanged and her physician has referred her to you for a medication therapy review.

You perform a medication therapy review using the MTM core elements service model. P.L. has not had prescriptions filled at your pharmacy, so you do not have a record of her prescription history and must rely on the interview to gather information. P.L. reports no other medications (prescription, nonprescription, herbal products, or dietary supplements). P.L. is able to demonstrate appropriate administration techniques for both of her inhalers. Next, you ask her about the use of the inhaled corticosteroid.

Pharmacist: "How does this medication fit into your daily routine?"

P.L.: "I keep it on my bathroom sink, so that I can take it when I am getting ready in the morning, and then at night when I am getting ready for bed."

Pharmacist: "That sounds like a good strategy. Even with their medication in a prominent location, some patients report that they sometimes forget to take it. On average, how many times a week do you forget to take this medication?"

P.L.: "Well, I guess I don't really *forget* to take it, because I see it every day, but sometimes I don't take it because I'm not really comfortable using a steroid."

At this point, you have established that the patient is not adhering to her controller medication. You probe further and determine that the patient used the inhaler for a few days at first, but has rarely used it since then because of her fears about "steroids."

You spend several minutes educating P.L. about asthma and its treatment with both controller and rescue medications. You also explore how P.L. feels about her asthma diagnosis, and she reports that it was really a shock to her to have developed this condition in her forties. "I've always been so healthy, and I'm just not used to the idea of having to take medication every day now," she reports. You allow her to express her feelings, and acknowledge that it can take some time to adjust to the diagnosis of a chronic condition. P.L. indicates that she is looking for some support, and you provide her with contact information for a support group of asthma patients in your area.

Finally, you discuss the distinctions between corticosteroids and the "steroids" that are often discussed in the media, and explain that inhaled corticosteroids primarily act in the lungs, minimizing the systemic risks. You provide her with a copy of her PMR and MAP with the action steps for her to follow. P.L. thanks you for this information, and agrees to return in 2 months for a follow-up visit. After documenting the visit, you provide a written summary of the visit to P.L.'s primary care physician.

When P.L. returns for her follow-up visit, she reports greatly improved adherence. "I'm not perfect," she admits, "I sometimes miss doses on the weekends when my schedule is different and I'm out with friends, but during the week I hardly ever miss a dose," she reports. She also indicates that her PEFR is improved based on at-home readings, and she now uses the short-acting β_2 -agonist only about once a week.

You compliment her on her progress, and affirm that she has made an important step toward controlling her asthma. You also help her brainstorm strategies to remember the medication on the weekend. She suggests that she could take the medication before going out, rather than waiting until bedtime, and you support this strategy.

At the conclusion of the visit, you document P.L.'s progress and provide her with an updated MAP listing her revised action steps. In your communication to her physician, you also recommend a trial of a lower dosage of the inhaled corticosteroid, because the higher dosage may no longer be necessary now that the improved adherence has brought her asthma under control. P.L. schedules a follow-up visit in 3 months to assess her progress.

Case 2

M.B. is a 62-year-old man who currently takes nine medications (seven prescriptions, one nonprescription, and one dietary supplement) to manage multiple chronic conditions. The presence of his multiple chronic conditions makes him eligible for MTM services through a new program from his insurer, and he schedules a comprehensive medication therapy review. His daughter, A.B., attends the MTM visit with him.

During the medication therapy review, you ask M.B. open-ended questions to learn about his use of each of these products. However, he has difficulty distinguishing among his medications, and confuses his multiple dosage schedules. A review of his medication refill history indicates an inconsistent pattern, with different medications being refilled at varying frequencies. A.B. appears mildly distressed and frustrated with her father's inability to manage his medications. She explains that she works full-time and has two children living at home, and is able to visit her father only during the weekends. Her father is otherwise generally able to care for himself and remain in the community.

Based on this information, you conclude that the patient's primary barrier to adherence is forgetfulness and confusion about his complex regimen. You assist M.B. and A.B. in the selection of a weekly adherence aid—a pillbox that has separate compartments for morning and evening doses for each day of the week. You discuss the usage of the adherence aid, and support M.B. through the process of filling the pillbox with his medications. M.B. and A.B. agree that he will fill the pillbox during A.B.'s weekly visits to help ensure that he fills it correctly at home.

You provide M.B. with a copy of his PMR and MAP, and schedule a follow-up visit in 1 month. After documenting the visit, you provide a written summary of the visit to M.B.'s primary care provider and other prescribing physicians.

When M.B. returns a month later, accompanied by A.B., he reports that the pillbox has been very beneficial in helping him organize and manage his medications, and he now rarely forgets to take his medications nor mixes up different products. A.B. reports that she now feels much more comfortable about M.B.'s health care and ability to care for himself.

Conclusion

MTM encounters provide excellent opportunities for pharmacists to identify and address problems with medications, including poor adherence. Patients may struggle with medication adherence for a number of reasons. When suboptimal adherence is identified, pharmacists should work with the patient to identify its cause(s) and develop a strategy to improve adherence. Adherence interventions must be customized to meet each individual patient's needs. Ultimately, as in all MTM strategies and interventions, the key to any adherence intervention is to empower self-treating patients to more fully engage in their health care and take responsibility for the self-management of their medications.

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CE Assessment Questions

Instructions: For each question, circle the letter corresponding to the correct answer on the CE Examination Form. **Please review all of your answers to be sure you have marked the proper letter.** There is only one correct answer to each question.

1. In adherence terminology, persistence refers to:

- a. Whether a patient is on time for appointments.b. The number of times each day that a patient must take
- medication.
- c. A patient's long-term adherence to a medication.
- d. Placing follow-up phone calls to support patient adherence.

2. One meta-analysis found that the most effective format for addressing adherence issues is:

- a. Postcards reminding patients of the importance of medication use.
- b. Monthly phone calls from a centralized location.
- c. Group meetings.
- d. One-to-one counseling interactions.

3. An important change in version 2.0 of the core elements MTM service model is:

- a. The addition of a sixth core element.
- b. Revisions to make patient documents more patient-friendly.
- c. An increased focus on patients in community pharmacies.
- d. Recommended revisions to the definition of MTM services.

4. The Morisky scale is used to identify:

- a. The likelihood that a patient is nonadherent to medications.b. The likelihood that a patient is nonadherent to lifestyle modifications.
- c. The percentage of medication doses that a patient misses.d. The underlying reasons why patients are nonadherent to medications.

5. When discussing adherence during an MTM visit, a good open-ended question to ask might be:

- a. Do you follow the doctor's orders when taking this medication?
- b. Do you ever forget to take this medication?
- c. Approximately how many times this past week have you missed a dose of this medication?
- d. Can you explain this medication to me?

6. When developing a plan of action to address a patient's adherence problem, it is important to:

- a. Involve the patient in the process.
- b. Consult with the patient's prescriber(s) before discussing the issue with the patient.
- c. Work with the patient to address all medication therapy problems during the first MTM visit.
- d. Ensure that all patients have a pillbox to organize their medications.

A good strategy to address health literacy problems that contribute to poor adherence is to:

- a. Provide written materials that have large type.
- b. Avoid the use of written material and provide all education verbally.
- c. Assess comprehension by asking the patient to explain the information provided in his or her own words.
- d. Recommend that the patient take classes to learn to read.

8. Which of the following statements is true?

- a. Medication adherence can effectively be supported with a single annual medication therapy review.
- b. Mental illness, such as depression, may negatively impact a patient's self-care behaviors.
- c. Motivational interviewing is a simple technique to learn that requires minimal training.
- Pharmacists should not provide documentation to the patient's prescribers unless therapeutic changes are recommended.
- 9. The Pharmacy Quality Alliance's initial set of quality measures:
 - a. Focus on ensuring 100% adherence to medications.
 - b. Assess quality using results of patient satisfaction surveys.
 - c. Address both medication adherence and persistence.d. Were developed in accordance with regulations from the
 - d. Were developed in accordance with regulations from the Centers for Medicare and Medicaid Services.

In the case vignette about P.L., one of this patient's primary barriers to adherence was: a. The cost of her medication.

- b. Confusion about a complex regimen.
- c. Physical impairment that interfered with inhaler use.
- d. Fear of adverse events.

CE Credit

To obtain 1.0 hour of continuing education credit (0.1 CEU) for "Medication Therapy Management Services: Identifying and Addressing Medication Adherence Issues," complete the assessment exercise, fill out the CE Examination Form at the end of this publication, and return that page to APhA. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before June 1, 2011, can receive credit.



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CE ASSESSMENT QUESTIONS-ANSWERS

| 1. | а | b | С | d | 4 |
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| 2. | а | b | С | d | 5 |
| 3. | а | b | С | d | 6 |

PARTICIPANT INFORMATION

| NAME | | |
|------------|-------|-----|
| | | |
| ADDRESS | | |
| | | |
| CITY | STATE | ZIP |
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 10. a b c d

 8. a b c d
 9. a b c d

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| PLEASE ANSWER EACH QUESTION. | ELLENT | r | | | | POOR |
|--|-----------|--------------------|---------|---------|-----------|---------------------|
| 1. Overall quality of the program | 5 | 4 | 3 | | 2 | 1 |
| 2. The program was relevant to pharmacy practice | 5 | 4 | 3 | | 2 | 1 |
| 3. Value of the content | 5 | 4 | 3 | | 2 | 1 |
| | | | | | | |
| PLEASE ANSWER EACH QUESTION MARKING WHETHER YOU AGREE OR DISAGREE. 4. The program met the stated learning objectives: | | | | | Agree | Disagree |
| Explain the medication therapy review process, as described in version 2.0 of the core elements | service m | nodel of | | | | |
| medication therapy management (MTM). | | | | | | |
| Describe effective strategies for identifying patients with suspected adherence problems. | | | | | | |
| Explain the role of the Pharmacy Quality Alliance adherence quality measures. | | | | | | |
| Discuss the appropriate use of selected adherence screening tools in MTM and overall patient c | are. | | | | | |
| Identify common causes of poor adherence and develop strategies for addressing adherence pro | blems in | diverse patient po | pulati | ons. | | |
| 5. The program increased my knowledge in the subject area. | | | | | | |
| 6. The program did not promote a particular product or company. | | | | | | |
| Impact of the Activity The information presented (check all that apply): | | | | | | |
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| 7. □ Reinforced my current practice/treatment habits □ Will improve my practice/patient outcome □ Enhances my current knowledge base | s 🖬 Pr | UVIDED HEW IDEAS | | JIIIAII | UNTEXPECT | เบ นระ |
| 8. Will the information presented cause you to make any changes in your practice? | | 🗅 Yes | | | 🗆 No | |
| 9. How committed are you to making these changes? | (V | 'ery committed) 5 | 4 | 3 | 2 1 (No | t at all committed) |
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Migraine-preventive medications: Ensuring their appropriate use

Richard G. Wenzel

Abstract

Objectives: To emphasize the magnitude and burden of migraine, the need for greater use of migraine-preventive medications in patients who could most benefit from them, and the role that pharmacists can play in migraine prevention.

Data sources: PubMed and Medline-based literature searches were conducted to determine the need for migraine-preventive medications, the treatment of migraine, and how pharmacists can assist patients in preventing and treating migraines. The literature search included articles from the previous 6 years, as well as earlier articles for historical perspective.

Data synthesis: Migraine is a prevalent, chronic, neurologic condition that imposes substantial disability on affected patients, leading to a poor quality of life. However, migraine remains underrecognized, underdiagnosed, and under- or suboptimally treated. In particular, migraine-preventive medications are greatly underused, which contributes to avoidable disability. Community pharmacists can play important roles in identifying these and other patients with headache who are in need of medical care, referring appropriate patients to a health care provider, and educating and counseling patients with respect to abortive and preventive medications.

Conclusion: Pharmacists are in a unique position to assist in migraine management, particularly with regard to migraine-preventive medications, because many patients may not be familiar with the benefits and use of these agents. Pharmacist involvement can have a measurable effect on patient care and improve the lives of migraine patients.

Keywords: Migraines, pharmacists, preventive medicine, headaches, quality of life, neurology, beta blockers, antidepressant medications.

Pharmacy Today. 2008(Aug);14(8):34-51.

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Disclosure: The author declares no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Acknowledgments: To Chris Conner, PharmD, Phase Five Communications, Inc., for editorial support.

Funding: Ortho-McNeil Neurologics.

Published concurrently in *Pharmacy Today* and the *Journal of the American Pharmacists Association* (available online at www.japha.org).

Learning objectives

- State migraine's prevalence and the percentage of sufferers prescribed migraine-preventive agents.
- Discuss migraine's impact on individuals in terms of decreased quality of life and reduced work productivity.
- List at least three barriers that prevent patients from recognizing migraine.
- Describe at least three opportunities for pharmacists to improve the diagnosis and treatment of migraine.
- State the goals of migraine-preventive therapy.
- Describe at least three key counseling points for patients prescribed migraine-preventive therapy.

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November 14, 2008 34 PHARMACY TODAY • AUGUST 2008 Page 817 www.pharmacytoday.org eadache is a common medical condition that causes patients to seek the assistance of a pharmacist.¹ Community pharmacists can, therefore, assume an important role, especially with respect to migraine medications. They are in a unique position to help patients in need of acute or preventive therapy and to counsel patients on their expectations and the appropriate use of medications. Recent studies also support the value of pharmacistrelated consultation regarding headache,^{2,3} and agreement exists regarding pharmacists contributing to migraine management.^{1,4–7} Similarly, evidence suggests a need to further educate pharmacists in the area of migraine.⁶

Migraine is a chronic, recurrent, and often debilitating neurologic condition that exacts a substantial toll on a patient's quality of life.^{8–10} In addition to the pain of an actual migraine attack, many patients with migraine worry about the next attack and how it may disrupt their life. Knowing that a migraine could

At a Glance

Synopsis: Although migraine is a common neurologic condition that exacts a considerable negative impact on patient quality of life, the disorder remains underrecognized, -diagnosed, and -treated. Migraine patients experience the pain and disruption of the migraine attack and anxiety regarding their next attack (the interictal period), which can result in a continuous cycle of suffering. Studies show that 40% to 60% of migraine patients should be on preventive medication, yet migraine-preventive medications are underused. Migraine-preventive agents can reduce headache frequency and severity, lessen disability, improve quality of life, and enhance the response to acute treatment medications.

Analysis: Pharmacists have an important opportunity to improve the poor diagnosis rate for migraine by identifying diagnosed patients who are in need of preventive therapy, referring appropriate patients for preventive consideration, and educating and counseling patients receiving preventive therapies on their proper and safe use. By dispelling misconceptions and informing patients of the availability of effective migraine treatments, pharmacists can facilitate more patients seeking effective care and adhering to prescribed regimens. Patient outcomes could also be improved by raising health care providers' awareness regarding migraine symptoms and diagnostic and treatment guidelines. Preventing migraine attacks is critically important to patients, and unrealistic expectations can lead to nonadherence and treatment failure. Therefore, reinforcing realistic expectations with the patient is paramount.

occur at any moment can be as disruptive as the acute attack itself. The clinical literature on the impact of migraine suggests that this "cycle of migraine" is often underemphasized or unappreciated by health care providers.

The worry between attacks (the interictal period) is evident in the recent nationwide Harris Survey of migraine patients,¹¹ in which 68% of patients polled indicated that they were concerned about their next migraine attack, even when not actively experiencing one. One-half of patients indicated constant concern about another migraine attack, and one-third of patients were always anxious, never knowing when or if another attack would disable them.

Although most migraine patients are currently taking some form of medication for acute attacks, few are receiving specific preventive therapy.^{12,13} Studies evaluating patterns of migraine prevention have concluded that migraine-preventive medications are greatly underused.^{10,13,14} The role of preventive therapy needs to be reassessed because many patients who could benefit from preventive medications are not receiving them^{10,14}; this is particularly true for patients whose disability impacts their daily life considerably.¹²

Objectives

The goal of this review is to highlight the need for greater recognition and use of migraine-preventive medications, to refresh the pharmacist's knowledge of migraine, and to illustrate the important role that pharmacists can play in migraine prevention.

Data sources

Literature searches were conducted in PubMed and Medline. Subject areas researched included migraine epidemiology and treatment, the use of preventive therapy, the role of the pharmacist in determining the need for migraine-preventive medications, and how pharmacists can assist patients in preventing and treating migraines. The literature search included articles from the previous 6 years, as well as earlier articles for historical perspective. Search terms included, but were not limited to, *migraine and pharmacist(s)*; *epidemiology; counseling patients; prevention: pharmacist(s) identifying patients; recognizing migraine;* and *patient communication.*

Magnitude and burden of migraine Steady numbers

In 1999, the prevalence of migraine in the United States was reported in the American Migraine Study (AMS) II as approximately 18% in women and 6% in men, with an overall prevalence rate of 13%.^{8.9} An earlier AMS conducted in 1989¹⁵ showed almost identical results, suggesting that the prevalence of migraine has remained constant. Additional data showed that at least one person with migraine resides in nearly one in four U.S. households and that the peak prevalence of migraine occurs in individuals

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aged 25 to 55 years.8

Disability: Substantial and pervasive

Migraine has been identified as 1 of the top 20 causes of disability worldwide.16 Migraine-related functional impairment can extend into every aspect of day-to-day living, disrupting work, family activities, and social relationships and activities.9.17-22 This has a substantial negative impact on health-related quality of life (HRQoL).7,13,20,23

Considerable disability in patients with migraine was reported in AMS II, with 91% of patients reporting functional impairment in association with headaches.⁹ Despite the greater preponderance of migraine in women, the frequency of severe disability was similar in men and women: 49% of men and 53% of women reported severe impairment in activities or needed bed rest because of their headaches. During the 3-month period before the survey was taken, 31% of all patients reported missing at least 1 day of school or work as a result of a migraine and 51% reported that their productivity at school or work was reduced by at least 50%; in addition, more than one-half indicated that they had missed family activities or social activities and were either unable to do household work or were less productive at household work. Work or school activities were disrupted less often than family/social activities or household work.

This level of disability was mirrored in the Migraine and Zolmitriptan Evaluation (MAZE) surveys, which evaluated the impact of migraine on a global level (United States, Canada, Europe, and other countries).19.24 These survey results also revealed a considerable negative impact on the home and family life of about onehalf of the individuals who lived with or were related to a patient with migraine. This latter finding is important because it highlights that migraine also places a burden on household partners and close family members of the individual with migraine. This has been shown in other studies in which patients with migraine and their partners were adversely affected.^{17,18} Less time was spent together, communication difficulties arose, and more arguments occurred. An additional component of emotional stress or even inadequacy was evident in individuals with migraine, with about 50% agreeing with the assertion, "If I didn't have a headache, I would be a better spouse."

Methods to measure disability and functional status in migraine include the Migraine Disability Assessment Scale (MIDAS) questionnaire and the Headache Impact Test (HIT). These instruments are being used more frequently in conjunction with migraine management strategies to improve communication between patients and health care providers. They can be used to assess the severity of migraine and its impact on daily life, assist in determining the most appropriate initial treatment, and assess response to treatment.7.25-27 MIDAS consists of five questions to determine headache impact during the previous 3 months, while HIT consists of six questions designed to assess the effects of headache on normal life and ability to function. HIT-6 is available

online and in a brief paper version at www.headachetest.com/ HIT6translations.html.

Most experience to date has been with MIDAS, which categorizes scores into four grades of severity: I, minimal or no disability; II, mild or infrequent disability; III, moderate disability; and IV, severe disability.^{7,27} The MIDAS questionnaire is also available online at www.achenet.org/tools/migraine/index.asp.

HRQoL: Important to patients

Improving HRQoL has become an important goal of treating chronic conditions. HRQoL questionnaires incorporating personal impact variables, such as functional status (e.g., ability to carry out daily activities), social functioning, and general wellbeing, as well as clinical symptoms, are now routinely used in clinical trials and daily practice. HRQoL questionnaires used in clinical studies involving migraine patients have been shown to be reliable and valid.²⁰ However, these questionnaires do not specifically measure the interictal burden in patients with migraine.

Using the Short Form 36 questionnaire, which measures eight aspects of HRQoL, Osterhaus et al.²⁸ showed that the restriction of daily activities and pain were significantly greater in those with migraine compared with those of patients with depression, osteoarthritis, diabetes, and hypertension. Mental health and social functioning were also significantly poorer in the migraine group relative to all of these other groups, except for patients with depression.

Deficiencies in migraine care

Despite its high prevalence and associated disability, migraine remains underrecognized and its management suboptimal.7.24,29 About one-half of patients with migraine remain undiagnosed or misdiagnosed and consequently remain undertreated.9,30 However, specific guidelines for diagnosis and treatment and effective acute and preventive treatment modalities are readily available. Most patients with migraine use only over-the-counter (OTC) medications for their headaches,³⁰ and most are unsatisfied with their current treatment.24 At least one-half of patients stop taking their prescribed medications or stop seeking medical care.^{12,24} Many migraine patients do not seek care at all (see "Patient perceptions: Barriers to care" section below).

A major deficiency is that only a handful of patients with migraine who could benefit from preventive therapy are receiving it (12%–13%), suggesting that migraine-preventive medications have been underemphasized in the medical community and among the public at large.^{10,12–14,31,32} Greater recognition of the value of preventive medications and ensuring their appropriate use are in themselves unmet goals.

Patterns of preventive treatment in the United States were analyzed by the American Migraine Prevalence and Prevention study.13 Individuals with migraine were identified from a questionnaire sent to 120,000 households representative of the U.S. population. Most people with migraine were using acute



treatments for their headache (OTC or prescription), but only 13% were using migraine-preventive medications; an additional 25% had discontinued preventive therapy. Among those in most need of preventive agents (e.g., three or more migraine days per month with severe impairment or needing bed rest), only 23% were receiving them. When this group of individuals was combined with those for whom migraine-preventive therapy should be considered (e.g., 2 migraine days per month with some or severe impairment), only one in five (19.6%) were currently receiving a preventive medication. Among those who had never used preventive agents, approximately one-third were considered candidates for them. This study strongly suggests that identifying candidates for migraine-preventive medications can improve headache outcomes.

What is needed

Greater understanding of migraine and preventive therapy by the patient and the health care provider could alleviate its underdiagnosis and -treatment.^{29,33} Educating patients on migraines would raise awareness, dispel misconceptions, and teach ways of recognizing migraines. Informing patients of the availability of effective treatments may result in more patients seeking effective care and adhering to prescribed regimens. Raising the awareness of health care providers about migraine symptoms and diagnostic and treatment guidelines could also help improve patient outcomes. A charge to health care practitioners is to reach patients who are unaware that they have migraine or who have lapsed from care.^{24,30}

Pathophysiology and clinical picture

Understanding that migraine is primarily a disorder of the brain,^{27,34} and not solely a vascular process,^{35,36} is important. Today, migraine is viewed as a heritable neurologic disorder involving the trigeminovascular system and the modulation of pain-producing structures of the brain.³⁴ Central neuronal hyper-excitability is considered an important predisposing factor for migraine, which may be related to calcium channel abnormalities.^{27,34,36,37} Environmental triggers can initiate neurochemical changes that progress to a critical threshold, and this threshold is lower in individuals with migraine. Once the threshold is reached, cortical spreading depression (CSD)—a slowly propagating wave of neuronal depolarization—occurs^{34,38}; CSD ultimately results in activation of the trigeminovascular system, release of vasoactive peptides from trigeminal afferents, and a sterile neurogenic inflammation, which is the likely cause of headache pain.^{34,35,37}

Alteration of the midbrain serotonergic system is also evident in migraine, and impaired serotonin (5HT) release may serve as an important precursor.^{36,39} Vascular changes such as dilation or constriction of intracranial arteries are an epiphenomenon to underlying neurologic processes and not a primary cause of headache.^{27,35,39}

Patients sense this complex, spreading inflammatory process

as it builds over hours or days. At the onset of this sensation, patients report that acute therapy has shown most benefit if taken "to catch it right away."³⁵ Preventive medications offer hope of taking this one step further by eliminating onset altogether.

Clinical course

Acute attacks. Migraine can be subdivided into three phases: an initial prodrome, the headache attack, and a postdrome.33.39 The prodromal period may last several hours or even 1 to 2 days, with typical symptoms of mood changes, irritability, yawning, fatigue, photophobia (light aversion), phonophobia (noise aversion), thirst, polyuria, and/or hunger. The ensuing headache itself may vary in duration from 4 to 72 hours, with most patients describing pulsatile or throbbing pain, which is frequently unilateral and exacerbated by activity.^{9,20,27,39} Phonophobia, photophobia, nausea with or without vomiting, numbness, and skin pallor may also accompany headaches. Aura, a visual phenomenon, occurs in 15% to 20% of patients with migraine and can either precede and/or accompany the headache. Generally lasting less than 20 minutes, visual symptoms (e.g., bright or sparkling light, tunnel vision) may also be accompanied by paresthesias, vertigo, speech disturbances, confusion, and/or weakness.20,27,33 After the headache, patients experience a postdrome, or recovery, phase that typically lasts about 25 hours⁴⁰ and is accompanied by symptoms of tiredness and low-grade headache.

The frequency of headaches may range from once in a lifetime to several each month³⁹; the median is 1.5 per month, and 10% of patients experience weekly attacks.¹⁵ Of participants in AMS II, 62% indicated that they experienced a severe migraine headache at least once per month, 37% reported the occurrence of 1 to 3 severe headaches per month, and 11% suffered a severe headache once weekly.⁹ Surprisingly, migraine may be more likely to occur in some patients during periods of relaxation, such as on weekends or during vacations.³⁹

Interictal phase and cycle of migraine. Pain and suffering for the migraine patient does not end when the acute attack subsides. For many patients, emotional disability persists in the period between headaches—the interictal phase. This disability is separate from migraine-related functional impairment but is linked directly to it. A population survey revealed that 40% of patients with migraine were worried about the occurrence of a headache at a future social or other event, and almost one-half were worried about driving.³² In further studies evaluating interictal well-being, considerably greater emotional distress was reported by patients with migraine compared with those without migraine; they exhibited a lower level of activity and disturbances in sleep, vitality, and contentment.^{21,41} A migraine cycle, consisting of headaches followed by an interictal period, is then formed.

Anticipation of disruption is at the core of the migraine cycle (Figure 1). In addition to fear of the pain of the next attack,^{20,42} patients worry about where they will be when the next attack occurs and what could happen when it does. They worry about

Go to www.pharmacist.com and take your test online for instant credit. Page 820 AUGUST 2008 • PHARMACY TODAY 37 how the next one will affect others who are close to them, such as family, friends, and particularly children,^{8,19,20,22,43} and how it will impact their own work and social obligations.^{8,20} These patients thus enter into a constant cycle of suffering, treating acute attacks and worrying about the consequences of the next attack. This is an important aspect of assessing migraine impairment that may often go unrecognized.

Patient perceptions: Barriers to care

Patient perceptions of migraine and its treatment are important because they further highlight deficiencies and clarify areas in which education efforts should be directed. The MAZE I and II studies²⁴ and a large Canadian population survey³² highlight important aspects of patients' perceptions of migraine. Most patients

- Did not believe they had migraine ("It's only a headache"; suggests inability to recognize migraine).
- Felt OTC medications worked just fine for them (unaware of more effective treatments).
- Believed a health care provider and prescriptions would not be able to do anything for them (low expectations).
- Had an unsatisfactory experience with or disliked a previous health care provider.
- Thought their headaches were not severe enough to seek help.

Many patients considered themselves self-medicators and felt

that they could treat their headaches with OTC products, or they stopped prescribed medications because of adverse events, lack of efficacy, lack of trust, cost, or rumors about dangers of medications. Most patients (90%) felt migraine was a more serious disorder than others realized and hoped for more public awareness. Only 22% of patients felt migraine did not significantly affect their lives. However, only 27% felt their medication consistently helped them through a headache attack and only 36% were very satisfied with current treatment, which is suggestive of undertreatment. The majority surveyed (65%) perceived that not enough was being done for them. No survey to date has measured patient perceptions about the potential usefulness or efficacy of migraine-preventive medications or their need.

Pharmacists and migraine: Overall roles

Pharmacists can offer great assistance to both patients and clinicians by educating, counseling, and referring patients with headache.^{1.2.7.44,45} The role of the pharmacist is largely dependent on the diagnostic status of the patient (Table 1). Another way of considering the roles of pharmacists is to assess how the pharmacist may affect the underrecognition and -diagnosis of migraine.

Affecting underrecognition and -diagnosis

Upon screening the patient with the MIDAS or HIT, the pharmacist should refer the patient to a health care practitioner for diagnosis and treatment when appropriate. The pharmacist should educate

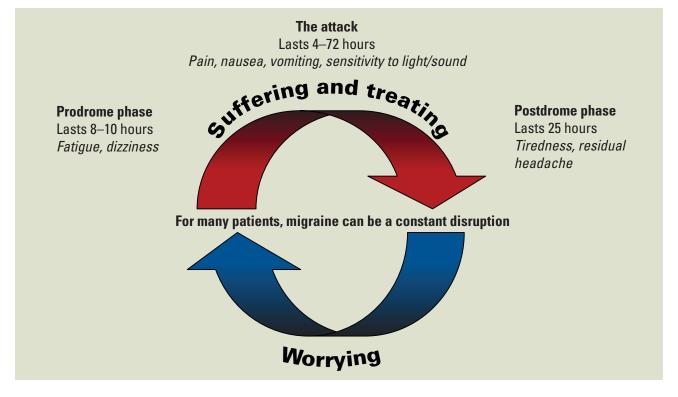


Figure 1. The cycle of migraine creates enormous emotional distress.

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| Table 1. Overall roles of the pharmacist in migraine man | nanagement |
|--|------------|
|--|------------|

| Patient type | Role | Activities ^{1,35,50} |
|---|--------------------------------|--|
| All patients with migraine | Education | Dispel myths and misconceptions about migraine, increase patient knowledge about migraine headache. |
| Patients with undiag- nosed headache | ldentification and referral | Recognizing and referring patients with suspected migraine to a physician. Referral indicated when (1) obvious signs of migraine on questioning (aura; pulsating, throbbing symptoms) are present; (2) headache is recurrent, episodic, and debilitating; (3) MIDAS grade III or IV. Chronic headache or no headache relief despite adequate OTC therapy. |
| | Education | Benefits of referral and efficacy of acute and preventive migraine treatments. |
| | Counseling | Selection and proper use of OTC medications in patients not in need of referral (e.g., MIDAS grade I or II). |
| Patients with self-con- sidered, undiagnosed migraine | ldentification and referral | Confirm migrainous nature via questioning (obvious signs; recurrent debilitating headache); once self-considered status realized, refer- ral to physician for accurate diagnosis and treatment. |
| | Education | Benefits of referral and accurate diagnosis; efficacy of acute and preventive treatments; hazards of overuse of OTC agents such as exacerbation of headache. |
| Diagnosed patients | ldentification and referral | Identify and refer patients who could benefit from preventive medi- cations: (1) specific questions (a pharmacy headache question- naire), (2) MIDAS or HIT. |
| | Counseling | Proper and safe use of acute or preventive medications after they are prescribed. |

Abbreviations used: HIT, Headache Impact Test; MIDAS, Migraine Disability Assessment Scale; OTC, over the counter.

the patient about the appropriate use of OTC medications and their associated risks and benefits. At this time, the pharmacist can reassure the patient that if he or she has migraine headache, medications can be taken to prevent and treat them and that both types of medications can be taken concomitantly.

The undiagnosed headache patient who may have migraine can be identified in the following ways:

- Discussing patient's headache characteristics and making appropriate referrals (Table 1).
- Using questionnaires such as MIDAS or HIT that are amenable to use in pharmacies.^{1.7} In particular, MIDAS has been suggested for use as a quick screening vehicle to distinguish patients who are in need of health care practitioner referral and diagnosis.¹ A MIDAS score of I or II suggests that nonspecific (OTC) headache therapy would be acceptable; a score of III or IV strongly suggests the need for health care practitioner referral and specific prescription headache therapy.¹

Similarly, pharmacists can refer the undiagnosed, selfconsidered migraine patient who is in need of health care practitioner diagnosis and treatment. Migraine usually can be confirmed with a simple question such as, "Why do you think you have migraine?" Pharmacists should educate these patients about the need for an accurate diagnosis to either confirm or rule out migraine (e.g., they may have tension headaches), as well as the short- and long-term benefits (and risks) of acute and preventive therapies.

For patients already diagnosed with migraine who are receiving acute treatment medications, pharmacists can identify those who would likely benefit from preventive therapy.

Affecting undertreatment and suboptimal treatment

Appropriate referral of undiagnosed patients to a primary health care practitioner will hopefully lead to effective acute or preventive treatment regimens. Identifying the diagnosed patient in need of preventive therapy may help detect those patients who would benefit from preventive therapy.

The role of the community pharmacist after diagnosis and instituting treatment with medications also includes further education and counseling of patients on the most appropriate

Go to www.pharmacist.com and take your test online for instant credit. Page 822 AUGUST 2008 • PHARMACY TODAY 39 and safest use of those medications.

Pharmacists and acute migraine treatment

Pharmacists are well positioned to educate and counsel patients on acute migraine therapies. Although the emphasis of this review is the pharmacist's role in ensuring appropriate referral of patients in need of underused migraine-preventive medications and ensuring the appropriate use of these medications, Table 1 also reflects involvement of the pharmacist in acute treatment of headache, which is equally as important.

In addition to identifying patients who appear to be candidates for prescription-abortive therapy, the pharmacist should counsel patients on the proper use of acute treatments. This might include administration technique, maximal doses, expected benefit, onset and duration of action, potential adverse events and how to deal with them, and precautions or contraindications. In general, if patients confirm that one-half or more of their headaches result in some sort of disability (e.g., need to rest, absence from work), they are unsuitable candidates for acute-treatment OTC medications.⁴⁵ The occurrence of vomiting during headaches or headache occurring more than 15 days per month also disfavors use of OTC products, as these patients are likely already overusing OTC products.⁴⁵ These particular patients may be in need of prescription medication for acute attacks or possibly preventive medications.

Pharmacists and migraine prevention

Pharmacist-assisted referral of undiagnosed headache patients and self-considered migraine patients to a health care provider (Table 1) can help to identify patients who could benefit from preventive therapy and make them aware of medications that were previously unknown or unavailable to them. The community pharmacist can ensure the optimal use of such medications by counseling patients on the use of preventive medications once they are prescribed and offering reassurance to these patients about what to expect in terms of efficacy and adverse events and how to manage such events if they occur. The pharmacist could have a great impact in these areas. In particular, prevention of a migraine attack is of immense importance to the migraine patient, and unrealistic expectations can lead to nonadherence and treatment failure.¹⁰ Discussing realistic expectations with the patient is paramount.

Before engaging in these activities, pharmacists may initially require some reeducation about preventive medications.^{6,35}

Current concepts in migraine prevention

Goals and benefits of prevention. The goals of preventive therapy include^{10,12,46,47} the following:

- Reduced frequency (50% from baseline is the goal) and duration of headaches.
- Reduced severity of headaches.
- Improved response to acute treatment.
- Reduced disability, functional impairment, and absence from

usual activities (e.g., reduced MIDAS score).

- Improved HRQoL.
- Decreased use and cost of acute treatments.
- Reduced likelihood of progression to chronic daily headache.
- Decreased use of the health care system.

When should preventive therapy be used? The timing of migraine-preventive therapy has been a controversial issue. Recommendations range from "when headaches are severe, frequent, and incapacitating"¹⁰ to "patient preference."¹² Ultimately, the patient should decide whether preventive therapy is prescribed after health care provider consultation and consideration of benefits and risks, potential sequelae of prolonged high frequency of headaches, and factors other than headache frequency. Some of the recommended indications for preventive medications advanced by authoritative sources are shown in Table 2.^{10,12,46,48–50}

As a general rule, preventive therapy should be considered for patients whose disability affects their lives considerably. Patients experiencing interictal worry and substantial disruption of their lives certainly represent patients who should be considered for preventive medication.

Is earlier preventive action better? The practice of withholding migraine-preventive medications until the disease and its disability become severe or incapacitating has also come under scrutiny; several lines of evidence now suggest that earlier, more aggressive preventive measures could benefit many patients and that it might be detrimental if such measures are not implemented.¹⁰ The reasons for this include the following: (1) clinical experience suggests that prolonged psychosocial impairment in patients with migraine may be less likely with preventive intervention; (2) reducing migraine frequency and severity with earlier preventive therapy may reduce the chance of escalation (transformation) to a more chronic and refractory form of migraine, although this remains controversial; (3) some evidence suggests that repeated episodes of migraine may lead to permanent central nervous system structural changes and neuronal injury that may be attenuated by early use of preventive medications; and (4) the longer migraine is left untreated, the more difficult it may be to inhibit attacks with preventive medications.10,51

Identifyng and referring diagnosed patients

Caveat. Referring patients with migraine for consideration of preventive therapy should be limited to those who are diagnosed and are receiving medications (OTC or prescription) and/or no pharmacologic therapy for acute migraine treatment. Referring undiagnosed patients for preventive medications, even though they might clearly benefit from them, could be viewed as interference with the health care provider–patient relationship. For the undiagnosed headache patient, referral is primarily to ensure health system access, accurate diagnosis, and treatment.

Factors to remember. Most patients have difficulty discuss-

ing medications with their health care providers. Traditionally, pharmacists have been the custodians of this information. Many patients may have been doing well on acute therapy when they last saw their regular health care provider but are no longer doing well, missing follow-up appointments, or lapsing from care for various reasons. Thus, their health care providers may not know that they are now in need of a preventive agent, and patients may be reluctant to return for various reasons. Knowledge gained from the pharmacist that preventive therapy might help considerably could persuade patients to return to their health care providers. These examples alone tend to support the need for identification and referral for preventive therapies.

Some patients with migraine will initiate the discussion of preventive medications with the pharmacist and ask if they may be candidates. Conversely, the pharmacist may

- Observe certain elements such as acute medication overuse (frequent refills of triptans or purchase of OTC products with the acute treatment prescription) (Table 3).
- Sense a potential need for preventive medications through tell-tale comments by the patient, such as, "These drugs just aren't doing any good."
- Ask a question to reveal patient satisfaction: "How are these medications working for you?" This is perhaps the most effec-

Table 2. When migraine-preventive medications areindicated $^{10,12,46,48-50}$

- Recurrent migraine headaches that, in the opinion of the patient, interfere with daily routines considerably, despite optimal use of acute treatments
- Two or more headaches per month that produce disability lasting longer than 3 days
- Use of acute (abortive) treatments more than two days per week
- Acute attacks that produce profound disability or prolonged aura
- Headache-related disability that occurs 3 or more days per month
- Frequent headaches (e.g., more than twice weekly) or a pattern of increasing attacks over time (e.g., over a period of 3–6 months)
- Duration of migraine greater than 48 hours
- Overuse or likely overuse of acute therapies
- Failure of acute therapies
- Adverse effects with or contraindications to acute therapies
- Patient preference for preventive therapy
- Uncommon migraine conditions such as hemiplegic migraine or migraine with prolonged aura

tive initiator.

Work in a pharmacy that has notified local health care providers of its identification service and routinely ask patients if they feel they might benefit from a preventive medication.

Evidence of potential need from these scenarios would prompt the pharmacist to suggest a quick verbal or written interview to determine whether the patient may in fact be a candidate for preventive medications, adding that it may result in referral for that purpose. Methods for this interview include assessing disability through a series of specific questions asked by the pharmacist or use of MIDAS or HIT questionnaires.^{17,25,29,52}

Specific questions pharmacists should ask. The following questions can quickly reveal the effects of migraine and its level of disruption for the patient already receiving prescribed acute treatment,^{25,33,45,53} with responses either favoring or not favoring the use of preventive medications:

- How frequently do you experience headache?
- How does migraine affect your daily life, including your work, family, and social life?
- How do your migraines affect your life in between attacks?
- How do you feel when having a migraine, and how do you feel between attacks?
- Has your headache pattern changed in the past 6 months?
- How often do you use medications to treat acute headache, and are they effective?

Patients responding to these questions with even one criterion outlined in Table 2 are not doing well with acute therapies alone and should be considered for referral. Pharmacies are encouraged to prepare the above questions on a sheet of paper (e.g., a pharmacy headache questionnaire), whereby the questions may be asked orally, with pharmacist notations, or the patient may respond with written answers. Additionally, the MIDAS and HIT questionnaires are easy to use, and the patient could fill out one of the questionnaires while waiting for a prescription. If a referral is suggested, the pharmacist should explain the benefits of the referral and offer to provide follow-up counseling regarding proper use of the preventive agent.

The final and most important step before referral is the patient's willingness or desire for it. In most instances, the referral itself would be passive, in that patients would present the pharmacy headache questionnaire to their health care provider, suggesting they would like to discuss the possible use of a preventive medication. On rare occasions, the pharmacist could contact the health care provider to indicate the patient's desire for preventive medications and to inform the health care provider that the patient may be a candidate based on headache questionnaire at the time of the referral appointment.

Alternatively, patients unwilling or unable to return to their health care providers could contact the National Headache Foundation online (www.headaches.org) or via phone (888-NHF-5552) for a state-by-state listing of headache specialists, one of whom

Go to www.pharmacist.com and take your test online for instant credit. Page 824 AUGUST 2008 • PHARMACY TODAY 41 would serve as the referral target. A similar service is provided by the American Headache Society (www.achenet.org).

Counseling patients on the use of preventive medications

To provide meaningful patient counseling on using preventive medications, pharmacists must remain up to date on preventive modalities and become familiar with practice guidelines.

Migraine-preventive medications. Preventive agents currently approved by the U.S. Food and Drug Administration (FDA) are divalproex sodium (Depakote, Depakote ER-Abbott), topiramate (Topamax—Ortho-McNeil-Janssen), and the beta-blockers timolol and propranolol. Although divalproex and topiramate are anticonvulsants, they are more properly termed neurostabilizers when used for migraine prophylaxis.⁵⁰ Analysis of clinical studies reveals that the efficacy of these drugs is generally similar, and any one can be considered first-line therapy for migraine prophylaxis. Topiramate has been the most widely studied among these agents. Although not FDA approved, amitriptyline has also shown consistent efficacy as a migraine-preventive medication; some also recommend this agent in the category of first-line therapy.^{48,54} A capsulized, literature-based, quick-reference look at these five agents, which are considered the most effective migraine-preventive medications, is presented in Table $4.^{10,12,37,46,48,49,55-59}$

Many other preventive medications from various pharmacologic classes have shown variable efficacy. Some of these are bupropion, cyproheptadine, fluoxetine, gabapentin, ibuprofen, magnesium, methylergonovine, methysergide, naproxen, nortriptyline, phenelzine, riboflavin, sertraline, verapamil, and venlafaxine. The angiotensin II receptor blocker candesartan and the angiotensin-converting enzyme inhibitor lisinopril demonstrated prophylactic benefits in randomized studies.³⁷ Previously approved by FDA as a preventive medication, the 5HT receptor blocker methysergide lost this status in 2003 because of the risk of retroperitoneal fibrosis.

Botulinum toxin type A (Botox—Allergan) is emerging as a candidate for migraine prophylaxis. Several recent studies have demonstrated the efficacy of this agent, with minimal or no toxicity.^{54,60}

Some aspects of commonly used preventive medications that may also be useful during counseling are summarized in Table $5.^{10.12,37.46,48,49,55.59}$

Counseling guidelines. Studies have shown that patients with chronic conditions have problems when starting new medication; many quickly become nonadherent for various reasons, have concerns and worries, and are in need of information.⁶¹ The pharmacist should serve as a conduit for counseling and educating patients with migraine in these areas; education alone may improve HRQoL.⁶²

Pharmacists should have rapid access to drug information to counsel patients. Some useful sources to have at hand are current editions of USP DI: Drug Information for the Health Pro*fessional* and *Drug Facts and Comparisons*. Patients have also indicated that information leaflets on the medications, if available, are useful.⁶³

Some areas to address during patient consultation that will have a positive impact are as follows:

- Goals and benefits of migraine-preventive therapy: Confidence in the medication is bolstered when the patients are aware of the goals of preventive therapy.
- How the medication works: Many patients with migraine want to know how migraines occur and how medications work.⁶⁴ This can be as simple as, "It reduces the excitability in the brain," or more complex, as indicated in Table 5.
- Expectations: Unrealistic expectations of preventive therapy can lead to frustration, nonadherence, perceived treatment failure, and lapse from medical care.^{10,65,66} Although the benchmark goal of treatment is a 50% reduction in headache frequency, patients should be informed that their response may range from 20% to 50%^{10,65} and that 10% or less of patients are actually free of headache episodes while receiving preventive medications.¹⁰ Patients should not expect an immediate response to preventive medications. Achieving full preventive effects may take 2 to 3 months.
- Appropriate dose and need for dose titration: The patient should be informed that incorrect dosage may lead to treatment failure^{10,66} or more adverse events and that self-adjustment of dose in an attempt to increase effectiveness must be avoided. The patient must be made aware that (1) target or optimal doses for preventive medications (Table 5) may vary depending on response; (2) dose titration is important—too

 Table 3. Medication-overuse headache versus

 rebound headache48

Medication-overuse headache

- Frequent use of acute treatments can result in increased headache frequency and possibly daily headaches.
- Migraine-preventive medications should be considered in patients with suspected drug overuse or at risk for overuse.

Rebound headache

- Associated with withdrawal of analgesics or abortive migraine medication.
- No clear consensus exists regarding which agents cause rebound headache. Generally, evidence points to triptans, opioids, ergotamine (not dihydroergotamine), and analgesics containing butalbital, caffeine, or isometheptene. The causal role of other antimigraine agents is even less clear.

rapid an increase can lead to poor tolerability and too slow an increase may result in a poor clinical response, which can lead to nonadherence⁴⁹; (3) the normal titration schedule may also be altered by the health care provider to accommodate the best response; and (4) target doses are usually reached in 4 to 6 weeks,⁴⁹ but again, this may vary.

- Take-home message: Adhere to the prescribed dose and dose-titration schedule. Unless in a prearranged setting with clinician approval and preestablished guidelines, the pharmacist should not recommend doses different than those prescribed, even if the dose prescribed seems incorrect. If concern exists, the pharmacist should contact the health care provider directly.
- Proper administration: Migraine-preventive medications are taken differently than medications for acute treatment. Patients should understand that preventive drugs are most effective when taken on a regular basis.

- Duration of trial therapy: The patient must be aware of the duration of treatment required before efficacy or maximal benefit is apparent. For most preventive medications, a trial period of 8 to 12 weeks is considered necessary to assess efficacy.^{10,65}
- Importance of adherence: Some key ways to enhance adherence include counseling about realistic expectations, adverse effects, and the duration of treatment required before improvement is seen.^{10,65}
- Need for acute therapy: Patients should be told that they could still need their acute therapy should breakthrough attacks occur.
- Adverse events, cautions, and drug–drug interactions: Concerns about adverse events have been shown to affect medication adherence considerably in patients with migraine.⁶⁷
 (1) Adverse events, cautions, and interactions should be discussed, emphasizing the most common complications

Table 4. Most effective migraine-preventive medications: Clinical data capsulized

Topiramate

- This anticonvulsant demonstrated significant efficacy in randomized controlled studies, with preventive effects often evident in the first month of treatment.^{10,37,55,56} The optimal maintenance dose is 100 mg/day.
- Collective data from several studies suggest a reduction in headache frequency by at least 50% in about one-half of patients receiving 100 mg/day.¹⁰
- More evidence supports the efficacy of amitriptyline compared with any other antidepressant.^{12,37,46} However, nor-triptyline, doxepin, and protriptyline have also been proven effective.
- Cross-comparison of clinical studies indicates that the efficacy of topiramate is similar to that of other preventive medications; however, studies with topiramate have involved larger numbers of patients with superior study design. This suggests use of topiramate as an agent of choice for migraine prophylaxis.⁵⁶
- Amitriptyline
- Several randomized studies have reported a significant reduction in headache frequency or headache index (a combination of headache frequency plus intensity and/or duration) with amitriptyline 30–150 mg/day versus placebo.^{12,48}
- Compared with propranolol, amitriptyline has been less effective in patients with migraine alone but has been significantly superior to propranolol in patients with mixed migraine and tension-type headache.¹²
- Amitriptyline has particular usefulness in patients with comorbid major depression.

Propranolol and timolol

- Beta blockers are the most frequently used preventive medications. Propranolol and timolol particularly are consistently effective in reducing headache frequency.^{12,57} The efficacy of propranolol has been similar to that of divalproex in patients without aura.¹²
- These two beta blockers have particular usefulness in migraine patients with comorbid hypertension, anxiety, or panic attacks.³⁷
- In contrast with these agents, beta blockers with intrinsic sympathomimetic activity such as acebutolol have no activity as migraine-preventive medications.^{10,48}

Divalproex

- Divalproex has shown consistent efficacy in reducing the frequency of headache in clinical studies; migraine frequency has been reduced by up to 27% relative to baseline.^{10,12,58,59}
- A dose-response relationship is seen with divalproex over the range of 500-1,500 mg/day.49
- Sodium valproate has also shown efficacy for migraine prophylaxis.³⁷ Both divalproex and valproate are logical choices for patients with comorbid seizure disorder, mania, and anxiety.

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| Preventive | Mechanism ^a | Target dose and titration49 |
|------------------------|---|---|
| Amitriptyline | Antinociceptive restoration, downregu- lates 5HT ₂ receptors, other mecha- nisms hypothesized | 50 mg/day (begin with 10 mg at bedtime, increase by 10 mg/week) |
| Divalproex | Modulates neural/cortical excitability, increases GABA activity, reduces sen- sitization of trigeminal nerve | 1,000 mg/day (begin with 250 mg twice daily, titrate by 250 mg/week; for ER form, start at 500 mg/day, increase to 1,000 mg/day after 1 week) |
| Magnesium gluconate | May restore a deficiency in brain mag- nesium in migraine; many other puta- tive mechanisms | 800 mg/day (begin with 400 mg/day, increase to 800 mg/day within 1 week) |
| Naproxen sodium | Antinociceptive activity; inhibits prosta- glandin synthesis | 550 mg twice daily (dose titration guidelines lacking) |
| Nortriptyline | Antinociceptive activity, downregulates 5HT ₂ receptors; other mechanisms hypothesized | 50 mg/day (begin with 10 mg at bedtime, titrate by 10 mg/week) |
| Propranolol | Reduces central excitability; antagonism of 5HT _{1B} , 5HT _{2B} receptors; inhibits NE release | 120–160 mg/day (begin with 40 mg/day divided doses, increase by 40 mg/week) |
| Riboflavin | Unclear; may affect mitochondrial func- tion (electron transport chain) | 400 mg (begin at target dose, 200 mg at bedtime) |
| Topiramate | Modulates neural/cortical excitability, blocks voltage-dependent sodium channels, potentiates GABA | 100 mg/day (begin with 25 mg/day, titrate by 25 mg/week in divided doses) |
| Venlafaxine (ER) | Unclear | ER 75–150 mg/day (begin with 37.5 mg/day, increase to 75 mg/day after 1 week, then increase by 75 mg/week based on response) |
| Verapamil | Inhibits neuronal NO synthase, blocks hyperalgesia, calcium-blocking effects reduce sensitization of central pain pathways | 240—480 mg/day (begin with 40 mg twice daily, titrate up by 40 mg/week; for ER form, begin with 160 mg/day, increase to 240 mg/day in 1 week) |

Table 5. Counseling sheet for some commonly used migraine-preventive medications^{10,12,37,46,48,49,55,58}

Abbreviations used: 5HT, serotonin; CHF, congestive heart failure; ER, extended release; GABA, gamma-aminobutyric acid; GI, gastrointestinal; ISA, intrinsic sympathomimetic activity; NE, norepinephrine; NO, nitric oxide.

^aMechanisms of most migraine-preventive medications are unknown; entries here are speculations based on what is currently known about migraine pathophysiology.

to be expected. (2) Methods to avoid these complications should be provided, if known. (3) Dose titration can minimize many adverse events and should be emphasized. (4) Specific preventive medications can be given to minimize specific adverse events of particular concern to patients.⁴⁹ (5) A quick check for relative or absolute contraindications is also in order because these may have been overlooked in a busy health care provider's office.

- Migraine triggers: The importance of the patient's headache diary for identifying specific triggers for each patient should be emphasized.
- Patient questions: Patients want to know that they can confide in someone for information on medications. The ability to ask

questions freely can remove some burden from the concerned patient. This will build patient confidence and is a deterrent to nonadherence. A simple statement such as, "Please feel free to ask me anything further about the medication or your migraine," from the pharmacist is encouraged.

Reassurance. Offering reassurance to the patient receiving a migraine-preventive medication is perhaps one of the most important roles of the pharmacist. Many patients need reassurance; they want to know what is wrong with them and how it can be fixed.⁶⁸

In particular, shifting out of a clinical discussion and into a discussion of the daily worries of the patient can contribute greatly to improving adherence and a better preventive outcome.

Adverse effects/precautions

- Drowsiness, dizziness, anticholinergic symptoms, weight gain, orthostatic hypotension. Less frequent or rare: tremors, dysrhythmias, photosensitivity. Avoid if comorbid mania
- Nausea, diarrhea, abdominal pain, somnolence, tremor, weight gain, alopecia. Less frequent or rare: hepatic enzyme elevations or overt hepatotoxicity, pancreatitis, thrombocytopenia
- Nausea; vomiting; diarrhea. Less frequent or rare: hypermagnesemia with prolonged or high doses, mainly in renal impairment (weakness, mental changes, dysrhythmias) Nausea, abdominal pain, constipation, dizziness. Less frequent or
- rare: vomiting, GI bleeding, peptic ulcer disease, hypersensitivity (e.g., bronchospasm), hepatotoxicity, nephrotoxicity
- Drowsiness, anticholinergic symptoms, weight gain, orthostatic hypotension. Less frequent or rare: agitation, tremors, dysrhythmias, photosensitivity. Avoid if comorbid mania
- Fatigue, depression, nausea, dizziness, insomnia. Less frequent or rare: depression, bradycardia, hypotension, CHF. Avoid if comorbid asthma, CHF, Raynaud's, or depression None significant
- Fatigue, somnolence, paresthesias, nausea, anorexia, weight loss, memory problems. Less frequent or rare: metabolic acidosis (obtain pretherapy bicarbonate level), renal calculi
- Nausea, somnolence, dry mouth, headache, insomnia, dizziness. Less frequent or rare: anxiety, tremor, male sexual dysfunction, hypertension
- Dizziness, flushing, edema, constipation. Less frequent or rare: peripheral edema, bradycardia, hypotension, CHF. Avoid if comorbid hypotensive condition or severe constipation

Comorbidity also treated/comments

- Depression, anxiety, pain. Well-documented consistent efficacy
- Epilepsy, bipolar disorder, anxiety. ER form preferred by many patients
- None. Moderate efficacy in clinical trials; some conflicting data
- Arthritis or other nonheadache pain conditions. Moderate efficacy
- Depression, anxiety, pain. Studied less extensively than amitriptyline as a preventive
- Hypertension, angina, anxiety, panic attacks. Timolol also effective; beta blockers with ISA ineffective
- None. Efficacy documented in randomized trial; an attractive option for use in pregnancy Epilepsy. The most well-studied migraine-preventive agent
- Depression. Preventive doses lower than usual antidepressant doses
- Hypertension, angina, asthma. Reasonable alternative to beta blockers in athletes or patients with coexistent hypertension and pulmonary disease

An overwhelming concern to the patient may be resolved by a simple comment from the pharmacist. For example, those experiencing the migraine cycle who see no hope of improving this constant disruption should be reassured that preventive medications will in all likelihood have some benefit by reducing the frequency and severity of attacks, disability, and absence from usual activities.⁴⁷ Reassurance, however, must still be tempered by realistic expectations.

Sensitivity is important to the patient, not only when a diagnosis is given⁶⁹ but also during counseling.⁷⁰ Similar to the benefits derived from patient education, the concern and sensitivity of the pharmacist in understanding the impact of migraine on a patient's life may alone lend itself to improving perceived HRQoL.⁷⁰

The pharmacist should also reassure the patient that he/she will be available for further questions that the patient may have about migraine prevention.

Communication techniques. Migraine is not diagnosed via objective data but by patient-reported symptoms. Thus, good communication is paramount.⁷¹ Yet patients are often unable to express concerns and fears about their headaches.⁷¹ This may lead to misunderstandings that can compromise the quality of care,⁷² including inappropriate treatment or even misdiagnosis.

Effective communication between the pharmacist and patient is also essential. Giving patients an opportunity to respond to questions without restriction, in order to gain a clear understanding of a patient's level of disability, is impera-

Go to www.pharmacist.com and take your test online for instant credit. Page 828 AUGUST 2008 • PHARMACY TODAY 45 tive. This also helps the patient who wants to be understood.⁷² Pharmacists must also be clear when providing counseling to avoid misinterpretations or lack of understanding on the part of patients that could compromise the success and safety of preventive therapy. An effort should be made to choose words that patients might recognize easily (e.g., effectiveness instead of efficacy). Clarification should also be sought (e.g., "How well have I explained your instructions?").

Results derived from the American Migraine Communication Study (AMCS) suggested that health care providers were often unaware of the degree of impairment in their patients with migraine, which is critical to appropriate prescribing of preventive medications.⁵³ This was related to a lack of communication techniques that were known to improve patient care outcomes. To facilitate improved communication, AMCS recommended the following:

- Using open-ended questions to ascertain migraine disability during and between attacks. Several open-ended questions are used in the pharmacy headache questionnaire described earlier.
- Using ask/tell/ask strategies. An example is asking patients what they know about migraine, then *telling* patients what they need to know (tailoring this to what patients have said), and then asking patients if they have further questions or foresee any problems adhering to what was recommended.
- Medications should be explained beyond referral to a drug class. For example, explain that divalproex and topiramate are migraine-preventive medications and antiepileptics and that amitriptyline is a preventive agent and an antidepressant drug. In the context of migraine-preventive medications, patients find drug-class descriptions confusing and misleading.

Conclusion

Migraine is a common disorder that imposes considerable pain and disability on patients; however, it remains underrecognized, -diagnosed, and -treated. The migraine cycle, which involves both the pain and disruption of the migraine attack and interictal worry, greatly affects patients' daily lives and emotional states. The interictal burden is often overlooked by health care providers, who may not consider the total disruption during and between migraine attacks.

Migraine-preventive medications are underused. Studies show that 40% to 60% of migraine patients should be on preventive medication. Migraine-preventive agents can reduce headache frequency and severity, lessen disability, improve quality of life, and enhance response to acute treatment medications.

The unmet needs in migraine may be at least partially addressed by involving the pharmacist in migraine management. The pharmacist can improve the poor diagnosis rate by referring undiagnosed headache patients with suspected migraine to a health care provider. They can identify diagnosed patients who are in need of preventive therapy, refer appropriate patients for preventive consideration, and educate and counsel patients receiving preventive therapies on their proper and safe use. Pharmacists are encouraged to become involved in migraine management because they can have a great impact on patient care.

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Assessment Questions

Instructions: You may take the assessment test for this program on paper or online. For each question, circle the letter on the answer sheet corresponding to the answer you select as being the correct one. There is only one correct answer to each question. **Please review all your answers to be sure that you have circled the proper letters.** To take the CE test for this article online, go to www.pharmacist.com and click Education. Once you are on the Education welcome page, search for this article with the search function, using "CE" and a keyword. Follow the online instructions to take and submit the assessment test. This CE will be available online at www.pharmacist.com after August 31, 2008. You can also find it on www.pharmacytoday.org.

- 1. Women are approximately how many times more likely to have migraine than men?
 - a. 2
 - b. 3
 - c. 4
 - d. 5
- 2. According to American Migraine Study II, approximately what percent of migraine sufferers report substantial debilitation with their attacks?
 - a. 2 of 10
 - b. 4 of 10
 - c. 7 of 10
 - d. 9 of 10
- 3. Assuming the population of the United States is 300 million people, approximately how many individuals suffer from migraine?
 - a. 50,000
 - b. 1 million
 - c. 15 million
 - d. 39 million

4. How many migraine sufferers are undiagnosed or misdiagnosed?

- a. 10%
- b. Approximately 50%
- c. 2 million
- d. 20%
- 5. Historically, migraine was viewed as a vascular disorder. Current data illustrate that migraine is primarily a
 - a. Nephrology disorder.
 - b. Peripheral vascular disorder.
 - c. Neurologic disorder.
 - d. None of the above alternatives are correct.

6. Goals for migraine-preventive drug therapy include

- a. Reducing attack frequency, duration, and severity.
- b. Ensuring patients take a drug daily.
- c. Creating a pharmacist-patient relationship.
- d. Improving cerebral circulation.
- 7. A biological marker useful for the diagnosis of migraine is
 - a. Magnetic resonance imaging.
 - b. Serum serotonin levels.
 - c. Currently no biological marker exists for migraine.
 - d. Computed tomography scans.

CE Credit:

To obtain 2.0 contact hours of continuing education credit (0.2 CEUs) for "Migraine-preventive medications: Ensuring their appropriate use," complete the assessment exercise, fill out the CE examination form at the end of this article, and return to APhA. You can also go to www.pharmacist.com and take your test online for instant credit. CE processing is free for APhA members and \$15 for nonmembers. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before August 1, 2011, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is 202-000-08-152-H01-P.

"Migraine-preventive medications: Ensuring their appropriate use" is a home-study continuing education program for pharmacists developed by the American Pharmacists Association.



Go to www.pharmacist.com and take your test online for instant credit.

November 14, 2008 48 PHARMACY TODAY • AUGUST 2008 Questions 8 to 14 refer to the following case: L.W., a 26-year-old women with "bad headaches that put me on the couch," seeks your advice. Upon questioning, she reports, "I get an attack every week or two, I'm always worried when the next one will strike." She reports that lately she frequently "misses work, much to the dismay of my boss. I'm so busy, don't exercise anymore, and live off of coffee. Plus, I recently got engaged and my future mother-in-law is driving me crazy about the wedding plans." L.W. says, "I pop ibuprofen all day long, even though it seems futile, yet I still keep taking more and more of it because I do not known what else to do."

8. Which of the following is correct?

- a. If L.W. increases her dose of ibuprofen, she may obtain relief.
- b. L.W. should try aspirin because it has proven more effective than ibuprofen.
- c. Given her attack frequency and considerable worry between attacks, L.W. is a candidate for migrainepreventive therapy.
- d. L.W. should be prescribed an antiemetic, as this could improve her response to ibuprofen.

9. Why is L.W. a candidate for migraine-preventive drug therapy?

- a. Her bothersome mother-in-law.
- b. The significant expense of ibuprofen.
- c. Her migraine attacks are disrupting her life.
- d. Poor response to an over-the-counter (OTC) product.

10. The best way in which you can help L.W. find a physician knowledgeable about headache treatment is

- a. Suggesting an Internet search.
- b. Suggesting the National Headache Foundation (www. headaches.org) or the American Headache Society (www.achenet.org).
- c. Pharmacists should not refer patients to physicians.
- d. Encouraging her to look in a local phone book.

- 11. Based on your recommendation, L.W. schedules an appointment with a physician, who diagnoses her with migraine without aura and prescribes both acute and preventive medications. Your counseling should include which of the following items:
 - a. Educating the patient about the need to consume her preventive drugs daily.
 - b. Educating the patient about incorporating healthy lifestyle activities.
 - c. Educating her that the preventive medications may require several weeks to reach full effect.
 - d. All of the above alternatives are correct.
- 12. L.W.'s physician calls you to ask which medications are currently approved by the Food and Drug Administration for migraine prevention. Your answer includes the following:
 - a. Divalproex sodium, atenolol, nortriptyline
 - b. Divalproex sodium, topiramate, propranolol
 - c. Propranolol, timolol, zonisamide
 - d. Topiramate, amitriptyline, butalbital/acetaminophen/ caffeine (Fioricet—Watson)

13. The best mechanism for L.W. (and all patients) to identify factors that may contribute to her migraine attacks is

- a. Consistently completing headache diary information.
- b. Internet search of the term *migraine triggers*.
- c. Routine pharmacy visits.
- d. Routine appointments at their physician's office.
- 14. Counseling L.W. (and all patients) about her preventive medications is best achieved by
 - a. Using open-ended questions.
 - b. Using tape recordings.
 - c. The pharmacist simply telling the patient about their drug.
 - d. All of the above alternatives are correct.

- 15. Withholding migraine-preventive medications until the attacks are severe or incapacitating may not be optimal drug treatment because
 - a. Preventive medications may reduce psychosocial impairment.
 - b. Reducing migraine frequency/severity may reduce the change of disease escalation.
 - c. Repeated migraine attacks may lead to permanent central nervous system changes.
 - d. All of the above alternatives are correct.

16. All of the following are opportunities for pharmacists to assist migraine patients except

- a. Identifying people who may benefit from preventive therapy.
- b. Identifying patients overusing acute agents.
- c. Identifying managed care plan patients.
- d. Identifying undiagnosed or misdiagnosed migraine sufferers.

17. According to the World Health Organization, migraine

- is
- a. One of the top 20 causes of disability worldwide.
- b. A predominantly European illness.
- c. Uncommon in third-world countries.
- d. Most common in Asian cultures.

18. The peak prevalence of migraine is among

- a. Men 25-55 years of age.
- b. Women older than 55 years.
- c. Women 25-55 years of age.
- d. Women 40-45 years of age.
- **19.** Emotional debilitation may persist between migraine attacks, which is known as the
 - a. Let-down phase.
 - b. Interictal phase.
 - c. Resting phase.
 - d. Pain-free phase.
- 20. Reasons patients may not seek help for migraine include all of the following except
 - a. They do not believe that they have migraine.
 - b. They believe that OTC agents worked just fine.
 - c. They do not know what migraine-specific medications are available.
 - d. Excess counseling fees charged by pharmacists.

CE EXAMINATION FORM

Migraine-preventive medications: Ensuring their appropriate use

To receive **2.0** contact hours of continuing education credit **(0.2 CEU)**, please provide the following information:

- 1. Type or print your name and address in the spaces provided.
- 2. Mail this completed form for scoring to: American Pharmacists Association—CE Exam P.O. Box 791082 Baltimore, MD 21279-1082
- 3. CE processing is free for APhA members. If you are not an APhA member, please enclose a \$15 handling fee for grading the assessment instrument and issuing the Statement of Credit.

A Statement of Credit will be awarded for a passing grade of 70% or better. If you fail the exam, you may retake it once. If you do not pass the second time, you may no longer participate in this continuing pharmacy education program. Please allow 6 weeks for processing. Pharmacists who complete this exercise successfully before **August 1, 2011**, may receive credit.



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|------------|-------|-----|
| | | |
| ADDRESS | | |
| | | |
| CITY | STATE | ZIP |
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| E-MAIL | | |
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| HOME PHONE | | |
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How long did it take you to read the program and complete this test?

____Hours ____ Minutes

My signature certifies that I have independently taken this CE examination:

CE ASSESSMENT QUESTIONS—ANSWERS Please circle your answers (one answer per question). 1. 6. abcd abcd 11. abcd 16. abcd 2. abcd 7. abcd 12. abcd 17. abcd 3. abcd 8. a b c d 13. abcd 18. abcd 4. abcd 9. a b c d 14. abcd 19. abcd 5. abcd 10. abcd 15. abcd 20. abcd

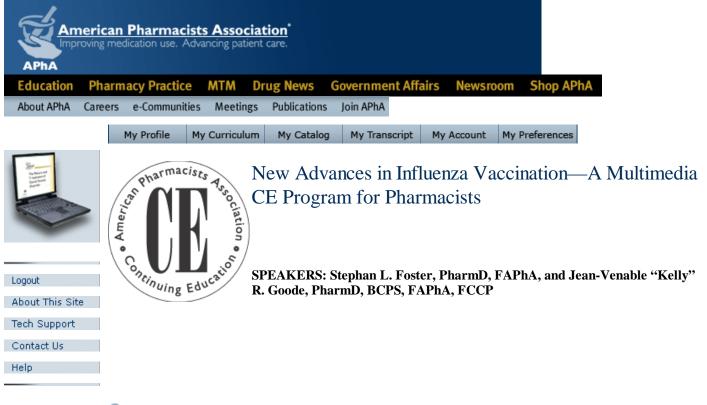
PROGRAM EVALUATION

| | EXCELLENT | | | | | POOR |
|---|-----------------------------|-----------------|---------------|------------|-------|-----------------|
| PLEASE RATE THE FOLLOWING ITEMS. | | | | | | |
| 1. Overall quality of the program | 5 | 4 | 3 | | 2 | 1 |
| 2. Relevance to pharmacy practice | 5 | 4 | 3 | | 2 | 1 |
| 3. Value of the content | 5 | 4 | 3 | | 2 | 1 |
| PLEASE ANSWER EACH QUESTION, MARKIN | IG WHETHER YOU AGRE | E OR DISAGR | EE. | | | |
| 4. The program met the stated learning objectives: | | | | | Agree | Disagree |
| After reading this CE article, the pharmacist sh | ould be able to: | | | | | |
| State migraine's prevalence and the percentag | | • • | | | | |
| Discuss migraine's impact on individuals in terr | | | work produc | tivity. | | |
| List at least three barriers that prevent patients | s from recognizing migraine | | | | | |
| Describe at least three opportunities for pharm | | osis and treatm | ent of migrai | ne. | | |
| State the goals of migraine-preventive therapy | | | | | | |
| Describe at least three key counseling points for | | aine-preventive | therapy. | | | |
| 5. The program increased my knowledge in the sub | | | | | | |
| 6. The program did not promote a particular produc | ct or company. | | | | | |
| IMPACT OF THE ACTIVITY | | | | | | |
| The information presented (check all that apply): | | | | | | |
| | oits 📮 Will impr | ove my practice | /patient outc | omes | | |
| 7. 🖵 Reinforced my current practice/treatment hab | | | | | | |
| A Reinforced my current practice/treatment hab Provided new ideas or information I expect to | use 🗳 Adds to r | ny knowledge | | | | |
| Provided new ideas or information I expect to | | , 0 | | 🖵 Yes | 🖵 No | |
| | e any changes in your prac | , 0 | 3 | 🖵 Yes 2 | | t all committed |

FOLLOW-UP

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Are you willing to participate in such a survey?

🖵 Yes 🛛 🖵 No



Program Description

According to the Centers for Disease Control and Prevention, influenza affects 5% to 20% of Americans each year. More than 200,000 people are hospitalized from flu complications, and about 36,000 people die. Although antiviral therapy can reduce the severity and shorten the duration of illness, experts agree that it is far better to *prevent* influenza than to treat it.

Annual immunization against influenza is recognized as the single most effective method for preventing influenza and its associated complications. In years when there is a good match between the influenza vaccine and circulating viruses, vaccination prevents illness in up to 90% of healthy adults. Unfortunately, controversies and misconceptions surrounding influenza vaccines cause many people to forego immunization.

Pharmacists who are knowledgeable about vaccine design, production, and distribution can play an important role in dispelling common misunderstandings. "New Advances in Influenza Vaccination" is designed to increase pharmacists' knowledge by reviewing the prevention, diagnosis, and treatment of seasonal influenza and providing in-depth information about influenza vaccines.

Learning Objectives

At the conclusion of this program, pharmacists will be able to:

- 1. Discuss the epidemiology, etiology, and pathophysiology of influenza.
- 2. Detail the diagnosis and classification and risk factors of influenza.
- 3. Summarize the manufacturing process of vaccine production and highlight new advances in production technology.
- 4. Counsel patients and caregivers on the current strategies for the prevention of influenza including the nondrug and drug therapy options.
- 5. Identify the patient criteria for specific product selection.

"New Advances in Influenza Vaccination—A Multimedia CE Program for Pharmacists" This program was developed by the American Pharmacists Association and supported through an independent educational grant from MedImmune. To obtain 2 hours of continuing education credit (0.2 CEUs) for completing **"New Advances in Influenza Vaccination—A Multimedia CE Program for Pharmacists,"** complete the assessment exercise and posttest. A Statement of Credit will be automatically generated upon achieving a passing grade of 70% or better.

APhA continuing education policy provides you with two opportunities to successfully complete this continuing education examination. Please note that you will not be permitted to submit the examination a third time.

The Statement of Credit should be printed upon receipt; a duplicate copy will be available in the participant's transcript for further viewing. Individuals completing this program by September 30, 2011, can receive credit.



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APhA

ACPE Universal Program Number: 202-000-08-154-H01-P.

ACPE Activity Type: Application-Based

Speakers



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Disclosures

Stephan L. Foster, PharmD, FAPhA, has served on the speaker's bureau for Merck Vaccine and Sanofi Vaccine.

Jean-Venable "Kelly" R. Goode, PharmD, BCPS, FAPhA, FCCP, has served on APhA's Immunization Advisory Board and is a grant recipient from the APhA Foundation.

APhA's editorial staff declares no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Activity Fee

The CE processing fee for grading the assessment instrument and issuing the Statement of Credit is supported by an independent educational grant from MedImmune.

System Requirements

PC

Windows 2000 or greater Flash Player Plug-in (9.0 or later) <u>Check my Flash version</u> Internet Explorer 5.5 or greater Firefox *Sound Card & Speakers 800 x 600 Minimum Monitor Resolution (1024 x 768 Recommended) **Adobe Acrobat Reader <u>Click here to download</u> MAC Mac OS 10.2.8 Flash Plug-in Player 7.0.1.9 <u>Check my Flash version</u> Safari Firefox *Sound Card & Speakers 800 x 600 Minimum Monitor Resolution (1024 x 768 Recommended) Internet Explorer is not supported on the Mac **Adobe Acrobat Reader <u>Click here to download</u>

*SLIDES AND AUDIO ONLY **REQUIRED TO VIEW REFERENCES AND PRINTABLE VERSION OF CE LESSON

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DISCLOSURES

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Printed in U.S.A.

rthritis is a common condition affecting an estimated 46 million American adults. It has significant impact on both the personal level and in the public health realm. As a leading cause of disability, arthritis negatively affects individual patients and the health care system at large. The most common type, osteoarthritis, is expected to increase significantly in coming years as the U.S. population ages and the trend toward obesity continues.

The foundation of treatment for osteoarthritis is self-management, with major emphasis on physical activity and weight management. Health care professionals who appreciate the extent to which nonpharmacologic interventions have been proven successful can best treat their patients affected by osteoarthritis. These patients also frequently require pharmacologic therapy. Here, again, health care professionals who understand the nuances of drug therapy for osteoarthritis, the risks associated with some commonly used medications, and ways to prevent or overcome common side effects can help to optimize outcomes for their patients.

Learning Objectives

Program Preview

After reading this monograph, the pharmacist will be able to:

- 1. Discuss the prevalence of osteoarthritis and its impact on health and quality of life.
- 2. Explain the pathophysiology, clinical presentation, and diagnosis of osteoarthritis.
- Describe the nondrug options for managing osteoarthritis, including self-management, exercise, weight control, joint protection strategies, and complementary therapies.
- 4. Compare and contrast the efficacy, adverse effects, and cautions associated with the various drug therapies used to manage osteoarthritis.
- 5. Outline patient education needs and describe strategies to facilitate self-care and optimize drug therapy outcomes for patients with osteoarthritis.

Introduction

A rthritis broadly refers to more than 100 different diseases and conditions affecting the joints—the most common is osteoarthritis (OA).¹ OA is similar to other chronic conditions such as diabetes and cardiovascular disease in certain ways:

- It is not curable, but its symptoms are treatable.
- Self-management is a cornerstone of treatment.
- Pharmacologic therapy is not necessarily the first step in treatment.

The term "arthritis" is somewhat misleading. It means "inflammation (itis) of the joint (arth)," yet in many types of arthritis, the joint is not inflamed. In fact, inflammation is uncommon in OA, and when it does occur, it is usually mild.^{1,2}

Other common types of arthritis are rheumatoid arthritis, fibromyalgia, and gout.^{2,3} Different parts of the joint are affected in different types of arthritis. In OA, the primary problem is breakdown of the joint cartilage. In rheumatoid arthritis, the synovial membrane is inflamed. In gout, crystals in the joint space cause inflammation and pain.²

Often categorized by location, OA is most common in the knees, hands, hips, and spine. Patients with OA of the hands develop small, bony knobs on their finger joints and at the base of the thumb. When these knobs are located at the end of the finger, they are called Heberden nodes; similar knobs on the middle joints of the fingers are called Bouchard nodes. The fingers may become enlarged and gnarled, and they may ache or be stiff and numb. OA of the hands tends to run in families.^{4,5}

OA is most often located in the knee joint, with symptoms of stiffness, swelling, and pain. OA in the knees is a leading cause of disability.⁴ The hips are also common sites of OA. Pain and stiffness are felt in the joint, but pain may also spread to the groin, inner thigh, or buttocks.⁴

In the spine, OA may cause stiffness and pain in the neck (cervical OA) or lower back (lumbar OA). Arthritisrelated changes in the spine can exert pressure on nerves where they exit the spinal column, causing weakness or numbness of the arms and legs.⁴

Prevalence

Estimates of the prevalence of arthritis range from 26.9 million to 46.4 million adults in the United States. The wide difference in estimates is due to the use of a variety of survey methodologies and different definitions.⁶ The prevalence of OA increases with age and is higher among women than men, particularly in older age groups owing to women's longevity.⁶⁻⁸ OA also increases with increasing body mass index (BMI).⁸ Radiographic changes can be seen in the majority of people by 65 years of age and are present in more than 80% of people

Table 1.

Arthritis: The Numbers

2003-2005 Period

- 46.4 million adults have self-reported physician-diagnosed arthritis—21.6% of U.S. adult population
- 18.9 million adults have activity limitation due to arthritis—8.8% of the population; 40.9% of those with arthritis
- 8.3 million adults have work limitations due to arthritis—30.6% of those with arthritis

By 2030

- 67 million adults (aged 18 years and older) will have physician-diagnosed arthritis—25% of the population
- 25 million adults will suffer activity limitations due to arthritis—9.3% of the population

Costs

- Total costs (2003): \$128 billion, 1.2% of the 2003 U.S. gross domestic product
 - Direct medical costs: \$81 billion
 - Indirect costs: \$47 billion
- National medical costs grew by 24% between 1997 and 2003, reflecting the increase in the number of people with arthritis

Source: References 3, 5, 7, and 10-14.

older than age 75 years. Half of people aged 65 years and older report symptoms of arthritis. 9

Public Health Impact

As the U.S. population ages, the number of people with physician-diagnosed arthritis is expected to increase dramatically—to 67 million—by the year 2030.^{3,7} The increasing burden of disease and disability associated with arthritis has been called "a significant public health problem," both in number of patients and number of patients with disability due to arthritis.^{8,9} It should also be noted that future prevalence estimates may be conservative, because they do not account for current trends in obesity (Table 1).¹¹

The demand on health care services by people with arthritis translates to significant costs. The Centers for Disease Control and Prevention (CDC) estimates a total of \$128 billion in 2003: \$81 billion in direct medical expenditures and \$47 billion in lost earnings.⁷

Impact on Quality of Life

Arthritis is the nation's leading cause of physical dis-

ability; nearly 19 million U.S. adults with arthritis report limitations on their activity. Work limitations due to arthritis affect 30.6% of people with arthritis, accounting for more than 5% of the general population.^{3,11} In a recent survey, 40% of arthritis patients reported that they cannot do, or it is "very difficult" to do, at least one of nine important activities of daily living (ADLs). Such impairment interferes with their ability to work, function in their community, and care for their family.¹¹

Besides the impact of pain and disability, OA often has a negative impact on other aspects of lifestyle, causing depression, anxiety, feelings of helplessness, and difficulty taking part in everyday personal and family activities and responsibilities. In addition, OA has financial impact caused by the cost of treatment and lost wages due to disability.⁴

Pathophysiology of Osteoarthritis

OA is characterized by progressive damage to the cartilage that causes changes in the structures of the joint, such as fluid accumulation, bony overgrowth, and loosening and weakness of the muscles and tendons—all of which may limit movement and cause pain and swelling.¹⁵

In addition to permitting limb movement, the body's joints are designed to absorb shock from that movement. In a healthy joint, the end of the bones is covered by a hard but slippery substance called cartilage. While cartilage is mostly water (65% to 80%), it also contains three important components:

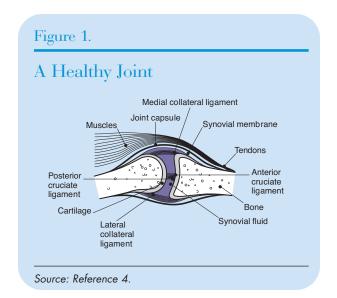
- Collagen—fibrous proteins that are the building blocks of skin, tendon, bone, and other connective tissues.
- Proteoglycans—glycoproteins that interweave with collagens to form a mesh-like tissue that allows cartilage to flex and absorb physical shock.
- Chondrocytes—cells that produce cartilage and help it stay healthy.

The joint is encased inside a joint capsule whose lining, the synovium, secretes synovial fluid. This fluid lubricates the joint and keeps the cartilage smooth and healthy (Figure 1).⁴

In an osteoarthritic joint, however, the cartilage is worn away. Osteophytes (bone spurs) may grow out from the bone, and there is an increase in synovial fluid. These cause the symptoms of stiffness, pain, and inflammation (Figure 2). Tendons and ligaments can stretch, and bones may touch one another.^{4,15}

Risk Factors

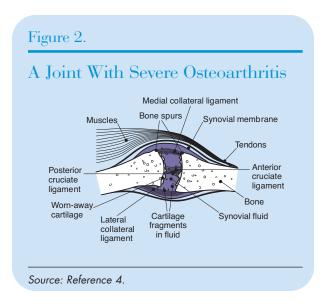
The interaction of systemic and mechanical factors determines the risk of developing OA and how rapidly the disease progresses in the affected joint. Systemic factors increase overall susceptibility to joint degeneration, while



local biomechanical factors impair the optimal functioning of a joint.¹⁶ Systemic factors include a person's age, sex, menopause, genetics, nutrition, and bone density. Mechanical factors include obesity, injury, surgery, muscle weakness, repetitive joint loading, and elite athletics.¹⁶

What causes damage to the cartilage is not specifically known, but risk factors include excess weight, which adds to the joint's stress; sports- and work-related activities and injuries; and a family history of joint and cartilage weakness. Aging does not cause OA directly, but the likelihood of deterioration does increase with age.¹⁵

Table 2 presents another way to look at risk factors: those that are modifiable and those that are not. This classification offers insight into treatment approaches aimed at preventing the development or worsening of OA and relieving symptoms.



Risk Factors for Osteoarthritis

Nonmodifiable Risk Factors

Modifiable Risk Factors

- Older age
- Eemale gender
- Overweight or obesity (knee OA)
 Preventable joint injury
- Prior joint injury
- Family history of osteoarthritis
- Preventable joint injuryOccupations involving repetitive
- hritis knee bending, squatting (knee OA)

Source: References 16 and 17.

Clinical Presentation and Diagnosis of Osteoarthritis

Patients with OA have pain that worsens with weight bearing and activity, and improves with rest. They also experience stiffness after periods of inactivity.¹ The pain of OA ranges from mild to severe. Many patients with OA do not experience pain at all: only one third of those with radiologic evidence of OA report pain or other symptoms.⁴ At the other end of the spectrum, nearly one quarter (24.6%) of arthritis patients in one survey reported having experienced severe joint pain in the previous month, which amounts to more than 5% of the total adult population.⁷

Physical examination may reveal tenderness on palpation; bony enlargement or joint deformity; crepitus on motion; swelling due to effusion with little synovial thickening, usually with little warmth; atrophy of surrounding muscles; restricted active and passive range of motion; and pain and muscle spasm at the extremes of the existing range of motion.^{1,4,13} The physical exam also affords the opportunity to observe the patient's ability to walk, bend, and carry out ADLs.⁴ Diagnostic testing such as x-rays, joint taps (aspiration of synovial fluid), magnetic resonance or computed tomographic imaging, bone scan, and laboratory tests may be done if the history and physical examination are not conclusive.¹⁸

Generally speaking, assessment of OA can be difficult, because the severity of the pathology does not necessarily correspond to the severity of symptoms. Some people have evidence of joint pathology but no symptoms, while others may have pain but no evidence of damage on xrays.¹⁹

Progression is slow, usually taking several years. Contrary to earlier thinking, OA can remain relatively stable for many years. Although x-rays provide clear evidence of ongoing deterioration in one third to two thirds of patients, symptoms may not worsen and, paradoxically, clinical improvement may occur despite exacerbation of the joint's condition seen radiographically.¹⁶

Treatment of Osteoarthritis

Although there is no cure for OA, treatment can reduce pain, maintain or improve joint mobility, and limit functional impairment.¹ The goals of treatment are listed in Table 3.

Current treatment guidelines are unanimous in recommendations for both nonpharmacologic and pharmacologic approaches to treatment, and all emphasize the importance of self-management.^{1,18,21,22} When those measures fail, and a patient has significant knee dysfunction, pain, or both, surgical alternatives, such as arthroscopic débridement or total joint replacement, should be considered.^{4,23}

Treatment decisions should be made on the basis of the degree of pain, disability, and distress, not on radiographic evidence of damage (i.e., not on the basis of the severity of the pathology).¹⁹

Self-Management in Osteoarthritis

A hallmark of arthritis treatment is collaborative care patients working together with health care providers to achieve the best possible management of their condition. As is the case with other chronic conditions, self-management is a cornerstone of treatment. Patients must be involved in—and committed to—their treatment program, every day, for the rest of their lives. Therefore, a fundamental aim of any treatment plan is to increase the patient's involvement and control in his or her treatment.²⁴ Interventions range from patient education to psychology and behavior modification as well as teaching skills, such as problem solving and goal setting, to increase a patient's self-efficacy.⁷ Recommended nonpharmacologic components of treatment are listed in Table 4.

Table 3.

Goals of Treatment of Osteoarthritis

- Control pain
- Improve function
- Reduce joint stiffness
- Limit subsequent joint damage
- Improve health-related quality of life
- Enhance patient understanding of the disease and self-care
- Improve joint health with appropriate exercises
- Improve patient safety
- Reduce weight if needed; maintain normal body weight
- Avoid toxic effects of therapy

Source: References 4, 18, and 20.

Table 4.

Nonpharmacologic Components of an Osteoarthritis Treatment Plan

- Education and counseling regarding weight reduction, joint protection, and energy conservation
- Range-of-motion, aerobic, and muscle strengthening exercises
- Physical therapy and occupational therapy for patients with functional limitations
- Assistive devices for ambulation and activities of daily living
- Appropriate footwear, orthotics (e.g., wedged insoles)
- Self-management resources (e.g., Arthritis Foundation self-help course and book)
- Complementary approaches (e.g., transcutaneous electrical nerve stimulation)

Source: References 2, 18, and 25.

Numerous self-management programs are available in communities across the country. The Arthritis Foundation offers a variety of classes designed for people with arthritis including self-help programs, exercise classes, aquatic therapy, tai chi, and walking programs.^{26,27} Another respected program is the Chronic Disease Self-Management Program developed at the Stanford Patient Education Research Center, which has been endorsed and recommended by the CDC, the Arthritis Foundation, and the American College of Rheumatology (see Sidebar).²⁸

Significantly, these programs work. Studies of the Stanford program's effectiveness have determined that its participants improve in the areas of exercise, communication with physicians, and self-reported general health, with decreases in health distress, fatigue, disability, and limitations on social and role activities.²⁸ The Arthritis Foundation has extensively evaluated its programs and cites similar benefits.^{26,29} These and other evaluation studies have documented improved quality of life, decreased pain, reduced use of medical services, and improved functioning, strength, mobility, range of motion, and self-confidence.^{7,26,29,30}

Patients can locate one of these programs near them at the organizations' Web sites: http://www.arthritis.org/ chaptermap/php for the Arthritis Foundation or http://patienteducation.stanford.edu/programs/cdsmp. html for the Stanford-developed program.

If suitable programs are not offered near a patient's home, there are numerous self-help books available, such as *The Arthritis Helpbook* by Kate Lorig, RN, DrPH, and James Fries, MD, which is based on the programs by Stanford and the Arthritis Foundation.

The Role of Exercise in Osteoarthritis

Physical activity plays a vital role in the management of OA, helping to strengthen the muscles around the affected joints and control joint swelling and pain. Regular activity replenishes lubrication to the cartilage and reduces stiffness and pain.³¹ Research has demonstrated that physical activity (e.g., strength training, aerobic exercise) benefits arthritis patients by decreasing pain, improving gait and function, and delaying disability.^{7,17} Physical activity also has psychological benefits; it has been shown to decrease anxiety, improve mood and well-being, and promote a state of relaxation.^{31,32}

Notably, physical activity of the type recommended for arthritis patients will not worsen arthritis. In fact, the opposite is true: lack of physical activity has been associated with increased muscle weakness, joint stiffness, reduced

The Stanford Arthritis Self-Help Course

What Is It?

The Arthritis Self-Management Program is a workshop given for 2 hours per week for 6 weeks in local community facilities such as senior centers, churches, libraries, and hospitals. Workshops are led by trained leaders, one of whom is an arthritis patient.²⁸

What Is Covered?

The workshop teaches participants about their condition and how to manage various aspects of it, including²⁸:

- Techniques to deal with problems such as pain, fatigue, frustration, and isolation.
- Appropriate exercise for maintaining and improving strength, flexibility, and endurance.
- Appropriate use of medications.
- Communicating effectively with family, friends, and health professionals.
- Healthy eating.
- Making informed treatment decisions.
- Disease-related problem solving.
- Getting a good night's sleep.

| | | Type of Exercise | |
|-----------------------|--------------------|----------------------|---------------------------|
| | Range of Motion | Strengthening | Aerobic |
| Examples | Neck stretch | Quadriceps extension | Walking |
| | Shoulder stretch | Knee raise | Low-impact aerobics |
| | Finger exercises | Back kick | Dancing |
| | Side bends | Straight leg raise | Swimming |
| | Back kick | | Bicycling |
| | Side kick | | |
| | Hamstring stretch | | |
| | Tai chi | | |
| | Yoga | | |
| Recommended frequency | 2—3 times/day | 2–3 times/week | 3—4 times/week |
| | 15-minute sessions | 30-minute sessions | 30- to 60-minute sessions |

range of motion, fatigue, and general deconditioning.³ There are no reports of worsening of symptoms in knee OA from strengthening or aerobic exercise.³²

Exercise recommendations should be tailored to each patient's physical and psychological needs.³¹ Patients with arthritis should get at least 30 minutes of moderate physical activity at least 3 days a week, and it can be done in 10-minute increments if 30-minute sessions are too strenuous.^{17,31} Patients should understand that their exercise does not have to be strenuous in order to be effective, and they will benefit from moderately intense activities such as walking and gardening.³¹

Exercise regimens for arthritis feature three types of activity: range-of-motion/flexibility; strengthening; and aerobic (Table 5).^{2,4} Since OA is primarily a problem with joint cartilage, an exercise program should address cartilage, which needs joint motion to stay healthy. When the joint moves or is squeezed by activity, cartilage soaks up fluid and nutrients and gets rid of waste products. If the joint is not moved regularly, the cartilage deteriorates. If the joint is continually compressed, such as the hips and knees during long periods of standing, the cartilage cannot expand and absorb needed nutrients and fluid. Therefore, any joint affected by OA should be moved through its full range of motion several times a day. Patients with hip or knee OA should avoid standing or walking for more than 2 to 4 hours at a time, and they should follow such prolonged activity with an hour off their feet to allow cartilage to decompress.²

Range-of-motion/flexibility activities should be done two to three times every day to regain and maintain maximum

range of motion for the affected joints. This helps to keep the joints limber, which improves the patient's ability to maintain ADLs.^{4,18} These exercises should also be done as warm-up before undertaking more strenuous exercise.²⁶

Strengthening exercises are done to build up the muscles that support those joints affected by arthritis.⁴ Strong muscles will lessen stress on the joints and absorb shock to protect joints from injury.²⁶

There are two types of strengthening exercise^{26,33}:

- Isometric exercise involves contracting the muscle without moving the joint.
- Isotonic exercise involves contracting the muscle while also moving one or more joints.

Strengthening exercises can be performed with weights or exercise bands, inexpensive devices that add resistance, to make the muscles work harder.^{4,26} Patients with knee OA have lower strength in the quadriceps than do age-matched subjects without OA—a weakness that is associated with both pain and physical function.³² Therefore, exercise regimens for knee OA should incorporate quadriceps strengthening exercise.^{18,22,32}

Aerobic activity refers to any physical exertion that uses the large muscles of the body in rhythmic, continuous motions. Activities such as walking or low-impact aerobics make the heart, lungs, blood vessels, and muscles work more efficiently.⁴ The benefits of cardiovascular health are well known; such activity can also result in improved endurance, stronger bones, improved sleep, controlled weight, and reduced stress, depression, and anxiety.²⁶

Patients with knee OA who have been sedentary may start a progressive walking program. They should begin at

a level that is well tolerated and does not cause increased knee pain over successive days. They should gradually increase their walking to a goal of 30 to 60 minutes on 5 to 7 days a week. If patients have limited tolerance for walking, they may consider walking in a swimming pool, pushing a shopping cart, or using an exercise bike or other exercise equipment.¹⁸ Many patients benefit from referral to a physical therapist for evaluation and instruction in appropriate exercises.²¹

Many patients find it easier to do their exercises in water. The buoyancy and soothing quality of warm water make it a safe, ideal environment for relieving arthritis pain and stiffness, and a gentle way to exercise joints and muscles. For exercising, the water should not be too hot (83°F to 88°F). Water supports the joints, encouraging free movement, and may act as resistance to help build muscle strength.^{10,27}

The American College of Sports Medicine has recommended the following for people with arthritis undertaking an exercise program^{31,33}:

- Begin slowly and progress gradually.
- Alternate periods of activity with rest.
- Avoid rapid or repetitive movements of affected joints—for example walk slowly and avoid movements that are highly percussive (e.g., jumping).
- Use appropriate joint protection measures for affected joints that are restricted in range of motion by pain, stiffness, swelling, or bone changes.

Adherence to exercise regimens is an ongoing challenge. Studies have shown that adherence drops without continued contact between health care providers and patients, suggesting that some degree of continued contact is desirable to maintain adherence.³² A review of evidence-based guidelines for the management of hip and knee OA revealed that the clinical status of such patients can be improved if health care providers regularly contact patients by telephone to promote self-care.²¹

The Weight Management Component of Osteoarthritis Care

Obesity has been strongly linked to OA.^{11,16} Weight management today utilizes the BMI for guidance. A BMI in the 18.5 to 24.9 range is considered normal; a BMI in the 25 to 29.9 range is considered overweight; and a BMI of 30 or higher is characterized as obesity.³⁴

Patients with OA who are above their normal weight should be encouraged to lose weight, and patients with normal weight should be encouraged to maintain their weight.³² Comprehensive information about weight management is available from many sources, including the National Heart, Lung, and Blood Institute (NHLBI) Guidelines at http://www.nhlbi.nih.gov/guidelines/obesity/ index.htm, and is beyond the scope of this publication. Weight management is a frustrating area for patients and health care providers alike. Many people who are overweight or obese have made attempts to lose weight, with varying degrees of success. Effective treatment for obesity is based on skillful and empathetic communication between health care providers and patients. The NHLBI has recommended these approaches³⁵:

- Establish rapport with patients.
- Solicit permission to discuss weight issues.
- Use preferred terms such as "weight," "excess weight," and "BMI" rather than "obese."
- Use a nonjudgmental tone.
- Express concern about the health risks associated with excess weight, including its effect on the patient's arthritis pain and mobility.

When evaluating a patient's readiness to make the lifestyle changes necessary to lose weight, health care providers should include a discussion of the reasons to lose weight, the patient's previous attempts at weight loss, attitudes toward physical activity, and whether the patient will have support from family and friends. It may also be productive to discuss potential barriers to success. Ask the patient if he or she would like help with diet and physical activity and provide handouts as appropriate; many are available from the NHLBI, the CDC, and other sites on the Internet.³⁵

Complementary and Alternative Therapies

Many arthritis patients turn to complementary and alternative therapies when conventional medical treatment does not provide adequate pain relief.⁴ While some scientific evidence exists for several of these therapies, for most, key questions regarding safety and efficacy have not been answered through well-designed scientific studies.³⁶

Nonetheless, these unconventional approaches are widely used. In a survey of patients with OA participating in drug trials of celecoxib, more than 80% reported having used some type of complementary or alternative medicine in the previous month. Dietary practices were most common (71.5%), followed by mind-body interventions (42.4%), topical agents (38.1%), dietary supplements or herbs (32.9%), and manipulation and body-based methods such as massage and yoga (21.4%). More than half (52%) reported use of over-the-counter (OTC) medications.³⁷

The National Center for Complementary and Alternative Medicine, an agency of the National Institutes of Health (NIH), defines these therapies as "systems, practices, and products that are not presently considered to be part of conventional medicine." The agency differentiates between *complementary* medicine, which is used together with conventional medicine, and *alternative* medicine, which is used in place of conventional medicine.³⁶ Unfortunately, numerous unproven remedies are promoted for people with arthritis. While most are harmless, some can be dangerous. Clues that a remedy may not be legitimate are³⁸:

- Claims that the product works for all types of arthritis and other diseases.
- Scientific support comes from only one research study.
- The label has no directions for use or warnings about side effects.

The real danger in resorting to unproven alternative therapies is that patients using them may delay or abandon conventional therapies that can help them.⁴

However, a number of complementary therapies are accepted treatments for patients with arthritis. These include thermotherapy, acupuncture, transcutaneous electrical nerve stimulation (TENS), and some nutritional supplements.

Thermotherapy has been used to relieve pain for centuries. Heat is most effective for reducing pain associated with muscle tension and stiffness, when there is little or no inflammation. Local application of heat with a heating pad, hot water bottle, hot towels, hot packs, or a heating lamp increases blood flow to the skin and muscles, which enhances muscle nutrition and relaxation. Patients should apply heat for a maximum of 15 to 20 minutes at a time and take care to avoid burns.²

Cold/ice helps stop muscle spasms and numbs the nerves that send pain signals. This treatment also reduces blood flow to the painful area, thereby reducing inflammation and swelling. Patients may use large bags of frozen peas or corn, or make an ice pack in a plastic bag with ice cubes; either way, the ice pack should be wrapped in a wet towel or cloth, and never applied directly to the skin. As with heat, application should be limited to 15 to 20 minutes.^{2,20,21}

Acupuncture may be a useful component in an OA treatment plan, and studies have shown it to be of symptomatic benefit in knee OA.²¹ Scientists speculate that the needles stimulate the release of natural, pain-relieving chemicals such as endorphins.⁴ Acupuncture is one of the most popular complementary medicine interventions for OA, especially for axial or peripheral sites of involvement.²⁰

TENS, a widely studied therapy, has been found to effectively relieve pain from OA. The best results are obtained when using high frequency applied repeatedly for more than 4 weeks.²⁰ TENS is used to relieve both acute and chronic pain in many conditions and has been shown to offer short-term pain control in knee or hip OA.²¹ TENS inhibits nerve transmission and may stimulate the release of endorphins.^{20,21} There have been no reports of serious adverse effects with TENS.²¹

Nutritional supplements are widely available for a

large variety of health conditions. Most lack good research data to support their claims of effectiveness and safety.^{4,15}

A systematic review of clinical trials investigating the effectiveness of antioxidant vitamins A, C, E, or selenium in arthritis concluded that there is "no convincing evidence" that selenium, vitamin A or C, or a combination product of selenium with vitamins A, C, and E are effective in treating any type of arthritis. These researchers report one trial that found vitamin E to be superior to placebo and five that suggested vitamin E was equivalent to diclofenac.³⁹ It is also thought that green tea may possess anti-inflammatory properties, and may inhibit the chemicals and enzymes that lead to cartilage damage.⁴

Other nutrients such as glucosamine and chondroitin sulfate have shown some potential for reducing OA pain and for slowing cartilage damage in patients with OA.^{4,40}

Glucosamine and chondroitin are natural substances that are found in human cartilage. Glucosamine is a type of sugar that plays a role in the formation and repair of cartilage, while chondroitin is part of the protein molecule that gives cartilage its elasticity. Glucosamine supplements are extracted from crab, lobster, or shrimp shells; chondroitin comes from animal cartilage such as tracheas or shark cartilage.⁴⁰

A major trial of these two supplements was undertaken to determine their effectiveness because earlier studies were poorly designed and results were inconclusive.⁴¹ The NIH-sponsored Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) showed that glucosamine and chondroitin alone or in combination did not reduce pain effectively overall in patients with knee OA. The combination did provide some pain relief in a subset of patients with moderate-to-severe knee pain.⁴¹ However, that trial utilized glucosamine hydrochloride. There is some evidence that the hydrochloride salt of glucosamine is ineffective; glucosamine sulfate may be more effective.^{42,43}

Many physicians concur in a trial of glucosamine and chondroitin if their patients inquire about them, noting that if no relief is seen in 30 to 90 days, patients should stop taking these agents.^{40,44} The usual dosage is 1500 mg of glucosamine and 1200 mg of chondroitin per day.^{18,44} Glucosamine sulfate is generally well tolerated.⁴⁴

The GAIT investigators caution that, if these agents are to be widely used in the treatment of OA, serious consideration must be given to their regulatory status to ensure potency and purity. Continuing research is needed to establish efficacy and to increase understanding of the biology, pharmacology, and pharmacokinetics of these agents.⁴¹

All dietary supplements are unregulated, and the quality and content of individual products vary widely—even from batch to batch from the same manufacturer.^{44,45} The Arthritis Foundation recommends these steps to help ensure use of a high-quality product⁴⁵:

- Choose supplements sold by large, well-established companies.
- Read the product label carefully to review the ingredients.
- Check with health care providers before trying a supplement to clarify how it would fit in with the current treatment program.

Patients—and pharmacists—can determine quality products by checking for U.S. Pharmacopoeia seals or researching products at http://www.consumerlab.com.

Joint Protection Strategies

Many assistive devices are available to help the patient with OA protect affected joints.²¹ Walking aids such as canes and walkers relieve stress on painful, unstable weight-bearing joints; they can reduce joint loading, alter adverse biomechanical stress, and help to realign misaligned joints, helping to maintain and improve mobility.²⁰ If a patient's knee or hip OA is limited to one side, a cane may be held on the opposite side of the body to reduce the load on the affected joint. In patients with bilateral OA, a walker may be needed.²¹ Many patients find that other aids such as reachers, bath benches, raised toilet seats, and grab bars are useful.¹⁸

Shoe orthotics may be helpful for patients with OA to eliminate the painful effects of shock that come with walking. Usually, shock is attenuated and distributed through joint mobility, muscular function, and articular cartilage. However, OA renders these inefficient due to soft tissue degradation and changes in the surface areas of the joint. Orthotics aid in shock absorption and restore or enhance the distribution of force.²⁰ Appropriate footwear, such as lateral wedged insoles, also has been shown to reduce pain and improve ambulation in patients with knee OA.²¹

There is a wide variety of knee braces, splints, and sleeves available for patients with knee OA, which improve joint stability, provide support, and partially unload the joint.^{20,21}

Patients should be educated to protect their joints through practices such as avoiding prolonged standing, kneeling, squatting, and stair climbing. They can minimize stress on their joints while exercising or performing ADLs through simple means such as using good posture and body mechanics while standing or sitting, climbing stairs, lifting, and carrying objects.²

Pharmacologic Therapy

Although nonpharmacologic approaches are fundamental to the treatment of OA, most patients will require pharmacologic interventions such as analgesics and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for pain relief. Patients with more severe pain who do not obtain relief from NSAIDs may require treatment with opioids, and they may benefit from intra-articular steroid injections.⁴⁶ Drug treatment for OA is most effective when combined with nonpharmacologic strategies.¹ Pharmacologic management of arthritis involves balancing the risks and benefits of the available medications.^{4,47-50}

Analgesics help relieve pain, but do not affect inflammation or swelling. The most commonly used analgesic in mild-to-moderate OA is acetaminophen. It is recommended as first-line therapy for OA because of its low cost, effectiveness, and safety.^{4,21,25} If acetaminophen successfully relieves the patient's pain, it should be used as the preferred long-term oral analgesic.²¹ Patients may take it in doses as high as 1000 mg four times per day; higher doses are associated with hepatotoxicity.⁴⁶

NSAIDs, which have both analgesic and anti-inflammatory properties, help reduce joint pain, stiffness, and swelling.¹⁸ They work by blocking the production of prostaglandins, which contribute to inflammation and pain. Traditional NSAIDs such as ibuprofen and naproxen are nonselective cyclooxygenase (COX) inhibitors; they inhibit both COX-1 and COX-2 enzymes involved in the formation of inflammatory mediators. Newer NSAIDs such as celecoxib are selective and inhibit only COX-2 enzymes. Initially, these agents were thought to cause fewer adverse effects, such as gastrointestinal bleeding and kidney problems, than analgesics and traditional NSAIDs.⁵⁰ However, since their addition to the market, it has been discovered that these agents offer little to no benefit over traditional NSAIDs and may increase the risk of serious cardiovascular events. That discovery led to the withdrawal from the market of two of these agents (i.e., rofecoxib and valdecoxib) 51

Salicylates are used to control arthritis pain and inflammation. However, at high doses, they cause serious side effects such as gastrointestinal bleeding and kidney problems.

Opioids are sometimes prescribed for treating chronic pain in patients who have not responded to, or cannot tolerate, other analgesics or NSAIDs.¹ Agents such as morphine and codeine reduce pain by blocking pain signals to the brain. Because of concerns for physical and psychological dependence on these agents, they are generally used as short-term therapy.⁴

Topical pain relievers are used to temporarily relieve arthritis pain. Some contain local anesthetics to relieve pain. Capsaicin uses a derivative of hot peppers to stimulate nerve endings, distracting attention from the joint pain. Other topical agents act by depleting the amount of a neurotransmitter (substance P) that sends pain messages to the brain or by blocking prostaglandins.⁴ Topical NSAIDs are widely recommended in guidelines for managing OA of the knee.²¹ They are safe, with no gastrointestinal side effects, although there may be local reactions such as itching, burning, and rashes.²¹ Capsaicin has been shown to reduce pain in OA of the knee and hand.^{19,21} While up to 40% of patients experience local burning, stinging, or erythema when using capsaicin, these side effects rarely lead to discontinuation of treatment.^{1,21}

Injectable agents such as corticosteroids may be injected into affected joints to relieve pain temporarily. These powerful anti-inflammatory hormones are usually administered only two to four times per year. They are not used routinely for OA, except when painful inflammatory flares occur.⁴ Hyaluronic acid substitutes, also called viscosupplements, are designed to replace a substance normally found in the joint that provides lubrication and nutrition. These hyaluronans aid the joint's reaction to stress. When joint stress is low, they are highly viscous. When joint stress increases, they become more elastic and absorb energy more efficiently.⁴⁶ Hyaluronic acid substitutes are approved only for use in the knee joint and are administered in a series of three to five injections.⁴ Improvement in pain symptoms may not be felt for 3 to 6 months after injection.46

Beyond medications for pain relief, patients with OA may be prescribed a number of other agents. It is not unusual for patients with arthritis to have concomitant depression; in these patients, antidepressants are used to break the pain-depression cycle.² Tranquilizers or muscle relaxants may be used to reduce painful muscle tension and spasms. They should be used for short periods because of their addictive potential.²

The Drug Selection Quandary

The U.S. Food and Drug Administration (FDA) now requires cautionary labeling for all selective COX-2

inhibitors and nonselective NSAIDs, both prescription and OTC, to warn of the risk of cardiovascular and gastrointestinal adverse events.^{46,51} Publicity over this situation has created confusion for patients and health care providers alike.

After the cardiovascular risks of NSAIDs became known, the American Heart Association (AHA) issued a position statement to guide clinicians on their use. The AHA suggests a staged approach, beginning with nonpharmacological methods such as physical therapy, thermotherapy, and orthotics. If such measures do not control symptoms, then pharmacologic treatment is indicated, with consideration given to safety and efficacy. Because of its safety profile, acetaminophen is usually tried before other medications are prescribed.^{47,52}

If patients do not achieve relief or cannot tolerate these measures, then the issue becomes more complex. Use of high doses of aspirin and other traditional NSAIDs for long-term treatment is associated with increased risk of gastrointestinal bleeding.^{48,52} Most OA guidelines recommend that proton pump inhibitors be prescribed to mitigate these adverse effects of NSAIDs.^{1,21,25,46,52,53}

Newer evidence points to increased risk of major thrombotic events with both nonselective and selective NSAIDs. If traditional NSAIDs do not provide relief, or if the patient is at risk for gastrointestinal bleeding, a COX-2 inhibitor may be used. However, patients at risk for active atherosclerotic processes—including those with recent bypass surgery, unstable angina, myocardial infarction, or ischemic cerebrovascular events—have an increased risk for adverse cardiovascular effects if given a COX-2 inhibitor.⁵² The AHA advises that extra caution be used in such patients when prescribing a COX-2 inhibitor, including use of only the recommended doses and for the shortest period of time required to control symptoms. COX-

Case Study

Cathy Price is a 67-year-old woman who sought medical attention for recurring knee pain. After performing a physical exam, which revealed limited range of motion and crepitus, her physician diagnosed the knee pain as OA and suggested that she take acetaminophen 500 mg every 4 to 6 hours for pain relief.

Mrs. Price is not significantly overweight; her BMI is 26.2. Her ability to perform normal ADLs is not compromised.

Question 1: What else could the physician have done for Mrs. Price?

Question 2: The following month, Mrs. Price comments to her pharmacist that she is not obtaining sufficient pain relief from acetaminophen. What should her pharmacist do?

Question 3: Mrs. Price is pleased with the pain relief from using naproxen but reports frequent heartburn. What can be done for her now?

Question 4: Mrs. Price's son is urging her to join a regular exercise program, but she is concerned about making her knee pain worse. What can she do?

(Answers appear on page15.)

2 inhibitors can lead to impaired renal perfusion, sodium retention, and increases in blood pressure, which may contribute to their adverse cardiovascular effects. Renal function and blood pressure should be monitored, especially for patients with preexisting hypertension, renal disease, or heart failure.⁵²

Questions about the true cardiovascular impact of NSAIDs remain. Researchers conducted a meta-analysis of randomized trials of COX-2 inhibitors and traditional NSAIDs. They confirmed that selective COX-2 inhibitors are associated with a moderate increase in the risk of vascular events and determined that high doses of ibuprofen and diclofenac have similar effects. The risks of high-dose naproxen were substantially smaller.⁵⁴ Naproxen is now the preferred choice, because it appears to be safer for the cardiovascular system.^{50,52}

The osteoarthritis management guidelines from the Michigan Quality Improvement Consortium contain concise risk management strategies for use of NSAIDs in patients with gastrointestinal and/or cardiovascular risks. Their recommendations appear in Table 6.

Table 6.

Risk Management in NSAID Therapy

| | No CV Risk | CV Risk |
|-------------------|-----------------------------|--|
| No or low GI risk | NSAID | NSAID |
| | Add PPI if on aspirin | Add PPI if GI risk of aspirin/NSAID |
| | If GI symptoms develop, | combination |
| | add antacid, H_2 blocker, | warrants |
| | or PPI | gastroprotection |
| GI risk | NSAID plus PPI | Naproxen plus PPI |
| | | if CV risk > GI risk |
| | If NSAID not tolerated, | |
| | COX-2 inhibitor | COX-2 inhibitor plus |
| | | PPI if GI risk > CV risk |
| | If prior GI bleed, avoid | |
| | all NSAIDs/COX-2; if | |
| | essential, use COX-2 | |
| | plus PPI | |

NSAID = nonsteroidal anti-inflammatory drug; PPI = proton pump inhibitor.

Source: Reference 25.

Optimizing Outcomes for Patients With Osteoarthritis

There are many ways in which pharmacists can help their patients with OA achieve the best possible outcome. The kinds of valuable information that pharmacists can impart to patients in the areas of self-management, exercise, and other nonpharmacologic therapies were discussed previously in this monograph.

Drug therapy also offers opportunities for pharmacists to assist patients in achieving success. The basic strategies include making sure that patients fully understand the rationale and directions for their prescribed medications.⁴ Another way to help ensure optimal pharmacotherapy is to monitor dosage. In OA drug therapy, doses should be low to start and increased only if the lower doses are ineffective in providing symptomatic relief. Patients who successfully incorporate exercise or weight loss programs may be able to reduce the NSAID dosage or replace an NSAID with acetaminophen. In all patients whose symptoms are well controlled, attempts should be made periodically to reduce the dosage and determine whether these agents may be used on an as-needed basis instead of a fixed-dose regimen.¹ Patients should be warned not to exceed the medication's maximum dosage recommendation. The recommended dosage ranges for many of the drugs used to treat the pain of OA are listed in Table 7.

Pharmacists should discuss with patients the expected outcomes of therapy, including the risk of adverse effects. Table 8 lists common side effects of the pain medications used in OA.

NSAIDs can cause ulcers and bleeding in the gastrointestinal tract. The risk increases among patients who are also taking corticosteroids and anticoagulants, who smoke, drink alcohol, are older or in generally poor health, and with longer use.⁵⁵ Patients who have had an allergic reaction to aspirin or any other NSAID should not take an NSAID, nor should anyone who is scheduled for, or recently had, heart bypass surgery.⁵⁵

Patients should be asked if they are experiencing any adverse effects from their medications. As previously discussed, taking an NSAID raises the risk of gastrointestinal upset and bleeding ulcers. Misoprostol may be helpful to reduce the risk of ulcer formation in patients who are considered at high risk. Misoprostol replaces prostaglandins blocked by NSAIDs, thus reducing ulcer risk.⁵³ Patients who are pregnant or plan to become pregnant should not take misoprostol, which may cause miscarriage, premature labor, or birth defects.⁵⁶ Patients could be advised to take NSAIDs with antacids or an OTC gastroprotective agent to avoid heartburn and nausea.^{1,21,52,57} Patients should be advised to avoid stomach irritants such as alcohol, tobacco, and caffeine.⁴ Suggestions for minimizing

Dosage Recommendations for Drugs Used in Osteoarthritis Pain Management

| Medication/Brand | Dosage |
|---|---|
| Acetaminophen | |
| Anacin Aspirin Free, Excedrin caplets, Panadol, Tylenol | 325—1000 mg every 4—6 hours as needed Maximum: 4000 mg/day |
| Tylenol Arthritis | 1300 mg every 8 hours as needed |
| , | Maximum: 3900 mg/24 hours |
| Acetaminophen + codeine | |
| Tylenol with Codeine No. 3 | Codeine: 15–60 mg |
| | Acetaminophen: 150–600 mg |
| | Every 4 hours as needed |
| Hydrocodone + acetaminophen | |
| Dolacet, Hydrocet, Lorcet, Lortab, Vicodin | 2.5–10 mg hydrocodone every 4–6 hours as needed |
| | (acetaminophen content varies) |
| Oxycodone | |
| OxyContin | 10 mg every 12 hours |
| Roxicodone, OxyFAST, OxyIR (liquid) | 5 mg every 6 hours as needed |
| Propoxyphene HCl | |
| Darvon, PP-Cap | 65 mg every 4 hours as needed |
| | Maximum: 390 mg/day |
| Propoxyphene + acetaminophen | |
| Darvocet | 50–100 mg propoxyphene (325–650 mg acetaminophen) every 4 hours as needed |
| | Maximum: 600 mg propoxyphene/day |
| Tramadol | |
| Ultram, Ultram-ER | 50—100 mg every 4—6 hours as needed |
| Tramadol + acetaminophen | |
| Ultracet | 75 mg tramadol every 4—6 hours as needed for up to 5 days |
| | Maximum: 600 mg/day |
| Aspirin | |
| Bayer Aspirin, St. Joseph Aspirin, Ecotrin | 2400—5400 mg/day in divided doses |
| Ibuprofen | |
| Motrin, Advil | 1200—3200 mg/day in 3—4 doses |
| Nuprin | 200–400 mg every 4–6 hours as needed |
| | Maximum: 1.2 g/day (analgesic) or 3.2 g/day (anti-inflammatory) |
| Indomethacin | |
| Indocin | 50—200 mg/day in 2—4 doses |
| Indocin SR | 75 mg/day in single dose or 150 mg/day in 2 doses |
| Naproxen | |
| Naprosyn | 500—1500 mg/day in 2 doses |
| Naprelan | 750 or 1000 mg/day in single dose |
| Naproxen sodium | |
| Anaprox | 550—1650 mg/day in 2 doses |
| Aleve | 220 mg every 8–12 hours as needed |
| Celecoxib | |
| Celebrex | 200 mg once/day or 100 mg twice/day |

Source: References 47 and 48.

Table 8.

Common Side Effects Experienced With Pain Medications for Osteoarthritis

| not associated with side effects doses (>4 g/day), occasionally results in hepatic toxicity, especially in patients who consume excess tion, dizziness, lightheadedness, nausea, sedation, shortness of breath, vomiting s, nausea, sedation, vomiting tion, diarrhea, dizziness, drowsiness, increased sweating, loss of appetite, nausea al or stomach cramps, pain, or discomfort; diarrhea; dizziness; drowsiness; edema; gastrointestinal ; headache; heartburn or indigestion; nausea or vomiting; peptic ulcer; risk of cardiovascular events |
|--|
| s, nausea, sedation, vomiting tion, diarrhea, dizziness, drowsiness, increased sweating, loss of appetite, nausea al or stomach cramps, pain, or discomfort; diarrhea; dizziness; drowsiness; edema; gastrointestinal |
| tion, diarrhea, dizziness, drowsiness, increased sweating, loss of appetite, nausea al or stomach cramps, pain, or discomfort; diarrhea; dizziness; drowsiness; edema; gastrointestinal |
| al or stomach cramps, pain, or discomfort; diarrhea; dizziness; drowsiness; edema; gastrointestinal |
| |
| heart attack, stroke, hypertension, and heart failure; kidney problems |
| s nonselective NSAIDs, except less likely to cause bleeding and ulcers mmon side effects are indigestion, diarrhea, stomach pain skin reactions or stomach problems can occur without warning |
| al or stomach cramps, pain, or discomfort; diarrhea; dizziness; drowsiness or lightheadedness; headache; heartburn or indigestion; nausea or vomiting |
| |
| n |

Table 9.

Patient Counseling Tips for Countering Stomach Problems With NSAIDs

- Avoid drinking alcoholic beverages, which increases the risk of gastric bleeding when taken with an NSAID.
- Take medications with food and water—even if it's just a few crackers and a full glass of water.
- If taking an NSAID once a day, consider scheduling it for the afternoon or evening, when it may be less likely to lead to stomach upset.
- Don't take more NSAIDs than prescribed or more often than prescribed. If not obtaining pain relief, ask about increasing the dose or changing to another medication.
- Don't take over-the-counter medications that also contain an NSAID.

NSAID = nonsteroidal anti-inflammatory drug.

Source: Reference 53.

stomach problems with NSAIDs are listed in Table 9.

Health care providers should also ask patients about their use of OTC medications and dietary supplements so that the potential for adverse reactions and drug interactions can be examined.⁹ One area of particular interest is the use of pain medications by people who are taking lowdose aspirin for cardioprotection. Specifically, questions have been raised regarding the ability of ibuprofen to interfere with the protective effect of low-dose aspirin. The FDA has therefore advised that people taking immediaterelease low-dose aspirin and 400 mg of ibuprofen should take the ibuprofen at least 30 minutes after or 8 hours before taking aspirin. Information on how best to avoid the interaction in patients taking enteric-coated aspirin for cardioprotection is not yet available.⁵²

A large study published in 2007 showed that use of aspirin reduced the risk of cardiovascular events when given with rofecoxib, celecoxib, sulindac, meloxicam, and indomethacin but not with ibuprofen. In large trials assessing gastrointestinal safety, fewer gastrointestinal events occurred in patients using both COX-2 inhibitors and aspirin than in those using traditional NSAIDs and aspirin. The authors concluded that COX-2 inhibitors are preferable to nonselective NSAIDs in patients with chronic pain and cardiovascular risks requiring the use of low-dose aspirin.⁵⁸

A more recent study confirmed the risks of this aspirinibuprofen interaction. Researchers determined that taking ibuprofen for arthritis and aspirin to reduce the risk of a second stroke undermined aspirin's inhibitory effect on platelet aggregation. In the study, 72% of patients on this regimen suffered a second stroke. When patients discontinued the NSAID, they regained their aspirin sensitivity.⁵⁹

Summary

Arthritis causes varying degrees of pain and disability for an estimated 46 million Americans. Treatment of the most common type, OA, addresses two broad clinical manifestations—symptoms and the degree of disability and encompasses both nonpharmacologic and pharmacologic components, with the emphasis on self-care. Selfmanagement programs help patients with OA understand the disease; reduce pain while remaining active; cope physically, emotionally, and mentally; have greater control over the disease; and build confidence in their ability to live an active, independent life. Patients should be encouraged to include regular physical activity and exercise in their lives, lose weight if needed, and consider attending specialized self-management programs for arthritis patients. Research has shown that people who participate in these programs are more likely to have positive outcomes, with less pain, fewer physician visits, and a better quality of life.

Pharmacologic treatment is complex, utilizing a wide variety of medications accompanied by potentially serious side effects. Health care providers can help their patients achieve optimal outcomes from drug therapy by monitoring dosage and providing information on managing side effects.

Additional Resources

American College of Rheumatology http://www.rheumatology.org

Arthritis Foundation http://www.arthritis.org

National Center for Chronic Disease Prevention and Health Promotion http://www.cdc.gov/arthritis

National Center for Complementary and Alternative Medicine http://www.nccam.nih.gov

National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov

National Institute on Aging http://www.nia.nih.gov

National Institutes of Health Office of Dietary Supplements http://www.ods.od.nih.gov

Stanford Patient Education Research Center Chronic Disease Self-Management Program http://patienteducation.stanford.edu/programs/cdsmp.html

U.S. Food and Drug Administration

http://www.fda.gov

Responses to Case Study Questions

Response to Question 1:

The physician should have explained the importance of self-care and described strategies for self-management. He could have recommended increased physical activity to improve joint circulation and keep the cartilage healthy, and exercise to improve flexibility and joint strength. He did not need to order an x-ray or other diagnostic tests, because Mrs. Price's symptoms and physical findings (which included crepitus and limited range of motion) clearly indicated OA.

Response to Question 2:

Ask Mrs. Price how she is taking the acetaminophen to determine whether the dosage is adequate for pain relief. If, after determining that she is taking the acetaminophen appropriately, consider recommending (or call her physician to request a prescription for) a traditional NSAID. Review her cardiovascular risks. Ask her if she is taking low-dose aspirin as a cardioprotective measure.

Response to Question 3:

Remind her to always take the medication with food and water, and advise her to take an OTC gastroprotective medication.

Response to Question 4:

Reassure Mrs. Price that exercise programs developed for arthritis will not increase her symptoms or worsen her condition. Suggest that she investigate local programs sponsored by the Arthritis Foundation; tell her that many of their programs include an aqua therapy class that minimizes stress on the joints and therefore is less likely to aggravate her joint pain. Direct her to the Arthritis Foundation Web page, http://www.arthritis.org/chaptermap/php, where she can enter her zip code to find the program closest to her home.

Alternatively, refer Mrs. Price to a physical therapist who can initiate a program of exercise specifically tailored to her condition and supervise her performance of the exercises to make sure she does not incur further damage to her knee.

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8

SSESSMENT QUESTIONS

INSTRUCTIONS: For each question, circle the letter corresponding to the correct answer on the CE Examination Form. **Please review all of your answers to be sure you have marked the proper letter.** There is only one correct answer to each question.

1. Osteoarthritis is similar to other chronic health conditions in that:

- a. It relies primarily on drug therapy for treatment.
- b. It is a major cause of mortality.
- c. Its precise causes are clear.
- d. Self-management is a foundation of its treatment.

2. Arthritis is a common disorder, affecting:

- a. An estimated 46 million American adults.
- b. 10% of the U.S. population.
- c. Men and women equally.
- d. Young adults and the elderly in similar proportions.

3. Arthritis encompasses more than 100 conditions, the most common of which is:

- a. Rheumatoid arthritis.
- b. Gout.
- c. Osteoarthritis.
- d. Fibromyalgia.

4. The gnarled nodes on the distal joints in the hands of people with osteoarthritis are called:

- a. Bouchard nodes.
- b. Heberden nodes.
- c. Delphian nodes.
- d. Osler nodes.

5. Estimates of the prevalence of arthritis vary widely, because:

- a. Data were collected in different years.
- b. Reports did not clearly identify the populations surveyed.
- c. Different survey methodologies were used to collect the data.
- d. It is not known why the estimates are so different from one another.

6. The most common site of osteoarthritis is the:

- a. Knee.
- b. Hand.
- c. Spine.
- d. Hip.

7. Osteoarthritis is a leading cause of disability, causing limitations on activity for:

- a. More than half of patients with osteoarthritis.
- b. Nearly 19 million adults.
- c. 30% of the adult U.S. population.
- d. One in three patients with arthritis.

8. Osteoarthritis is a disease of the cartilage, which is:

- a. The slippery covering of the end of the bones.
- b. Made up of glucosamine.
- c. One of the components of synovial fluid.
- d. Located only in the knee joint.

9. A primary cause of osteoarthritis is:

- a. Aging.
- b. Inflamed synovial membrane.
- c. Loss of cartilage.
- d. Obesity.

10. Patients whose x-rays show deterioration of the joint:

- a. Always have severe pain.
- b. Have the rapidly progressing form of osteoarthritis.
- c. May or may not experience pain.
- d. Should not expect to experience clinical improvement.

11. Current treatment guidelines recommend:

- a. First-line NSAID therapy.
- b. A combination of nonpharmacologic and pharmacologic treatments.
- c. Initial treatment should focus on severe pathology as seen on x-rays.
- d. Use of alternative therapies.

12. Successful self-management strategies:

- a. Consist primarily of patient education.
- b. Focus exclusively on exercise and weight management.
- c. Employ behavioral therapy only.
- d. Encompass a combination of education, behavior modification, and self-efficacy skills.

13. Patients with osteoarthritis should aim to engage in moderate physical activity:

- a. Daily.
- b. At least 3 days a week.
- c. At least 60 minutes at a time.
- d. When their pain level permits.

14. One exercise that is particularly vital for patients with knee osteoarthritis is:

- a. Quadriceps strengthening.
- b. Flexibility exercise.
- c. Hamstring stretch.
- d. Isotonic exercise.

15. Adherence to self-management activities and exercise can be improved by:

- a. Frequent follow-up visits.
- b. Use of TENS prior to exercise.
- c. Regular telephone contact with health care providers.
- d. There is no agreement on ways to improve adherence.

16. A patient with osteoarthritis whose BMI is 24.3 should:

- a. Try to maintain his current weight.
- b. Aim to lose 10% of his current weight.
- c. Initiate a program of diet and exercise.
- d. Reduce his amount of dietary fat intake.

17. The most commonly recommended first-line medication for osteoarthritis is:

- a. Celecoxib.
- b. Acetaminophen.
- c. Ibuprofen.
- d. Aspirin.

18. Nonselective NSAIDs relieve pain by:

- a. Inhibiting only COX-2 enzymes.
- b. Distracting attention away from the joint pain.
- c. Blocking neurotransmitters.
- d. Inhibiting COX-1 and COX-2 enzymes.

19. The best choice of NSAID for patients with cardiovascular risk is:

- a. Naproxen.
- b. Celecoxib.
- c. Ibuprofen.
- d. Acetaminophen.

20. If a patient is experiencing inadequate pain relief on the prescribed NSAID, he should:

- a. Take the medication more often.
- b. Stop taking it.
- c. Add an over-the-counter anti-inflammatory drug.
- Ask his health care provider about increasing the dose or switching to another medication.

CE Credit

To obtain 3.0 hours of continuing education credit (0.3 CEUs) for "Supporting Patient Self-Care for Osteoarthritis," complete the assessment exercise, fill out the CE Examination Form at the end of this publication, and return that page to APhA. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before May 23, 2011, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is 202-000-08-143-H04-P.

"Supporting Patient Self-Care for Osteoarthritis," is a home-study continuing education program for pharmacists developed by the American Pharmacists Association and supported by an independent educational grant from McNeil Consumer Healthcare.





CE EXAMINATION FORM

Supporting Patient Self-Care for Osteoarthritis

To receive **3.0** contact hours of continuing education credit **(0.3 CEUs)**, please provide the following information:

- 1. Type or print your name and address in the spaces provided.
- 2. Mail this completed form for scoring to:

American Pharmacists Association—CE Exam P.O. Box 791082 Baltimore, MD 21279-1082

 The CE processing for grading the assessment instrument and issuing the Statement of Credit is supported by an independent educational grant from McNeil Consumer Healthcare.

A Statement of Credit will be awarded for a passing grade of 70% or better. If you fail the exam, you may retake the exam once. If you do not pass the second time, you may no longer participate in this continuing pharmacy education program. Please allow 6 weeks for processing. Pharmacists who complete this exercise successfully before **May 23, 2011**, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is: 202-000-08-143-H04-P.

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CE ASSESSMENT QUESTIONS-ANSWERS

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PARTICIPANT INFORMATION

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| HOME PHONE | | |

How long did it take you to read the continuing education program and complete this test? ______Hours ______Minutes

My signature certifies that I have independently taken this CE Examination:

Please circle your answers (one answer per question). a b c d 16. 11 a b c d 12. abcd 17. a b c d 13. abcd 18. a b c d 14. 19. abcd abcd a b c d 15. 20. a b c d

PROGRAM EVALUATION

| PLEASE ANSWER EACH QUESTION. | EXCELLENT | | | | POOR | |
|--|-----------|---|---|---|------|--|
| 1. Overall quality of the program | 5 | 4 | 3 | 2 | 1 | |
| 2. The program was relevant to pharmacy practice | 5 | 4 | 3 | 2 | 1 | |
| 3. Value of the content | 5 | 4 | 3 | 2 | 1 | |

| PLEASE ANSWER EACH QUESTION MARKING WHETHER YOU AGREE OR DISAGREE. 4. The program met the stated learning objectives: | Agree | Disagree |
|--|-----------------|----------|
| Discuss the prevalence of osteoarthritis and its impact on health and quality of life. | | |
| Explain the pathophysiology, clinical presentation, and diagnosis of osteoarthritis. | | |
| Describe the nondrug options for managing osteoarthritis, including self-management, exercise, weight control, joint protection strategies, and complementary therapies. | | |
| Compare and contrast the efficacy, adverse effects, and cautions associated with the various drug therapies used to manage osteoarthritis. | | |
| Outline patient education needs and describe strategies to facilitate self-care and optimize drug therapy outcomes for patients with osteoarthritis. | | |
| 5. The program increased my knowledge in the subject area. | | |
| 6. The program did not promote a particular product or company. | | |
| Impact of the Activity | | |
| The information presented (check all that apply): | | |
| 7. 🗅 Reinforced my current practice/treatment habits 🛛 Will improve my practice/patient outcomes 🖓 Provided new ideas or information I expect | t to use | |
| Enhances my current knowledge base | | |
| 8. Will the information presented cause you to make any changes in your practice? Yes No | | |
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| 8. Will the information presented cause you to make any changes in your practice? | 🖵 Yes | | LI NO |
|---|----------------------|----|----------------------------|
| 9. How committed are you to making these changes? | (Very committed) 5 4 | 43 | 2 1 (Not at all committed) |
| 10. Do you feel future activities on this subject matter are necessary and/or important to your practice? | 🗅 Yes | | 🗅 No |

Follow Up

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

Yes, I am interested in participating in a follow-up survey.

Novemalso can go to http://www.pharmacist.com and take your test online for instant crediteso





Overcoming Race-Based Disparities in Pain Management

A Continuing Education Monograph for Pharmacists



October 2008

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APhA's editorial staff declares no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

This publication was prepared by Judy Crespi Lofton, MS, of JCL Communications on behalf of the American Pharmacists Association.



This program was developed by the American Pharmacists Association and supported by an independent educational grant from the Pain Management Partnership.

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PHARMACEUTICALS

Learning Objectives

After reading this monograph, the pharmacist will be able to:

- **1.** Describe the extent and nature of race-based disparities in the management of pain in the United States.
- 2. Identify the presence of any unintentional disparity in his or her own practice.
- **3.** Explain strategies that can be used to improve communication with patients and assess pain in patients from a variety of sociocultural backgrounds.
- Discuss strategies that pharmacists can use to support access to appropriate pain management for all patients.

ACPE Activity Type: Knowledge-Based

Introduction

Disparities in health care based on race and ethnicity are widespread and have deep roots in American society. Prior to the Civil Rights Act of 1964, racial segregation in hospitals was legal and commonplace, and represents only one aspect of the systematic discrimination that existed in health care. Much progress has been made in the ensuing decades, but inequities remain in many areas of health care. Although socioeconomic status plays a role in disparities, it does not fully explain them.

In 2002, the Institute of Medicine (IOM) released a groundbreaking report titled *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare*. The IOM concluded that even when controlling for other factors, "minorities are less likely than whites to receive needed services.... These disparities exist in a number of disease areas, including cancer, cardiovascular disease, HIV/AIDS, diabetes, and mental illness, and are found across a range of procedures, including routine treatments for common health problems."¹

One of the myriad areas in which racial disparities in health care have been noted is pain management. This monograph explores evidence of these disparities, reasons for race-based biases, and strategies that can be used to help eliminate inequities.

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Racial Disparities in the Treatment of Pain

acial disparities have been noted in many aspects of pain management, including patient assessment and treatment for chronic nonmalignant pain, acute pain presenting in emergency departments, and cancer pain. Management of pain can be influenced by various members of the health care system, including physicians and other prescribers, as well as pharmacists. A systematic review of published results of the interface between race and pain treatment found that, compared with white patients, minority patients are²:

- More likely to have their pain underestimated by providers.
- Less likely to have documented pain scores.
- Less likely to receive opioids.
- More likely to have their pain undertreated.

Assessment of Pain

An accurate pain assessment is the cornerstone for developing an appropriate treatment plan. A physician's estimation of the severity of pain experienced by patients has been shown to be a critical factor affecting pain management. In one study, it was found to be the only factor that affected pain management, regardless of race.³

Physicians are much more likely to underestimate pain than to overestimate it, even in patients whose pain results in poor physical function. Panda et al. found a discordance of 2 or more points on a 10-point rating scale between physician and patient ratings of pain in 54% of encounters with 463 patients with chronic nonmalignant pain. Pain was underestimated by physicians 39% of the time, and overestimated 15% of the time. When physicians underestimated pain, they did so by a mean of 3.9 points on the 10-point rating scale. Black patients were twice as likely as others to have their pain underestimated (P<.05).⁴

Treatment of Pain in Emergency Departments

Some, but not all, studies of the treatment of pain at emergency departments in the United States have found that patients' race/ethnicity affects providers' opioid prescribing practices. Evidence of these disparities has been found in patients with long-bone fractures, back pain, migraine, and musculoskeletal pain.⁵⁻⁸ Furthermore, one study found that when opioids are prescribed, white patients are administered the medication faster than individuals from other ethnic groups.⁹

Two studies conducted in the United Sates found no evidence of bias.^{10,11} Researchers who have documented equitable pain treatment in emergency departments have postulated that differences in study populations, as well as characteristics of the hospital, contribute to this divergence.^{10,11} Some researchers suggest that hospitals treating larger proportions of minority patients may be more sensitive to the needs of minority patients than other institutions.^{10,11}

Nevertheless, the National Hospital Ambulatory Medical Care Survey—the largest, nationwide assessment of emergency department practices—indicated that, although disparity is not universal, it is pervasive. This 13-year (1993–2005) review of treatments received by patients at a nationally representative sample of U.S. emergency departments found significant disparities in opioid prescribing (FIG-URE 1).¹² Although overall rates of opioid prescribing increased over

Figure 1. | Overall Rates of Opioid Prescribing for Patients by Race/ Ethnicity in U.S. Emergency Departments, 1993–2005

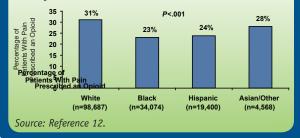
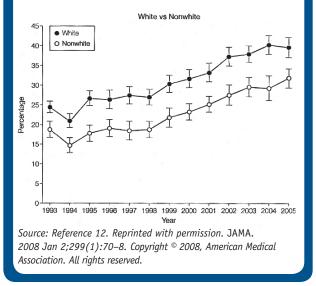


Figure 2. |Rates of Opioid Prescribing in U.S. Emergency Departments Over Time, 1993–2005



time (coinciding with national pain-related quality improvement efforts [e.g., The Joint Commission initiatives]), disparities in prescribing by patient race/ethnicity were not affected (FIGURE 2). Differential opioid prescribing became more pronounced as the reported level of pain increased. Disparity was detectable for all types of pain, among all diagnoses, and even among children.¹²

Treatment of Pain in the Veterans Affairs Health Care System

Saha et al. conducted a systematic review of racial disparities in the Veterans Affairs (VA) health care system—an institution in which financial barriers to receiving care are minimized and commitment to delivering equitable care is expected. This review found racial differences in the rates of analgesic prescribing: fewer opioid prescriptions were written for blacks. When blacks were prescribed an opioid, they had a lower mean days' supply, and lower morphine equivalent doses than whites. Furthermore, less analgesia was prescribed even though blacks tended to report higher levels of pain than whites.¹³

Cancer Pain

Opioid prescribing disparities are also evident among patients who have cancer.¹⁴ Being nonwhite has been associated with poor pain management in patients with cancer in several studies.¹⁴⁻¹⁶ For example, in a study by Cleeland et al., the percentage of patients with cancer whose pain was poorly managed was 38% for white patients and 59% for minority patients (P<.001).¹⁶

The Impact of Pharmacists on Pain Management Disparities

acial disparities in pain management often arise during patient assessment and in prescribing decisions, which typically occur before the patient interacts with a pharmacist. Nevertheless, many aspects of the patient-pharmacist interface can be influenced by racial disparities, including pharmacist interactions with patients and pharmacy practices of stocking an adequate supply of opioids.

Patient Interactions

Although data regarding the potential appearance of race-based disparities in pharmacists' interactions with patients have not been published, there are areas that pharmacists should consider as they evaluate their own practices. For example, each time a patient presents a prescription for a controlled substance, the pharmacist must make a determination about the legitimacy of the prescription. There is a chance that the patient's race could affect this determination.

Racial disparities could also appear while providing patient education during dispensing of a prescription. This could manifest in the amount of time and effort spent ensuring that the patient understands the appropriate use of the medication, and whether the patient leaves the interaction feeling that the pharmacist demonstrated an appropriate level of respect and courtesy.

In addition, the number of pharmacists who are providing medication therapy management and other direct patient care services is increasing rapidly. During such patient encounters, pharmacists must assess the patient, make clinical judgments about the patient, and communicate with the patient and the other members of the health care team. Each of these steps could be influenced by racial biases. Finally, the level of advocacy the pharmacist provides for patients with poorly managed pain could be affected.

Opioid Availability

A pharmacy's decision whether to stock a sufficient supply of analgesic medications and formulations to meet varying patient needs can have an important influence on a patient's access to appropriate analgesia. Existing data indicate that minority patients have reduced access to opioids as a result of pharmacy stocking patterns in predominantly minority neighborhoods.¹⁷⁻¹⁹

Stop and Think: What opioids do you routinely stock in your pharmacy? Do these stocks meet the needs of the patients in your community, or do you often find that you must order the medications or send the patients elsewhere?

In 2000, Morrison et al. found that New York City pharmacies in nonwhite neighborhoods were significantly less likely than those in predominantly white neighborhoods to carry sufficient opioids for treating severe pain (25% vs 72%, P<.001).¹⁷ The primary reasons given by pharmacies that did not stock opioids included regulatory concerns (including oversight and paperwork), low demand, and fear of theft. Pharmacy theft rates across neighborhoods could not account for this disparity.¹⁷

Most New York City pharmacies that did not stock the opioids stated that they could order the medication and have it for the patient within 72 hours.¹⁷ However, 72 hours is a long time to wait for a patient in severe pain. If a patient chooses to travel to another pharmacy for the medication, it could add increased financial and practical burdens for the patient, and result in the primary pharmacy not having a complete record of that patient's medications.

Stop and Think: How often do patients bring prescriptions for opioids to your pharmacy? Do you feel that members of your pharmacy community are prescribed an appropriate level of analgesia? Have you noticed any racial influences on prescribing patterns?

A study by Green et al. published in 2005 found similar opioid stocking patterns in Michigan. Even when all other factors were held constant, the racial composition of the neighborhood was found to play a significant role regarding whether a pharmacy stocked opioids for white compared with minority neighborhoods (86% vs 54.2%, P <.01).¹⁸

In 2008, Mayer et al. reported evidence of race-based disparities in Washington State pharmacies. Pharmacies located in nonwhite neighborhoods were more likely to be deficient in opioid stocks. However, the authors noted that over 90% of the pharmacies surveyed had a broad supply of opioids available.¹⁹ Thus, they postulated that most residents would have access to a pharmacy with sufficient opioids available.¹⁹ The authors concluded that the high rate of opioid availability in responding pharmacies in Washington State, compared with those noted in other surveys, was attributable to regional differences, including a regional culture that promotes adequate pain treatment.¹⁹

Stop and Think: Why do you think racial disparities exist in pain management? What actions do you think could help reduce inequities?

Understanding the Causes of Racial Disparities in Pain Management

ost health care providers are troubled by vestiges of bias within health care. Health care providers take oaths of practice and dedicate themselves to provide ethical care to all patients. Surprisingly, health care disparities are noted even among health care providers who describe themselves as committed to egalitarian principles.¹ Socioeconomic status and access to health care may play a part in contributing to disparities in pain management. Socioeconomic inequality is an important issue that affects health care, but is beyond the scope of discussion in this monograph.

Differences in patient preferences for treatment also may play a role in racial disparities. Ethnic and cultural variations have been reported regarding patient beliefs and expectations about experiencing pain and receiving treatment.^{20,21} However, according to the IOM, "though myriad sources contribute to these disparities, some evidence suggests that bias, prejudice, and stereotyping on the part of healthcare providers may contribute to differences in care."¹

Patient Attitudes About Pain Treatment

Persons from diverse ethnic and cultural backgrounds may have different expectations for their pain care and interactions with the health care system. In one study, over 80% of socioeconomically disadvantaged black and Hispanic patients stated that they would wait until their pain severity reached a "10" before contacting a health care provider.¹⁵ This study also found a large percentage of minority patients who wondered why their health care providers did not know about their pain and take care of it.¹⁵ However, other studies have found that minorities seek treatment for pain at the same rates as whites, and have similar expectations for pain treatment.²

In addition, patients from diverse cultural backgrounds may express their pain differently, and have dissimilar attitudes about stoicism and the use of opioids in the treatment of pain.²² Health care providers who participate in cultural competence training may be more adept at navigating and interpreting varying attitudes and communication styles.

The Subjective Nature of Pain

Pain is a subjective experience. Although rating scales and similar tools are often used to elicit patient reports of pain as well as to assess and monitor the patient's experience and functional capacity (e.g., quality of sleep, ability to work, capacity to maintain a household), these tools largely rely on the patient's reports of the experience. Because these reports are subjective, it is possible that stereotypes may influence health care providers' interpretations of the patient's report.

On occasion, health care providers may not fully trust patients' reports of pain for a variety of reasons. These reasons may include believing that the patient is exaggerating pain because of poor coping skills, judgments about the value of stoicism, or misestimating how much pain a condition should cause. In addition, health care providers must balance appropriate pain management with the need to identify individuals who intentionally provide dishonest answers to obtain controlled substances for misuse, abuse, or diversion.

Therefore, health care providers must carefully evaluate patients' reports of pain and functional status when determining the appropriate course of treatment. These decisions are often made in conditions where the provider is pressed for time and may be juggling many competing demands—situations in which stereotypes tend to be more influential.²³

Stereotypes

Stereotypes are defined as beliefs, feelings, and expectations about a category or group of people. Stereotyping is a component of normal human cognitive psychology. The development and application of stereotypes is an almost universal phenomenon and may have been evolutionarily adaptive.²³ People hold stereotypes about all types of groups and have certain expectations about members of those groups.

| Stop and Think: What the following groups of | | o mind for each of |
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| | LawyersMovie stars | PhysiciansTriathletes |
| Each of these images that group. | s is a stereotype | about members of |

Stereotypes are often unconsciously and automatically activated to influence judgments and behaviors toward individuals in a category.²³ Stereotypes are likely to be damaging when they are applied to groups that face stigma within the larger culture.²³ Negative images of minorities that are sometimes presented in American culture and the media may contribute to unconscious negative stereotypes about these groups.

Because stereotyping is pervasive, "healthcare providers sometimes activate and apply stereotypes when making sense of patients regardless of level of commitment to equality and desire to make decisions on the basis of clinically relevant attributes of the individual patient."²³

Stereotypes can influence interactions with patients both by setting the tone for the interaction and by influencing provider decision making. The influence of a patient's race on the provider's decisionmaking process appears to increase as the complexity of the decision increases.²³ The complex and subjective nature of making decisions about pain management are further complicated by risks associated with some of the most powerful analgesics (including risks to the patient, society, and the provider as a result of regulatory oversight). Thus, it is likely that pain management can be affected by stereotypes.

Good pain management requires a positive relationship with open communication between the health care provider and the patient. Stereotypes held by both patients and health care providers can influence the interaction, and can lead to a self-fulfilling prophecy. Physicians have reported that their decisions whether to prescribe an opioid for a patient are sometimes guided by "gut feelings," "hunches," or "instinct," rather than any specific objective criteria.²³ Such feelings may hinder a positive relationship, particularly if they are based on an unconscious negative stereotype. Conversely, if a patient fits a positive stereotype held by the health care provider, it could cause the provider to underestimate that patient's risk for misusing, abusing, or diverting medications, and fail to appropriately screen and monitor the patient's use of controlled substances.

Because of the pervasiveness of stereotypes, individuals from minority populations may experience subtle racism on a regular basis and may occasionally encounter overt acts of racism.²⁴ Furthermore, many black and Hispanic patients report that they perceive racism in the health care system.²⁵

Such perceptions by patients may possibly contribute to racial disparities in several ways. For example, if a hypothetical patient were concerned that a pharmacist might question the validity of his prescription because he belongs to a minority racial group, the patient may be nervous and act fidgety and fail to look the pharmacist in the eye. In this scenario, the pharmacist, in turn, might notice the behavior, think the patient has something to hide, and be more likely to question the legitimacy of the prescription. Such

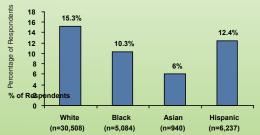
Do Rates of Opioid Misuse and Abuse Influence Treatment Decisions?

Is it possible that minorities receive fewer opioids for pain management than whites because they have higher rates of misuse of these medications? Available evidence indicates that minority patients do not appear to be more likely than white patients to misuse prescription medications. Notably, the opposite appears to be true.

Overall rates of substance dependence and abuse in the United States are tracked in the National Survey on Drug Use and Health (NSDUH). The most recent results, from 2006, found that the rate of substance abuse/dependence to any illicit substance was lower in Asians (4.3%) and similar among Hispanics (10.0%), whites (9.2%), and blacks (9.0%).²⁶

As illustrated below, the NSDUH results also showed that whites appear to be more likely than other racial/ethnic groups to use pain relievers for nonmedical purposes.

Lifetime Nonmedical Use of Pain Relievers in Adults, NSDUH 2006²⁶



Furthermore, in another study of patients who abused sustained-release oxycodone, 91% of patients who abused the medication were white.²⁷ In separate surveys of college students, one showed that blacks, Hispanics, and Asians were less likely than whites to use prescription opioids for nonmedical reasons,²⁸ and the other showed that both whites and Hispanics were significantly more likely to engage in illicit use of prescription drugs than blacks.²⁹

interactions can then reinforce the patient's initial expectations and inhibit a productive clinical relationship.²³

Observations of clinical encounters at the VA suggest that the provider's expectations about the patient's demographic group influence both the degree of empathy displayed during the interaction and the quality of the communication with the patient. These effects were strongest in encounters with patients whose pain complaints were most ambiguous.²³ In this study, physicians' negative expectations before meeting patients were found to set the tone for entire encounters, cause physicians to rush through encounters, and give patients fewer opportunities to ask questions.²³ Thus, negative stereotypes can have a pervasive influence on patient-provider relationships.

Strategies to Overcome Disparities

everal strategies can be used to help reduce racial disparities in pain management. The IOM stresses that a key way to address disparities is to make health care providers aware that these disparities exist, and often arise unconsciously. Such awareness may allow for more mindfulness of the factors that affect decision making when faced with an ambiguous clinical situation. Furthermore, it facilitates the self-examination necessary to consider one's own stereotypes of various groups, and how these can unconsciously affect health care decision making. Thus, greater awareness of the existence and nature of disparities may in and of itself help to counter the effects of stereotypes.²⁴

In addition, the IOM calls upon health care professionals to participate in cross-cultural training. Research shows that such training can improve communication with patients from diverse racial and ethnic backgrounds.¹

Increase the Proportion of Minority Health Care Professionals

More than one quarter of the U.S. population is nonwhite, however minority groups comprise only 10% of health care professionals.³⁰ Among the 2007 graduating class of doctor of pharmacy students, only 7% were black, and 4% were Hispanic.³¹

Many have cited the need to increase the ranks of minorities among health care professionals as an important step toward reducing disparities.^{30,32} However, patients should be able to receive top quality care from all providers. Currently practicing health care providers, regardless of their race and ethnicity, must commit to understanding and addressing the causes of disparities and help to eliminate them.

Countering Stereotypes

Research from cognitive psychology provides insights regarding how to counteract the negative influence of stereotypes. This research indicates that openly acknowledging the existence of stereotypes can facilitate sensitivity to the negative impact of the stereotype; once acknowledged, strategies can be developed to counteract the stereotype.³³ This strategy appears more effective than denying and acting to suppress stereotypes.³³ Attempting to suppress stereotypes appears to lead to short-term benefits followed by a "rebound" effect, in which the stereotype has a stronger influence later.³³ Furthermore, the cognitive effort required to suppress a stereotype can impair the quality of decision making.³³

Increased interactions with members of the group that is the subject of the racial stereotype can also help improve interracial interactions.³³ Researchers recommend that health care providers seek out collegial interactions with members of other racial and ethnic groups to increase their comfort level with members of those groups and help diminish an "us versus them" mentality.³³

People tend to have more empathy for those who are perceived as similar to themselves.²³ Therefore, health care providers may have less empathy for members of other racial and ethnic groups.²³ Programs designed to increase empathy skills have been shown to reduce bias and inhibit unconscious stereotypes.³³ The simple act of attempting to view things from the other's perspective can have a strong impact on reducing the negative influence of stereotypes.³³

Communication Strategies

Good communication is essential for pain to be appropriately assessed and treated. Communication techniques such as trust building and including patients in the decision-making process have been identified as pivotal areas for addressing disparities.¹⁴

Pharmacists can work to develop communication skills to help foster positive relationships with patients. Strategies for improving communication include:

- Asking open-ended questions (those that cannot be answered with "yes" or "no").
- Using active listening techniques.
- Allowing patients to finish expressing their thought without interruption.
- Being aware of nonverbal communication including body language, eye contact, and tone of voice.
- Responding to the patient with empathy.
- Summarizing for patients your understanding of what they said. For example, "Mrs. Smith, what I'm hearing you tell me is that one of your primary concerns about your pain is that you don't think you can care for your children as well as you would like."
- Taking into account the patient's health literacy and ensuring that the patient understands the information provided, and can explain it back to you.
- Considering the patient's cultural background and seeking to value and appreciate cultural differences as well as their influences on the patient's expression of symptoms and interest in treatment strategies.
- Assessing patients' expectations for treatment to ensure that their beliefs and hopes are reasonable and consistent with the treatment plan, and providing additional education as needed.
- Obtaining an interpreter as needed for individuals who have difficulty understanding or speaking the English language.

These communication strategies may help to address disparities in pain management, as well as improve overall communication with patients.

Using Objective Criteria in Pain Management

According to the IOM, "Any degree of uncertainty a [health care provider] may have relative to the condition of a patient can contribute to disparities in treatment." When health care providers are uncertain, they are more likely to make judgments about patients based on their stereotypes about those patients.¹

Therefore, reducing the clinical ambiguity that may be present in pain management may also reduce disparities. Many tools, beyond simple rating scales, can help serve this purpose.

Stop and Think: What objective criteria could you use to guide your assessments of pain and the legitimacy of controlled substance prescriptions?

Some authors promote the use of "universal precautions" to treat patients with chronic pain for the purpose of reducing stigma and overall risk associated with prescribing controlled substances.³⁴ These precautions call for a standardized series of steps that should be applied to all patients receiving chronic therapy with controlled substances. Such measures may help to reduce the ambiguity inherent in prescribing controlled substances, thereby reducing disparities.

Standardized assessments can be useful in evaluating the risk for misuse of opioid prescriptions. If assessment tools are used in practice, they should be employed in a systematic fashion that is consistent across all patients that fit appropriate criteria. Available tools include:

- Opioid Risk Tool. This instrument can help providers predict which patients receiving chronic opioid therapy will develop aberrant behaviors.³⁵
- Screener and Opioid Assessment for Patients in Pain (revised). This tool assists in predicting the amount of monitoring a patient receiving long-term opioid therapy will require.³⁶

Many pain management practitioners advocate the use of formal, written controlled substance agreements, particularly in the treatment of chronic pain. These agreements specify the conditions under which opioids will be prescribed. Criteria listed in these agreements include³⁷:

- Requirements that the patient receive controlled substance prescriptions from only one prescriber and have the prescriptions filled at only one pharmacy.
- Consent to random urine drug screens.
- Behaviors, such as the concurrent use of alcohol and/or illegal substances or unsanctioned dose escalations, that will result in termination of controlled substance treatment.
- Identification of a contact person in case of an emergency.
- Defined goals of therapy.
- Informed consent statement.

Health care practitioners may feel more comfortable prescribing to members of other ethnic groups when a written contract clearly describes the criteria for opioid provision.³⁰ Such agreements generally require increased communication with the patient, which can improve the patient-provider relationship, enhance patient education, and contribute to a better therapeutic relationship.³⁰ Furthermore, if patients are educated that controlled substance agreements are used routinely in practice, it may alleviate perceptions of being singled out for a heightened level of scrutiny.

In some, but not all, cases, patients are asked to have these contracts signed by their pharmacy to facilitate better communication among team members. Pharmacists who dispense opioids to patients with chronic pain may opt to contact the prescriber to determine whether there is an opioid agreement in place and ask to receive a copy of it (along with the care plan and/or SOAP notes), so that they can participate more fully in monitoring the patient's care.

Prescription Legitimacy

Pharmacists have both legal and ethical responsibilities not to fill prescriptions that are fraudulent. Great care must be taken when evaluating the legitimacy of prescriptions to create an appropriate balance between providing access to controlled substances when there is a medical need, and preventing their misuse, abuse, and diversion.

In addition to assessing the clinical appropriateness of a prescription, pharmacists should look for physical signs that the prescription may have been tampered with or forged, or raises other red flags.

When pharmacists have concerns about the legitimacy of the prescription, they should pause to examine whether there are any specific objective criteria that led to the concern. This recommendation does not necessarily indicate that pharmacists should ignore the sense that "something just doesn't feel right," but they should reflect to ensure that the patient's appearance does not have an unjustified influence on their assessment. When concerns about a prescription's legitimacy exist, the pharmacist should attempt to contact the prescriber for verification of the prescription. If the prescriber cannot be contacted, a partial fill may be issued to allow additional time for follow-up.

Pharmacy Stocking

Medication stocking is a complex task that must balance many factors, including demand for the medications. However, pharmacists who do not carry adequate supplies of opioids should carefully evaluate this decision to determine whether it is being made for the right reasons. As part of this analysis, pharmacists should consider whether they have any patients who are required to have their prescriptions filled at their pharmacy as a stipulation of a controlled substances agreement, and take steps to maintain adequate stocks to ensure access for these patients.

Stop and Think: Are any of your patients required by a controlled substances agreement to use only your pharmacy? If you answered no, how can you be certain? If yes, how do you think these patients would be affected if you were temporarily out of stock of their medications?

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Conclusion

acial disparities in health care generally arise unintentionally and are driven in part by unconscious activation of negative stereotypes about minorities. Health care providers can take steps in their own practices to help ensure fair and appropriate treatment for all, including being aware of the stereotypes they may have regarding different racial or ethnic groups, working to improve communication skills in a culturally competent manner, and incorporating objective criteria whenever possible.

Pharmacists must provide reasonable safeguards to protect their practices against counterfeit prescriptions and ensure that the medications that they dispense are clinically appropriate. Nevertheless, pharmacists should be mindful not to allow negative stereotypes to influence their perception of the legitimacy or appropriateness of a prescription. Furthermore, pharmacists can assess and reassess patients' pain to help support optimization of treatment outcomes, and should make efforts to provide high-quality care to all patients, regardless of their race or ethnicity.

Ultimately, pharmacists have an obligation to their patients and society to maintain a careful balance between providing analgesics for legitimate patients and preventing the misuse, abuse, and diversion of controlled substances. Pharmacists must also strive to keep racial biases, including unintentional ones, from affecting this balance.

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CE EXAM ASSESSMENT QUESTIONS

INSTRUCTIONS: The assessment questions printed below allow you to preview the online CE exam. For each question, circle the letter corresponding to the correct answer. There is only one correct answer to each question. Please review all of your answers to be sure you have properly marked them when you take the CE exam online.

- 1. Compared with minority patients, white patients are:
 - a. More likely to have their pain undertreated.
 - b. Less likely to receive opioids.
 - c. Less likely to have their pain underestimated.
 - d. Less likely to have documented pain scores.
- 2. In the study by Panda et al. of patients with chronic nonmalignant pain, physicians who underestimated patient's reports of pain did so by how many points on a 10-point rating scale?
 - a. 1.2 points.
 - b. 2.2 points.
 - c. 2.9 points.
 - d. 3.9 points.
- 3. A study that reviewed opioid prescribing practices at a nationally representative sample of emergency departments found that:
 - a. Disparities in opioid prescribing decreased over time.
 - b. Hispanics were prescribed opioids significantly less frequently than blacks.
 - c. Overall rates of opioid prescribing increased over time.
 - d. Disparities were detectable only among patients with chronic nonmalignant pain.

4. In a study of patients with cancer pain by Cleeland et al., which of the following findings was reported?

- a. More than half of white patients had poorly managed cancer pain.
- b. More than half of minority patients had poorly managed cancer pain.
- c. Blacks were less likely than whites to have poorly managed cancer pain.
- d. There were no racial disparities noted in the management of cancer pain.

5. Which of the following statements about pharmacy stocking of opioids is true?

- a. Disparities in opioid stocking among neighborhoods in New York City can be attributed to rates of pharmacy theft.
- b. More than 90% of pharmacies in Michigan carried adequate supplies of opioids.
- c. In New York City, Michigan, and Washington State, the racial composition at a pharmacy's location has a significant impact on opioid stocking.
- d. Most pharmacies that do not stock opioids also refuse to order them for patients.

6. Which of the following statements about pharmacists and pain management disparities is true?

- a. If their pharmacy stocks an adequate supply of opioids, pharmacists can feel comfortable that they are not contributing to disparities.
- b. Pharmacists could unconsciously be more suspicious of prescriptions for controlled substances from minority patients than from white patients.
- c. Substantial published evidence indicates that pharmacists intentionally refuse to dispense controlled substances to minority patients.
- d. Pharmacists do not have an impact on racial disparities in health care.

7. Which of the following statements about pain assessment is true?

- a. The subjective nature of pain allows stereotypes to play a larger role in decision making by health care providers.
- b. The use of pain rating scales eliminates subjectivity in the assessment of pain.
- c. Health care providers do not need to worry about being duped by individuals who are seeking controlled substances.
- d. All patients express and cope with pain in the same manner, regardless of race or ethnicity.

CE EXAM ASSESSMENT QUESTIONS

8. Stereotypes are:

- a. Present only in individuals who are racist.
- b. A normal component of human psychology.
- c. The root cause of all racial disparity in pain management.
- d. Usually applied intentionally.

9. Which of the following statements about stereotypes is true?

- a. Patients' stereotypes about health care providers have no effect on treatment.
- b. Stereotypes generally have no influence until the end of the patient encounter.
- c. Stereotypes are always negative.
- d. Stereotypes can set the tone for the entire patient encounter.

10. National survey data indicate that which racial group is most likely to use pain relievers for nonmedical purposes?

- a. Whites.
- b. Blacks.
- c. Asians.
- d. Hispanics.

11. What percentage of health care providers in the United States belong to minority racial groups?

- a. 5%.
- b. 10%.
- c. 15%.
- d. 20%.

12. Cognitive psychology research indicates that an effective way to counter the negative influence of stereotypes is to:

- a. Encourage health care providers to suppress their stereotypes.
- b. Have patients treated only by health care providers of their own race or ethnic group.
- c. Acknowledge the existence of stereotypes and attempt to view the situation from the other person's perspective.
- d. Implement sanctions against health care providers whose practices show evidence of racial disparity.

13. Which of the following strategies is likely to foster improved communication?

- a. Providing all patients with written instructions for how to use a medication.
- b. Focusing on asking questions that can be answered simply "yes" or "no."
- c. Assuming that all patients have the same goals for treatment.
- d. Summarizing for the patient your understanding of what the patient said.

14. In the context of pain management, what are "universal precautions"?

- a. A standardized series of steps that should be applied to all patients receiving chronic therapy with controlled substances.
- b. A list of behaviors that suggest a patient may be misusing, abusing, or diverting controlled substances.
- c. A series of steps designed to prevent opioidinduced adverse events including constipation and respiratory depression.
- d. A prescription stocking management framework designed to minimize the risk of theft.

15. Which of the follow statements about written controlled substances agreements is true?

- a. They often require patients to have all controlled substances filled at only one pharmacy.
- b. Their use should be limited to patients who have a prior or current history of substance abuse.
- c. Their use is limited to the treatment of patients with acute pain.
- d. Their wording is usually vague and ambiguous to allow clinicians to use their own judgment in interpreting them.

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To obtain 1.5 hours of continuing education credit (0.15 CEUs) for "Overcoming Race-Based Disparities in Pain Management," complete the assessment exercise and submit it online by following the above-mentioned instructions. A Statement of Credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before October 1, 2011, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is 202-000-08-224-H01-P.

"Overcoming Race-Based Disparities in Pain Management," is a home-study continuing education program for pharmacists developed by the American Pharmacists Association and supported by an independent educational grant from the Pain Management Partnership.







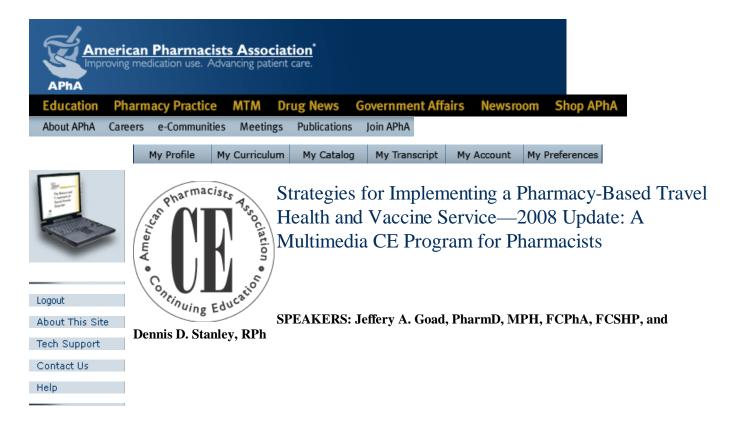
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Program Description

Each year more than 60 million travelers leave the United States for international destinations. Whether traveling to New Delhi for business, South America for humanitarian missions, or the plains of Africa on safari, travelers are at increased risk of disease. As international travel becomes increasingly more common, pharmacists have the opportunity to assume new roles as providers of pre-travel health education, counseling, and immunization services. Of the millions of Americans traveling abroad each year, few seek travel health advice before departure thus increasing their health and safety risks. Because of their accessibility and knowledge about immunizations and infectious diseases, pharmacists are in an excellent position to serve as pre-travel health advisors and, depending on the state, to advocate, facilitate, or administer travel vaccines. Pharmacists also play a valuable role in counseling patients about other travel health issues, such as the prevention of malaria, managing traveler's diarrhea, avoiding vector-borne disease, and other safety concerns.

This multimedia educational program presents the many reasons and opportunities for pharmacists to become involved in travel health, reviews currently available travel vaccines, and discusses counseling strategies for diseases that cannot be prevented by vaccination. Travel health and vaccine services can produce new revenue streams for pharmacists, not only for vaccine administration but also for sales of ancillary products, such as water purifiers, insect repellants, and various prescription and nonprescription medications. Strategies to implement a pharmacy-based travel clinic, including liability issues, workflow considerations, reimbursement, and marketing, also are discussed.

Learning Objectives

At the end of this activity, pharmacists will be able to:

- Explain the need for appropriate travel immunizations.
- Review current travel immunization rates.
- List the most common diseases that travelers need to be immunized against.
- Discuss the business potential in developing a travel immunization service.
- Identify the regulatory issues of a pharmacy-based travel

Strategies for Implementing a Pharmacy-Based Travel Health and Vaccine Service—2008 Update: A Multimedia CE Program for Pharmacists" was developed by the American Pharmacists Association and supported by a grant from VaxServe, a sanofi pasteur company. immunization service.

- Discuss various technology programs that pharmacists can use to help travelers get the appropriate immunizations.
- Outline strategies for implementing a travel immunization service.



CE Credit

To obtain 3 hours of continuing education credit (0.3 CEUs) for completing "Strategies for Implementing a Pharmacy-Based Travel Health and Vaccine Service-2008 Update: A Multimedia CE Program for Pharmacists," complete the assessment exercise and posttest. A Statement of Credit will be automatically generated upon achieving a passing grade of 70% or better.

APhA continuing education policy provides you with two opportunities to successfully complete this continuing education examination. Please note that you will not be permitted to submit the examination a third time.

The Statement of Credit should be printed upon receipt; a duplicate copy will be available in the participant's transcript for further viewing. Individuals completing this program by April 30, 2011, can receive credit.



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ACPE Universal Program Number: 202-000-08-113-H01-P.

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Financial Disclosures

Jeffrey A. Goad, PharmD, MPH has served on the speakers bureau for Merck and on an advisory board for Vaxserve. Dennis D. Stanley, RPh has served on advisory boards for GlaxoSmithKline and VaxServe.

November 14, 2008

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Activity Fee

The CE processing fee for grading the assessment instrument and issuing the Statement of Credit is supported by an educational grant from VaxServe, a sanofi pasteur company.



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Hyperhomocysteinemia is a disease-state in which clinical pharmacists in the ambulatory care practice setting can be involved through lifestyle modification counseling interventions. High levels of serum homocysteine may result from renal dysfunction, enzyme deficiencies, and advanced age. However, environmental factors also contribute. Cigarette smoking and deficiency of the folic acid and B vitamin cofactors involved in homocysteine metabolism may result in hyperhomocysteinemia. In light of conflicting information in the literature regarding supplementation and changing clinical guidelines, the role vitamin supplementation is becoming increasingly ambiguous.

For the last five decades, the endogenous amino acid, homocysteine, has become a culprit in coronary disease. For the last three decades, the medical literature has correlated homocysteine reduction

by Whitney Raper, PharmD 2008 and Sarah Shrader, PharmD, BCPS Medical University of South Carolina

Controversy in Cardiovascular Risk Reduction: Folic Acid & Vitamin B Supplementation

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ACCP Ambulatory Care PRN Newsletter

may notice, it has received a face-lift this year! Enjoy, and please let us know what you think! ~Karen

with cardiovascular risk reduction in numerous observational studies. including meta-analyses and retrospective casestudies. Accontrol cording to this literature, a 5 μ mol/L increase in serum homocysteine correlates with a two-fold increase in cardiovascular and stroke risk. Conversely, a 3 µmol/L reduction in homocysteine correlates with an 11-16 percent reduction in cardiovascular risk, and a 19-25 percent reduction in stroke risk. Thus, the medical community has been hopeful about combating the number one killer in the United States with drug therapy targeted to lower ser serum homocysteine levels.

Folic Acid and B vitamin supplementation also appeared in observational studies in the 1980's as the hopeful silver bullet of cardiovascular risk reduction through its effect on homocysteine levels. Those studies showed a

Patients look to pharmacists for recommendations with respect to vitamin supplementation!

direct correlation between folic acid and Vitamin B6 and B12 supplementation and serum homocysteine reduction. Thus, the stage was set for a prospective clinical trial to directly correlate supplementation with cardiovascular risk reduction. The 2002 Swiss Heart study showed significant reduction in secondary cardiovascular events following folic acid and B vitamin supplementation, and folic acid and B vitamin supplementation was incorporated into the clinical guidelines listed below.

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Student's Corner: Tekturna®—a new treatment for hypertension

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Volume I, Issue I April 2008

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PRN Chair's Corner Eric MacLaughlin, PharmD, BCPS

Thank you for electing me to serve as your Chair. It is a privilege and honor to serve the PRN.

There are a number of specific goals that I would like to accomplish as Chair this year. These include:

Increase research opportunities and networking for PRN members. This is being accomplished through the work of the



Research Committee who will be streamlining the PRN seed grant process and exploring development of a Practice Based Research Network.

- Develop a pre-meeting symposium for our PRN members and collaborate with other PRNs/organizations to deliver high-quality educational programming. This is being accomplished through the work of the Education Committee, who has worked on, or is current working, on *four educational symposiums* with two other PRNs (Pharmacokinetics/Pharmacodynamics and Cardiology) and two external organizations (American Society of Hypertension and the Primary Care Special Interest Group of the European Society of Clinical Pharmacists).
- Develop a document that characterizes our PRN's history and the key roles it has played in the success of the College. This is being accomplished through the work of the Ad Hoc Committee on PRN History, who is currently developing a paper that describes our history as an organization.
- Continue to grow the PRN membership while also meeting the needs of our very diverse members. This is being accomplished through the work of the Budget and Finance Committee who is exploring methods to increase PRN and student membership.

While these are four specific goals that I would like to accomplish this year, there is of course other important work that needs to be done. I would like to personally thank all of the PRN officers, committee chairs, and committee members for their dedication and efforts. This has made my job as chair much easier, and without them would not be possible. I would also like to thank all of those who responded to my request for committee volunteers this last fall. The response was overwhelming with *more than 75 volunteers*. If you were not selected for a committee, please consider volunteering again in the future.

I hope to see many of you at our PRN Business Meeting and Networking forum in Louisville.

Best regards,

Eric

Give me a stock clerk with a goal and I'll give you a man who will make history. Give me a man with no goals and I'll give you a stock clerk.

- J.C. Penney



Rxtra! Rxtra!

Vitamin Supplementation Continued from page I

The Swiss Heart Study would be the first and only positive trial in a series of eight prospective trials to assess the efficacy of folic acid and B vitamin supplementation in cardiovascular risk reduction.

Impact on the Guidelines

In 2007, following publication of the AS-FAST, NORVIT, HOPE-2, and VITATOP trials' negative outcomes, the Women's Health Initiative Guidelines were up-The revised dated. guidelines omit recommendations for use of folic acid and B vitamin supplementation in reducing cardiovascular risk. Other guidelines will likely follow suit in forthcoming revisions, and homocysteine reduction will most likely fall out of the guidelines altogether.

While the general outcomes of the trials warrant the shifting of the Women's Health Initiative guidelines, a closer look at trial design issues may point to the need for continued research before completely discounting the therapy.

The Power Issue

Some of the trials are problematic because they had enough enrollees to establish power, but they were powered to detect more cardiovascular risk reduction (17-35%) than is clinically anticipated with folic acid and B vitamin supplementation (11-16%).

Future Trial Direction

* Pursuing more aggressive lowering of homocysteine levels
* Conducting primary prevention trials

* Determining if homocysteine is truly deleterious in the vasculature or simply a marker of existing vascular damage and increasing age

* Assessing the epidemiologic impact of the 1996 U.S. Folic Acid and B Vitamin Food Fortification Program on cardiovascular risk

Pharmacists' Role Today

* Recommend commercially available supplementation therapy conservatively

* Guide patients toward other therapies with proven morbidity and mortality.

* Participate in future research

| | | _ . | – • |
|----------------------|---|---|--|
| Trial | Endpoints | Regimen | Results |
| | | Duration of Study | |
| Swiss Heart Study | *Need for Revascularization *Non-fatal MI | Img FA, 0.4mg B12, | ↓ Need for Revasculari- zation |
| (2002) | | 10mg B6 | ↓ Secondary CV Events |
| Secondary Prevention | *Cardiac Death *CV Events | II months | |
| N = 553 | | | |
| VISP (2004) | * Recurrent Cerebral | * 2.5mg FA, 0.4mg B12, | No↓ in Secondary |
| Secondary Prevention | Infarction *CHD Events | 25mg B6 | Strokes No↓in CHD Events |
| N = 3680 | * Death | * 0.02mg FA, 0.006 mg B12, 0.2 mg B6 | No ↓ in Death |
| | | 2 years | |
| ASFAST (2006) | * Composite of CV | 15mg FA | 19% ↓ Hcy |
| Secondary Prevention | Events + CV Death * Change in rate of CIMT | | No ↓CV Events or Death No ↓ change in rate of |
| N = 315 | | 3.6 years | CIMT |
| NORVIT (2006) | * Composite of CV Event | * 0.8mg FA, 0.4mg B12, | 27% ↓ in Hcy |
| Secondary Prevention | or CHD-related Death | 40mg B6 | ↑ in endpoints (trend) |
| N = 3749 | | * 0.8mg FA, 0.4mg B12 | |
| | | * 40mg B6 | |
| | | 3.3 years | |
| HOPE-2 (2006) | * Composite of Death | 2.5 mg FA, 1mg B12, | I9% ↓ in Hcy |
| Secondary Prevention | from CV causes, MI, stroke | 50mg B6 | $No \downarrow endpoint$ |
| N = 5522 | | 5 years | |
| VITATOPS | * Composite of stroke, | 2mg FA, 0.5mg B12, | Pending |
| (ongoing) | MI, CV-related Death | 25mg B6 | Substudy of N=285 |
| Secondary Prevention | | 2.5 years | $No \downarrow CRP$ |
| N = 8000 | | | No Δ endothelial fxn |
| | | | No Δ clotting factors |

B6= pyridoxine; B12= cobalamin; CHD=coronary heart disease; CIMT=carotid artery intima media thickness; CRP=C-reactive protein; CV= cardiovascular; FA=folic acid; fxn=function; Hcy=homocysteine; MI=myocardial infarction.

Volume I, Issue I

PRN Committee Reports

Advocacy

Chair: Bob DeYoung, PharmD, BCPS

The advocacy committee members have been reviewing the ACCP 2008

Advocacy Agenda and planning for ways to increase the number of PRN members who are actively involved in some type of advocacy work. The Advocacy Agenda includes seven priority issues. The inclusion of and payment for the direct patient care medication management services of qualified pharmacists under Part B of the Medicare program and other major health insurance plans continues to be a focus for the advocacy work of the College.

The committee is also exploring ways to keep the PRN membership routinely informed of advocacy issues and opportunities. Beyond increasing awareness, the committee is considering tools to assist PRN (and ACCP) members to more easily take action related to these matters. Promoting both the ACCP Legislative Action Center (http://capwiz.com/accp/ home/) as an updated, easily accessible information source and encouraging members to participate in the ACCP Advocates program are just two ways the committee members have identified to help meet these goals. Members should look for more communications from this committee in the coming months.

Busniness Meeting & Networking Forum Phoenix, Arizona April 2008



Dee Melnyk of the networking committee helped coordinate the activities of the evening, including the "ice breaker".

Budget & Finance

Chair: Nicole Culhane, PharmD, BCPS

The Budget and Finance Committee, together with the Networking Committee will sponsor the business/networking forum for this Spring 2008 Practice and Research Forum. A special thank you goes out to Christina Choy and her committee for all of their hard work to put the forum together. Together with the Research and Scholarship Committee, we would like to congratulate Dr. Kevin Fuji, Research Fellow and Assistant Instructor at Creighton University, and the recipient of the second annual Ambulatory PRN seed grant. He

recently received a grant for \$2000 for his research entitled "Electronic Health Record Adoption in Pharmacy Practice". Thank you to Julie Wright and her committee for all of the hard work that went into this process. The committee has also begun discussions surrounding donations to the Frontier's Fund as we value our contributions and the exceptional research that occurs as a result of the Fund. We intend on contributing \$1 for every \$5 donated by a PRN member up to at least \$3,000 for 2008. The committee decided

that we will not solicit industry support this year as our budget remains in good fiscal shape. Should we have the opportunity to accept industry sponsorship, we would only do so if the support did not influence or change the tone of our programming. We are proud to continue to be the largest PRN in ACCP. However, the committee is also working on ways to increase our PRN membership. We are discussing innovative ways to do this and perhaps will offer an incentive program to our current members. Stay tuned for more details!!!!





PRN members enjoyed the fun evening of socializing, learning as well as partaking of the fine food and libations!



Business Meeting &

Networking Forum

A positive benefit to this meeting is renewing ties with colleagues you may see only once or twice a year.









This year's presentation at the Forum was given by Dr Jacquelyn Klootwyk who hails from Midwestern University. It was entitled, "The impact of a pharmacist-managed spironolactone laboratory protocol on the rates of laboratory monitoring and hyperkalemia: a pre- and post- intervention study."

PRN Committee Reports (cont)

Communications Chair: Jeanette Altavela, PharmD, BCPS

The Communications Committee has been hard at work giving this newsletter a completely new look (we hope you like it!). We have also recently surveyed the membership (achieving a 29% response rate) regarding new list-serve usepolicies regarding jobpostings and independent research efforts. Based on these results, the following new policies have gone into effect:

Conducting Surveys

The mailing list may be used by PRN members to disseminate surveys in an effort to facilitate research. The surveys may be a direct function of the PRN or ACCP, as well as support an individual's outside research. Only current members of the PRN will be allowed to send surveys. Sending surveys "on behalf" of someone that is not a current member of the PRN will be discouraged. Nonmembers can send the survey to chair of the communications committee for their endorsement.

E-Mail requirements for sending a survey:

1. Assure the subject line includes "Survey/survey topic/topic detail" (content in *italics* should be changed to your topic) so users may easily judge if they want to open the email.

2. In the body:

a.

Succinctly describe

the purpose of the survey such as if it part of a research project or not (is it preliminary or part of a more well-defined research project)

Rxtra! Rxtra!

b. Provide the expected time it will take to complete the survey (i.e. 10 minutes. Do not state it will only take "a few minutes", or "it won't take long")

c. Provide your credentials (pharmacist vs. pharmacist in residency)

3. Do not send the survey to the list-serve more than twice. Upon the second mailing, assure the subject line includes the words "Second Notice" at the end of the subject.

Recruitment Postings

Recruitment postings are authorized on the PRN list serve. Members posting opportunities must not abuse the list serve for the sole purpose of recruitment. Members may post opportunities that are specific to their institution or from a colleague who has provided the information. Postings from recruitment agencies are not authorized and if the list serve is being abused, the member will be removed from the list serve. Assure the subject line includes "Recruitment Posting/position/city and state" (content in *italics* should be changed to your detail) so users may easily judge if they want to open the email.

there is a section of the ACCP website dedicated to posting job positions where a position may be posted for 60 days at a time. It is available 24 hours a day and searchable by position type, geographical region, and keywords. Full and Associate Members of ACCP may list an available position for \$150 per position. Affiliate members of ACCP, nonmembers of ACCP, and recruiting agencies placing ads on behalf of employers may list an available position for \$500 per position. Each job listing must contain only one position.

Communications Committee Chair

"97% of the voters wished to have the elected position of secretary of the PRN automatically be the standing chair of the communications committee. Other voters also encouraged having a vice-chair for this particular committee, not only so the position is not too overwhelming for one person, but also to encourage more involvement of the membership".

This committee will be tracking communications sent regarding the new policies. Finally, members of our committee are also reviewing the Survival Guide (which will be available in July through ACCP) and preparing a poster for the 2008 Annual Meeting.

Please be aware

More information about posting job positions on the ACCP Web Site:

http://www.accp.com/reconlin.php

<https://webmail.stlcop.edu/exchweb/bin/redir.asp?URL=http://www.accp.com/reconlin.php>

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latory Cardiology." Cur-

rently, we are working to

finalize the speakers for

collaborated with the car-

American Society of Hv-

pertension (ASH) to pre-

meeting in New Orleans.

The ASH meeting will be

sent a joint program at

the 2008 Annual ASH

held May 14-17. Our

diology PRN and the

We have also

these programs.

PRN Committee Reports (cont)

PRN members Barry

Carter and Mike Ernst will

be speaking at the meet-

ing. In addition, the com-

mittee has also started

planning a joint sympo-

sium with the Integrated

from the European Soci-

ety of Clinical Pharmacy

for the 2009 International

Pharmacy meeting in Or-

Primary Care section

Congress on Clinical

lando, Florida.

Education Chair: Alan Zillich, PharmD

The Education Committee has been very busy planning programs for the 2008 Annual Meeting in Louisville, Kentucky. This programming will include a joint focus session with the PK/PD PRN on the "Science and Practice of Pharmacogenetic Guided Warfarin Dosing" and a joint premeeting symposium with the Cardiology PRN on "Current Topics in Ambu-

Nominations

Chair: Kelly Ragucci, PharmD, FCCP, BCPS

The Ambulatory Care PRN Nominations Committee consists of the following members: Kelly Ragucci (Chair), Jill Burkiewicz, Joy Boresi, Daniel Riche, Ann Phillips, Melissa Somma McGivney and Nancy Shapiro. Over the past few months, the committee has identified and

nominated deserving PRN members for ACCP fellowship status, ACCP elected offices and ACCP awards. Currently, we are accepting nominations for PRN offices (Chair-elect/Chair and Treasurer). Responsibilities of officers can be found through the ACCP PRN webpage and nominations can be emailed directly to <u>raguc-</u> <u>cik@musc.edu</u> through the end of April. Beginning in May, the committee will be soliciting nominations for the PRN Achievement Award, reviewing applications and selecting a recipient for presentation at the fall ACCP meeting.

Business Meeting & Networking Forum

Another benefit of the forum is meeting new people, and what better way to accomplish this goal then with the "ice breaker". This year's game was "The Power of 10".





Research & Scholarship Chair: Julie Wright, PharmD, FCCP, BCPS

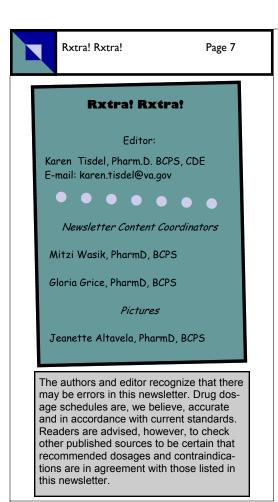
The Research and Scholarship Committee is pleased to announce that Kevin Fuji, Pharm.D. is the recipient of the 2007-2008 Ambulatory Care PRN Pilot Grant, Dr. Fuii is a research fellow for Creighton University Health Services Research Program at **Creighton University** School of Pharmacy and Health Professions in Omaha, Nebraska, The PRN awarded \$2000 in

support of his project entitled, "Electronic Health Record Adoption in Pharmacy Practice". Dr. Fuji will present his research results at a future Ambulatory Care PRN meeting in 2008 or 2009. In July 2008, the committee will be inviting members to submit proposals for the 2008-2009 grant cvcle. The committee would like to thank Drs. Steven Boyd and Andrea Wessel for developing the grant

application process. Currently the committee members are working to identify a scholarly project for the PRN. A **case series based publication** is under consideration. The committee needs input from the membership (see side bar) in selecting a topic that will make a significant contribution for clinical pharmacy.

Put on Your Thinking Cap: If you have a case series topic with a supporting rationale please send it to Julie Wright:

wrightj@umkc.edu.



** IMPORTANT WEB UPDATE **

When sending a message to our list-serve, do "out-ofoffice" messages make you want to tear your hair out? Relief is in sight! A scheduled software update (hopefully within the next 30 days) will take care of this problem. All you need to do in your "out of office" auto reply, is to use one of the following two phrases ("out of the office" or "out of my office") in the first ten lines of the body of your message. The software will then block your replies from being sent back to everyone on the list.

> The second largest of the ACCP Practice & Research Networks (PRN), the Ambulatory Care PRN is dedicated to improving patient care in ambulatory and family practice settings.

New Drug Update: Tekturna[®] (aliskiren)

By Scott T McDowell, PharmD Candidate 2009 Thomas G Clement, PharmD Candidate 2009 University of Georgia-College of Pharmacy

It is estimated that 1 in 3 individuals in the United States (73 million) have hypertension (HTN) and many of these have not been diagnosed. It is no wonder that HTN has been dubbed "the silent killer". Hypertension can lead to both microvascular (e.g., retinopathy, nephropathy) and macrovascular disease (e.g., myocardial infarction, stroke). Furthermore, HTN can lead to target-organ injury or failure. It follows, therefore, that safe and effective drug therapy is vitally important.

Currently, there are multiple antihypertensives in a variety of drug classes offering practitioners many choices. These include diuretics, betablockers, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers, vasodilators and other drugs such as clonidine. The newest alternative is Tekturna[®] (aliskiren).

Aliskiren (approved by the FDA in March 2007) is the first of a new class of direct renin inhibitors. Renin is involved in the renin-angiotensinaldosterone-system (RAAS), catalyzing the conversion of angiotensinogen to angiotensin I. Ultimately, angiotensin I is converted to angiotensin II, and this increases blood pressure through multiple mechanisms. ACE inhibitors and ARBs also work in the RAAS pathway. However, aliskiren differs from these as it works earlier in the pathway directly inhibiting renin and thereby blocking the formation of angiotensin I and II.

Additionally, aliskiren decreases plasma renin activity (PRA) and increases plasma renin concentration (PRC).⁴ There is speculation that decreasing PRA may decrease the incidence of myocardial infarction. Currently, long-term cardioprotective and renoprotective effects are being studied in an extensive clinical program known as ASPIRE HIGHER.⁶ However, to date, the clinical benefit of lowering PRA long-term, aside from the blood pressure benefits, is still largely theoretical.

In clinical trials, once daily aliskiren in doses of 150-300 mg either as monotherapy or in combination with other antihypertensives (eg, thiazides, ACE inhibitors, or ARBs) was safe and effective for the management of mild to moderate HTN. Aliskiren has a half-life of ~30 hours; it undergoes metabolism by CYP P450 3A4 and also undergoes some renal elimination. Dose adjustments are not required in patients with severe renal impairment, but caution is indicated. Drug interactions most commonly occur with other CYP P450 3A4 medicathose agents that also increase potassium levels (eg, amiloride, ACE inhibitors, spironolactone, etc). Most common side effects include: dizziness, headache, diarrhea. Other effects commonly known to occur with ACE inhibitors (eg, cough, hyperkalemia, angioedema) have occurred with aliskiren, though perhaps at a lower incidence rate. To date, clinical trials with aliskiren have been short (8-weeks in duration), and no outcomes trials are yet available.

tions and

Student Corner

In conclusion, many formulary managers have decided to forego the addition of aliskiren to their formularies based on the limitations of existing research and presence of other effective agents. However, aliskiren, may be useful in patients who are refractory to or intolerant of other agents.