

The Impact of Pharmaceutical Care Practice on the Practitioner and the Patient in the Ambulatory Practice Setting: Twenty-five Years of Experience

Linda M. Strand*, Robert J. Cipolle, Peter C. Morley and Michael J. Frakes

Peters Institute of Pharmaceutical Care, College of Pharmacy, University of Minnesota, 3-160 Weaver-Densford Hall, 308 Harvard Street SE, Minneapolis, Minnesota 55455-0343, USA

Abstract: This manuscript reviews 25 years of experience that include developing the practice of pharmaceutical care and initiating new practices. The impact this practice has on practitioners in the ambulatory setting is described as well as data that reflect its clinical and economic impact.

There is a great need to prepare new practitioners to provide pharmaceutical care. A focused training program was developed and delivered to over 300 practitioners. The practitioners were prepared by providing direct patient care. They learned the philosophy of pharmaceutical care practice, to identify, resolve and prevent drug therapy problems, to document care using a specially designed software program called the Assurance Pharmaceutical Care[®] program.

The practitioners who participated in the training program reported that the average amount of time spent with patients increased three-fold, they now see four times more patients than prior to training, and the number of new patients referred by physicians increased nine-fold as a result of the program. These practitioners have now provided care to more than 25,000 patients in their practices. These data have now been consolidated and analyzed, and a portion of these results is reported here.

The clinical and economic outcomes from 2,985 adult patients, who received pharmaceutical care between January, 2000 and December, 2003, are presented. At the first assessment by the pharmaceutical care practitioner, 61% of the patients had one or more drug therapy problems identified and resolved. This resulted in an improvement in the clinical status or maintaining a stable status in 83% of the patients. The health care savings realized from pharmaceutical care were \$1,134,162. This represented a benefit to cost ratio of 2:1. Physicians who collaborate with pharmaceutical care practitioners have validated the work of the practitioners, and patients are recognizing the benefits of pharmaceutical care.

Key Words: Pharmaceutical Care, Drug Therapy Problem, Patient Outcomes, Health Care Savings, Assessment, Care Plan, Follow-up Evaluation, Practitioner Training.

INTRODUCTION

For more than two decades we have focused our attention on the development, implementation, and evaluation of pharmaceutical care practice. Indeed, as we look back and contemplate those formative years and the struggle to create a new practice, we realize that no matter how serious the debates, no matter how much resistance to change was encountered, this was a productive period, which profoundly influenced the development and direction of a profession.

Our initial preoccupations focused on the prevailing realities of pharmacy as a profession grounded in what is often referred to as the "real world." In essence, we struggled to understand both the nature and dynamics of a profession that was clearly in need of serious critical analysis. We swiftly learned that professions, as organizational entities, do not take too kindly to criticism or even intellectual exchange no matter how positively or responsibly applied. The public face of "profession" very rapidly becomes personal, and the debate-of-the-day is recast in defensive posturing and

political positioning that serve no progressive purpose whatsoever. Our observations that pharmacy, at least in the United States, was far too preoccupied with 'product' and too little committed to cognitive functions were generally seen as idealistic, unreal, or simply the wrongheaded notions of academics cloistered in colleges, detached from such practical matters as survival in the marketplace.

In the face of considerable opposition, at both the grass roots and organizational levels, we continued to assert that pharmacy must seriously begin to refocus and move in a direction that would establish more productive, expanded roles and responsibilities. We recognized the inherent tension that exists in pharmacy culture—the push and pull of the commercial and the clinical. Indeed, we concluded that in many ways pharmacy experiences a form of "schizophrenia" that in itself produces contradictions and conflicts that have a negative impact on progressive thought and action. Moreover, we observed that such tensions produced many conflicts of interest and ethical issues that contribute to inertia and resistance to change. We concluded that somehow a new direction was called for and that this was important enough to warrant significant time, energy, and effort to determine.

And so our journey began. Our motivation was clear: we believed that pharmacy could do more. We came to terms

*Address correspondence to this author at the Peters Institute of Pharmaceutical Care, College of Pharmacy, University of Minnesota, 3-160 Weaver-Densford Hall, 308 Harvard Street SE, Minneapolis, Minnesota 55455-0343, USA; Tel: 612-625-5194; Fax: 612-625-9983; E-mail: pipe@umn.edu

with our own particular values and theoretical orientations. Philosophical differences were debated, and conceptualizations of profession and practice were shared. We soon realized that while we held some similar values, commitments, and philosophical predilections, there was a healthy degree of discord between us that served as a "force field" to push us toward compromise and a stronger developmental program. We sought to create a model of practice strong in practicality and directed toward ethical values that could justly transform a profession by moving it from product to person, and at more idealistic moments, from commercial to clinical.

These early days, while sometimes frustrating and laborious, were exciting and intellectually rewarding. The pace of change itself, while usually slow and gradual, masked the more rapid exchange of ideas and the dynamic nature of the ideas themselves. There were suddenly international debates, and as the momentum grew so did the distance that the ideas traveled [1-6]. Generally, we were overwhelmed with feedback and requests to exchange ideas. Thus, while the languages spoken differed, and the pharmacy operations were truly international and diverse in structure and function, an emerging "sameness" began to appear. There was a universal appetite for change, growth, and improvement. There was widespread dis-ease with the present professional identity, and pharmacists hungered for transformative ideas and practices.

Through dialogue, experience, mistakes, and on-going developmental testing, we learned what was necessary to develop a patient care practice for pharmacy that is consistent with and measures up to the standards required by medicine and nursing. For more than two decades we have researched and taught pharmaceutical care practice to students, graduate pharmacists, and the occasional physician and nurse. We have learned that documentation of patient care is essential, and we have developed a software program that comprehensively records pharmaceutical care. We have also learned that economic viability and justification are important to any successful practice, and we adapted the resource-based relative value scale to pharmaceutical care practice. This established a reimbursement mechanism that is recognized throughout health care and utilized around the world. These are but a few of the exciting developments that preoccupied us and our academic and practice colleagues in many countries.

This paper presents an overview of the reflections, observations, experiences, developmental transformations, and program initiatives that we have implemented over the past twenty-five years. Since developing the practice, we have trained more than 300 practicing pharmacists, thousands of professional pharmacy students, and have assisted in the development and support of more than 50 new practices involving over 100 individual practitioners. We have standardized and consolidated their documentation, analyzed their practice-based results, and provided them with feedback and guidance. We have now accumulated and analyzed data that include more than 25,000 patients and over 65,000 pharmaceutical care encounters from these practices. This is truly a joint effort and reflects the work of dedicated individuals who remain certain that pharmaceutical care offers great health care value at a reasonable cost.

We will describe our experiences by first examining the impact pharmaceutical care has had on pharmacists practicing in the ambulatory setting, followed by a presentation of data that illustrates the impact pharmaceutical care has had on patients.

THE IMPACT OF PHARMACEUTICAL CARE ON PRACTITIONERS

As we introduced pharmaceutical care to pharmacists it soon became obvious that it would have a dramatic impact on their lives as they confronted, with some trepidation, the necessary changes required to accommodate the new practice. Changes had to be made in the way they thought about practice, in the responsibilities they accepted, and even in the manner in which they communicated with patients and other health care practitioners. These were no small tasks! Focused training was required to facilitate these changes. Many of the pharmacists assumed they already knew what they needed to practice and were quite surprised to discover this was not the case. It was also necessary to change the tangible structures of the practice itself in order to provide care to a viable number of patients. This structural dimension of practice had serious economic implications, for without a "critical mass" of patients, economic viability is questionable. We will discuss the major dimensions of each set of changes.

Preparing to Provide Pharmaceutical Care

At the outset we found that it was difficult for pharmacists to understand what information was missing in order for them to practice pharmaceutical care. Their first instinctive response was that they needed more pharmacology—more pharmacotherapy. Upon investigation, however, we found that while this was true in many cases, this was not the place to start. The first step they were required to take was largely cognitive and conceptual. First, they had to fully understand and internalize the philosophy of pharmaceutical care and internalize this in such a way that it became a tacit comprehension of the caring paradigm [7].

The philosophy of pharmaceutical care explicitly states that the obligation of the pharmaceutical care practitioner to society is to ensure effective and safe medication use. This obligation is met one patient at a time when the practitioner accepts the responsibility to identify, resolve, and prevent each patient's drug therapy problems. These responsibilities are met by using the caring paradigm in a patient-centered manner [8].

The philosophy of pharmaceutical care practice is embodied in the professional standards developed for the practice. These standards are summarized in Table I, however complete measurement criteria for each standard can be found in the 2nd edition of *Pharmaceutical Care Practice: The Clinician's Guide* [9]. This reference contains additional detail on all of the topics and data described in this manuscript.

Next on their learning agendas came the Pharmacotherapy Workup (the rational decision making process) and the patient care process. Because pharmacy education has not traditionally taught or utilized these dimensions of practice it was essential to persuade pharmacists that this,

Table 1. Professional Behavior Standards for Pharmaceutical Care Practice

Category	Standard
Quality of Care	The practitioner evaluates his/her own practice in relation to professional practice standards and relevant statutes and regulations.
Ethics	The practitioner's decisions and actions on behalf of patients are determined in an ethical manner.
Collegiality	The pharmaceutical care practitioner contributes to the professional development of peers, colleagues, students, and others.
Collaboration	The practitioner collaborates with the patient, family and/or care-givers, and health care providers in providing patient care.
Education	The practitioner acquires and maintains current knowledge in pharmacology, pharmacotherapy, and pharmaceutical care practice.
Research	The practitioner routinely uses research findings in practice and contributes to research findings when appropriate.
Resource Allocation	The practitioner considers factors related to effectiveness, safety, and cost in planning and delivering patient care

and not pharmacology, or pharmacotherapy, was where pharmaceutical care began. For some it appeared counter-intuitive. For others it lacked logic. There was a perceived need that more drug information was essential before any clinical intervention could take place. Of course no one is claiming that additional knowledge of any kind is unnecessary. The point is that the first step is to understand the practice. This requires the development of a "cognitive map" that enables the application of knowledge to problem resolution, and the conceptualization of the *in toto* nature of practice itself. Once the map is drawn and practice begins, then accumulated knowledge combined with experience finds its placement. To this day it is a significant challenge to convince individuals intent on practicing pharmaceutical care that this is where they begin, all else follows and, over time, integrates into the *modus operandi* of practice.

It became clear to us that it would be necessary to transform the pharmacist from a predominantly product-focused employee into a patient-centered care provider. The importance of this cognitive shift cannot be overemphasized. This takes time. Through considerable experimentation we found that the transformation could more effectively occur through an eight week training program rather than through the more familiar short sessions such as those we customarily find in continuing education programs. The training itself was quite comprehensive and included didactic presentations, case presentations, the actual provision of care to at least fifty patients, reading, writing, documenting care, and attendance at group practitioner meetings. The training was practice-based and patient-centered [10-14]. This was easily accomplished because most pharmacists were employed at the time of enrollment, and patients were recruited from their daily practice.

Of particular importance during the training program was the emphasis placed on assuming the responsibility to provide care that consistently meets standards for all patients regardless of disease state, age, gender, ethnicity, drug regimen(s) involved or other variables such as social class, income, or level of education. All medical indications for drug therapy were assessed, cared for, and evaluated. Because pharmaceutical care is a generalist practice, all patients were offered care.

The Pharmacotherapy Workup

All pharmacists participating in the training program were introduced to the rational thought process of the Pharmacotherapy Workup [9, 15]. This process for the assessment of each patient's drug-related needs allows the practitioner to systematically and comprehensively determine if all of a patient's medications were appropriately indicated, the most effective available, and the safest possible. The patient's behavior was then assessed to determine the level of compliance with the drug regimen(s). This initial formative assessment established the clinical base-line data for further clinical judgment and action. The basic structure of the Pharmacotherapy Workup is illustrated in Fig. (1) and is described in detail in Chapter 6 of Pharmaceutical Care Practice: The Clinician's Guide [9].

Drug therapy problems occur at all stages of the medication use process and rarely fit any convenient timeframe. Fig. (2) describes the seven different categories of drug therapy problems and where they can occur in the decision making process.

Pharmacists quickly understood—although not entirely without resistance—that in order to conduct themselves as clinicians they had to adopt a conceptual framework that would contain all the questions, organize patient-specific data, and frame the clinical decisions inherent in the pharmaceutical care process. While the Pharmacotherapy Workup is necessarily lengthy and detailed, and it does take time, patience, and practice to clearly understand its structure and function, it is not difficult to master. Training sessions committed a significant amount of time to learning this instrument as it is the essence of pharmaceutical care practice. We observed that learning the Pharmacotherapy Workup was a defining step for the pharmacists. As soon as they could "see" this rational decision making process, significant progress could occur. We did everything we could to avoid any situation where participating pharmacists had to accept anything on "faith" rather than from drawing their own conclusions through reflective critical analysis.

The Patient Care Process

Patient care is face-to-face interaction with a complete and complex human being. We begin with the embodied

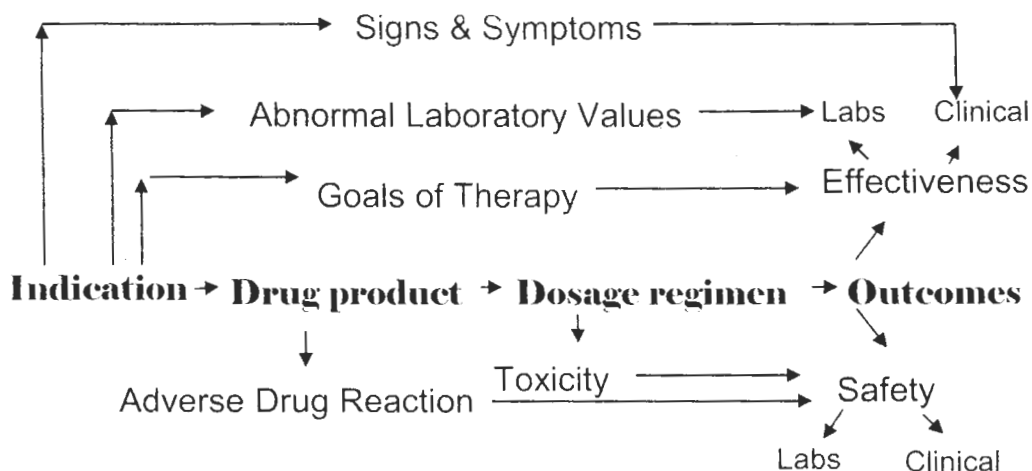


Fig. (1). Structure of the Pharmacotherapy Workup.

individual at a macro-level with all of his or her diverse expressions of need. Pharmacists were taught to assess these drug-related needs from the perspective of each patient's unique medication experience.

The medication experience is a new concept in practice that we have recently defined as the sum of all events in a patient's life that involve medication use [9]. It includes the patient's expectations, wants, concerns, preferences, attitudes, and beliefs, as well as the cultural, ethical, and religious influences on his/her medication taking behavior. In short, the patient's medication experience is the context in which all drug therapy decisions are made in pharmaceutical care practice. This experience will have a profound effect on the decisions a patient makes everyday as to whether or not to take his/her medications and exactly how he/she will take them. It should be clear why the pharmaceutical care practitioner needs an in-depth understanding of each patient's medication experience to have a positive impact on the patient's decisions and experiences.

We have long been aware that pharmaceutical care involves rational decisions made with and for each patient, however starting this process at the point of the patient's medical problem or drug therapies never allowed the

practitioner to individualize assessment or decision making sufficiently to contribute to each patient's care. Therefore, we surmised that it would be necessary to "back up" all the way to the patient's most fundamental thoughts about taking medications. This revealed the medication experience as an important, unique context in which to make decisions about drug therapy in patient care.

Pharmaceutical care practitioners must understand the patient's medication experience better than all other health care providers because it is their primary responsibility to optimize it. Once a patient's medication experience is known and understood, the practitioner can successfully execute his/her responsibilities of identifying, resolving, and preventing drug therapy problems.

Practice is first and foremost the application of knowledge to the resolution of problems. In this context we can see the relationship between theory (the Pharmacotherapy Workup) and action (the patient care process). All professions have a reasonably clear and coherent understanding of practice as it articulates with its stated purpose, rules, roles and responsibilities. Physicians, dentists, and lawyers share a common worldview of what it means to practice their art and science. All professions define and legitimize a normative

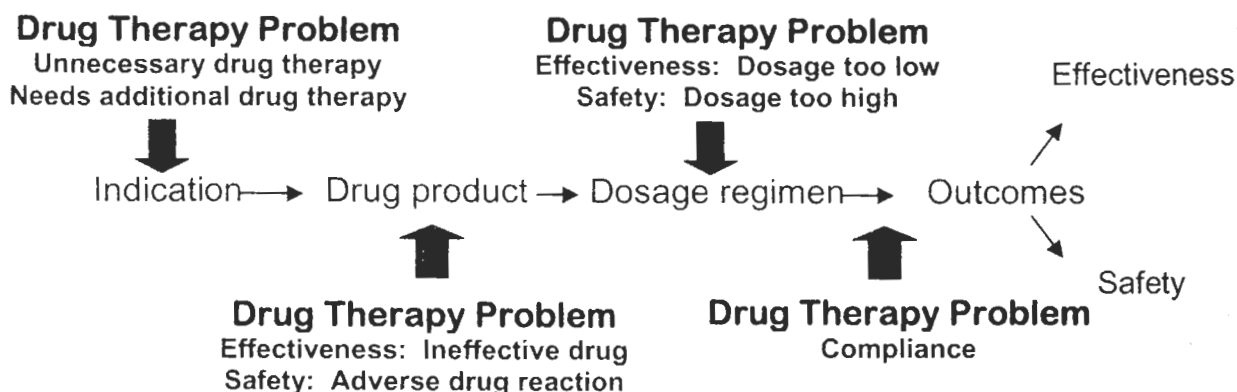


Fig. (2). Drug Therapy Problem Categories.

structure and function that becomes the cultural context for all that they consider worthy and of value – this is the patient care process.

We have long argued that to this end pharmacy has not evolved to the same level of professional solidarity as found elsewhere. That is to say, pharmacy has failed to develop a clearly defined statement of its role in the provision of patient care. Despite the efforts of numerous professional associations, there remains universal evidence that drug products and dispensing commodities remain the foremost rationale for pharmacy's existence. Such an ancestry appears difficult to abandon. We introduce this topic here to draw attention to an important identity issue. Most of the participants in the training sessions would certainly admit to considerable role ambiguity especially as discussion moved toward the idea of expanded responsibilities executed with a singular philosophy of practice and specific patient care process. This should not have been unexpected, for when there is little or no discernable clinical patient care foundation upon which to build a practitioner identity, ambiguity is a natural consequence. In short, pharmacists can only be known and recognized as patient care providers when their collective actions in direct patient care become an integral part of widespread health care provider discourse, and positive health outcomes reflect their contributions. This requires that all adopt a structured patient care process.

Participants were introduced to the patient care process in practice. They were introduced to the three steps of practice: the assessment, the care plan, and the follow-up evaluation. They were provided with opportunities to discuss the content, relationships, and ramifications of each step. Figure (3) illustrates these steps as well as the objectives to be accomplished in each [9].

They were first taught to assess each patient to determine if the therapeutic agent(s) in question was appropriately indicated, the most effective, and the safest possible as well as assess each patient's compliance with the drug regimen(s). The assessment step concludes with the clinical decisions

about drug therapy problems—was the patient experiencing any at this time, and if so, which of the seven categories of problems was present and what was its cause? This step is the most time consuming both to teach and to learn because it establishes the work to be completed in the care plan and follow-up evaluation. The participants were then instructed to produce a care plan(s) for each patient in their care. The purpose of the care plan is to resolve any drug therapy problems identified in the assessment, meet the agreed upon goals of therapy, and prevent drug therapy problems. Next they carried out the necessary follow-up evaluation(s) to determine if the goals of therapy have been met and to assess whether or not any new problems developed.

The patient care process was taught through the provision of direct patient care to at least 50 patients throughout the eight-week training session. We can report that most participants found this part of the program to be very rewarding, and they reported that it provided them with an experiential dimension of practice that brought about a significant measure of reality to their interventions.

Accountability, that somewhat worrying cousin of responsibility, goes with the more engaging social act of direct patient care. Patients who pay for pharmaceutical care have a right to expect that the same standards of practice will be met each time they receive care. In light of these standards, and the issue of accountability, pharmacists were instructed that the general philosophy of practice, their responsibilities, the patient care process, and the documentation of each patient case through the Pharmacotherapy Workup are all non-negotiable elements of pharmaceutical care practice. Individuals are not at liberty to pick and choose which portion of the patient care process they will perform. It is imperative to carry out all aspects of the care process! This is what those who support pharmaceutical care, both financially and organizationally, expect and demand. For both ethical and clinical reasons fragmented services cannot be tolerated. The future of pharmaceutical care practice will rest on how well we maintain integrity, keep promises, and meet the standards

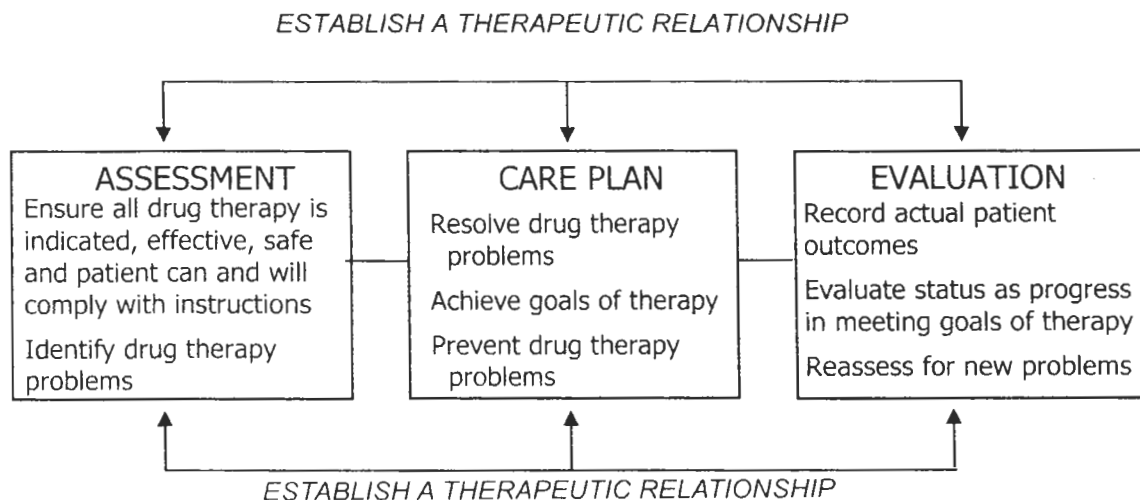


Fig. (3). Components and Objectives of the Patient Care Process.

of care for the practice. These standards of care have been developed and are summarized in Table 2. The complete measurement criteria for all of the standards are described in Cipolle, *et al.* [9].

Our performance must meet these standards and be exemplary at all times. Pharmacists quickly came to terms with these demands, and with understanding came an acceptance and strong commitment to their roles and responsibilities in patient care.

The central issue confronting the participants in our training programs was that of re-conceptualizing roles from the "technical" to the caring. This required significant effort because to a large extent it is not only a transformative act *writ large*, but it is also a re-learning process that requires considerable un-learning and other anxiety provoking changes. But, we argued, this transformation is essential to reinvent pharmacy and its practitioners in such a way that a new caring-based, patient-centered, clinical identity could emerge and prevail.

Learning Pharmacology and Pharmacotherapy

The training programs that we conducted did not include the formal teaching of pharmacology or pharmacotherapy. Conventional pharmacy education teaches abstract pharmacology usually far removed from patient care. We have found that participants find both pharmacology and pharmacotherapy more relevant and more meaningful when learned in relation to the realities of specific patients, their needs, and the act of caring for them. This general problem-based learning method has been used by us for more than twenty years, and we are convinced that it is the most effective way to prepare future providers of pharmaceutical care [16]. The need for specific knowledge was identified through interaction with individual patients. Each patient became a learning experience during which the practitioner negotiated between patient needs and required knowledge. Knowledge was seen

to be more 'fluid' and pragmatic. Important skills of knowledge retrieval were developed and became a major part of clinical work. The important lesson here is the centrality of the patient's condition and the relevance of pharmacological knowledge for problem identification and problem solving.

Pharmaceutical Care Practitioners Collaborate

During the training sessions it became readily apparent that pharmacists tend to see themselves as independent professionals who simply "do their own thing". That is to say they commonly work alone in a job, and depend upon themselves to complete the traditional activities of the dispensing pharmacist. Perhaps this is an occupational hazard resulting from predominantly technical performance and the under-utilization of knowledge and other skills. In any event, we have found that a strong individualism characterized the pharmacists in our training programs—an individualism that seemed to legitimize any personal idiosyncratic approach to "practicing" pharmacy. Interestingly, during the course of our travels we have encountered similar behavior in pharmacists throughout the world.

We are of the opinion that this individualistic approach to "practicing" pharmacy must change. Pharmaceutical care cannot simply be characterized and performed by those who insist that whatever they personally do is appropriate and adequate to define the practice. Too often we encounter individuals who insist that they "do" pharmaceutical care when all evidence indicates that what they are doing is only a variation on a vague theme of counseling, pharmacokinetics, or therapeutic drug monitoring.

We present patient cases in a structured format with a view to fostering group participation in the problem solving process [9]. Individuals soon realize their strengths and weaknesses and become comfortable offering, and seeking, consultation from colleagues. The exercise of group work involves free discussion, information seeking and the recog-

Table 2. Standards of Care for Pharmaceutical Care Practitioners

Category	Standard
Assessment	<ol style="list-style-type: none"> 1. The practitioner collects relevant patient-specific information to use in decision making concerning all drug therapies. 2. The practitioner analyzes the assessment data to determine if the patient's drug-related needs are being met, that all the patient's medications are appropriately indicated, the most effective available, the safest possible, and the patient is able and willing to take the medication as intended.
Drug Therapy Problem Identification	<ol style="list-style-type: none"> 3. The practitioner analyzes the assessment data to determine if any drug therapy problems are present.
Care Plan Development	<ol style="list-style-type: none"> 4. The practitioner identifies goals of therapy that are individualized to the patient. 5. The practitioner develops a plan of care that includes interventions to: resolve drug therapy problems, achieve goals of therapy, and prevent drug therapy problems. 6. The practitioner develops a schedule to follow-up and evaluate the effectiveness of drug therapies and assess any adverse events experienced by the patient.
Follow-up Evaluation	<ol style="list-style-type: none"> 7. The practitioner evaluates the patient's actual outcomes and determines the patient's progress toward the achievement of the goals of therapy, determines if any safety or compliance issues are present, and assesses whether any new drug therapy problems have developed.

nition of the need for consistent, comprehensive practice. Group norms are soon realized as essential to the formation of a strong program of clinical practice – the core of pharmaceutical care.

We have learned that communication is the social matrix of pharmaceutical care practice. Developing a shared technical vocabulary, held in common with other health care providers, is as essential as the development of the necessary verbal and written skills used when communicating outside pharmacy's borders. The use of internally consistent and externally valid terminology brings with it the confidence and security to speak to and for the patient on matters of drug therapy. With these strengths the pharmacist becomes the patient's advocate and represents him/her in all areas of drug therapy. The glossary of practice terminology for pharmaceutical care has been developed and published [9].

Another observation we made during the training of more than 300 practitioners in six different countries is that those who are considered to be the best practitioners take the time to reflect and engage in self-criticism on a daily basis. Practitioners set aside time each day to review current patient cases. The pharmacist reviews what went well in each case, and what did not go as expected. This clinical reflection centered on what could or should have been done differently. This reflective act is extremely important when learning a new practice. Indeed, it is our view that the reflective practitioner is engaged in a far more dynamic learning process than that customarily found in didactic programs [17]. Learning to ask questions and thinking more dialectically is a useful clinical skill. Perhaps the Socratic Method has a legitimate and necessary place in pharmacy education when preparing pharmaceutical care practitioners.

Documentation of Care in Practice

When pharmacists became actively involved in providing pharmaceutical care to patients it quickly became clear that this level of performance cannot be sustained without a sophisticated system to document the requisite information. Decisions cannot be made and justified, and outcomes are, in most cases, impossible to evaluate without a valid documentation system. It remains an indispensable part of the care process, and we continue to introduce documentation as a *sine qua non* of practice. A significant portion of any training program must focus on this important process.

We have developed a format for documenting pharmaceutical care, which we have found to be very useful during the formative period of training [9]. Although we use this written format throughout the first few weeks of the training program (and the first semester of the University of Minnesota professional pharmacy program) we rapidly move toward teaching pharmacists and students how to document care electronically using the Assurance Pharmaceutical Care system (©2001-2003, Regents of the University of Minnesota). The software program is now available in English and Spanish via the Internet. Enquiries regarding the licensing of this software should be directed to the e-mail address of picp@umn.edu.

We have concluded that it is almost impossible to support a busy pharmaceutical care practice without an electronic

documentation system. There are several reasons for this, not the least of which are the overwhelming amount of patient-specific information required, the quantity of decisions made in each patient case, and the number of patients necessary for an economically viable practice to flourish over time. It is necessary to have the capability to create patient charts, schedule follow-up visits, create written care plans and medication records for patients and other care providers, communicate with providers, and charge for the service. All of these require electronic documentation.

Pharmaceutical care practice impacts the practitioner in a number of ways. We have tried to describe the most significant factors above. In addition to the training that has to occur, it is often necessary to make a number of changes in the physical space and administrative structure we use to provide pharmaceutical care to patients. Some of these changes are described below.

ESTABLISHING A PHARMACEUTICAL CARE PRACTICE

Starting a pharmaceutical care practice is a serious, full time undertaking. Patient recruitment, providing care, documenting care, improving clinical skills, obtaining reimbursement, expanding the practice, and establishing professional relationships are demanding but rewarding activities. However, the process itself is not complicated. In fact, every health care practitioner who has ever established a new practice (physicians, nurses, dentists, and veterinarians) follows the same process and organizes the practice around specific objectives and responsibilities. Numerous resources exist that introduce readers to the basics of practice development and implementation [18-21]. All materials that focus on other health care professionals and their experiences developing practices can be extrapolated from and made to fit the exigencies of pharmaceutical care practitioners.

Where to Practice Pharmaceutical Care

Over the past twenty-five years we have researched, developed, and evaluated numerous approaches to pharmaceutical care. We have had many discussions and disputations on the subject of where it is appropriate to practice patient care. We have concluded that contrary to widespread received wisdom, it is extremely difficult, if not impossible, to provide pharmaceutical care to patients while dispensing medications in the retail setting. This is an important issue to reflect on because we continue to find many pharmacists who strongly believe that it can be done. Based on considerable evidence, we disagree.

The provision of pharmaceutical care services is completely different in nature than the commercial retailing of a product. These two distinct interests have quite different priorities, rules, relationships, aspirations, and expectations, yet each demands the pharmacist's complete attention. They are managed differently, rewarded differently, and require dissimilar values, skills, and knowledge. Therefore, there is a considerable divide between the two sets of objectives and responsibilities. We concede, however, that the same pharmacist might be reasonably expected to provide both dispensing and pharmaceutical care services (with the appropriate training), but we remain convinced that he/she

cannot accomplish both of these at the same time and in the same place. We also conclude that the two activities must be kept physically and economically separate.

Perhaps of equal importance is the simple fact that both patients and payers will be confused if the traditional role of the dispensing pharmacist is not clearly demarcated from the practice of pharmaceutical care. To date, we have found this division of labor to be of paramount importance attested to by both payers and patients. In our experience, almost all of the successful pharmaceutical care practices have been established in an ambulatory clinic where the practitioner is located in a complete patient care environment alongside physicians, nurses, and nurse-practitioners. This did not come as a surprise because this is where patient care is expected and delivered. Also, it is legitimized by its very nature. This is not to say that pharmaceutical care cannot be provided in a community pharmacy environment. This approach requires a patient care area that is physically separated from the commercial business that also occurs in this setting. This clinical space must be conducive to the creation of a therapeutic relationship devoid of interruptions or immediate commercial interests. An environment that has privacy and an ambience conducive to clinical engagement is essential. Such a therapeutic milieu makes it possible to work on developing the necessary therapeutic relationship of trust and confidentiality that becomes an expected part of practice.

How to Begin

Perhaps the most frequent question we are asked is: "With which patient should I start?" Our unwavering response is "the next person who walks through the door." Although this might sound somewhat facile, it is nevertheless the rule we follow. As practitioners we cannot ethically choose the patient with the "right" or most interesting disease, or the patient who would be happy to enrich us, or the patient who fits some predetermined selection criteria. Pharmaceutical care practitioners must provide care to all those in need, and not merely to those who meet the practitioner's interests. Self-interest must be tempered with the recognition of the primacy of patient need and all that this entails. This is quite a large commitment, and a willingness to put the patient's needs above all else is the essence of an ethical practice. Indeed, the test of an individual's commitment to pharmaceutical care is found in the acceptance of such a serious responsibility.

All individuals, including those who are presently taking medications, or need to take them, are included in the pharmacist's clinical remit. There is certainly no lack of potential patients and no shortage of drug therapy problems waiting to be discovered. In effect, any individual who is willing to accept the offer of pharmaceutical care, or who asks for it, is a potential patient. Moreover, we have found that a financially viable practice requires a patient base of 1200 to 2500 patients. Given this seemingly large number, it can be seen that the issue of recruitment, and informing the public of new services offered, is not to be taken lightly. A word of caution: do not overly concern yourself with the nature and type of your patient's diseases or drugs. All of them are of interest to you and all of them can benefit from your knowledge and skills to resolve drug therapy problems.

The Impact of Training Programs on Practitioners

The most significant impacts of pharmaceutical care practice on practitioners were the need to prepare differently and more extensively than first imagined and the need to establish a separate and different "business" from dispensing. We realized that accomplishing these relatively complex objectives required structured education and experience. To determine the impact of this training on practice we sent an evaluation survey to 142 pharmacists who we were able to locate and 56 completed and usable surveys were returned. Thirty-one (59%) of the respondents were male and the remaining 22 (41%) were female. Eleven (20%) of the sample was less than 30 years of age, while 43 (78%) were between 30 and 70 years old. Only one respondent (2%) was over 70 years old.

Sixteen (31%) of the respondents worked in chain store practices, while 25 (48%) of the respondents were practicing in independent pharmacies. Ten practitioners (19%) were practicing in either clinic or hospital settings. Twenty-eight (53%) of the respondents were employees and the remaining 25 (47%) were either owners or managers.

Ninety-one percent (91%) of the practitioners judged the training to be beneficial to their practice. Ninety-five percent (95%) indicated that the training had made a meaningful contribution to the quality of care they provided to their patients. The average amount of time spent with patients increased three-fold as a result of the program. The number of patients seen by practitioners, on average, increased four-fold, and the number of new patients referred to the practitioners by physicians increased nine-fold as a result of the program. Appropriate preparation of pharmacists can have a significant impact on the care they provide to patients. The most valid assessment of the training program, however, can be found in the 25,000 patients cared for and documented by these practitioners. A subset of these data will be examined now to describe the impact that pharmaceutical care practitioners can have on patients.

THE IMPACT OF PHARMACEUTICAL CARE PRACTICE ON PATIENTS

In order to describe the impact that pharmaceutical care practice has on patients, we have conducted a review of the electronic records of adult patients who received pharmaceutical care over a four year period from 36 practitioners who completed the training program described earlier, and who documented the care provided using the Assurance Pharmaceutical Care© system. All adult patients who had an initial assessment and a minimum of one follow-up evaluation were included for this manuscript. Most of our practitioners provided care for patients in collaboration with family practice, general internal medicine, or other adult medical practitioners. For our purposes here, we did not include the records of a relatively small number of younger patients as we have not accumulated sufficient experience with this group to determine the impact of pharmaceutical care. It should be noted that the results reported here are not from a specific research project, but reflect data generated directly from practice. Two different subsets of patient data are reported elsewhere [9-11].

The practitioners provided pharmaceutical care for 2985 adult patients between January 1, 2000 and December 31, 2003. The patients' ages ranged from 18 to 100 years. Every patient was seen a minimum of two times by the practitioner. These visits included an initial assessment and at least one follow-up evaluation. Approximately one-half (52%) of these patients were older than 65 years old. Females represented 66% of these patients, while 33% were male. In general, they had relatively complex drug-related needs as determined at their initial assessment.

Medical Conditions and Drug Therapies Used

At this first encounter, these patients presented with an average of 5 to 6 medical conditions requiring drug therapy. The most common medical conditions identified at the patients' first pharmaceutical care assessment are listed in Table 3. We display these common indications for drug therapies and the percent of total represented by each condition in order to emphasize the point that focusing on only one disease is not an approach that will adequately meet all of a patient's drug-related needs. As described in Table 3, even though hypertension is the most commonly occurring medical indication for drug therapy, it represents less than 10% of all of the indications encountered by the pharmaceutical care practitioners.

Table 3. Common Medical Indications

	Most Common Medical Indications Requiring Prevention or Treatment with Drug Therapy	% of Total Indications
1	Hypertension	9.6%
2	Hyperlipidemia	6.8%
3	Diabetes	6.1%
4	Osteoporosis	5.2%
5	Esophagitis/Gastritis	4.4%
6	Depression	3.4%
7	Allergic Rhinitis	3.1%
8	Menopausal Symptoms	3.1%
9	Hypothyroidism	2.6%
10	Insomnia	2.6%
11	Arthritis Pain	2.5%
12	Pain-general	2.0%
13	Headache/Migraine	1.8%
14	Anxiety	1.8%
15	Osteoarthritis	1.7%
16	Asthma	1.7%
17	Constipation	1.7%
18	Cardiac Dysrhythmias	1.6%
19	Stroke CVA prevention	1.6%
20	Back Pain	1.4%

The 10 most frequently encountered medical indications for drug therapy represented nearly one half (47%) of all of the indications for drug therapy, while the 20 most frequently encountered indications represented 65% of the total. 16,710 individual indications for drug therapies were assessed by pharmaceutical care practitioners in this group of 2985 patients.

The pharmaceutical care practitioners assessed a total of 24,136 individual drug regimens during the initial encounters. This group of adult patients was taking an average of 8 medications in order to manage their health needs. Approximately 70% of these drug products were obtained through a written prescription. Interestingly, over 5% (n=1182 different drug products) of all of the medications taken by these patients at the time of their first pharmaceutical care encounter was obtained directly from a friend or a family member. This large portion of drug therapies used by patients on a daily basis is frequently not accounted for in traditional pharmacy or medical records. These products, obtained from friends or family, were used by 486 different patients to manage a variety of medical indications including osteoporosis, diabetes, arthritis pain, osteoarthritis, and hyperlipidemia. In addition to the products obtained from friends or family, patients also commonly used alternative (or non-traditional) drug therapies. Practitioners assessed 381 alternative drug therapies in these patients to determine if they were appropriately indicated, effective, and safe.

Table 4 describes the pharmacological agents most commonly used by these patients to manage their common medical conditions.

Drug Therapy Problems Identified and Resolved

At their first assessment by the pharmaceutical care practitioner, 61% of these patients had one or more drug therapy problems identified and resolved. Three or more drug therapy problems were identified and resolved in 392 (13%) patients at their first visit. During these initial assessments, practitioners identified a total of 3407 drug therapy problems.

Throughout the three years of analysis described here, 84% of these patients experienced at least one drug therapy problem at some time. This supports the notion that drug therapy problems can occur at any time during a patient's course of treatment and can be identified during any follow-up evaluation [22, 23]. These practice-based observations also support the idea that patients who do not have a drug therapy problem can still benefit from pharmaceutical care. This is primarily through the establishment of measurable goals of therapy and providing other supportive and reassuring advice to patients.

The most common categories of drug therapy problems were patients requiring additional drug therapies to manage their medical conditions and patients receiving inadequate dosages of medications to provide therapeutic benefit. Many patients present to the pharmaceutical care practitioner with a clinical indication for drug therapy that has not been previously identified. The most common type of drug therapy problem identified was the need for preventive medications to prevent serious health problems such as myocardial infar-

Table 4. Most Commonly Used Drug Classes

Medical Condition	Most Frequently Used Drug Classes (listed in order of frequency of use)
Hypertension	ACE inhibitors (captopril, enalapril, lisinopril, ramipril) Beta blockers - cardio-selective (atenolol, metoprolol) Calcium blockers (nifedipine, amlodipine) Thiazide diuretics (hydrochlorothiazide) Angiotensin II receptor antagonists (valsartan, irbesartan) Loop diuretics (furosemide)
Hyperlipidemia	HMG CoA reductase inhibitors (atorvastatin, simvastatin, pravastatin) Fibric acid derivatives (gemfibrozil, fenofibrate) Nicotinic acid
Diabetes	Biguanides (metformin) Thiazolidinediones (rosiglitazone, pioglitazone) Sulfonylureas (glyburide, glipizide, glimepiride) Human Insulin
Osteoporosis	Calcium supplements Bisphosphonates (alendronate, risedronate) Antacids containing calcium salts Selective estrogen receptor modulators (raloxifene)
Esophagitis/Gastritis	Proton pump inhibitors (lansoprazole, omeprazole, rabeprazole, pantoprazole) H-2 antagonists (ranitidine, famotidine, cimetidine) Antacids
Depression	Selective serotonin reuptake inhibitors (sertraline, paroxetine, fluoxetine, citalopram) Other antidepressants (bupropion, venlafaxine, nefazodone, trazodone, mirtazapine) Tricyclic agents (amitriptyline, nortriptyline)
Allergic Rhinitis	Antihistamines non-sedating (loratadine, fexofenadine, cetirizine) Nasal steroids (mometasone furoate, fluticasone, triamcinolone)
Menopausal symptoms	Conjugated estrogens Conjugated estrogen & progestin Estradiol Vaginal estrogens
Hypothyroidism	Thyroid Hormones (levothyroxine)
Insomnia	Trazodone, zolpidem, amitriptyline, melatonin, lorazepam

tion, stroke, or osteoporosis. Also, these patients required additional medications to prevent acute exacerbations of arthritis pain, asthma, and esophagitis.

On 695 occasions, the pharmaceutical care practitioner resolved the patient's drug therapy problem by increasing the dosage of medication. This was accomplished with the assistance of the prescribing practitioner whenever necessary. Dosage increases were most often required in order to produce effective outcomes in patients with diabetes, hypertension, hyperlipidemia, depression, or arthritis. The classes of drug products that most often required dose increases included: ACE inhibitors, insulin, HGM CoA Reductase inhibitors (statins), warfarin, and selective serotonin reuptake inhibitors. The necessity to improve effectiveness of drug therapies the patient is already taking is a common drug-related need for many patients. Providing individualized dosages of drug products sufficient to ensure the patient can experience a positive outcome has a dramatic impact on the health of patients receiving pharmaceutical care.

Over their entire course of care, these 2985 patients had 11,626 documented encounters with a pharmaceutical care practitioner. During these visits there were 9845 drug therapy problems identified, documented, and resolved. These data reveal that pharmaceutical care practitioners identify a drug therapy problem in over 8 out of every 10 visits with a patient. Table 5 below lists the number of drug therapy problems identified and resolved in each of the seven categories over these patients' entire course of therapies.

It is noteworthy that these adult patients required the dosages of their medications to be increased 3.8 times more frequently in order to provide effective therapy than they required dosage reductions. This observation holds true in almost every age group. These practice-based results indicate that patients are taking sub-therapeutic dosages of medications 2 to 3 times more often than they are taking potentially toxic dosages. Table 6 displays the number of patients (n=2985 total patients) in each age group who had a drug therapy problem at sometime during his/her course of care.

Table 5. Number of Drug Therapy Problems Identified and Resolved

Drug Therapy Problem Category	Number of Drug Therapy Problems	% of Total
Unnecessary Drug Therapy	542	5.5 %
Needed Additional Drug Therapy	3,009	30.6 %
Ineffective Drug Product	849	8.6 %
Dosage Too Low	2,087	21.2 %
Adverse Drug Reaction	997	10.1 %
Dosage Too High	550	5.6 %
Noncompliance	1,811	18.4 %
Total Number of Problems	9,845	100.0%

Table 6. Number of Drug Therapy Problems by Age Group

Drug Therapy Problem	Age 20-30 n=49	Age 31-40 n=141	Age 41-50 n=331	Age 51-60 n=576	Age 61-70 n=695	Age 71-80 n=780	Age 81-90 n=389	Age 91-100 n=24
Unnecessary Drug Therapy	1	14	45	90	112	110	55	7
Needed Additional Drug Therapy	26	68	205	332	367	432	212	13
Ineffective Drug Product	9	28	63	122	171	172	74	3
Dosage Too Low	16	38	134	246	307	335	162	9
Adverse Drug Reaction	5	27	73	144	190	190	103	4
Dosage Too High	5	15	37	83	105	119	54	4
Noncompliance	12	31	85	149	224	294	171	12
TOTAL NUMBER (average)	74 (1.5)	221 (1.6)	642 (1.9)	1166 (2.0)	1476 (2.1)	1652 (2.1)	831 (2.1)	52 (2.2)

Pharmaceutical care practice as emphasized above is founded on the concept of ensuring effective and safe pharmacotherapy for every patient. Note that the order in which these are assessed by the pharmaceutical care practitioner is always effectiveness first and safety second. Experienced pharmaceutical care practitioners understand that in order to ensure that a patient is receiving effective drug therapy, each patient must be provided with not only an efficacious drug product, but must also be directed to take a sufficient dosage to provide the desired pharmacological response and outcomes. When patients are allowed to take a sub-therapeutic dosage of a drug, they are exposed to the risks of adverse reactions and side effects, yet have little hope of realizing positive outcomes.

The drug therapy problems encountered most often involved patients with common medical conditions who needed additional drug therapies to produce the desired outcomes, or who required increases in their dosage (most often increased dose or more frequent dosing), to meet the established goals of therapy. These are listed in Table 7 below in order of

frequency beginning with the most common drug therapy problem identified in this group of adult patients, that is, patients who required the additional drug therapy to adequately manage an episode of major depression.

The drug products involved in these patients' drug therapy problems included the products frequently used throughout any modern health care system. The medications which were most commonly assessed as being used in ineffective (or sub-therapeutic) dosages included: calcium supplements, HMG CoA Reductase inhibitors (statins), ACE inhibitors, insulin, warfarin, and beta-blockers. The medications which were most commonly used in excessive (unsafe) dosages included: salicylates, warfarin, calcium supplements, insulin, and thyroid hormones. Adverse drug reactions most frequently were found to involve aspirin, nonsteroidal anti-inflammatory agents (NSAIDs), selective serotonin reuptake inhibitors (SSRIs), ACE inhibitors, and HMG CoA Reductase inhibitors (statins). Compliance problems most often involved HMG CoA Reductase inhibitors (statins), steroid inhalants, ACE inhibitors, and proton pump inhibitors.

Table 7. Most Common Drug Therapy Problem Associated with Medical Conditions

Medical Condition	Drug Therapy Problem Category
Depression	Needed additional drug therapy
Diabetes	Needed additional drug therapy
Hypertension	Dosage too low
Arthritis pain	Needed additional drug therapy
Hypertension	Needed additional drug therapy
Hyperlipidemia	Dosage too low
Hyperlipidemia	Compliance- patient could not afford drug
Asthma	Preventive therapy required
Depression	Undesirable effects
Menopausal symptoms	Dosage too low

Our experience clearly demonstrates that drug therapy problems can occur in any patient, with any medical condition, from any drug regimen, obtained from any source. The most frequent drug therapy problem involving drug products obtained through a physician-initiated prescription is *noncompliance* primarily because the patient cannot afford the prescribed product, or the patient did not understand the instructions. The next most frequently encountered drug therapy problem involving prescribed drug products was dosages that were too low to achieve the established goals of therapy. Patients using nonprescription products most often experienced drug therapy problems in the categories of taking dosages that were too low to be effective and selecting ineffective products for the medical condition being treated. Interestingly, when medications were obtained from friends or family members, the most frequently encountered drug therapy problems were dosages that were too low, or the drug therapy was assessed by the practitioner to be unnecessary. Noncompliance was the least frequently encountered problem involving medications obtained from friends or family members. These practice-based experiences indicate that when patients are encouraged to initiate a new form of drug therapy by a trusted friend or a family member, the patient often decides to use the product, but the dosage suggestions made by friends and family members are frequently too low to be effective.

Drug therapy problems must be identified and resolved in order for patients to achieve their goals of therapy. Pharmaceutical care practitioners accomplish this by working directly with each patient and his or her other health care providers to individually adjust drug dosage regimens, discontinue unnecessary medications, add medications to prevent illness, and personally explain how to properly use each drug product. Whenever a change must be made in drug therapy that requires a physician prescription, the pharmaceutical care practitioners secure agreement with the prescriber prior to instituting that change. This is accomplished either by instructing the patient of the recommended change so he/she can communicate it to the physician, or through

direct communication with the physician. This comprehensive, patient-centered service can have a dramatic impact on the health and welfare of patients. The overall clinical impact of pharmaceutical care services can best be analyzed by examining the clinical impact that this practice has in each individual patient. This was accomplished using the Assurance Pharmaceutical Care[®] system.

Evaluating Patient Outcomes

In order to analyze the clinical impact of any drug therapy, practitioners must document several components of the patient's care. The impact on each patient must be considered separately. The medical condition (indication for the drug) must be documented in a standard format. We have chosen to use the International Classification of Diseases (9th Revision) - Clinical Modification (ICD-9CM) codes to facilitate documentation of our patient's indications for drug therapy [24]. Each drug therapy must be associated with a clinical indication at the time of the assessment. Goals of therapy must be established for each condition being managed with drug therapy. Drug therapy problems identified are documented and include the drug therapy involved, the primary cause of the problem, and the medical condition affected. At each follow-up evaluation, the status of the medical condition being treated is compared to the desired goals of therapy and is documented. All of these components of pharmacotherapy must be documented within an individual patient's record in order to be able to determine outcomes of drug therapies or the clinical impact of pharmaceutical care services.

The Assurance Pharmaceutical Care[®] system is a state-of-the-art clinical documentation system providing the capability to document the change in clinical status of each patient's medical condition resulting from drug therapy. For each patient, improvement or lack of improvement in each medical condition can be recorded at each pharmaceutical care encounter. The clinical status codes defined in our books serve as the basis for this unique, efficient method to analyze clinical outcomes for any patient being treated for any medical condition [9-11].

For example, if a patient's osteoarthritis was evaluated to be *unimproved* with existing therapy, and the practitioner identified and resolved a drug therapy problem which was preventing the patient from achieving the intended goals of therapy (e.g. dosage too low), then at the next follow-up evaluation the patient's osteoarthritis would be evaluated again. If at this subsequent follow-up evaluation the patient reported improvement in pain and range of motion consistent with his/her goals of therapy, then the practitioner might document that the status of the patient's osteoarthritis therapy was now *stable*. This would represent an improvement compared to the previous documented status. Conversely, if the status of a patient's condition being managed with drug therapy changed from *stable* to *worsened* over several follow-up evaluation visits, this would represent a decline in the clinical status.

The Assurance Pharmaceutical Care[®] system also consolidates outcome data for numerous patients being treated with various drug therapies for the same medical condition. This feature allows practitioners to analyze the clinical

impact that pharmaceutical care can have on groups of patients with similar disorders. It also allows us to compare the efficacy of numerous drug therapies used to treat the same medical condition. These data can be useful in making decisions as to which products are more efficacious and therefore should be made available through health systems formularies.

Practice-based results, in these 2985 adult patients who were seen and evaluated an average of 3.9 times, were consistently positive. 88% of the 16,132 total medical conditions being managed by drug therapy within these practices either improved or their status remained unchanged during their course of pharmaceutical care services. In this group, 5166 of their conditions improved by the identification and resolution of drug therapy problems. This represents a clinical improvement in 32% of the medical conditions being managed with pharmacotherapy. In other words, one third of our patients' medical conditions improve as a result of the provision of pharmaceutical care. These positive outcomes were the result of practitioners using standard marketed drug products, but consistently applying a rational decision making process to identify the most appropriate drug, individualize the dosage regimens, as well as provide personal verbal and often written instructions for each patient.

In 56% of these patients' medical conditions, there was no demonstrable change in status while receiving pharmaceutical care. This figure represented patients whose chronic conditions were stable at the first pharmaceutical care encounter and remained stable (43%) until the most recent documented encounter.

No form of drug therapy or any clinical practice can be expected to improve all conditions in all patients in all cases. Our practice-based results indicate that 12% of our patients' conditions (n=1922) declined in clinical status despite the best efforts of practitioners and patients to achieve desired goals of therapy. These included patients in whom one or more of their medical conditions worsened while receiving pharmaceutical care, and patients who died while receiving drug therapy.

The practice-based results reported here are not from a controlled clinical trial involving carefully selected subjects, but rather represent the outcomes of daily practice. We believe that the positive clinical impact is a direct result of applying a rational decision-making process in a comprehensive manner for every patient. This allows the identification, resolution, and prevention of numerous, common, previously unrecognized drug therapy problems.

Outcomes of Patients Experiencing Specific Diseases

Examining the clinical outcomes that can be achieved through the provision of pharmaceutical care within specific disease categories yields interesting results. For instance, patients with diabetes often seek the services of a pharmaceutical care practitioner. Our experience reveals that of the 863 patients with Type II diabetes, 51% showed clinical improvement while receiving pharmaceutical care. Approximately one-third of these patients' diabetic conditions did not change and 16% declined during the care experience.

These practitioners also provided care for 355 patients with hypothyroidism in which the clinical outcome of their thyroid supplement pharmacotherapy was evaluated on at least two separate occasions between 2000 and 2003. In 20% (n=72 patients) of these individuals there was a documented improvement of their thyroid status. These results were associated with the use of primarily one agent (levothyroxine). In these cases, the choice of the drug product was seldom the issue, rather, the positive outcomes were a result of resolving problems related to the dosage of levothyroxine. In 71% of these patients there was no change in thyroid status, indicating that the patient's condition remained stable, and in 9% of patients the clinical status declined. This represents a situation in which ensuring effective, yet safe, drug therapy can have an important and direct impact on patient outcomes.

An analysis of the clinical impact on patients being treated for major depression yielded similar results. There were 483 patients being treated for major depression who experienced a minimum of two follow-up evaluations. Goals of therapy were being achieved in 87% of these patients at their most recent follow-up evaluation. These positive outcomes were similar using a variety of individually selected drug regimens including: selective serotonin reuptake inhibitors (89% meeting goals of therapy), tricyclic agents (84% meeting goals of therapy), alpha-2 receptor antagonists (84% meeting goals of therapy), and modified cyclics (89% meeting goals of therapy). The remaining 66 patients (13%) with major depression represent an important challenge for practitioners.

Our experience with patients suffering from back pain revealed that the practitioners often had to recommend a change in drug products to find effective therapy. The efficacy of the various classes of drug products used to manage back pain had similar, but unimpressive results (50-60%). Patients taking analgesics such as acetaminophen were able to achieve their goals of therapy in 58% of cases. Patients treated with NSAIDs achieved goals of therapy in 62% of the cases. Narcotic agonists were successful 58% of the time, while central muscle relaxants helped 57% of the patients achieve satisfactory relief from back pain. The Assurance Pharmaceutical Care© system can facilitate the continued care of these patients by making it easy for the practitioners to identify who is responding to drug therapy and who is not. A rapid search of the practitioner's entire patient case load can identify which patients need continued and intensive follow-up care in an attempt to find a therapy that will be effective and which patients will require referral to a specialist.

Our practice-based data reveal that measurable improvements have been achieved in these adult patients including: 82 patients treated for migraine headache, 23% improved, while the clinical status declined in 16% of patients. In 29 patients with dementia, 24% improved, while 31% declined over the course of therapy. There are new agents being developed for both of these disorders as well as specialists who have considerable expertise in providing individualized care and treatments for patients with these life altering medical conditions. Referrals to specialists may be appropriate for patients in whom goals of therapy cannot otherwise be achieved.

Economic Impact of Pharmaceutical Care Practice

Pharmacists have long argued that improving patients' drug therapies could have a substantial positive impact on other health care costs such as clinic and/or hospital expenses. Such conclusions, although theoretically sound, have not been carried to their rightful conclusions due to a lack of data to support this argument. Therefore we created a simple, yet effective, method for practitioners to document health care savings that result from pharmaceutical care services at the time the service is rendered. This unique routine is imbedded within the Assurance Pharmaceutical Care[®] system and provides evidence of the economic impact of pharmaceutical care on individual patients and on the entire health care system. In addition, the work of pharmaceutical care practitioners has been validated by peer review panels of physicians and other practitioners [25].

Practitioners often improve a patient's pharmacotherapy and thus avoid a physician (or nurse) clinic visit, a visit to the emergency department, or an admission to a hospital. These events save substantial health care resources. Table 8 lists the number of times practitioners resolved drug therapy problems that resulted in the avoidance of an office visit, saving an employee work day, laboratory test, emergency department visit, or hospitalization. Because emergency department visits and hospitalization represent such large health care expenses, practitioners provide additional documentation in these cases including supportive evidence from the patient's physician and/or the patient.

The total health care savings realized from providing pharmaceutical care to these 2,985 patients was \$ 1,134,162. Every health care system in every country has different expenses for the delivery of these health care services. Therefore we use U.S. national average figures from the year 2001 for these comparisons. Using these data and our average patient charge per visit of \$47.64 (generated by the

resource-based relative value scale) we have realized a 2 to 1 benefit to cost ratio. This means that the provision of pharmaceutical care by trained, community-based pharmacists can save the health care system \$ 2 for every \$ 1 that is invested in providing the service.

Our experience over the past quarter of a century supports the argument that pharmaceutical care ensures the appropriate and rational use of effective pharmacotherapies and is one of the most cost-effective health care services that can be made available to patients. The broad implementation of pharmaceutical care will certainly have a positive and lasting impact of the investments our countries make in the provision of health care.

CONCLUSION

For over a quarter of a century, we have committed our available resources to describe and develop the numerous components of a practice that must be integrated in order to develop a new patient care service. These practice components include: the application of a new practice philosophy to the patient care environment, explicit description of practitioner responsibilities, establishing drug therapy problem categories and their common causes, describing the Pharmacotherapy Workup, defining standard terminology to describe clinical outcomes from drug therapies, structuring an assessment, care plan, and follow-up evaluation that focus on improving outcomes from drug therapies, defining professional standards and standards of care for pharmaceutical care practitioners, adapting a reimbursement structure compatible with existing health care payment systems, developing a computer program to document patient care and manage a new service, creating a training program for pharmacists who wanted to learn new skills, and analyzing and publishing practice-based data describing the clinical and economic impact of pharmaceutical care practice.

Table 8. Health Care Savings in Pharmaceutical Care Practice

Health Care Savings*	2,985 patients 11,626 encounters	
	# of events	\$ Savings
Clinic outpatient visit avoided (\$265/visit) [26]	2210	\$ 585,650
Specialty office visit avoided (\$304/visit) [27]	185	\$ 56,240
Employee work days saved (\$237/day) [28]	124	\$ 29,388
Laboratory service avoided (\$24/ test) [29]	214	\$ 5,136
Urgent care visit avoided (\$82/visit) [27]	41	\$ 3,362
Home health care visit avoided (\$271/visit) [30]	12	\$ 3,252
Long term care admission avoided (\$56,000 cost/year) [27, 31, 32]	1	\$ 56,000
Emergency department visit avoided (\$452 charges/visit) [27, 30]	91	\$ 41,132
Hospital admission avoided (\$16,091/admission) [32]	22	\$ 354,002
Total	2900	\$ 1,134,162

*Health care savings are represented by U.S. national averages for the year 2001.

All of these components of the new practice needed to be clearly integrated with the others and each practice component needed to be validated within the existing health care system. Only with all the components defined and working as one cohesive unit could we have hoped to help enough patients to support the integration of pharmaceutical care into the mainstream of our health care systems. Today patients are recognizing the benefits of pharmaceutical care. Physicians who collaborate with pharmaceutical care practitioners report improved care of their patients. Such positive beginnings for a new practice could only be realized through the tireless efforts of devoted pharmacists who transformed themselves into pharmaceutical care practitioners.

We had the distinct pleasure to work with several cohorts of dedicated pharmacists who not only stepped forward to learn the new skills of pharmaceutical care practice, but also contributed to our knowledge through their questions, commitment, and caring for thousands of patients. This first generation of pharmaceutical care practitioners is to be congratulated. They accepted the challenge to become pharmacy's first pharmaceutical care representatives to patients, physicians, government, payers, and students. This initial group of practitioners set the direction and cleared the path for the future generations of pharmaceutical care practitioners. Future practitioners can be expected to possess the knowledge and skills required to ensure that every patient realizes the maximum effectiveness and safety from all of the life saving and life supporting medications available in the 21st century.

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