

NEED TO DEVELOP A LEGAL AND ETHICAL BASE FOR PHARMACEUTICAL CARE

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"If you don't know where you're going, any road will get you there."

Alice in Wonderland

THE EVOLUTIONARY ROAD OF PHARMACY PRACTICE from the early years of the clinical pharmacy movement to the present era of pharmaceutical care has been impacted by both external and internal influences. There has been a continuous effort to increase the importance of pharmacy practice by expanding the number of clinical practitioners and the scope of their practice.

This movement has been hindered by the lack of an accepted definition of practice with both professional and societal acceptance. The lack of a mandate continues to be the most significant hurdle in the maturation to a clinical profession. Francke et al. addressed the issue of ideals for the professional practice of pharmacy in 1964: "The future development of American hospital pharmacy depends on the clarity and enthusiasm with which its ideals of pharmaceutical service are stated and the degree to which they find common acceptance."¹ In 1980, Brodie presented a well-developed discussion on the need for a theoretical base for pharmacy practice.² In the past 10 years there have been several significant conferences and papers that have increased the awareness of a theoretical base.³⁻⁵ We believe that the success of the pharmaceutical care movement will be a function of three factors: demand, cost justification, and our acceptance of legal and ethical standards of practice, with the latter being the most important.

Demand

Demand for clinical pharmacy was starting to appear by the late 1960s. At least four factors contributed to this initial demand for clinical services, which at that time primarily involved the provision of information on drugs and drug use. These factors included (1) the rapid expansion of the

medical literature database and success of drug information centers, (2) the significant increase in the number of drug products available and recognition of toxicity associated with drug use/misuse, (3) the success and acceptance of a few individual clinical pharmacists, and (4) the concern with a potential shortage of physicians and the need for physician extenders.

Up to the late 1970s, the success (S) of clinical pharmacy was usually a function (f) of the demand (D) and individual pharmacists' efforts. One could express the success of clinical pharmacy by the following formula: $S = f(D)$.

Cost Justification

By the late 1970s, the rising costs of healthcare and financial concerns began to become more prominent, the call for cost justification (CJ) of clinical services was voiced. As justification became more important, the equation for success took on this new variable: $S = f(CJ + D)$.

Cost justification of clinical pharmacy services in institutions is well described in the literature. In 1986 Hatoum et al. reviewed 11 years of the pharmacy literature on the value of inpatient clinical services, summarizing 93 studies that dealt with research on justification issues in the provision of clinical services.⁶ Certainly, many more have been published since 1986.⁷⁻⁹

The issue of economic justification of clinical pharmacy services remains debatable for healthcare in general, and at the individual hospital level, even with the vast numbers of studies dealing with this topic. With all the attempts to demonstrate cost justification for clinical practice, only a few services or responsibilities have been added to the legal and ethical standards of practice. Recent Omnibus Budget Reconciliation Act legislation for drug use review and patient counseling is a positive illustration.

For example, even with significant cost justification studies of pharmacokinetic services, universal implementation of pharmacokinetic services does not exist. This is demonstrated by the recent American Society of Hospital Pharmacists national survey, which showed only 56.8 percent of hospitals provide pharmacokinetic consults to some of their patients.¹⁰ One must conclude that the success of clinical pharmacy cannot rely totally on demand and justification.

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Legal/Ethical Standards

Pharmacists need to assume a proactive role in defining what part of patients' outcomes depend on, or could be improved by, their knowledge, skills, and services. Pharmacists have not developed the needed legal and ethical standards of practice that are conducive to the provision of pharmaceutical care. In fact, although most would argue that pharmacy is practiced in a very regulated environment, it is difficult to identify control processes aimed at ensuring that quality pharmaceutical care is provided to the patient.

The only two mechanisms provided to regulate pharmacy are the licensure needed to practice and the regulatory mechanisms to ensure no gross violation of the letter and intent of the law takes place. Munger et al. in 1987 reviewed the pharmacy practice acts to identify the support for the expanded role of pharmacists, and found that most practice acts defined dispensing and compounding as part of the practice of pharmacy. However, reference to consultation, prescribing and administration of drugs, and research were rarely defined as part of the act. In a more recent review there were some improvements, yet only 13 percent of the state acts identify patient assessment or pharmacokinetic consultation and only 72 percent list interpretation and evaluation of prescriptions as a role of the pharmacist. Munger et al. argue that the practice acts continue to limit the role and expectations of pharmacists.^{11,12}

The National Association of Boards of Pharmacy (NABP) revised and published a new model pharmacy practice act in 1992. This new statement endorsed the concept of pharmaceutical care and listed several functions as components of the practice of pharmacy. These functions include patient counseling, monitoring appropriate drug use, providing information, participating in drug selection, and applying pharmacokinetics to designing drug regimens.¹³ Several states have subsequently developed new practice acts based on this model.

It is clear that this model practice act does not require pharmacists to perform these clinical functions. It clearly states that the pharmacist can perform these activities when applicable in the pharmacist's professional judgment. They are enabling statements that allow pharmacists to expand their clinical base, but do not establish a standard of practice that is to be applied by every pharmacist for all patients.

The Office of the Inspector General, in the US Department of Health and Human Services, published two reports on the practice of pharmacy. One of the major findings and recommendations of the Inspector General's reports relates to the limited use of peer review processes by many professional pharmacy associations, particularly in comparison with other professions. The American Pharmaceutical Association and most state professional pharmacy associations, according to the Inspector General, have not monitored the performance of members. Peer review by professional associations in other disciplines, such as medicine, dentistry, and podiatry, has been less limited. Furthermore, the Office of the Inspector General reported that pharmacy boards rarely address quality of care issues in spite of the increasing emphasis in the profession on the clinical aspects of pharmacy practice.^{14,15}

It is obvious, then, that cost justification and demand alone will not be adequate predictors of our professional

success; eventually responsibility needs to be assumed that is based on both legal and ethical standards (STDS). This concept can be described by the following equation: $S = f(CJ + D + STDS)$.

Recommendation

"Can you talk the talk and walk the walk?"

Full Metal Jacket, movie

The term pharmaceutical care can serve us well as the theoretical model, as requested by Brodie, but it does not define our roles and responsibilities. This concept needs to be put into action, and we must demonstrate to our patients and others that we "walk the walk."

The concept of pharmaceutical care as articulated by Hepler and Strand does in fact aid in understanding the original concepts of the early advocates of clinical pharmacy. There is certainly a strong correlation of this new term and the aspirations and intent of the original pioneers in clinical pharmacy. This term is helpful as it can serve to pull us back from the task-oriented functions that many pharmacists have assumed, but it is only clarification of a mission statement. It does not serve as an action plan.

If we continue as a profession to refuse to make major changes in our behavior and accept responsibility, our future will not be bright. Pharmacists individually and collectively must undergo a major transformation. If we will not or cannot articulate our clinical roles and professional responsibilities to patient outcomes, how can we survive? If we do not assume legal and ethical responsibilities for our actions, we will not survive, nor should we. Without a clear description of how to meet our mission, it will continue to be difficult if not impossible to convince students, other healthcare professionals, patients, policy makers, third-party payers, and others of our roles and value to society.

We need to develop a clinical profession based on standards of practice. We believe that we can accomplish this most effectively by focusing on the structure, process, and outcomes necessary for pharmaceutical care and resolve major problems relating to drug use.

Pharmacy must identify the structures, processes, and outcomes of pharmaceutical care. Under each of these three components we need to develop criteria. Once identified and stated, these will provide a measure by which we can evaluate our success.

Structural components are the starting conditions and resources that are available to the providers of care. Structure is the physical and operational resources and instruments necessary for providing service. Structure includes material resources, human resources, and organizational structure. Standards for each structural component need to be identified.

Process is the actual implementation of the structural components of the system. Process includes the tasks, functions, and skills provided in performing a service. Process is what is actually done in giving and receiving care. The quality of the outcome is predicated by the effectiveness and efficiency of the processes, as well as the magnitude and appropriateness of the structure. Process standards should be developed that are action oriented, and thus are measurable. These standards define the activities, tasks, and functions to be performed. Process standards should

enable the pharmacist to measure the degree to which the process occurred. Process standards are essential in defining the responsibilities of clinical pharmacists and establishing a basis for accountability.

Outcomes are the end points and results of services provided. Outcome assessment involves a measurement of the end result of care. Specific outcomes that are easily identified and measured, and which correlate most directly with the provision of pharmaceutical care, need to be listed.

Outcome indicators for quality pharmaceutical care may include such measurable indicators as medication errors, number of unnecessary drugs, number of drug adverse effects or allergic reactions, and reduction in drug cost. Each of these measurements must be documentable.

The current challenge before pharmacy is for all individual pharmacists, colleges of pharmacy, pharmacy organizations, and the profession collectively to move the concept of pharmaceutical care from a theoretical statement to an operational level. The following serves as a basis by which the pharmacist's success might be enhanced. It helps to develop a legal and ethical basis for the practice of pharmacy:

1. All pharmacists and pharmacy educators must develop a belief that the profession has a higher professional calling—that we need to educate and empower pharmacists to accept responsibility to provide the care and standards of practice articulated by pharmaceutical care. A clear mission statement that sets a priority for pharmaceutical care needs to be made. There needs to be acceptance and articulation of the standards of practice for which all pharmacists will be responsible, and their expected impact on patient outcome.
2. Pharmacy will need to decrease its emphasis on traditional roles. The drug delivery process will have to be deemphasized and delegated. The profession will have to commit to automation, robotics, and technicians. The profession may even need to give up much of its distribution responsibility.
3. Colleges of pharmacy and faculty must aggressively accept the recommendations for change by the American Association of Colleges of Pharmacy.¹⁶⁻¹⁹ This process must not be delayed. The profession needs to make an immediate commitment to produce practitioners who are capable of delivering pharmaceutical care and able to deliver the accepted standard of care.
4. Pharmacy organizations, colleges, and especially state boards need to move quickly to define the legal standards of practice. Pharmacists need to be educated, trained, and empowered to meet these standards and held responsible for outcomes.
5. All pharmacists and pharmacy departments must develop a practice model that provides favorable outcomes. Structure and process that optimize patient improvement and emphasize preventive care, provided routinely and in a timely manner, need to be developed. Furthermore, this commitment needs to be articulated to patients and other health practitioners, and documented.

Pharmaceutical care will fail if each pharmacy organization or individual pharmacists are allowed to define pharmaceutical care for their own short-term or political agenda. All professional organizations and legal bodies need to ensure that we meet the needs of our patients.

A major change in pharmacy leadership at all levels is needed if the concept of pharmaceutical care is to be successful. The leaders need to move all pharmacists forward.

Our conclusion is that the lack of consistency, commitment, leadership, and defined standards of practice for the profession of pharmacy results in a diminished understand-

ing of what clinical pharmacy (pharmaceutical care) actually is, and prevents the collective effort needed to achieve it. Though clinical pharmacists' actions are accepted on an individual basis, clinical services have not become the foundation of practice—we have not yet become a clinical profession. In the words of Zellmer, "The greatest force for change in pharmacy lies within pharmacists themselves. If they truly see themselves as practitioners of a clinical profession, they will behave accordingly, others will perceive them as such, and the pace of professionalization will accelerate."²⁰ ∞

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