ACCP White Paper

Clinical Pharmacy Practice in the Noninstitutional Setting

A White Paper from the American College of Clinical Pharmacy

The ACCP Clinical Practice Affairs Committee, 1990–1991

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The great majority of patients seek care and are managed in noninstitutional settings. Many procedures that were recently performed only in the hospital are now done on an ambulatory basis due to the emphasis on outpatient care. The profession of pharmacy is well positioned to meet the primary care needs of consumers. However, there continue to be major challenges to the provision of clinical pharmacy services in noninstitutional settings. Numerous studies have demonstrated the value of clinical pharmacists in the long-term management of hypertensive, diabetic, and anticoagulated patients in the ambulatory environment.[1–14] Studies in noninstitutional settings have documented that clinical pharmacy services can improve disease control, and that they can reduce adverse drug reactions and noncompliance.[13–15]

Purposes

The purposes of this white paper are as follows:

1. To identify the variety of environments in which noninstitutional pharmacy practice occurs;
2. To review guidelines for clinical pharmacy practice in noninstitutional settings;
3. To highlight barriers to the provision of clinical pharmacy services in these settings; and
4. To make recommendations designed to promote the growth of clinical practice in these settings.

Definitions and Philosophy

By definition, ambulatory care consists of health-related services provided to patients who are able to walk to seek their care and who are not confined to an institutional setting.[13, 16] Noninstitutional pharmacy services are offered to patients in a wide range of settings. For the purpose of this paper, noninstitutional pharmacy refers to practice sites that are not located in the traditional inpatient environment, including those listed below:

1. Community pharmacies
   a. Traditional independent or chain
   b. Clinic pharmacies
2. Family practice groups or residency training sites
3. General medicine clinics (primary care)
   a. Pharmacy clinics
4. Geriatric primary care clinics (geriatric assessment clinics)
5. Health maintenance organizations
6. Home health care programs or agencies
7. Mental health clinics (e.g., chemical dependence, affective disorders, movement disorders, lithium clinics)
8. Outpatient pharmacy services
   a. Hospital outpatient pharmacies
   b. Emergency room/urgent care centers
   c. Private group practices
9. Pediatrics
   a. General pediatrics
   b. Asthma or allergy
10. Public health services
    a. Indian Health Service
11. Specialty medicine clinics (e.g., hypertension, anticoagulation, diabetes, asthma or allergy, lipid clinics)

Such services differ from those provided to institutionalized patients in several respects. Ambulatory care pharmacists devote significant time to the care of patients with chronic disease. A particular aspect of this care is long-term monitoring and continuity. The ambulatory care practitioner has the advantage of following patients for months or years in order to monitor and evaluate the course of the illness and the response to treatment. In many such cases pharmacists are actively involved in episodic, short-term care and in disease prevention.

Ambulatory care is a broad term that includes short-term, episodic care (e.g., urgent care

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centers) as well as long-term management. It can be divided further into types of care by specific philosophies of practice. Primary care is one subset that has special features and a specific philosophy. Primary care refers to the initial point of entry into the health care system. It includes the provision of preventive care, treatment of a wide range of illnesses, and long-term coordination and management. A key component of primary care is continuity.[17]

Primary care practitioners must be competent to assist patients with a wide variety of illnesses or several concomitant disease states, many of which are rarely treated in the institutional setting. These practitioners must also identify delayed adverse drug reactions, monitor long-term therapy, and evaluate compliance. In many settings such as pharmacy clinics, anticoagulation clinics, and family practice offices, physicians refer patients to pharmacists for monitoring, dosage adjustments, and long-term follow-up. Indian Health Service pharmacists have long been pioneers in providing primary care services, including diagnosing and treating common conditions with protocols and standards of practice.[14, 18, 19]

The goal of the American College of Clinical Pharmacy (ACCP) is to promote excellence in clinical pharmacy practice, research, and education. This report offers recommendations on how that goal can be realized in noninstitutional settings.

Guidelines for Clinical Practice

Many noninstitutional pharmacy practice settings incorporate some aspects of clinical pharmacy services (e.g., patient counseling). However, such individual services provided alone can no longer be considered state of the art. All noninstitutional pharmacy programs should strive continually to upgrade the level of their clinical pharmacy programs. Several organizations, including ACCP, the American Society of Hospital Pharmacists, the American Pharmaceutical Association, and the Indian Health Service, have developed standards of practice or practice guidelines that apply directly to pharmacists working in noninstitutional settings.[18, 20–22]

This paper will not generate new standards of practice for clinical pharmacy services in noninstitutional settings. Rather, it will highlight previously published standards and guidelines that are essential for the provision of state-of-the-art services and thus set a mark at which noninstitutional practitioners, managers, and administrators can aim.

Pharmacists practicing in noninstitutional settings should strive to offer all of the following comprehensive clinical and educational services as part of their responsibility to deliver the pharmaceutical care required by their patients[20, 21]:

1. Provide primary or consultative care as a member of the health care team. The pharmacist must maintain a high level of communication among patients, physicians, nurses, and other health professionals, and recommend appropriate referrals to other health care professionals as required. Together with the prescriber, the pharmacist should take responsibility for patients' therapeutic outcomes. The pharmacist should strive to ensure a positive therapeutic outcome with the lowest probability of an adverse reaction or lack of effect.
2. Provide clinical pharmacy services on a continuing basis, and assist physicians and other drug therapy prescribers with *therapeutic decisions* by
   a. Designing, implementing, monitoring, evaluating, and modifying pharmacotherapy to ensure effective, safe, and economical patient care.
   b. Prospectively formulating individualized drug regimens based on the indication(s) for the medication(s), drug product selection, concurrent disease(s), laboratory results, allergies, concurrent drug therapies, pharmacokinetics of the agent(s), and patients' clinical condition.
   c. Using interviews, physical assessment skills, and interpretation of laboratory test results, monitor therapy for its effects or adverse reactions.
   d. Managing patients' drug therapy by
      i. Designing treatment plans and advising prescribers on their implementation.
      ii. Using established therapeutic protocols.
      iii. Independently prescribing or adjusting drug therapy in instances where supportive legislation or regulations exist.
3. Effectively counsel patients on prescription and nonprescription drug use; on the use of devices, injectables, and complicated dosage forms; and on the administration or application of topical therapy. Reassess patients' level of comprehension and ability to use devices correctly.
4. Evaluate studies published in the literature in terms of research design, reliability and validity of results, and clinical applicability.
5. Develop criteria for safe and effective drug use and coordinate drug use evaluations and patient care audits.
6. Develop a quality assurance program to measure the quality of care provided by the pharmacy service.
7. Develop and maintain excellent writing skills in order to prepare consultations, newsletters,

and memoranda to physicians and other health professionals, and prepare manuscripts for publication.
8. Develop and maintain excellent verbal communication skills in order to conduct consultations, continuing education lectures, grand rounds, and other educational interventions to physicians and other health care professionals.
9. Provide a teaching environment to educate and train pharmacy students, residents, fellows, and pharmacotherapy specialists.

Need

Although progress has been made, aspects of pharmaceutical care described by these guidelines are not being provided in the majority of noninstitutional settings in which pharmacy is practiced. The recently published report of the Inspector General of the United States on the role of the community pharmacist emphasized that clinical pharmacy services are needed and justifiable but are not widely provided in community pharmacy settings.[15] Because the majority of patient care is provided in noninstitutional settings, and since clinical pharmacy services can improve therapeutic outcomes and reduce costs,[14, 15] the greatest need for growth and development of clinical pharmacy services is in those settings. Major teaching, research, and patient care resources must be committed to promote excellence and expand clinical pharmacy services in noninstitutional settings.

Barriers to the Provision of Clinical Pharmacy Services in Noninstitutional Settings

Several barriers impede the development of clinical pharmacy services in noninstitutional settings. These may include the following:

1. Absence of a formal structure and communication network between the pharmacist and other health professionals
2. Inadequate patient data
3. Lack of direct physician contact
4. Insufficient time and inadequate resources and reimbursement
5. Absence of an effective information or referral network among pharmacists practicing in different locales
6. Inadequate educational opportunities
7. Limited research or research funding focused specifically on noninstitutional pharmacy practice
8. Attitudinal barriers on the part of pharmacists or physicians

Structure and Communication

One of the major reasons that clinical pharmacy practice has been successful in institutional settings is the availability of a formal structure and communication network among physicians, pharmacists, and other health care professionals. This includes both the availability of patient data and the closed network of policies and procedures (e.g., Pharmacy and Therapeutics Committee policies). This structure is also available in most primary care clinics affiliated with institutions, staff model or group/network model health maintenance organizations (HMOs), and family practice residency training offices. However, in the majority of settings where pharmacy is practiced, pharmacists have no structured communication link with physicians, nor do they generally have access to medical records and laboratory data. In addition, there is no method to provide formalized policies and procedures sanctioned by oversight committees. This isolation makes it extremely difficult to provide comprehensive clinical pharmacy services. These problems are compounded in rural areas or in settings where pharmacists are isolated from peers and educational resources. If the following recommendations are not implemented, state-of-the-art clinical pharmacy services cannot be provided.

Recommendations

1. Settings that remain physically isolated from direct, personal physician contact will find it increasingly difficult to provide comprehensive clinical pharmacy services. Therefore, some pharmacy settings will have to be philosophically and physically restructured so that pharmacists are incorporated into the prospective drug therapy decision-making loop and have access to patient-specific data. This may mean that pharmacists will have to locate their practice with, or adjacent to, a group of physicians.
2. Pharmacy organizations, individually and collaboratively, should foster the development of demonstration projects in which innovative clinical pharmacy services can be incorporated into private group practice.
3. Pharmacists who wish to provide state-of-the-art services in settings that remain physically isolated from direct physician contact must identify physicians who are willing to collaborate closely, must establish techniques for obtaining patient-specific data, and must develop methods to interact immediately with physicians when necessary for all of the patients whom they serve. This may involve incorporating high-technology communication links with physician offices. Most important is for pharmacists to have the ability immediately to receive diagnostic and laboratory information through communication links (e.g., modem) or plastic cards with computer-recorded data

carried by patients (smart cards, laser cards). Not only must data flow from physicians to pharmacists, but pharmacists must routinely provide physicians with patient-specific recommendations, which result from patient monitoring, therapeutic information, and the results of drug use evaluations conducted routinely by the pharmacists. In many instances these recommendations will be initiated by pharmacists to promote rational drug therapy.

4. Pharmacy and other health care organizations should work closely to promote the development and use of technology that provides community pharmacists with a patient-specific data base in order to provide state-of-the-art clinical pharmacy services.
5. Managed care and home health care settings provide excellent atmospheres for providing clinical pharmacy services.[23–26] Although these settings are quite diverse, they are frequently structured environments that have few barriers, especially regarding medical record data. Because of their structures and philosophies, these settings should receive a high priority for the above demonstration projects.

Time and Resources

Whether the setting is an ambulatory clinic in a tertiary medical center or a community pharmacy, a major limitation to the provision of comprehensive clinical pharmacy services is insufficient time and resources. Insufficient time may result from management philosophy, inefficient use of technicians for prescription preparation and paper work, or lack of a reimbursement structure. Even in settings where they have no dispensing functions, it is not possible nor necessary for pharmacists to interact with each patient or with every physician during each patient encounter. This necessitates that priorities be established for interventions.

Recommendations

1. Reimbursement for the services listed above will not occur until sufficient numbers of noninstitutional pharmacists make a commitment to these practices, document their delivery, and demonstrate their importance to improved quality of care. It is clear that examples of innovative pharmacy practices do exist in the community setting, and that the major factor in their success is a strong professional commitment on the part of individual practitioners.[15] The ACCP and other pharmacy organizations must encourage innovation in noninstitutional practice and a commitment to excellence on the part of their members who practice in these settings.
2. Managers and administrators must develop and implement innovative ideas to improve efficient use of time. Employment of technicians in settings where dispensing occurs must be increased in order to provide sufficient time for pharmacists to implement comprehensive clinical services. State pharmacy practice acts must be revised to include a greater role for technicians, and to facilitate and enable expanded pharmacy services.
3. Efficient use of time may be improved in some settings by having patients with more complex disease or therapy problems make appointments to see pharmacists. In some settings, it may be useful to designate blocks of time when pharmacists schedule follow-up visits for monitoring and counseling.
4. Physical settings must be restructured to be conducive to counseling ambulatory patients.
5. The Inspector General's report on the clinical role of the community pharmacist recommended that the Health Care Financing Administration and the Public Health Service develop a strategy that includes research, demonstration projects, and education efforts to reduce the barriers to clinical pharmacy services in community settings.[15] In response to this report, ACCP should assist members, other pharmacy organizations, third-party payers, and the federal government to establish model demonstration projects that document the value of innovative clinical pharmacy services. These demonstration projects should incorporate methods to evaluate patient outcomes, treatment costs, and reimbursement strategies for these services. A high priority must be placed on methods to identify the level of intervention that should be provided to specific patients and physicians.[15,27]

Information and Referral Network

There is no formal information or referral network among pharmacists who practice in different settings, or between general practice and specialized pharmacy practice.

Recommendations

1. Noninstitutional clinical pharmacists must develop a network of consultants for their own personal information needs.[28] These networks must also be used to refer patients and provide formal consulting services between pharmacy generalists and pharmacy specialists. This can be accomplished only by the initiative of individual pharmacists; however, if these practitioners are to assume responsibility for patients' outcomes, these communication networks must be developed.
2. Noninstitutional clinical pharmacists must

provide relevant and sufficiently detailed patient summaries to institutional clinical pharmacists when ambulatory patients enter the institutional setting. This will require authorization by patients for release of information. Similarly, when patients are discharged from the hospital or nursing facility, institutional pharmacists must provide similar summaries of institutional care to primary care clinical pharmacists.
3. Pharmacy organizations should assist practitioners to explore methods to improve communication links between different pharmacy settings (inpatient and outpatient) and different pharmacy practitioners (generalists and specialists) who may care for patients.

Educational Opportunities

Undergraduate and postgraduate educational opportunities in innovative, noninstitutional clinical pharmacy programs are extremely limited.[29] Most didactic, clerkship, residency, and fellowship training focuses on the inpatient setting. Even for settings that emphasize ambulatory care, many are so specialized that it is difficult for students or postgraduate trainees to relate the experience to mainstream ambulatory pharmacy practice. Specific recommendations have been made by the American Association of Colleges of Pharmacy Committee on Clinical Services in Community Pharmacy Practice.[29]

There is a critical shortage of postgraduate training programs that offer advanced ambulatory residencies and fellowships. In many instances, the demand for ambulatory specialists is so great that positions go unfilled, or they are filled by individuals who lack advanced training specific to ambulatory care.

Recommendations

1. Colleges of pharmacy should develop educational programs in community pharmacies, family practice offices, HMOs, and primary care clinics. However, to be considered optimal educational settings, they must strive to implement and ultimately to provide all of the comprehensive clinical pharmacy services outlined above.
2. Pharmacy students require a broad foundation of clinical experiences that should include a mixture of institutional and noninstitutional settings. Every pharmacy student should receive a minimum of one clinical clerkship in an appropriate noninstitutional setting. The goal of every college of pharmacy should be to provide 30-50% of each student's clerkship training in a noninstitutional setting that provides the services outlined above.
3. The performance criteria for community pharmacy externships and ambulatory clerkships must be strengthened and require that students demonstrate the competence to provide the clinical pharmacy services outlined above. In many instances, this will mean that colleges of pharmacy must restructure their externship programs and reevaluate the training sites.
4. Colleges of pharmacy should expand the scope of their clinical faculty to include several individuals who have clinical practice and research programs in noninstitutional settings.[29] These settings should ideally be a mixture of the ones outlined above. These faculty should serve as role models and as instructors in didactic courses so as to provide the ambulatory care perspective.
5. The number of postgraduate residencies and fellowships in primary care and ambulatory care settings must be greatly expanded in order to meet the need for continued growth and expansion of clinical pharmacy services. The most appropriate growth would be in programs that fill the greatest immediate need. These would include postgraduate training in primary care, family medicine, managed care, and community pharmacy practice, rather than subspecialty ambulatory areas. All residencies must conform to the standards for specialty residency training in primary care from the American Society of Hospital Pharmacists.[21]

Health Services Research

Little research has been conducted that documents the role or value of clinical pharmacy services in community practice and managed care settings. Research funding for noninstitutional clinical pharmacists is limited.

Recommendations

1. Pharmacy organizations should promote funding for studies that evaluate the costs and benefits of clinical services, and for the development of innovative practices in noninstitutional settings. The ACCP should work with the Public Health Service to develop potential funding opportunities and to alert College members when these sources are available.[15]
2. The ACCP Research Institute recently introduced the ACCP-Mead Johnson Family Medicine Research Award as a means to foster clinical pharmacy research in this environment. Pharmacy organizations should seek additional sources of funding for clinical research in ambulatory settings.

Attitudinal Barriers

Attitudinal barriers on the parts of pharmacists, managers, health care administrators, or

physicians may prevent the development of clinical pharmacy services in noninstitutional settings. Such barriers exist on the part of many clinical pharmacists who view noninstitutional practice as less challenging or as an environment that is not conducive to the provision of clinical pharmacy services.

Recommendations

1. All members of the health care system, including pharmacists, must be convinced that the pharmacy profession has a responsibility to provide the clinical services identified above.
2. All pharmacists must affirm their willingness to provide pharmaceutical care, must be willing to take responsibility for their patients' drug therapy, and must ensure that the above services are incorporated into their practice.
3. The model pharmacy practice act of the National Association of Boards of Pharmacy and the practice acts of individual states must enable pharmacists to provide comprehensive clinical pharmacy services in all practice locales.
4. Primary care and ambulatory care should be the foundation of the health care system. Appropriate emphasis must be placed on the establishment of comprehensive, state-of-the-art clinical pharmacy services in these settings.
5. The ACCP and other pharmacy associations must inform their members of the importance that the organizations place on the promotion of clinical pharmacy services in noninstitutional settings. This should include continuous dissemination of information concerning research and innovations in noninstitutional pharmacy practice.
6. The ACCP and other pharmacy associations must foster the publication of research, and must disseminate information to health care professionals, patients, corporate executives, administrators, and other decision makers concerning the value of clinical pharmacy services and the potential for cost avoidance in noninstitutional settings.
7. Pharmacy students and residents should receive some of their educational training together with medical students and residents in noninstitutional settings. Whenever possible, physicians must be exposed to and receive didactic instruction from clinical pharmacists. The most effective way to accomplish this is for active clinical pharmacists to provide didactic and one-on-one instruction to the entire health care team.
8. Practicing physicians should be informed about the value of clinical pharmacy services in noninstitutional settings.

Conclusion

It has long been recognized that ambulatory and primary care should be the cornerstone of a health care delivery system. However, this has not been the case in the United States, where much more emphasis has been placed on specialty practice and technologic advances in health care. This has led to a shortage of primary care clinicians in rural and many urban centers.

Pharmacy has an abundance of generalists who are in a position to have a major impact on the ambulatory patient population. Whereas numerous innovative settings can be cited, the majority do not provide advanced, comprehensive clinical pharmacy services. To a great extent, recent graduates of clinical programs, colleges of pharmacy, and pharmacy organizations have avoided these sites as places to expand clinical pharmacy services. It is hoped that this paper will provide direction and will help the profession meet the challenges of expanding state-of-the-art clinical pharmacy services, education, and research in noninstitutional settings.

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