Comprehensive Pharmaceutical Care: An Overview of an Evolving Practice Model

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SUMMARY. This manuscript briefly describes the Minnesota Pharmaceutical Care Project and explains how those involved in the Project worked to apply the *philosophy* of pharmaceutical care in actual daily *practice*. The end product of these efforts has been the development of the Comprehensive Pharmaceutical Care practice model. The practice model has been developed by pharmacists, for pharmacists, in the community practice setting. We will describe the process used to develop the model that begins with a practice philosophy, includes the use of a therapeutic relationship and identification of patient need and culminates in the definition of a basic pharmaceutical care service. *[Article copies available from The Haworth Document Delivery Service: 1-800-342-9678. E-mail address: getinfo@haworth.com]*

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INTRODUCTION

The Minnesota Pharmaceutical Care Project is designed to understand how the philosophy of pharmaceutical care might function in the community practice setting. The focus of the Project is to turn a theoretical concept into the reality of a new practice method. The end product of these efforts is the development the Comprehensive Pharmaceutical Care practice model. The practice model has been developed by pharmacists, for pharmacists, in the community practice setting. This manuscript briefly describes the Minnesota Pharmaceutical Care Project and explains how participating pharmacists applied the philosophy of pharmaceutical care to their actual daily practices.

THE MINNESOTA PHARMACEUTICAL CARE PROJECT: SOME BASICS

The Project is one of the primary research efforts of the Peters Institute of Pharmaceutical Care. The Institute is a research and program development unit within the College of Pharmacy at the University of Minnesota. The mission of the Institute is to design and implement pharmaceutical care practice models, develop educational programs to disseminate these models to practitioners and students, and conduct research to evaluate the models in practice.

The Minnesota Pharmaceutical Care Project is a collaborative effort between the College of Pharmacy, the Minnesota Pharmacists Association, and the Minnesota State Board of Pharmacy. The purpose of the three-year demonstration project is to take the philosophy of pharmaceutical care, as described by Hepler and Strand (1), to community pharmacy practitioners to answer the question: How can these concepts be implemented in the community practice setting? We sought to answer this question by recruiting pharmacists for the Project who were interested in working as collaborators in the research process, rather than as subjects in a study. As collaborators, participating pharmacists assume responsibility for the practice and its outcomes. We believe that this aspect of the study's design creates a higher level of credibility and "doability" for other

practitioners who adopt the practice model. The final decisions about how pharmaceutical care evolves in practice are made by the pharmacists. These practitioners have completed the development of a community-based practice of pharmaceutical care and their experiences are described here.

Pre-Study Period (May 1 to September 30, 1992)

The pre-study period was designed to allow for the organization of Project staff, formation of an advisory committee, and definition of work groups. In addition, pre-study activities included the recruitment of pharmacies and pharmacists and the selection of study sites.

Recruitment for the study began in June, 1992, with a mailing to all community pharmacies licensed in the state of Minnesota. Initially, 229 pharmacists expressed interest. A total of 100 pharmacists from 71 pharmacies throughout the state accepted invitations to attend a recruitment seminar designed to provide more information about the study and the application process. Final applications were received from 51 pharmacies across the state. Three members of the project staff visited each of the eligible sites. At the conclusion of an extensive evaluation process, including actual site visits, 20 community practice sites and 56 pharmacists were chosen to participate in the Project. Five chain store pharmacies, 13 independently-owned, and two clinic-based pharmacies were selected. Six of the 20 pharmacies were located in an urban setting (population over 50,000) and 14 were rural practices (population under 50,000).

Study Year One (November 1, 1992-October 31, 1993)

The first year of the Project was designated the "pilot study" year. The objective of the first year was to determine if the philosophy of pharmaceutical care could be translated into a community pharmacy practice model. The challenge was accepted by ten pharmacists representing four pilot pharmacies. The pilot group consisted of two chain pharmacies (one urban and one rural) and two independently-owned pharmacies (one urban and one rural).

In order to meet the objective of the first year, the pharmacists

and staff addressed two more basic questions: (a) What would this philosophy look like in practice? and (b) How would pharmacists make the transition to the new practice? Day-long planning meetings between the Project staff and pilot site pharmacists were held monthly to address these questions. The methods by which these questions were answered is elaborated in the section of this paper titled "The Process of Developing a Practice Model." In addition, the Project staff made site visits and maintained frequent telephone contact with pharmacists to monitor progress and resolve issues. These encounters were focused on defining a new practice model.

To implement the model, the following had to occur: definition of new responsibilities and processes for delivering pharmaceutical care, development of a documentation tool for the new work, recommendations for the design and layout of the pharmacy, and creation of a reimbursement formula for the new service. Additionally, educational materials to prepare the pharmacists with the knowledge and skills needed to provide pharmaceutical care were designed.

Study Year Two (November 1, 1993-October 31, 1994)

The objective for the second year of the study was to determine if the practice model developed by the pilot site pharmacists could be generalized to 14 additional pharmacies. In the process, new pharmacists were asked to improve the practice model developed by the first-year pilot pharmacists and to further refine the implementation program. During the second year, the Project team held training sessions for the pharmacists and a training forum for technicians. At the same time, team members tested the reimbursement model, developed a patient care software program, and defined and applied experimental certification and accreditation criteria. The criteria, developed in conjunction with participating third-party payers, include pharmacists' completion of training seminars and participation in regional work groups, a passing score on a practical exam, and modification of in-situ pharmacy consultation areas to assure patient privacy.

The major activities involved in developing the Comprehensive

Pharmaceutical Care practice model during years one and two of the Project, are described below.

Study Year Three (November 1, 1994-October 31, 1995)

Evaluation of the Comprehensive Pharmaceutical Care practice model is the objective of year three of the Project, and is ongoing. The data generated by the pharmacists and captured in the patient care software system will allow us to evaluate the impact of the practice on the prevention, detection, and resolution of drug therapy problems. By describing and quantifying the frequency of drug therapy problems of ambulatory patients, the research team will study and analyze individual patient characteristics, specific drug therapies, and the medical conditions associated with these drug therapy problems.

The value of the service provided by the pharmacist will be calculated when possible, and inferred when prevention of potential problems has occurred. Efforts are currently underway to determine the association between Comprehensive Pharmaceutical Care outcomes and medical care outcomes. However, we are at an early stage in these efforts. Current data collection systems for medical data do not presently provide adequate information.

Descriptive data gathering techniques will be used in the last year of the Project to determine the impact of the service on the pharmacists providing it; physicians who come in contact with it; and, most importantly, the patients who receive it.

THE PROCESS OF DEVELOPING A PRACTICE MODEL

The major objective of the Minnesota Pharmaceutical Care Project was to determine if a community pharmacy practice model could be developed from the philosophy of pharmaceutical care as described by Hepler and Strand (1). Intuitively, the investigators of the Project concluded that two very different approaches could be used to answer this research question. The most common approach to answering this type of question is what we define as the "directed" or prescriptive approach. This approach requires investigators to inform subjects (the pharmacists) of what should occur in

practice, complete with specific directives for implementation. Thereafter, the investigator measures the impact of specific interventions on the practice.

An alternative approach, which we call the discovery approach, is similar to the methods used in grounded theory research. The pharmacists themselves develop the answers to the research questions. Instead of the investigators informing the pharmacists what should occur, the pharmacists identify the appropriate answers in practice, subsequently informing the investigators of their experiences and conclusions. The alternative approach was chosen for the Project for a number of reasons. First, the prescriptive or directed approach has been tried frequently in pharmacy, with relatively little impact on practice. Examples of this approach include mandatory counseling by state boards of pharmacy, the implementation of OBRA legislation by legal mandate, and the heavy emphasis on institutional clinical pharmacy practice in pharmacy education. After many years, only a small proportion of pharmacists are involved in these practices, and an even smaller proportion of patients are receiving patient-specific services.

Past experience would suggest that when practice changes are dictated to pharmacists from outside the practice–whether from legislators, professional associations, or the academic community–practitioners are reluctant to adopt the concepts and take personal responsibility for their implementation. Can practitioners be held accountable for resisting change? Perhaps not, especially since in the real world of commerce few pharmacists have ever received reimbursement for the services described above.

Perhaps the simplest reason for not using the "directed" approach in the Project was that when this project began, no practice model consistent with the Hepler and Strand philosophy of pharmaceutical care had been developed or implemented in any practice setting. Although portions of a practice model exist in clinical pharmacy, long-term care and home-health care, a generalist (primary care) practice of pharmaceutical care was nonexistent in the community pharmacy setting. It would have been difficult to prescribe what should be done when no developmental work had yet occurred. Therefore, the decision was made to help the pharmacists

discover whether a practice model of pharmaceutical care could be developed in the community.

Preliminary observation and interviews indicated that the pharmacists were motivated and willing to reinvent their practices. To accomplish this, the team worked together to create an environment in which pharmaceutical care could be defined by practitioners, for practitioners, in the practice setting. This was necessary to develop a practice which would survive the test of time, third-party payers, physicians, patients, and other pharmacists. It was agreed that the final decisions about the shape pharmaceutical care would take in practice would belong to all pharmacists interested in changing their practices. Our intentions were to find out if we, as a team, could design and deliver a patient service that was practical and achievable for the pharmacist and of value to the patient and the health-care system. We found out it was indeed possible.

PHARMACEUTICAL CARE: A PRACTICE PHILOSOPHY

The development of a practice model must begin with the philosophy for that practice. In year one we began discussing the philosophy of pharmaceutical care as described by Hepler and Strand (1). First and foremost, the philosophy requires the profession of pharmacy to accept its social responsibility to reduce preventable drug related morbidity and mortality. To do so, the pharmacist must "accept professional responsibility for patient welfare." Additionally, they state that the pharmacist must "restore what has been missing for years: a clear emphasis on the patient's welfare, a patient advocacy role with a clear ethical mandate to protect the patient from the harmful effects of . . . drug misadventuring." Finally, they emphasize that the philosophy of pharmaceutical care must move pharmacists beyond the traditional parameters of clinical pharmacy to assume responsibility for the whole patient and all of the patient's drug related needs, rather than focus on specific pharmacist functions, drugs, or diseases (2).

From this work, the pilot site pharmacists were able to identify three important concepts which form the foundation for the development of Comprehensive Pharmaceutical Care:

Societal Need. Pharmacists must acknowledge that society needs

a health-care provider to successfully address (identify, prevent, and solve) drug-related illness, and that pharmacists can meet this need.

Caring. Pharmacists must "care" for their patients. This requires an assessment of each patient's drug-related needs, doing all that is necessary to meet these needs and ensuring that no harm is done to the patient.

Patient Centeredness. To have a meaningful impact, pharmacists must provide care on a patient-specific basis, attending to the patient's total drug-related needs.

With these concepts in mind, the pilot site pharmacists created a pragmatic working definition of pharmaceutical care. Simply put, pharmaceutical care is seeing and responding to the drug-related needs of patients. With a commitment in place and a working description of the philosophy clarified, we were prepared to next identify drug-related needs of patients.

THE THERAPEUTIC RELATIONSHIP

The next step was to move from discourse to action. This was not an easy step. Project pharmacists and staff spent long hours in the planning and discovery process. With the assistance of our resident medical anthropologist, an understanding was gained of the new practice philosophy and its potential impact on patients, physicians, and the pharmacists themselves. We used a construct called the "therapeutic relationship." In this relationship, pharmacist and patient enter into a reciprocal agreement to work together to prevent and resolve drug therapy problems. Hepler and Strand described this as a "covenantal relationship" (1). In effect, we encouraged the pharmacists to talk to patients about their concerns, level of therapeutic understanding, and expectations about their drug therapy. In discussions with patients, pharmacists were asked to obtain basic and specific information about the patient's drug therapy. They started with one patient at a time and increased the number as their confidence grew.

Talking with patients proved to be a good mechanism to guide our practice. Initially, all the Project pharmacists had reported good relationships with their patients. However, they are quick to point out that a therapeutic relationship is significantly different from the more "commercial" interactions they have had with "customers" in the

past. The pharmacists learned more intimate details about their patient's medical problems, their medications, and their concerns. To establish a therapeutic relationship, pharmacists ask different questions, assume a different level of responsibility for the patient, and perform activities based on a new set of standards and expectations.

In the therapeutic relationship, pharmacists assume responsibility for each patient's entire drug therapy, regardless of the source of the drug product. Each practitioner is directly accountable to the patient and does whatever is necessary to assure that the prescribed drug therapy is appropriate and that it will be effective and safe. Within the therapeutic relationship, pharmacists must function as patient advocates and can no longer make assumptions about the indication for a medication. They must confirm this information with the patient or physician prior to initiating care. In this role, pharmacists must ask direct and sometimes personal questions about a patient's condition and health-related behaviors. For example, in early encounters with female patients regarding hormone replacement therapy, male pharmacists cited initial discomfort with questions regarding menstrual cycles and surgical procedures such as hysterectomy. In the past, we had assumed that the physician has covered these subjects as they relate to drug therapy.

Through the development of a therapeutic relationship the pharmacists uncovered the many drug-related needs of their patients. They learned that many patients are reluctant to share information and ask few questions of their physicians concerning drug therapy. In addition, the pharmacists discovered that patients believe no health-care provider in the present health-care system is really managing, or aware of, their drug-related needs. Most importantly, they learned that patients value and appreciate the service.

Patients expressed so many different needs that it became difficult for the pharmacists to know how to respond to them. Moreover, some of the needs were drug-related and others were not related to drug therapy at all. The pharmacists expressed a serious concern that they did not know where their responsibilities began and ended. Boundaries were vague. Thus, it was necessary for us to help the pharmacists establish parameters to define their new responsibilities. First, the needs of patients related to drug therapy were defined and include appropriateness of indication, efficacy, and safety. Sec-

ondly, a taxonomy of drug therapy problems was developed. Within this framework, patient medication use could be understood and, if required, modified. Finally, we defined a basic service which allows pharmacists to demonstrate to the patient their ability to consistently meet the patient's needs.

THE BASIC SERVICE

The pharmacists decided to develop a basic service that would address the drug-related needs of their patients. A clearly defined service allows third-party payers and patients to understand exactly what is expected from a pharmacist. Therefore, we examined the individual needs of each patient (objective pharmacotherapeutic needs as well as patient preference), what the pharmacist was actually able to provide, and what was of value to the health-care system. In essence, the basic service represents the actual commitment that a pharmacist makes to a patient.

The new practice method allows the patient (and others) to hold the pharmacist accountable for a measurable service. Perhaps more important than anything else, the service has to be deliverable. All of these considerations, combined with the pragmatics of practice in a competitive business world, led to the basic service described here.

- *Patient consultation* to discuss patient expectations, concerns, and understanding of drug therapy, to collect information from the patient, and to identify the patient's drug-related needs.
- *Assessment and the pharmacist's diagnosis* of the patient's entire drug therapy needs for the purpose of identifying any actual or potential drug therapy problems.
- *Care planning* to develop specific goals for therapy and to establish a monitoring schedule and written patient record to resolve any actual drug therapy problems and to prevent all potential drug therapy problems.
- *Patient education, recommendations, and referrals* that will provide individualized current information about the patient's drug therapy, give instructions for proper use of medications and related products, demonstrate any special techniques or devices and provide health and disease information.

- *Patient monitoring and follow-up* at planned intervals to assure that new drug-related problems do not develop, therapeutic goals are being met, and actual patient outcomes are evaluated and documented.

Project pharmacists agreed that none of the service components are optional. Moreover, true Comprehensive Pharmaceutical Care is provided only when all five components are provided. We concluded that unless the basic service is documented in a patient record, complete with all its components, the service is not considered to have been delivered. It is essential for reimbursement purposes that written evidence be present to legitimize the claim that a specific service has been provided.

The pharmacists place significant emphasis on distinguishing the difference between the service the patient receives and the interventions a pharmacists makes. The easiest way to explain the distinction is to think of the basic service as "what" a pharmacist must provide each time a patient receives pharmaceutical care and the pharmacist's interventions as "how" the service is provided. The "how" is often patient-specific. For instance, if a protocol calls for pharmacist follow-up by phone to determine whether patients are compliant with their medication regimen, a pharmacist may determine that an in-store appointment is more appropriate for a particular patient. The distinction allows for necessary variation between pharmacists in "how" a basic service is delivered. The variations may be referred to as "individualized practice," "professional judgment," or "the art of practice." However, all health-care providers must be held accountable for providing a basic service on a consistent basis. Accountability is the "currency" of third-party payers. Therefore, in the Comprehensive Pharmaceutical Care model the basic service represents what the pharmacist offers each patient who receives pharmaceutical care.

COMPLETION OF THE PRACTICE MODEL

Once the pharmacists were able to describe the basic service, work on more complicated components of the practice model began. For example, it became necessary to construct an infrastructure to support the delivery of the service. The infrastructure includes, but is not

limited to, development of the physical layout of the pharmacy, revised workflow, a software documentation system for patient care, communication mechanisms with other health-care professionals, continuing education efforts, and a reimbursement system.

CONCLUSION

We have attempted to describe how a small group of pharmacists have made the transition from a philosophy to a new model of practice. We should emphasize that the development process is ongoing. The practice is refined as we learn more about each of its components. It will be several years before this practice stabilizes and can be easily taught. Most importantly, the practice that evolves from this Project must meet the needs of the patient, the pharmacist, and the health-care system.

This brief description cannot adequately communicate the dedication and tenacity displayed by Project pharmacists. They were willing to critically reflect on their profession and their behavior as professionals. The practitioners have set very high standards for themselves and are unwilling to return to former roles, relationships, and responsibilities. They have become very active in disseminating what they have learned, and express the hope that others will rise to meet the challenge.

We acknowledge that this practice model could never have been implemented without the initiative and hard work of our pharmacist-collaborators. We believe that they paved the way for those who will follow in this difficult, yet rewarding, professional change.

Through these efforts we have come to believe that if professional change is to occur, it will be driven by practitioners. The change must be accompanied by educational, professional, and regulatory support. We remain convinced that the social value of pharmaceutical care can be easily demonstrated and we are confident that the profession of pharmacy is up to the task.

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