ACCP WHITE PAPER

Establishing and Evaluating Clinical Pharmacy Services in Primary Care

American College of Clinical Pharmacy

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Health care reform has renewed the interest in primary care. Major problems with America's health care system include escalating health care costs, maldistribution of health care providers into urban areas, lack of health care insurance, and the excessive utilization of specialists. These issues have assured that health care reform will take place. At the time of this report, the nature and format of a reform plan has not been determined. Nevertheless, many agencies are rapidly evaluating their current health care coverage and are preparing for the inevitable reform that will take place.

There have been disproportionately high numbers of medical specialists compared with generalists since the 1960s.[1] Worldwide, there are approximately five to six generalists for every subspecialist. For various reasons, perhaps most importantly, economics, this ratio is reversed in the American health care system. For well over 20 years, governmental agencies and medical academicians have tried to increase the numbers of primary care providers without significant success. With millions of underinsured Americans, the provision of primary care has become a national priority. Clinical pharmacists must become more involved in the provision of primary patient care. Most clinical pharmacists, however, have not viewed themselves as primary care providers and, therefore, may not feel adequately prepared to become a member of an interdisciplinary primary care team.

This report is an extension of a previous ACCP White Paper on Clinical Pharmacy Practice in the Noninstitutional Setting.[2] That White Paper described the functions that should be expected of clinical pharmacists in ambulatory care settings. The purpose of the present report is to assist practitioners and administrators who wish to establish and evaluate services in ambulatory care and primary care settings. This paper presents approaches to define the scope of a pharmacist's practice and obtain clinical privileges, evaluate the process of delivering care, evaluate patient outcomes related to pharmacotherapeutic decisions, and define the legal implications of providing primary patient care.

Definitions

There is considerable confusion in pharmacy concerning current definitions of practice sites and practice philosophies. *Ambulatory care* includes all health-related services in which patients walk to seek their care.[1] These services may be provided in emergency rooms, urgent centers, private offices, primary care clinics, specialty and subspecialty clinics, and community pharmacies.

Primary care is a subset of ambulatory care with unique features and philosophies.[1] (By definition, inpatient care is never a primary level of care.) One set of definitions[3] suggests that primary care is a form of care that includes:

1. "first-contact" care, serving as a point-of-entry for the patient into the health care system;
2. continuity by virtue of caring for patients over a period of time, both in sickness and in health;
3. comprehensive care, drawing from all the

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traditional major disciplines (medical specialties, nutrition, and social) for its functional content;
4. the assumption of continuing responsibility for individual patient follow-up and community health problems; and
5. highly personalized care.

Dr. Elizabeth Short of the Veterans Administration (VA) Central Office has stated, "Primary care is the coordinated, interdisciplinary provision of health care that consists of health promotion, disease prevention, comprehensive management of acute and chronic medical and mental health conditions, and patient education. A primary care physician coordinates access to and integration of other components of health care, such as inpatient, long-term, or subspecialty care, and psychosocial support. Under primary care, a provider or provider team is the primary source of a patient's care, and the place that a patient turns to for health care information and support."[4]

The key feature of primary care clinicians is that they handle a wide range of medical conditions. They serve as the entry point into the health care system and decide on referral or triage to secondary or tertiary levels of care. Specialty clinics provide ambulatory care, and, in many cases, some primary care. Most specialists (e.g., cardiology, neurology, nephrology, etc.), however, are considered secondary levels of care. These secondary and tertiary levels of care should be utilized when a problem is beyond the expertise of the primary care clinician. The typical family practice physician or general internist cares for well over 90% of problems that present to them. There is a small percentage of problems that would require referral to secondary or tertiary care. Even when a patient is referred for a specific problem, the primary care clinician should maintain overall care for the patient and coordinate all other aspects of care. This continuity implies chronic care and preventive care that are more conducive to long-term assessments of patient outcomes than can be achieved with acute illness managed in the inpatient setting.[3]

Clinical pharmacists and pharmacotherapy specialists provide care in a wide variety of ambulatory care and primary care settings.[1, 2] There are two major types of practice that are very distinct. While currently more common in structured settings such as hospitals and health maintenance organizations, primary care is increasingly being provided in many settings including community pharmacies. The first type of practice is one in which the pharmacist is *independently responsible for providing primary care*, typically between regularly scheduled physician visits. This includes conducting complete histories; obtaining objective information including physical assessment and ordering laboratory tests; starting, stopping, or changing drug therapy; and determining the appropriate timing of follow-up visits. These activities are common in pharmacist-managed clinics in the Indian Health Service, medical centers, and VA hospitals, including hypertension, diabetes, hyperlipidemia, anticoagulation, and pharmacy service clinics. These activities are in contrast to those provided by other professionals such as physician assistants or nurse practitioners who may perform functions traditionally performed by a physician.

The second type of setting is an *interdisciplinary team approach* to care of the patient where the pharmacist sees patients with physicians. Pharmacists who work in such teams assist with care at the same time other health professionals see the patient. In this setting, they may have independent patient care activities but these would not be as extensive as are generally seen in pharmacist-managed clinics. These settings would include family practice offices, general medicine clinics, or pediatric clinics.

Establishing an Ambulatory Care or Primary Care Practice

Obtaining Clinical Privileges

Prior to any patient intervention, it is essential that the clinical pharmacist has in place a document that outlines specifically the practitioner's scope of practice.[5] It is important that the scope of this document be sufficient to allow the clinical pharmacist to function as a member of an interdisciplinary primary care team. This document could be in the form of clinical privileges or a scope of practice statement (Appendix 1). This approach could be used for developing a practice for a new practitioner or used for a previous clinician who has not formally obtained scope of practice privileges. If the facility is an organized health care center (hospital or managed-care organization), it would be worthwhile to review the facility's guidelines for clinical privileges granted to the physician's assistants and/or nurse practitioners if these are available. Depending on the institution, approval is required by the Chief of Pharmacy, Chief of Staff, Clinical Executive Board, and the Institutional Director. Once these privileges are established, only then can the clinical pharmacist provide

primary patient care (e.g., in pharmacist-managed clinics).

In the past, formal guidelines to obtain clinical privileges were often not commonly developed in private practice or other settings such as outpatient family practice settings. However, clinical pharmacists in private practice, community pharmacies, family practice residencies, and health maintenance organizations should develop these guidelines for their clinical pharmacy practitioners to ensure quality and evaluate performance. For clinicians in these settings, it is less likely that formalized arrangements for scope of practice privileges exist with physicians or other health professionals. However, similar templates as those for institutions (Appendix 1) could be used and modified for these settings.

The application form in Appendix 1 also requests data on whether the clinical pharmacist is board certified in pharmacotherapy or another specialty. Board certification should be considered strongly desirable, if not required. At the present time, the most appropriate specialty certification process for ambulatory or primary care pharmacists would be certification in pharmacotherapy. This would be analogous to physician certification in the broad-based specialty of family practice. Board certification in pharmacy will be increasingly important and it should be achieved by all ambulatory care/primary care pharmacy practitioners who provide the services outlined in this report.

Quality of Care Provided by Pharmacists in Primary Care: Evaluating Process and Outcomes of Patient Care

A comprehensive discussion of quality of care assessments is beyond the scope of this paper. This area of assessment, however, will become increasingly important in the near future. This report is intended to provide the pharmacist who practices in ambulatory care with an understanding of basic principles used to assess quality. For more in-depth reviews in this area, the reader is referred to the references and the Appendixes.

There is a great deal of interest in measuring or assessing patient outcomes. As Donabedian points out, however, outcomes can only be assessed within the overall context of health care.[6] For instance, the therapy that a pharmacist selects may have minimal influence, or perhaps even a detrimental influence on patient care, depending on the care of other practitioners, demographic factors, and the interpersonal relationship. Donabedian maintains that quality can only be assessed by examining the three components: structure, process, and outcome.[6] He suggests that there must be a knowledge of how structure and process are linked, and how outcome and process are linked before quality assessments can be made. Structure not only refers to the facility, its services and its location, but also the number and characteristics of the providers. For providers this would mean whether they are in solo or group practice and whether they are board certified.[6, 7] For physicians it has been shown that board certification is a predictor of good process, but only by implication, of good outcomes. Process refers to what is done for the patient in providing care.[6, 7] This includes making diagnostic and treatment decisions. Outcome refers to what happens to the patient and this may include the patients' knowledge or satisfaction with care.

Lohr and Brook have stated that quality of care is composed of both technical care and the art of care.[7] The art of care includes the practitioner's ability to provide reassurance, obvious concern of the patient's well-being, good counseling, and sensitivity to the patient. As examples, they cite whether the provider introduces himself to the patient, refers to the patient specifically by name, announces and/or explains activities before or while doing them (such as physical examination), and says goodbye to the patient. Obviously, these are all critical factors to address if patient satisfaction is being assessed. Providing these personal services is not new but it is increasingly important when patient satisfaction drives third-party contracts in managed care. Pharmacists must provide these personal levels of care if they truly are delivering pharmaceutical care.

Evaluating the Process of Delivering Care

Performing quality assurance evaluations of specific pharmacists' performance does not measure patient outcomes, but rather, the process of delivering care. However, providing an acceptable or ideal process (or standard of care) should, by implication, create an environment conducive to better patient outcomes. However, to move from evaluating process to evaluating outcome, other specific tools must be used (see below). Appendix 2 is an example of a quality assurance form that might be used in a pharmacist-managed primary care clinic.

Guidelines are being developed for a wide range of disease states and conditions. These essentially describe processes for delivering care. They can be

used by the individual clinician to prospectively guide appropriate therapy. In contrast, they can be used retrospectively as a quality assurance measure. Appendix 3 lists 12 disease states that are critical to outpatient primary care, and that are currently the most common conditions cared for by pharmacists in primary care settings. While these are not all-inclusive, they provide examples that can be followed in other therapeutic areas. Where possible, nationally accepted clinical practice guidelines are provided for each of these disease states. It is imperative that clinical pharmacy practitioners be aware of nationally accepted guidelines for specific conditions they may treat in their settings. The importance of this is discussed below.

The Agency for Health Care Policy and Research (AHCPR) was created by Congress to be the successor of the National Center for Health Services Research. This agency explores medical conditions that affect large populations, have multiple therapeutic interventions, and have a large economic impact. Through the Medical Treatment Effectiveness Program (MEDTEP), the AHCPR examines variations in health care practices on patient outcomes.[8] The MEDTEP involves patient outcomes research, clinical guideline development, scientific data development, and research dissemination. The agency has supported the development of numerous guidelines such as the guidelines for depression and for angina.[9] The AHCPR is currently developing practice guidelines for the effective therapeutic management of asthma, arthritis, hypertension, and congestive heart failure. In addition to this federal agency, private groups such as the American College of Physicians, the American Medical Association, the BlueCross BlueShield Association, and other specialty societies are developing new treatment guidelines.

It is important to note that AHCPR is not a regulatory agency and is not involved with reimbursement. Application of the guidelines is not enforced by the government. Using these guidelines that were prepared by multidisciplinary panels of experts may allow primary care providers to deliver scientifically sound care to the patient.

There are also medical-legal issues pertaining to clinical practice guidelines developed by specialty societies. The general counsels who are involved with these issues, private practice attorneys, and the counsel of the American Medical Association generally believe that following established clinical practice guidelines would be a strong defense in malpractice cases. However, if a practitioner deviated widely from these guidelines, he or she would need to have a strong rationale, documented in the patient's record, to support the use of an alternate regimen.

A major issue that needs to be addressed is what standards or methodologies should be followed when guidelines are developed.[10] A structured, systematic, science-based approach should be used whenever developing these guidelines. The Institute of Medicine has identified the necessary characteristics which would enhance a guideline's effectiveness: sensitivity, specificity, patient responsiveness, readability, minimal intrusiveness, feasibility, and computer compatibility.[11, 12] If guideline development followed these scientific methods, it would be difficult to criticize the process.

In contrast to good guideline development, the determination of whether guidelines are useful depends upon their readability, computer compatibility, and other factors. Outcomes management takes the results of the outcomes research and incorporates them into clinical practice guidelines to theoretically help ensure all patients receive the most effective treatment available.[11, 12]

Assessing Health Outcomes

Another objective of this report is to determine the best method to measure the impact of pharmacotherapeutic decisions made by clinical pharmacists on patient outcomes. There are several approaches that can be used to assess outcomes. These include disease- or treatment-related outcomes (e.g., blood pressure, seizure frequency, medication adherence, target serum concentrations). The Task Force felt that it was not appropriate for this report to delineate specific clinical outcomes such as level of blood pressure control or serum drug concentrations. While these are important outcome measures, the Task Force wanted to highlight optimum methods for documenting positive outcomes of clinical pharmacy interventions. To keep in step with health care reform, a good method of assessing the impact of therapy on a specific chronic disease is health-related quality-of-life (HRQL) outcome measures. The pharmaceutical industry, the medical profession, and governmental agencies have shown increasing interest in assessing new measures of a drug's overall effectiveness. Quality of life (QOL) will be considered as seriously as safety and efficacy when evaluating response to therapy.

Even when primary care providers follow accepted clinical practice guidelines, there is no assurance of a favorable outcome. That is why it is important for the clinical pharmacist to understand and use appropriate, clinically relevant outcome measures to quantify the impact of their interventions.[12] Bungay and Wagner argue that HRQL outcome measures should assess physical, social, and role functioning; emotional distress and well-being; general health perceptions; and energy and fatigue.[13] They also stress that the assessment of health status must be integrated into the care of patients. HRQL measures can be used to assess a population with a specific disease, or as a research method to examine how changes in process affect outcomes.[14] The current challenge is to develop tools and operations that can be used in the office setting to evaluate care, and hopefully direct treatment for individual patients. It is critical, however, that these assessments be performed while considering the patient mix, timing of data collection (timing during the evolution of a disease process), patient characteristics, and measurement properties. The reader is referred to a more comprehensive discussion of these issues.[14, 15] We will briefly discuss the importance of HRQL outcomes, the types of instruments available, and how to choose a specific instrument for a specific patient population.

Quality of life includes many issues occurring in a person's life, such as health status, job satisfaction, family issues, and overall well-being.[6, 7, 14, 15] Since these are nonspecific, this measurement may not be the best indicator of positive or negative pharmacotherapeutic interventions made by a clinical pharmacist. Health-related quality-of-life assesses those aspects of a patient's life specifically related to physical and mental well-being. "Hard data" such as treadmill time in patients with heart failure may be of interest to clinicians, but is of little value to the patients. Frequently, "hard data" correlate poorly with the patient's actual functional status. An additional reason to add HRQL instruments to clinical outcomes measurements pertains to the phenomenon that patients with the same medical condition often respond differently to therapy. HRQL is a complementary method of measuring the impact of therapy on chronic disease. Thus, HRQL might be used in tandem with explicit or implicit quality assurance review that is measuring the process of delivering care along with clinical outcome measures (e.g., blood pressure for hypertension or peak flow measures for asthma).[6]

Primary care providers, patients, and health care administrators are interested in HRQL outcomes because they are a method to measure the impact of therapy on the disease process. Hospital administrators and other policy makers have a high stake in these issues because payers are beginning to use HRQL data in their reimbursement policies.[16]

It is imperative that clinical pharmacists involved in providing primary patient care have a good working knowledge of HRQL instruments and are competent in choosing the appropriate methods to assess their interventions. Generic instruments and disease-specific instruments are the two general means by which HRQL can be measured.

The first modern health status questionnaires were very long, but their results were well validated. The Sickness Impact Profile (SIP) is an example of an early profile. It includes a physical dimension and a psychosocial dimension.[14–18] A dimension is a quality or aspect that is a component of health. The SIP also includes five independent categories including sleep, rest, eating, work, and home management, as well as recreation and pastimes. More recently, shorter profiles have been developed such as the Nottingham Health Profile and the Medical Outcomes Study (MOS) 36-Item Health Survey (SF-36) (Appendix 4).

The other approach in assessing HRQL is to focus on the aspects of health status that are specific to a particular area of interest or disease. By narrowing the area being observed, it is possible to gain increased responsiveness to changes in therapeutic interventions. Responsiveness relates to the instrument's ability to detect changes in the patient's status over time.[15–17] The instrument may be specific to a particular disease state (e.g., angina or arthritis), or to a population (e.g., the frail elderly), or to a physiologic problem (e.g., pain). In addition to responsiveness, these disease-specific instruments evaluate areas routinely addressed by primary care providers.[17]

Most generic and specific HRQL measures used today have been validated, but not in all populations. If an instrument is valid, it has been statistically determined to measure what it is intended to measure. Compendia of available measures, including critical reviews, can facilitate the choice of an instrument for a specific setting or purpose.[18] Appendix 4 contains some generic health profile instruments that can be used for various disease states, and, where possible, a disease-specific instrument was listed.

The Health Outcomes Institute has developed and validated several outcome instruments that can

be used to evaluate patient outcomes following interventions by pharmacists.[19] These include hypertension/lipids, angina, asthma, chronic obstructive pulmonary disease, chronic sinusitis, hip replacement, hip fracture, depression, low back pain, osteoarthritis, alcohol abuse, stroke, rheumatoid arthritis, and prostatism (Appendix 4). The Health Outcomes Institute is located at 2001 Killebrew Drive, Suite 122, Bloomington, MN 55425; telephone (612) 858-9188.

Example

If pharmacists were providing primary care for hypertensive patients and wanted to compare the results of an intervention, they should first provide interventions based upon established therapeutic guidelines for treating hypertension such as those outlined by the Fifth Joint National Committee on Detection, Evaluation, and Treatment of Hypertension (JNC-V). With each patient encounter, they would collect the data in Appendix 2. These two procedures would ensure that the pharmacist is providing an appropriate process of care.

Prior to the intervention, the pharmacist would assess health outcome measures such as blood pressure, current medication adherence, and forms such as a general form (e.g., SF-36) and a disease-specific form (e.g., Hypertension/Lipid Form 5.1) (Appendix 4). After the pharmacist intervention, a predetermined period of time must elapse before these questionnaires can be repeated (e.g., 6–12 mo). The questionnaires and blood pressure assessments are then repeated and it is determined whether the intervention had any effect on the patient outcome.

Recommendations

1. When appropriate, generic assessment measures should be used to develop methods to evaluate overall patient outcomes after pharmacists' interventions. However, since these may not be the most appropriate techniques for specific pharmacotherapy interventions, disease-specific methods should also be considered.
2. Centers or individuals who wish to evaluate patient outcomes that result from pharmacists' interventions should utilize instruments that have been developed and evaluated by experts.
3. When appropriate, patient outcomes after pharmacists' interventions and primary care activities should be assessed with disease-specific instruments that have been validated appropriately.
4. The choice of generic and/or disease-specific instrument(s), should be made by the multidisciplinary team when patient care is being assessed.

The Professional Relationship

Since primary care often involves an interdisciplinary team, many health care professionals provide care to the patient. Clinical pharmacists need to understand the legal implications of the care they provide, or of their patient interventions. Some of the medical-legal concepts that need to be addressed include: what establishes a professional relationship, how to terminate this relationship, abandonment, and harmful neglect. These issues are rooted in both tort and contract law. In actions of negligence, four legal elements must be addressed: duty, breach of this duty, damage, and causation.[20] In determining a pharmacist's duty, the central question is whether a particular conduct is a standard of pharmaceutical care. This is often quite controversial in that there may be certain activities, such as duty to warn, that are not accepted by all courts as a standard of care for pharmacists. If it is decided that the action is not a standard of care, the pharmacist cannot be held negligent. If it is, then the issues are whether the pharmacist breached that duty (standard of care), whether the patient was harmed (and to what extent), and whether the breach of duty caused the harm.

The essence of primary care is taking responsibility for the care of the patient to improve outcomes. Therefore, the following discussion is essential for the pharmacist-patient relationship in primary care.

Duty to Care

It is the pharmacist-patient relationship that gives rise to the pharmacist's duty to care.[21] The pharmacist-patient relationship usually involves an expressed or implied contractual agreement whereby the pharmacist offers to treat the patient with proper professional skill and the patient agrees to pay for such treatment. The pharmacist has the responsibility for practicing all facets of the profession competently. This could involve, for example, drug distribution, providing primary care, patient monitoring, patient and provider consultation/education, and other activities. As a result, the legal principles governing contract formation apply to the establishment of the pharmacist-patient relationship. At issue, however, is whether this contractual arrangement really exists between the pharmacist and the patient or

whether it is between the pharmacist and some other entity such as the physician. The answer may depend on what the pharmacist is actually doing. If the pharmacist provides primary care functions, the contractual arrangement should be viewed as being with the patient.

Terminating the Relationship

If a pharmacist-patient relationship exists and it is to be terminated, the pharmacist must give the patient sufficient notice so that he may secure other professional care.[21] Even though the pharmacist's powers in terminating the relationship are limited, the patient has broad powers in terminating the relationship. The patient is free to unilaterally terminate the relationship at any time. From the moment the pharmacist is dismissed or discharged, he is relieved of all future professional responsibility to the patient.

Abandonment

Once established, the pharmacist-patient relationship imposes a duty of care upon the pharmacist that continues as long as attention is required, unless the pharmacist gives sufficient notice of termination or is discharged.[21] While this case law currently only applies to physicians, pharmacists who assume a caregiver role would also be subject to this duty. To recover on the theory of abandonment, the plaintiff must prove the following:

a) existence of a pharmacist-patient relationship;
b) unilateral severance by the pharmacist without reasonable notice and without providing an adequate substitute;
c) necessity of continuing pharmaceutical attention;
d) proximate cause; and
e) damages.

A pharmacist is immune from the abandonment charge when the patient voluntarily chooses not to return or discharges the pharmacist.

Abandonment may thus occur in two ways: through explicit withdrawal from a case or failure to attend the patient with due diligence. If the pharmacist fails to attend the patient with due diligence, he may also be liable under negligence principles. If he prematurely terminates the relationship despite the patient's continued need for care, he may also have abandoned the patient. The pharmacist has a definite right to withdraw from the case provided he gives the patient reasonable notice so that a patient may secure other attention. Failure by the patient to cooperate with the pharmacist may justify termination of the professional relationship by the pharmacist. The pharmacist is not justified in abandoning the patient unless the patient obstinately refuses treatment. Differences of opinion on the factors surrounding a case may occur. Therefore, it would be prudent for the pharmacist to document carefully events and to offer to obtain a substitute clinician for the patient, and even then alternative care arrangements must be made.

Harmful Neglect

Decisions concerning frequency of patient visits are an important medical-legal issue. Pharmacists can be held liable for harmful neglect, an act of negligence involving nondiligent care of the patient. Courts have ruled, "A physician is not chargeable with neglect on account of the intervals elapsing between visits, where the injury requires no attention during the intervals, but is negligent where attention is required."[22]

The establishment for "proximate" or "legal" causation is the first step.[23] A factual link between the pharmacist's conduct and the patient's injury and whether the pharmacist could have foreseen the harm must be determined. The plaintiff must compare what did occur with what would have occurred if contrary-to-fact conditions existed. As an example, in a case involving a pharmacist, if the pharmacist had provided more frequent visits, would a more favorable outcome have resulted? The plaintiff would have to prove, by a preponderance of the evidence, that the infrequency of visits was the cause of damages to him. In addition, even if it is established that the pharmacist's conduct caused the patient's injury, a question of forseeability may be raised. In general, unless the pharmacist could have foreseen that harm would occur, there will be no liability. The issue of foreseeability would most likely be part of the determination of duty. Many of the consensus statements and guidelines included in this paper describe appropriate intervals of follow-up that, if followed, might reduce the liability of clinical pharmacists.

The jury would be instructed not to consider a pharmacist's workload as a legitimate determination of frequency of follow-up care. Pharmacists should be aware that having more patients than time allows does not relieve them of their responsibility to provide proper follow-up care.

Pharmacists do not carry the sole burden of what

happens to their patients during intervals between appointments. Patients also have responsibilities with regard to the management of their illnesses. The Supreme Court of Maine ruled "it is the duty of a patient to follow the reasonable instructions and submit to the reasonable treatment prescribed by his physician or surgeon."[24] If the patient fails in his duty and his conduct directly contributes to the injury, he may be precluded from or limited in seeking damages. Some state laws provide for contributory negligence where any negligence by the plaintiff completely bans recovery. Other states have comparative negligence where blame is essentially apportioned between the plaintiff and defendant.

In summary, pharmacists' decisions regarding follow-up care are subject to legal scrutiny. As standard guidelines concerning the appropriate frequency of follow-up visits for outpatient management of most diseases are not routinely available, clinicians are vulnerable to actions for harmful neglect. Lacking such standards, a jury of laypersons listens to "expert testimony" and decides whether appropriate care was given. Busy workloads of pharmacists who service a large number of patients are not considered a defense against harmful neglect. If a practitioner cannot provide adequate care to each patient, an equally competent substitute must be named. Finally, it is essential to remember that the patient has obligations in the management of his own health. To document appropriate pharmacists' advice to patients, written instructions should be provided that clearly and specifically outline what the patient should do during intervals between visits, and full and appropriate records of patient visits must be maintained.

Summary

This Task Force report is designed to provide administrators and pharmacy practitioners with recommendations that assist them in establishing and evaluating pharmacy services and assessing patient outcomes in ambulatory/primary care. Each setting will have unique features requiring specific processes be tailored to that institution or clinic. By utilizing the outcome instruments, practice guidelines, and other materials listed in this report, the clinician should be able to establish a valuable practice in most primary care settings.

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References

1. **Carter BL.** Ambulatory care. In: Brown TR, ed. Handbook of institutional pharmacy practice, 3rd edition. Bethesda: American Society of Hospital Pharmacists, 1992:367–73.
2. **The ACCP Clinical Practice Affairs Committee, 1990–1991.** Clinical pharmacy practice in the noninstitutional setting: a white paper from the American College of Clinical Pharmacy. Pharmacotherapy 1992;12:358–64.
3. **Rakel RE.** The family physician. In: Rakel RE, ed. Textbook of family practice, 4th edition. Philadelphia: WB Saunders, 1990: 3–18.
4. **Short EM.** Primary care education (PRIME) program for medical residents and associated health trainees in AY 94–95. Department of Veterans Affairs Memorandum, July 19, 1993.
5. **Hutchinson LC, Wolfe JJ, Padilla CB, Forrester CW.** Clinical privileges program for pharmacists. Am J Hosp Pharm 1992;49:1422–4.
6. **Donabedian A.** The quality of care: how can it be assessed? JAMA 1988;260:1743–8.
7. **Lohr KN, Brook RH.** Quality assurance and clinical pharmacy: lessons from medicine. Drug Intell Clin Pharm 1981; 15:758–65.
8. **Raskin IE, Maklan C.** Medical treatment effectiveness research: a view from inside the Agency for Health Care Policy and Research. U.S. Department of Health and Human Services, Public Health Service, AHCPR Pub. No. 91–0025, June 1991.
9. **Agency for Health Care Policy and Research.** Clinical Practice Guideline Development. U.S. Department of Health and Human Services, Public Health Service, AHCPR Pub. No. 93–0023, August 1993.
10. **Woolf SH.** Practice guidelines: a new reality in medicine. II: methods of developing guidelines. Arch Intern Med 1992;152:946–52.
11. **Ware JE Jr.** Standards for validating health measures: definition and content. J Chronic Dis 1987;40:473–80.
12. **Woolf SH.** Practice guidelines: a new reality in medicine. III: impact on patient care. Arch Intern Med 1993;153:2646–55.
13. **Bungay KM, Wagner AK.** Comment: assessing the quality of pharmaceutical care. Ann Pharmacother 1993;27:1542–3.
14. **Greenfield S, Nelson EC.** Recent developments and future issues in the use of health status assessment measures in clinical settings. Med Care 1992;30(suppl 5):23–41.
15. **Patrick DL, Erickson P.** Health status and health policy: quality of life in health care evaluation and resource allocation. New York: Oxford University Press, 1993.
16. **Guyatt GH, Feehey DH, Patrick DL.** Measuring health-related quality of life. Ann Intern Med 1993;118:622–9.
17. **Bungay KM, Ware JE.** Measuring and monitoring health-related quality of life. In: Current concepts. Kalamazoo: The Upjohn Company, 1993.
18. **Palmer RH, Banks N, Edwards J, Fowles J, Necenz D, Zapka J.** Interim report: external review performance measurement of Medicare HMOs/CMPs. New York: Delmarva Foundation for Medical Care, Inc., February 1994.
19. **Health Outcomes Institute.** Outcomes Management System (OMS). Bloomington, Minnesota, 1993.
20. **Fink III, JL, Marguardt KW, Simonsmeier LM, eds.** Pharmacy law digest, facts and comparisons. St. Louis, MO: Facts and Comparisons, 1994.
21. **Perdue JM.** The law of Texas medical malpractice. In: Houston law review, University of Houston Law Center, 2nd edition. Houston: University of Houston Law Center, 1985:2–20.
22. **Tomer v. Aiken et al.,** 101 N.W. 769 (Iowa 1904).
23. **Keeton WP.** Prosser and Keeton on the law of torts, 5th edition. St. Paul: West Publishing Company, 1984;263–321.
24. **Merrill v. Odiorne,** 94 A. 753 (Maine 1915).

Appendix 1. Application for Scope of Practice

Clinical Pharmacy Specialists

Name: _____
Position on hospital staff: _____
Pharmacy school(s): _____
Date(s) of graduation: _____
Graduate degree: _____
Graduation: _____
Board certified in pharmacotherapy?: Yes____ No____
Board certified in other pharmacy specialty?: Yes____ No____ NA____
Specialty area: _____
States currently licensed: _____

The following are the clinical scope of practices granted to you as a member of the staff of the _____ Hospital (Clinic), located in _____ (city), _____ (state). These determinations were made through a thorough review of your education, training, and experience, and demonstrated competence by the Professional Standards Board and approved by the Director. If you change positions and/or if your duties change (i.e., a geriatric clinical pharmacist moves to medical oncology), then you must reapply for practices specific to that area.

Areas of Practice:

A = Ambulatory Care

A. Routine duties: Routine duties are defined as those duties that are performed on a regular, repetitive basis.

(1) Category A-1: Routine duties that require review by the physician supervisor who will note concurrence or addendum as indicated. Countersignature of the medical record is required within 24 hours.

	Requested
• taking and recording verbal orders from physicians	A

(2) Category A-2: Routine duties that do not require review by the physician supervisor unless so indicated. These duties will be reviewed by the physician supervisor on a regular basis through a random sampling process. Results of this review will be discussed with the clinical pharmacist as appropriate.

	Requested
• provision of formal written consultations upon request in the areas of pharmacotherapy and pharmacokinetics	A
• provision of written initial assessments in the progress notes	A
• provision of follow-up notes within the progress notes	A
• taking medication/therapeutic histories	A
• measuring vital signs and performing physical examinations of relevant organ systems for the purpose of monitoring drug therapy	A
• collecting laboratory specimens (i.e., drawing blood)	A
• order the following noninvasive tests:	
(a) laboratory tests (e.g., PT, CBC)	A
(b) EKGs	A
(c) Holter monitors	A
(d) PFTs	A
(e) echocardiograms	A
(f) x-rays (e.g., CXR)	A
• order appropriate consultations from the following services:	
(a) dental	A
(b) dietetics	A
(c) medical specialties	A
(d) psychiatry	A
(e) psychology	A
(f) radiology	A
(g) social work	A
(h) surgical specialties (old problems)	A

Appendix 1. Application for Scope of Practice (continued)

B. Non-Routine/Non-Emergency Duties:

	Requested	
• authority to write prescriptions for medication refills for medical problems that are stable in patients followed in outpatient clinics. The clinical pharmacist is not authorized to write prescriptions that are used to initiate any form of drug therapy.	A	
• authority to make adjustments in dosage as clinically indicated for a period of up to 3 months between physician visits using the following classes of drugs:		
1. antihistamine drugs	A	
2. antiinfective agents	A	
3. antineoplastic agents	_____	{indicates not applicable to this ambulatory care pharmacist}
4. autonomic drugs	A	
5. blood formation and coagulation	A	
6. cardiovascular drugs	A	
7. central nervous system agents	A	
8. gastrointestinal drugs	A	
9. hormones and synthetic substitutes	A	
10. respiratory smooth muscle relaxants	A	
• limited authorization to approve the use of restricted or nonformulary medications when the use of such agents is within the established guidelines or approved criteria for use at this facility (i.e., antibiotics, chemotherapy)	A	

C. Emergency Duties: Carried out for patients in life-threatening situations where a physician is not immediately available. The clinical pharmacist initiates this activity but makes every effort to summon a physician as soon as possible (i.e., cardiopulmonary resuscitation, and, if advanced cardiac life support-certified, electrodefibrillation).

D. Miscellaneous Duties: Those duties that do not fall into the first category.

• conduct clinical research protocols	A	

I do hereby request the above outlined scope of practices. I have read and agree to abide by the bylaws of the _____ Hospital.

Signature of applicant _____ Date _____

Signature of physician supervisor _____ Date _____

Chief, Pharmacy Service _____ Date _____

Chief of Staff _____ Date _____

Director _____ Date _____

Appendix 2. Evaluating Process of Care: Example Quality Assurance in Primary Care

Medical Records will be reviewed on a quarterly basis. Twenty-five charts will be randomly selected and reviewed for the following items:

1. Progress notes written in an appropriate S.O.A.P. format.
2. Determine if the subjective and objective information is consistent with the assessment and plan.
3. Past medical history and family history is obtained at least once for each patient.
4. Social, diet, and exercise history is recorded at least every 4 months.
5. Medication history recorded at least once.
6. Current prescription and nonprescription medication recorded on each visit.
7. Compliance is assessed on each visit.
8. Each visit contains thorough questioning concerning disease control, signs or symptoms of disease progression or new complications, and signs or symptoms of adverse reactions.
9. Each visit documents appropriate objective information such as laboratory, physical assessment data, vital signs, etc.
10. All patient counseling concerning drug therapy, compliance, diet, exercise, and other lifestyle factors are recorded.
11. Therapeutic goals are clearly stated.
12. Appropriate recommendations and drug regimen changes are made and documented in the plan.
13. Documentation of any actions that are beyond the scope of practice that were authorized by a physician.
14. Appropriate timing of follow-up visit is included in every plan.

Appendix 3. Treatment Guidelines and Review Articles

Hypertension Guidelines

1. The fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC V). Arch Intern Med 1993;153:154–83.
2. Frohlich ED, Apstein C, Chobanian AV, et al. The heart in hypertension. N Engl J Med 1992;327:998–1008.
3. National High Blood Pressure Education Program. National High Blood Pressure Education Program Working Group report on hypertension and chronic renal failure. Arch Intern Med 1991;151:1280–7.
4. National High Blood Pressure Education Program. National High Blood Pressure Education Program Working Group report on primary prevention of hypertension. Arch Intern Med 1993;153:186–208.
5. National High Blood Pressure Education Program Working Group report on the heart in hypertension. National High Blood Pressure Education Program. U.S. Department of Health and Human Services. NIH Publication No. 91-3033. September 1991.
6. National High Blood Pressure Education Program Working Group. National High Blood Pressure Education Program Working Group report on hypertension in the elderly. Hypertension 1994;23:275–85.
7. National High Blood Pressure Education Program Working Group. National High Blood Pressure Education Program Working Group report on hypertension in diabetes. Hypertension 1994;23:145–58.
8. Bussey HI, Hawkins DW. Hypertension. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1991:1–26.
9. Bussey HI, Hawkins DW. Hypertension. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.

Diabetes Guidelines

10. Lebovitz HE, Clark CM, DeFronzo RA, et al, for the American Diabetes Association Clinical Education Program. Physician's guide to non-insulin-dependent (type II) diabetes. Diagnosis and treatment, 2nd edition. American Diabetes Association, 1990.
11. American Diabetes Association. Clinical practice recommendations, 1992–1993. Diabetes Care 1993;16(suppl 2):1–113.
12. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977–86.
13. Bartels DW. Diabetes mellitus. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1993:145–167.
14. Bartels DW. Diabetes mellitus. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.

Hyperlipidemia Guidelines

15. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Summary of the second report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). JAMA 1993;269:3015–23.
16. Israel MK, McKenney JM. Hyperlipidemias. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1991:27–47.
17. Israel MK. Hyperlipidemias. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.

Appendix 3. Treatment Guidelines and Review Articles (continued)

Heart Failure Guidelines

18. Chow MSS, Scheife RT, eds. Therapeutic and research strategies for congestive heart failure. Pharmacotherapy 1993;13(5 pt 2):71S–99.
19. Munger MA, Stanek EJ. Heart failure. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1991:85–99.
20. Stanek EJ, Moser LR, Munger MA. Heart failure. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
21. Brutsaert DL, Sys SU, Gillebert TC. Diastolic failure: pathophysiology and therapeutic implications. J Am Coll Cardiol 1993;22:318–25.
22. Heart failure: evaluation and care of patients with left ventricular systolic dysfunction. Agency for Health Care Policy and Research (under development).

Coronary Artery Disease Guidelines

23. Frishman WH. Conference on optimizing antianginal therapy. Am J Cardiol 1992;70:1G–76.
24. Hamilton SF. Angina pectoris. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1991:49–64.
25. Hamilton SF. Angina pectoris. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
26. Diagnosis and management of unstable angina. Agency for Health Care Policy and Research (under development).

Asthma/Chronic Obstructive Pulmonary Disease Guidelines

27. The Expert Panel on the Management of Asthma. National Asthma Education Program. Guidelines for the diagnosis and management of asthma. National Asthma Education Program. Office of Prevention, Education, and Control. National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland 20892. NIH Publication No. 91-3042, August 1991.
28. Ferguson GT, Cherniack RM. Management of chronic obstructive pulmonary disease. N Engl J Med 1993;328:1017–22.
29. Kelly HW. Asthma. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:3–16.
30. Kelly HW. Asthma. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
31. Stratton MA. Chronic obstructive pulmonary disease. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:17–38.
32. Stratton MA, Noyes M. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.

Peptic Ulcer Disease Guidelines

33. Soll AH. Pathogenesis of peptic ulcer and implications for therapy. N Engl J Med 1990;322:909–16.
34. Fish DN, Siepler JK. Gastroesophageal reflux disease. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:123–33.
35. Fish D. Gastroesophageal reflux disease. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
36. Piscitelli SC, Garnett WR. Peptic ulcer disease. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:145–57.
37. Piscitelli SC. Zollinger-Ellison disease/NSAID-induced gastropathy/peptic ulcer disease. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
38. Hixson LJ, Kelly CL. Current trends in the pharmacotherapy for gastroesophageal reflux disease. Arch Intern Med 1992;152:717–23.
39. Hixson LJ, Kelly CL. Current trends in the pharmacotherapy for peptic ulcer disease. Arch Intern Med 1992;152:726–32.
40. National Institutes of Health Consensus Development Conferences Statement. *Helicobacter pylori* in peptic ulcer disease. February 7–9, 1994.

Seizure Disorders Guidelines

41. Scheuer ML, Pedley TA. The evaluation and treatment of seizures. N Engl J Med 1990;323:1468–74.
42. Miyahara RK. Seizure disorders. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:47–61.

Thromboembolic Disorders Guidelines

43. Dalen JE, Hirsh J, for the Third ACCP Consensus Conference on Antithrombotic Therapy. Chest 1992;102:303S–549.
44. Carter BL. Therapy of acute thromboembolism with heparin and warfarin. Clin Pharm 1991;10:503–18.
45. Rodvold KA, Erdman SM. Pulmonary embolism. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:39–53.
46. Rodvold KA, Erdman SM. Thrombosis. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.

Estrogen Replacement Therapy Guidelines

47. American College of Physicians. Guidelines for counseling postmenopausal women about preventive hormone therapy. Ann Intern Med 1992;117:1038–41.

Appendix 3. Treatment Guidelines and Review Articles (continued)

48. Lourwood DL. Estrogen replacement therapy. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1993:189–202.
49. Lourwood DL. Hormone replacement therapy. In: Carter BL, Angaran DM, Lake KD, Raebel MA, eds. Pharmacotherapy self-assessment program, 2nd edition. Kansas City: American College of Clinical Pharmacy, In press.
50. Grady D, Rubin SM. Hormone therapy to prevent disease and prolong life in postmenopausal women. Ann Intern Med 1992;117:1016–41.
51. Wood H, Wang-Cheng R. Postmenopausal hormone replacement: are two hormones better than one? J Gen Intern Med 1993;8:451–8.
52. Belchetz PE. Hormonal treatment of postmenopausal women. N Engl J Med 1994;330:1062–71.

Rheumatologic Disorders Guidelines

53. Anonymous. Drugs for rheumatoid arthritis. Med Lett Drugs Ther 1991;33:65–70.
54. Harris ED. Rheumatoid arthritis: pathophysiology and implications for therapy. N Engl J Med 1990;322:1277–89.

Depression Guidelines

55. Clinical practice guidelines. Depression in primary care, volume 1. Detection and diagnosis. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 93-0550, April 1993.
56. Clinical practice guidelines. Depression in primary care, volume 2. Treatment of major depression. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 93-0550, April 1993.
57. American Psychiatric Association. Practice guidelines for major depressive disorders in adults, 2nd edition. Washington, DC, 1993.
58. Grimsley SR. Depression. In: Carter B, Angaran D, Sisca T, eds. Pharmacotherapy self-assessment program, 1st edition. Kansas City: American College of Clinical Pharmacy, 1992:127–50.

Appendix 4. Bibliography on Patient Outcomes Measurement

Generic Tools

1. Stewart AL, Ware JE Jr, eds. Measuring functioning and well-being: the medical outcomes study approach. The Rand Corporation. Durham, NC: Duke University Press, 1992.
2. Parkerson GR, Gehlbach SH, Wagner EH, et al. The Duke-UNC health profile: an adult health status instrument for primary care. Med Care 1981;19:806–28.
3. *Hunt SM, McEwen J, McKenna SP. Measuring health status: a tool for clinicians and epidemiologists. J R Coll Gen Pract 1985;35:185–8.
4. Nelson EC, Wasson JH, Kirk JQ. Assessment of function in routine clinical practice: description of the COOP chart method and preliminary findings. J Chronic Dis 1987;40(suppl 1):55S–63.
5. Stewart AL, Hays RD, Ware JE. The MOS short-form general health survey: reliability and validity in a patient population. Med Care 1988;26:724–35.
6. Ware JE, Snow K, Kosinski M, et al. SF-36 health survey manual and interpretation guide. Boston: Nimrod Press, 1993.
7. Bergner M, Bobbitt RA, Carter WB, et al. The sickness impact profile: conceptual formulation and methodology for the development of a health status measure. Int J Health Serv 1976;6:393–415.

*The Nottingham Health Profile

Disease-Specific Tools to Measure Outcomes

Hypertension Outcomes

1. Flack JM, Grimm RH. Hypertension/Lipid Form 5.1. Bloomington, MN: Health Outcomes Institute, 1993. (200 Killebrew Dr., Suite 122, Bloomington, MN 55425).
2. Bulpitt CJ, Fletcher AE. Quality of life in hypertensive patients on different antihypertensive treatments: rationale for methods employed in a multicenter randomized controlled trial. J Cardiovasc Pharm 1985;7(suppl 1):137–45.
3. Chang SW, Fine R, Siegel D, et al. The impact of diuretic therapy on reported sexual function. Arch Intern Med 1991;151:2402–8.
4. Croog SH, Levine S, Testa MA, et al. The effects of antihypertensive therapy on the quality of life. N Engl J Med 1986;314:1657–64.
5. Levine S, Croog S, Sudilovsky A, et al. Effects of antihypertensive medications on vitality and well-being. J Fam Pract 1987;25:357–63.
6. Testa MA, Anderson RB, Nackley JF, et al. Quality of life and antihypertensive therapy in men: a comparison of captopril with enalapril. N Engl J Med 1993;328:907–13.
7. Testa MA, Sudilovsky A, Rippey RM, et al. A short form for clinical assessment of quality of life among hypertensive patients. Am J Prev Med 1989;5:82–9.
8. The Treatment of Mild Hypertension Research Group. The treatment of mild hypertension study: a randomized, placebo-controlled trial of a nutritional-hygienic regimen along with various drug monotherapies. Arch Intern Med 1991;151:1413–23.

Appendix 4. Bibliography on Patient Outcomes Measurement (continued)

9. Watters K, Campbell B. Can an antihypertensive agent be both effective and improve the quality of life? A multicenter study with indapamide. Br J Clin Prac 1986; 40:239–44.
10. Wenger NK, Mattson ME, Furberg CD, Elinson J, eds. Assessment of quality of life in clinical trials of cardiovascular therapies. New York: Le Jacq Publishing Inc., 1984.

Diabetes Outcomes

11. Given CW. Measuring the social psychological health states of ambulatory chronically ill patients: hypertension and diabetes as tracer conditions. J Comm Health 1984;9:179–95.
12. Hanestad BR, Polit RN. Perceived quality of life in a study of people with insulin-dependent diabetes mellitus using the Hornquist model. Qual Life Res 1994;3:79.
13. Hanestad BR, Hornquist JO, Albreksten G. Self-assessed quality of life and metabolic control in persons with insulin-dependent diabetes mellitus (IDDM). Scand J Soc Med 1991;19:57–65.
14. Kaplan SH. Patient reports of health status as predictors of physiologic health measures in chronic disease. J Chronic Dis 1987;40:27S–35.
15. Marquis KH, Ware JE, Johnston R, et al. Appendix B to summary report: an evaluation of published measures of diabetes self-care variables. Publication No. N-1152-HEW. Santa Monica, CA: The Rand Corporation, June 1979.
16. Nerenz DR, Repasky DP, Whitehouse FW, et al. Ongoing assessment of health status in patients with diabetes mellitus. Med Care 1992;30(suppl 5):MS112–24.
17. Testa MA, Simonson DC. Measuring quality of life in hypertensive patients with diabetes. Postgrad Med J 1988;64(suppl 3):50–8.
18. The Diabetes Control and Complications Trial (DCCT) Research Group. Reliability and validity of a diabetes quality-of-life measure for the Diabetes Control and Complications Trial. Diabetes Care 1988;11:725–32.
19. Wenneker MB, Mchorney CA, Kieszak SM, et al. The impact of diabetes severity on quality of life: results from the medical outcomes study [abstr]. Clin Res 1991;39:612A.

Hyperlipidemia Outcomes

20. Flack JM, Grimm RH. Hypertension/Lipid Form 5.1. Bloomington, MN: Health Outcomes Institute, 1993. (200 Killebrew Dr., Suite 122, Bloomington, MN 55425).

Heart Failure Outcomes

21. Guyatt GH, Nogradi S, Halcrow S, et al. Development and testing of a new measure of health status for clinical trials in heart failure. J Gen Intern Med 1989;4:101–7.
22. Bulpitt CJ, Fletcher AE. Measurement of the quality of life in congestive heart failure—influence of drug therapy. Cardiovasc Drug Ther 1988;2:419–24.
23. Feinstein AF, Fisher MB, Pigeon JG. Changes in dyspnea-fatigue ratings as indicators of quality of life in the treatment of congestive heart failure. Am J Cardiol 1989;64:50–5.
24. Gorkin L, Norvell NK, Rosen R, et al. Assessment of quality of life as observed from the baseline data of the Studies of Left Ventricular Dysfunction (SOLVD) trial quality-of-life substudy. Am J Cardiol 1993;71:1069–73.
25. Guyatt G. Methodological problems in clinical trials in heart failure. J Chronic Dis 1985;38:353–63.
26. Massie BM, Berk MR, Brozena SC, et al. Can further benefit be achieved by adding flosequinan to patients with congestive heart failure who remain symptomatic on diuretic, digoxin, and an angiotensin converting enzyme inhibitor? Results of the Flosequinan-ACE Inhibitor Trial (FACET). Circulation 1993;88:492–501.
27. Rector TS, Tschumperlin LK, Kubo SH, et al. Clinically significant improvements in the living with heart failure questionnaire score as judged by patients with heart failure. Qual Life Res 1994;3:60–1.
28. Rector TS. Outcomes assessment: functional status measures as therapeutic endpoints for heart failure. Top Hosp Pharm Manag 1990;10:37–43.
29. Rector TS, Cohn JN. Assessment of patient outcome with the Minnesota living with heart failure questionnaire: reliability and validity during a randomized, double-blind, placebo-controlled trial of pimobendan. Am Heart J 1992;124:1017–25.
30. Rector TS, Kubo SH, Cohn JN. Patients' self-assessment of their congestive heart failure—Part 2: content, reliability and validity of a new measure, the Minnesota living with heart failure questionnaire. Heart Fail 1987;3:198–209.
31. Rector TS, Kubo SH, Cohn JN. Validity of the Minnesota living with heart failure questionnaire as a measure of therapeutic response to enalapril or placebo. Am J Cardiol 1993;71:1106–7.
32. Retchin SM, Brown B. Elderly patients with congestive heart failure under prepaid care. Am J Med 1991;90:236–42.
33. Romm FJ, Hulka BS, Mayo F. Correlates of outcomes in patients with congestive heart failure. Med Care 1976;15:765–76.
34. Wiklund I, Lindvall K, Swedberg K, et al. Self-assessment of quality of life in severe heart failure: an instrument for clinical use. Scand J Psychol 1987;28:220–5.

Coronary Artery Disease Outcomes

35. Vaisrub S. Quality of life manque. JAMA 1976;236:387.
36. Permanyer-Miralda G, Alonso J, Anto JM, et al. Comparison of perceived health status and conventional functional evaluation in stable patients with coronary artery disease. J Clin Epidemiol 1991;44:779–86.
37. Smith HC, Frey RL, Piehler JM. Does coronary bypass surgery have a favorable influence on the quality of life? Cardiovasc Clin 1983;12:253–64.
38. VandenBurg MJ. Measuring the quality of life of patients with angina. In: Walker SR, Rosser RM, eds. Quality of life: assessment and application. Lancaster, England: MTP Press Limited, 1988:267–78.
39. Westaby S, Sapsford RN, Bentall HH. Return to work and quality of life after surgery for coronary artery disease. Br Med J 1979;2:1028–31.

Appendix 4. Bibliography on Patient Outcomes Measurement (continued)

40. Spertus JA, Winder JA. The Seattle angina questionnaire: validation of a new functional status measure for patients with coronary artery disease (submitted 1993).
41. Pryor DB. Angina Form 9.1. Bloomington, MN: Health Outcomes Institute, 1993. (200 Killebrew Dr., Suite 122, Bloomington, MN 55425).

Asthma/Chronic Obstructive Pulmonary Disease Outcomes

42. Alonso J, Auto JM, Gonzalez M, et al. Measurement of general health status of non-oxygen dependent chronic obstructive pulmonary disease patients. Med Care 1992;30:MS125–35.
43. Barber BL, Santanello NC, Epstein RS. Clinical meaning of change in an asthma-specific questionnaire. Qual Life Res 1994;3:58–9.
44. Bishop J, Carlin J, Nolan T. Evaluation of the properties and reliability of a clinical severity scale for acute asthma in children. J Clin Epidemiol 1992;45:71–6.
45. Eakin EG, Kaplan RM, Ries AL. Measurement of dyspnea in chronic obstructive pulmonary disease. Qual Life Res 1993;2:181–91.
46. Guyatt GH, Thompson PJ, Berman LB, et al. How should we measure function in patients with chronic heart and lung disease? J Chronic Dis 1985;38:517–24.
47. Guyatt GH, Townsend MB, Pugsley SO, et al. Quality of life in patients with chronic airflow limitations. Br J Dis Chest 1987;81:45–54.
48. Guyatt GH, Berman LB, Townsend M, et al. A measure of quality of life for clinical trials in chronic lung disease. Thorax 1987;42:773–8.
49. Hyland ME, Finnis S, Irvine SH. A scale for assessing quality of life in adult asthma sufferers. J Psychosoc Res 1991;35:99–110.
50. Juniper EF, Guyatt GH, Griffith LE. Determining a minimal important change in a disease-specific quality of life questionnaire. J Clin Epidemiol 1994;47:81–7.
51. Juniper EF, Guyatt GH, Epstein RS, et al. Evaluation of impairment of health related quality of life in asthma: development of a questionnaire for use in clinical trials. Thorax 1992;47:76–83.
52. Bethel RA. Asthma Form 10.1. Bloomington, MN: Health Outcomes Institute, 1993. (200 Killebrew Dr., Suite 122, Bloomington, MN 55425).
53. Bethel RA. COPD Form 15.1. Bloomington, MN: Health Outcomes Institute, 1993. (200 Killebrew Dr., Suite 122, Bloomington, MN 55425).

Peptic Ulcer Disease Outcomes

54. Dimenas E, Glise H, Hallerback B, et al. Quality of life in patients with upper gastrointestinal symptoms. An improved evaluation of treatment regimens? Scand J Gastroenterol 1993;28:681–7.
55. Garratt AM, Ruta DA, Abdalla MI, et al. The SF-36 health survey questionnaires: an outcome measure suitable for routine use within the NHS? Br Med J 1993;306:1440–4.
56. Guyatt GH, Mitchell A, Irvine E, et al. A new measure of health status for clinical trials in inflammatory bowel disease. Gastroenterology 1989;96:804–10.
57. Pincus T, Griffin M. Gastrointestinal disease associated with non-steroidal anti-inflammatory drugs: new insights from observational studies and functional status questionnaires. Am J Med 1991;91:209–12.

Seizure Disorder Outcomes

58. Baker GA, Smith DF, Dewey M, et al. The initial development of a health-related quality of life model as an outcome measure in epilepsy. Epilepsy Res 1993;16:65–81.
59. Baker GA, Smith DF, Dewey M, et al. The development of a seizure severity scale as an outcome measure in epilepsy. Epilepsy Res 1991;8:245–51.
60. Chaplin JE, Yepez R, Shorvon S, et al. A quantitative approach to measuring the social effects of epilepsy. Neuroepidemiology 1990;9:151–8.
61. Jacoby A, Baker G, Smith D, et al. Measuring the impact of epilepsy: the development of a novel scale. Epilepsy Res 1993;16:83–8.
62. Jacoby A. Epilepsy and the quality of everyday life: findings from a study of people with well-controlled epilepsy. Soc Sci Med 1992;34:657–66.
63. Jacoby A, Johnson A, Chadwick D. Psychosocial outcomes of antiepileptic drug discontinuation. Epilepsia 1991;33:1123–31.
64. Perrine KR. A new quality-of-life inventory for epilepsy patients: interim results. Epilepsia 1993;34(suppl 4):S28–33.
65. Smith D, Baker G, Davies G, et al. Outcomes of assessing treatment with lamotrigine in partial epilepsy. Epilepsia 1993;34:312–22.
66. Smith DF, Baker GA, Dewey M, et al. Seizure frequency, patient-perceived seizure severity and the psychosocial consequences of intractable epilepsy. Epilepsy Res 1991;9:231–41.
67. Vickrey BG. A procedure for developing a quality-of-life measure for epilepsy surgery patients. Epilepsia 1993;344(suppl 4):S22–7.
68. Vikrey BG, Hays RD, Brook RH, et al. Reliability and availability of the Katz adjustment scales in an epilepsy sample. Qual Life Res 1992;1:63–72.
69. Wagner AK, Bungay KM, Bromfield EB, et al. Health-related quality of life of adult person with epilepsy as compared with health-related quality of life of well persons. Epilepsia 1993;6:5.

Appendix 4. Bibliography on Patient Outcomes Measurement (continued)

70. Wagner AK, Keller S, Baker GA, et al. Improving health-related quality of life measures for use with people with epilepsy. Epilepsia 1993;2:30.
71. French J. The long-term therapeutic management of epilepsy. Ann Intern Med 1994;120:411–22.

Estrogen Replacement Therapy Outcomes

72. Daly E, Gray A, Barlow D, et al. Measuring the impact of menopausal symptoms on quality of life. Br Med J 1993;307:836–40.
73. Wiklund I, Holst J, Karlberg J, et al. A new methodological approach to the evaluation of quality of life in postmenopausal women. Maturitas 1992;14:211–24.

Rheumatologic Outcomes

74. Bombardier C, Ware J, Russell J, et al. Auranofin therapy and the quality of life in patients with rheumatoid arthritis. Am J Med 1986;81:565–78.
75. Blair PS, Silman AJ. Can clinical trials in rheumatology be improved? Curr Opin Rheumatol 1991;3:272–9.
76. Bjelle A. Functional status assessment. Curr Opin Rheumatol 1991;3:280–5.
77. Bakker CH, Rutten-van MM, Van Doorslaer E, et al. Health related utility measurement in rheumatology: an introduction. Patient Educ Counsel 1993;20:145–52.
78. Meenan RF, Gertman PM, et al. Measuring health status in arthritis: the arthritis impact measurement scales. Arthritis Rheum 1980;23:146–52.

Depression Outcomes

79. Alden D, Austin C, Sturgeon R. A correlation between the geriatric depression scale long and short forms. J Gerontol 1989;44:124–5.
80. Borson S, McDonald GJ, Gayle T, et al. Improvement in mood, physical symptoms, and function with nortriptyline for depression in patients with chronic obstructive pulmonary disease. Psychosomatics 1992;33:190–201.
81. Brooks W, Blair J, John S, et al. The impact of psychologic factors on measurement of functional status: assessment of the sickness impact profile. Med Care 1990;28:793–804.
82. Given C, Stommel M, Given B, et al. The influence of cancer patients' symptoms and functional states on patients' depression and family caregivers' reaction and depression. Health Psychol 1993;12:277–85.
83. Grégoire J, de Leval N, Mesters P, et al. Validation of the quality of life in depression scale in a population of adult depressive patients aged 60 years and above. Qual Life Res 1994;3:51–2.
84. Gurland B, Golden RR, Teresi JA, et al. The short-care: an efficient instrument for the assessment of depression, dementia and disability. J Gerontol 1984;39:166–9.
85. Lambert MJ, Hatch DR, Kingston MD, et al. Zung, Beck and Hamilton rating scales as measures of treatment outcome: a meta-analytic comparison. J Consult Clin Psychol 1986;54:54–9.
86. Light RW, Merrill EJ, Despars JA, et al. Prevalence of depression and anxiety in patients with COPD: relationship to functional capacity. Chest 1985;87:35–8.
87. Norris JT, Gallagher D, Wilson A, et al. Assessment of depression in geriatric medical outpatients: the validity of two screening measures. J Am Geriatr Soc 1987;35:989–95.
88. Prusoff BA, Klerman GL, Paykel ES. Concordance between clinical assessments and patients' self-report in depression. Arch Gen Psychiatry 1972;26:546–52.
89. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. J Appl Psychol Meas 1977;1:385–401.
90. Revicki DA, Turner R, Brown R, et al. Reliability and validity of a health-related quality of life battery for evaluating outpatient antidepressant treatment. Qual Life Res 1992;1:257–66.
91. Stewart AL, Sherbourne CD, Wells KB, et al. Do depressed patients in different treatment settings have different levels of well-being and functioning? J Consult Clin Psychol 1993;6:849–57.
92. Stoker MJ, Sunbar GC, Beaumont G. The SmithKline Beecham 'quality of life' scale: a validation and reliability study in patients with affective disorder. Qual Life Res 1992;1:385–95.
93. Tambs K, Moum T. How well can a few questionnaire items indicate anxiety and depression? Acta Psychiatr Scand 1993;87:364–7.
94. Tanaka JS, Huba GJ. Confirmatory hierarchical factor analyses of psychological distress measures. J Pers Soc Psychol 1984;46:621–35.
95. Tanaka-Matsumi J, Kameoka VA. Reliabilities and concurrent validates of popular self-report measures of depression, anxiety, and social desirability. J Consult Clin Psychol 1986;54:328–33.
96. Wells KB. Commentary: assessment of psychological morbidity in primary care. J Chronic Dis 1987;40(suppl 1):81S–3.
97. Wells KB, Stewart A, Hays RD, et al. The functioning and well being of depressed patients. JAMA 1989;262:914–19.
98. Wells KB, Hays RD, Burnam MA, et al. Detection of depressive disorders for patients receiving prepaid for fee-for-service care: results from the medical outcomes study. JAMA 1989;262:3298–3302.
99. Radloff LS. The CES-D scale: a self reported depression scale for research in the general population. Appl Psychol Meas 1977;1:385–401.