INTRODUCTION

The purpose of this study is to: (1) examine the current level of clinical services available in community pharmacy settings, (2) identify barriers that limit the availability of such services, and (3) suggest actions that can be taken to reduce barriers and improve pharmaceutical care for ambulatory patients.

We undertook this study to examine more closely an issue raised in a previous report entitled, "Medicare Drug Utilization Review." Drug Utilization Review (DUR) is also referred to as Drug Use Evaluation (DUE) and defined as a "structured, ongoing, organizationally authorized quality assurance process designed to ensure that drugs are used appropriately, safely and effectively."[1]

The incidence of mismedication and adverse drug reactions (ADRs) and other drug-related illness among older adults is relatively high. Beyond the incalculable human costs associated with mismedication among the elderly, there are significant financial costs borne by patients, families, and public and private health insurers. One recent study conducted by the California State Assembly's Office of Research documented annual costs in that State of $340.1 million associated with hospitalizations of elderly patients for treatment of ADRs.[2]

One level of the health care delivery system that focuses specifically on drug therapy is that of clinical pharmacy care, sometimes referred to as pharmaceutical care. Its three major functions on behalf of the patient are: "(1) identifying potential and actual drug-related problems, (2) resolving actual drug-related problems, and (3) preventing potential drug-related problems."[3]

As the pharmacy profession has matured, the clinical care function has evolved and has gained increasing emphasis over the past decade. (For a discussion on the history of clinical pharmacy see appendix I.)

This report focuses on clinical services available to ambulatory patients in community pharmacy settings. Community pharmacy refers to walk-in pharmacies in non-institutionalized settings and includes chain drugstores, independent pharmacies and apothecaries. (Appendix II includes a detailed discussion of these and other pharmacy settings.) The role of the community pharmacist in patient care can be critical, particularly for older adults who may have complex drug regimens prescribed for them by more than one physician. In that context, policy makers and health care providers who are committed to improving the quality of care for the elderly and reducing health care utilization costs associated with drug therapy problems are turning more attention to the role clinical pharmacy can play in achieving those goals. It is our hope that this report will assist them in expanding the level of pharmaceutical care available to all patient groups,and particularly older Americans at high risk of drug-related illness.

FINDINGS

I. THERE ARE FOUR COMPONENTS OF CLINICAL PHARMACY PRACTICE: COLLECTION OF PATIENT INFORMATION, PROSPECTIVE DUR, PATIENT COUNSELING, AND PHYSICIAN CONSULTATION. EACH OF THESE COMPONENTS ENCOMPASSES A CONTINUUM OF POSSIBLE SERVICES.

Clinical pharmacy practice is composed of four major components: collection of patient information, Drug Regimen Review (DRR), patient counseling, and physician consultation. Research on clinical pharmacy that supports this four-part analysis includes: the American Association of Colleges of Pharmacy's (AACP) Committee Report on Clinical Services in Community Pharmacy Practice,[4] the American Pharmaceutical Association's (APhA) Standards of Practice,[5] and Dennis Helling's study of the functions of clinical pharmacists in family practices.[6] Our analysis is intended to be general enough to apply to many pharmacy settings, though our primary interest is in the clinical service profile of community pharmacy settings.

Within each component of clinical pharmacy there is a range of services that define the pharmacist's activities. In that context it should be noted that none of these components is simply either practiced or not practiced, in any setting. In each of these components, i.e., areas of practice, a pharmacist may provide any combination of a wide range of possible services. The intensity of these services, in terms of the resources required to perform them, varies greatly, ranging from a minimal level of service to a maximal level. The level of services provided also varies greatly among types of pharmacy setting, among individual pharmacists, and among patients and patient groups, even within a single pharmacist's practice. The reasons for these variations in clinical practice are discussed throughout this report. It should be noted that we are not discussing only prevalent practices, or even accepted standards of practice, but all possible practices. Virtually any pharmacist in any setting can say, with some fairness, that she or he provides some level of clinical services; there is virtually no such thing as a pharmacist who provides no clinical care at all.

The continuum of services offered within each component affects but does not determine the range of services within the other three. For example, extensive data collection could enhance the pharmacist's ability to closely monitor a patient's regimen. Nevertheless, a given community pharmacist could perform a maximal level of data collection, but still provide only minimal or moderate monitoring services.

III. THERE IS STRONG EVIDENCE THAT CLINICAL PHARMACY SERVICES ADD VALUE TO PATIENT CARE AND REDUCE HEALTH CARE UTILIZATION COSTS.

The value of clinical services is substantiated by the scientific literature on the subject. A number of research projects conducted in institutional and ambulatory settings have documented this added value:

- A study conducted in six pharmacies in Virginia measured the effect of pharmacists' monitoring and educational services provided to hypertensive patients. Results demonstrated better compliance in the experimental group of patients (44 of 70) than in the control group (23 of 66). Improved blood pressure was achieved in 74 percent of the experimental group and 58 percent of the control group.[9]

- A study in Memphis of non-institutionalized patients of a hospital outpatient clinic measured the relationship between the pharmacist's communication of different levels of written drug therapy information and patients' compliance rates with antibiotic drug regimens. The experimental group that received the highest level of information had a mean compliance rate of 84.7 percent while those patients receiving less information had a compliance rate of 63 percent.[10]

- A literature review of studies assessing costs and benefits of pharmacist-conducted drug regimen reviews in skilled nursing facilities was published by Samuel Kidder in 1987. The studies showed decreases in number of medications prescribed per patient, hospitalizations, cost of medications and other factors. Kidder's analysis projected annual savings of $220 million in averted health care costs resulting from clinical pharmacy interventions.[11]

- Integration of clinical pharmacy services within a private medical practice is one technique that has been used on a limited basis to involve clinical pharmacists in primary care. Under this model, the pharmacist provides a number of services to the office, including drug therapy consultation with physicians, monitoring of drug therapy for each patient, and patient education and counseling.[12] (Under this model pharmacists do not dispense drugs.) An evaluation of one such practice by the University of Iowa was able to document favorable effects of pharmacy interventions on patient care. In a retrospective review of recommendations made by pharmacists regarding specific drug therapy for patients, a peer review panel of physicians and pharmacists found that such recommendations resulted in favorable outcomes in patient care for two thirds of all cases.[13]

2. *Lack of availability:* Patients may not have direct contact with the pharmacist when purchasing a prescription drug or may perceive the pharmacist as unavailable for consultation. In pharmacies where the pharmacist, rather than a technician, conducts the counting and pouring activities, a patient's interaction may be with a clerk who is staffing the front counter. In other cases, patients may perceive that the pharmacist is too busy to answer questions. Consumers' perception of pharmacists' unavailability was well documented in the Schering survey previously cited. Respondents ranked the statements "feel pharmacist available to ask about medications" and "it's easy to get pharmacists to talk" in seventh and eighth place (of 15 items), respectively.[40]

3. *Situational impediments:* The architectural design of some pharmacies may discourage patients from consulting with pharmacists. If the prescription filling area is small and crowded with customers, the noise level and lack of privacy will not be conducive to effective communication.[41] Further, if the pharmacist operates from a floor raised above the level of where the patient stands, they may be forced to raise their voices in order to engage in conversation. Several studies have demonstrated that the quality of patient counseling is clearly effected by the environment in which pharmacist counseling is conducted.[42]

4. *Communication skills/baseline information:* In some cases patients may be generally aware of potential risks but may not feel comfortable about asking specific questions, or may lack the necessary communications skills. Additionally, the absence of baseline information from which questions can be formulated may also serve as an impediment. There is some evidence that providing patients with basic written information will encourage them to be more aggressive in seeking consultation. Medical Strategies, Inc. of Boston has developed a public access software product to provide consumers with current information on medications using patient package insert data developed by the U.S. Pharmacopoeial Convention. Based on touch screen technology, PIC enables patients to query a data base about prescription or OTC drugs and obtain both print and screen displays. The PIC program is in use in a number of pharmacy settings including independents, HMOs, and teaching hospitals. In our interviews with a number of PIC users, pharmacists consistently reported a high level of customer satisfaction with the service; one independent pharmacist credited the PIC system with a significant increase in his customer base. In all cases, pharmacists reported that the information printouts stimulated questions from patients and increased the quality and quantity of verbal counseling provided.

On a positive note, there is some evidence that patient demand for more and better information about drug therapy is increasing. Research indicates that "in general, over the

COMMENTS

Within the Department of Health and Human Services, the Public Health Service and the Health Care Financing Administration (HCFA) provided comments. The American Pharmaceutical Association, the American Society of Hospital Pharmacists, the American Society of Consultant Pharmacists, and the American Association of Colleges of Pharmacy also commented.

With the exception of HCFA, all commenters expressed support for the findings and recommendations. Most provided some technical suggestions and comments that we have included in the final draft. With the support and leadership these organizations are committed to providing, we look forward to initiatives that will expand clinical pharmacy services and improve patient care, particularly for groups who are at high risk of drug-related illness. In appendix VI, we present, in full, each set of comments and respond to each of them.

illnesses. Finally, the pharmacist may inquire about the patient's concerns about the drug regimen, such as whether previous reactions to other medications will reoccur.

The pharmacist most likely gets all this information directly from the patient. (OTC drug information typically can be obtained *only* from the patient, since these drugs are usually purchased without the express instructions of a physician, and often are not purchased at a single pharmacy or at any pharmacy, with the result that no complete record of their purchase exists anywhere except in the patient's memory.)

Information from Physicians

In addition to collecting this information from the patient, as well as determining the patient's main concerns and questions, the pharmacist can obtain data from the patient's physician or physicians that can be useful in managing the patient's drug therapy. Most basic here are the patient's vital statistics—though the pharmacist may occasionally read the patient's blood pressure or perform cholesterol screenings, if State law allows. Next is information concerning the patient's general course of medical treatment, both present and past, including hospitalizations. Finally, the physician can share with the pharmacist data from the patient's lab tests (e.g. blood or liver function tests), and information concerning the diagnosis, which could help the pharmacist understand why the physician has prescribed a certain drug. This information is readily available to a pharmacist working in a more institutionalized setting such as a hospital, a nursing home or a home health agency where physicians typically cooperate closely with pharmacists. But it is not routinely available to pharmacists working in a community setting. The practicing community pharmacists we spoke with all said that among the information about a patient that they usually do not possess, lab test data and diagnostic data would be the most helpful to them if they had it.

33. Billow J.A. et al., "A Comprehensive Communication Skills Program in a Four-Year Pharmacy Curriculum," *American Journal of Pharmaceutical Education*, 48:42-6, 1984.

34. Kimberlin, "Communications."

35. Morris L.A. et al., *A National Survey of Prescription Drug Information Provided to Patients*, OPE Study 73, prepared for the U.S. Food and Drug Administration, 1986, p.4.

36. Institute for Health Policy Analysis of the Georgetown University Medical Center, workshop on "Communicating the Benefits and Risks of Prescription Drugs" (Isle of Palms, South Carolina, March 1988) and National Council on Patient Information and Education" conference on "New Frontiers in Patient Education" (Washington, D.C, May 1989).

37. McCallum D.B. et al., "Communicating the Benefits and Risks of Prescription Drugs," Monograph 106, prepared for the Institute of Health Policy Analysis, Georgetown University Medical Center, 1989, p.7.

38. Smith M. et al., "A Study of Pharmacists' Involvement in Drug Use by the Elderly," *Drug Intelligence and Clinical Pharmacy*, 18:525-28, 1984.

39. *Pharmacist Perception Versus Consumer Realities*, Schering Report IV, (New Jersey: Schering Laboratories, 1982.

40. Ibid.

41. Knapp, "Barriers Faced," p.358.

42. Ludy J.A. et al., "The Patient-Pharmacist Interaction in Two Ambulatory Settings-Its Relationship to Patient Satisfaction and Drug Misuse," *Drug Intelligence and Clinical Pharmacy*, 11:81-89, 1977.

Beardsley R.S. et al., "Privacy As A Factor in Patient Counseling," *Journal of the American Pharmaceutical Association*, NS17:366-68, 1977.

McBean B.J. et al., "An Evaluation of Four Methods of Pharmacist-Conducted Patient Education," *Canadian Pharmacy Journal*, 115:167-172, 1982.

43. McCallum, p.7.

44. Marks M.R., "A Medication Sleuth at the End of a Phone Line," *California Pharmacist*, 33:3, 1985; also, telephone interview with Richard Oksas, July 1989.

COMMENTS OF THE PUBLIC HEALTH SERVICE ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORTS "THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST," OAI-01-89-89160, AND "THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST: CASE STUDIES," OAI-01-89-89161

General Comments

The reports effectively capture the dilemma facing community pharmacists regarding the implementation of progressive patient oriented pharmacy services, i.e., clinical pharmacy services. The reports should have a positive impact on the pharmacy profession by identifying the most significant barriers to the provision of pharmaceutical care for patients, especially older persons.

A recent strategy planning conference on "Pharmacy in the 21st Century," held in October 1989, examined many of the major issues confronting pharmacy today and projected for the next 15-20 years. The consensus statements of the conference support the findings of these reports. The participants included practitioners, pharmacy leaders, selected representatives of consumer groups, and government and corporate health care decision makers. A copy of the Executive Summary (Attachment A) is attached.

We regret that the OIG inspectors did not include in their inspection and case studies the Indian Health Service (IHS) pharmacy program. IHS has nearly 30 years of experience in providing clinical pharmacy services with extensive utilization of patient consultation. The IHS practice model has eliminated most of the barriers described in the OIG report.

The PHS comments on the OIG recommendations that pertain to PHS are presented below. Additional comments regarding alternative viewpoints are also included, which we believe would strengthen the overall content of the report. The additional comments relate to (1) the concept of a needs based system, and (2) the description of clinical services, especially the graphic representation in Appendix IV of the OIG report.

OIG Recommendation I.

The Public Health Service (PHS) and the Health Care Financing Administration (HCFA), individually and collaboratively, should develop a strategy to reduce the barriers to clinical pharmacy services, particularly for ambulatory elderly patients.

PHS Comment

We concur, noting that it is essential to develop a strategy that includes research, demonstration, and education efforts to reduce each of the barriers to clinical pharmacy services as described by OIG. PHS welcomes the opportunity to develop strategies to reduce the barriers to clinical pharmacy services for ambulatory patients, with emphasis on older persons.

IHS has extensive experience in the provision of progressive pharmaceutical care and is the prototype of a functional practice model that clearly demonstrates the pharmacy services concept described in the report. IHS will develop a descriptive strategy for reducing barriers to clinical services and demonstrate its application by September 30, 1990.

The Bureau of Health Professions in the Health Resources and Services Administration, PHS, will further develop the strategy described above in collaboration with IHS and HCFA. The strategy will be developed and implemented by October 31, 1990.

OIG Recommendation II.

The National Institute on Aging (NIA) should take a leadership role in developing risk indicators and treatment priorities for elderly ambulatory patients.

PHS Comment

We concur. NIA has taken action to increase its knowledge in the area of geriatric pharmacology, including the areas of risk indicators and treatment priorities for elderly ambulatory patients. NIA has recently published a Request for Applications (RFA): "Pharmacology in Geriatric Medicine" which solicits research applications on drug utilization reviews, pharmaco-epidemiology, and other areas related to the improvement of medication prescribing and use by older persons. Two million dollars have been set aside for this RFA. Scientific review of proposals will be accomplished by a special initial review group in June 1990, with secondary review to be completed at the September 1990 meeting of the National Advisory Council on Aging. It is anticipated that approximately 8-10 high quality applications will be funded with starting dates of December 1, 1990.

However, this recommendation may be more effectively accomplished if conducted in conjunction with an expert panel from appropriate PHS agencies and professional organizations. Indicators can be developed but they will only tell you which patients may be at

A practical shortened version of the comprehensive approach results in (1) successful needs assessment and intervention in the vast majority of patients, and (2) identification of those requiring comprehensive evaluation. Physicians do not perform a complete history and physical on every patient they encounter. They reserve that time for those who need it most.

B. Description of Clinical Pharmacy Services (Graphic Representation), Part I., "Findings," and Appendix IV.

The breakdown of clinical pharmacy services into four groups is generally correct. However, the assumption that within each component there is a continuum and the description, especially the graphic representations, of that supposed continuum is inaccurate and/or misleading.

1. Graph "Patient Counseling," Page 5. This graph creates confusion and inaccuracy rather than clarifying concepts because it attempts to illustrate a continuum that does not exist. Instead, it describes a combination of apples and oranges, including prospective drug utilization review (DUR), pharmacist management of chronic patients, and some patient consultation activities.

2. Appendix IV, "The Four Components of Clinical Pharmacy Care," Graph "Collection of Patient Information," Page IV-1.

While most of the important items are listed, they are grouped improperly by source rather than by patient need-based continuum that this report is trying to describe and propose. The reason for the pharmacist collecting a database is to determine what type and intensity of clinical pharmacy services the patient needs. The continuum should address which type of data are most important to determine patient needs. Where the pharmacist obtains the data, e.g., from a medical record, patient profile, physician interview, or patient interview, is a totally separate issue and is a function of the practice environment and the pharmacist's professional commitment to provide clinical services.

3. Page IV-3, Paragraph 1, "(2) Prospective Drug Utilization Review (DUR)"

The report does not clearly define the DUR. Based on what is included in the report, it appears to be too narrowly defined around ADRs and drug interactions. A more appropriate definition of DUR appears on page 1, paragraph 2, of the introduction, i.e., a review of the patient, drug, and disease databases to provide those functions listed in the second half of the paragraph. IHS utilizes the term *negative patient outcomes* to encompass those three functions. The focus of clinical pharmacy practice is this review process to determine the need for pharmacy intervention at each patient encounter. Attachment C presents the IHS standards of practice. Standard I of the IHS standards is a more comprehensive version of a prospective DUR process.

In prospective DUR processes the pharmacist compares therapy against the criteria such as those listed in the IHS standards. How much, how well, and whether the DUR is done at all is determined by:

a. the extent of the database available to the pharmacist;

b. the knowledge of the pharmacist in both drug and disease information;

c. the ability of the pharmacist to collect and integrate drug, disease, and patient data to identify and solve drug related problems;

d. the pharmacist's efficiency in performing item c, and once the pharmacist has optimal data, knowledge, integration skills, and efficiency (items a-d), then workload becomes a factor; and

e. commitment for providing these services.

4. Graphs on Page 4 and Appendix IV-4 on Prospective DUR.

Once again as in the collection of patient information, no continuum exists and the continuum presented in both graphs consist more of how it is done rather than what needs to be done.

Date

From Gail R. Wilensky, Ph.D
Administrator

Subject OIG Draft Reports: "The Clinical Role of the Community Pharmacist," OAI-01-89-89160, and "The Clinical Role of the Community Pharmacist: Case Studies," OAI-01-89-89161

To

The Inspector General
Office of the Secretary

We have reviewed the subject reports. One of the reports addresses the barriers to the provision of clinical services to ambulatory patients in community pharmacy settings. The other report presents case studies of community pharmacists who have succeeded in providing a broad range of these clinical services.

The reports recommend that HCFA develop a strategy, individually and with the Public Health Service, to reduce barriers to providing clinical pharmacy services, particularly for ambulatory elderly patients. We do not concur with this recommendation. HCFA already has a strategy to improve clinical pharmacy services through its managed care initiative. Through the managed care initiative, many State Medicaid programs have or are testing drug utilization review systems and capitation programs that encourage the kind of coordinated care called for in the OIG report. Unfortunately, the report did not address these efforts by HCFA and the States.

Medicare coverage of drugs for outpatients is extremely limited in scope and, for the most part, does not pay for drugs that ambulatory beneficiaries could obtain from community pharmacies. Thus, the recommendations cannot apply to the non-Medicaid population of Medicare beneficiaries.

Moreover, because of the limited scope of the Medicare outpatient drug benefit, we do not have sufficient data files to establish the comprehensive drug utilization review program that would be needed to monitor the effectiveness of clinical pharmacy services.

AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

March 8, 1990

Mr. Richard P. Kusserow
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Mr. Kusserow:

Thank you for the opportunity to review the two draft reports, *The Clinical Role of the Community Pharmacist*, and *The Clinical Role of the Community Pharmacist: Case Studies*. Overall, the reports are very well written, comprehensive and accurately reflect the opportunities and barriers confronting pharmacists in their ability to enhance the public health in the community setting.

I am pleased to offer these comments, directed specifically at *The Clinical Role of the Community Pharmacist* with the hope that these remarks will assist you and your colleagues as you prepare the final report. My comments are directed at three areas:

- Issues related to Drug Utilization Review (DUR);
- Functions performed by community pharmacists in providing clinical services in ambulatory care settings; and
- Cost effectiveness of ambulatory clinical pharmaceutical services.

Drug Utilization Review

Page one offers a definition of DUR attributed to Rucker. AACP prefers the definition of DUR which has been adopted by the American Society of Hospital Pharmacists:

> *A drug use evaluation program is a structured, ongoing, organizationally authorized, quality-assurance process designed to ensure that drugs are used appropriately, safely and efficiently.*

A copy of the ASHP Guidelines on the pharmacist's role in drug use evaluation is enclosed for your information. This definition, and these principles, are applicable to the ambulatory care setting with slight modification in language only.

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In conclusion, the Inspector General's Report outlines in succinct detail the need for clinical pharmaceutical services in the community environment and the barriers to their full implementation. AACP will consider carefully those recommendations addressed to it and will join with other organizations in pharmacy to ensure that the benefits of ambulatory clinical pharmacy are made available to as broad a population of patients as possible.

Sincerely,

Carl E. Trinca, Ph.D.
Executive Director

CET:jnc

enclosures