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CLINICAL PHARMACY, PHARMACEUTICAL CARE, AND THE QUALITY OF DRUG THERAPY

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Abstract

Background. Because of concerns about patient safety and the quality of health care in America, in particular about drug therapy, pharmacists have unprecedented opportunities to increase their value and significance. When defining clinical pharmacy and pharmaceutical care, pharmacists long ago recognized the need to improve the safety and effectiveness of drug therapy.

Objective. To describe how clinical pharmacy and pharmaceutical care, closely related concepts, can contribute to a strategy for improving the quality of drug therapy.

Design. Commentary and review of selected publications.

Conclusion. Pharmacists can improve the quality of drug therapy by improving the organizational structures through which drug therapy is provided, specifically by creating medications use systems and by regularly evaluating their performance. As envisaged by the Institute of Medicine, these systems must be patient centered, cooperative, and interprofessional. To maximize pharmacists' participation in such systems, pharmaceutical education should include courses in medications use systems as necessary counterparts to courses in pharmacotherapeutics. Clinical functions must be organized around patient need and directed at outcomes. Clinical practice should constitute the mainstream practice of pharmacy rather than an "optional" specialty. Pharmaceutical care describes the original purpose of clinical pharmacy, when it was understood as a professional practice rather than a health science. It describes a way that clinical pharmacy, especially specialists and subspecialists, could coordinate their work more effectively. The concept of clinical pharmacy

adds essential clarity about the process component of pharmacists' participation in, and strengthens the academic basis of, pharmaceutical care. The clinical, humanitarian, and economic case for preventing drug-related morbidity is strong, and pharmacy has much to offer. It is, again, time to work together as a profession to plan our common future.

Key Words: clinical pharmacy, pharmaceutical care, medications use systems.

Introduction

Current concerns about patient safety and the quality of health care in America prominently.
include concerns about drug therapy.[1, 2] Influential groups and individuals have called for "new rules" for delivering health care, essentially for the creation of patient-centered cooperative systems for the delivery of health care.[3] These circumstances may provide long-awaited opportunities for many pharmacists to increase their role in patient care. I wonder if pharmacy is Pharmacists recognized long ago the need to improve the safety and effectiveness of drug therapy. Both clinical pharmacy and pharmaceutical care are ideas about that very subject. They are closely related concepts. Although they may not completely define pharmacists' full potential, they are a valuable beginning.

Unfortunately, some pharmacists and pharmacy leaders, perhaps preoccupied with political concerns, think about clinical pharmacy and pharmaceutical care as if they were competitive or incompatible, as if one idea were right and legitimate and the other wrong and illegitimate. Although this view may be honored by pharmacy's long tradition of factional squabbling, it may limit many pharmacists' ability to fully comprehend their opportunities and responsibilities in the current environment. We would make an error if we tried to choose between them. Using both ideas to formulate even more complete definitions of pharmacists' roles would be much more fruitful.

One way to explore the complementary nature of clinical pharmacy and pharmaceutical care would be to discuss the latter in terms of the former, and vice versa. Such comparisons of pharmaceutical care and clinical pharmacy should unite pharmacists, not divide them. A thorough discussion of the relationship of clinical pharmacy to pharmaceutical care requires examination on many levels, from semantics or philosophy of practice (ideas and their labels) to practice (ideas and their application) to politics (ideas and their advocates). A discussion that is correct philosophically may be misleading on the level of practice or be distorted in the political process. This exercise is a bit risky because uncomplimentary contrasts have been used to divide rather than unite, by advocates of either idea. Some people may talk about the academic elites of clinical pharmacy. Others may say that pharmaceutical care is a popularization (in a pejorative sense) of clinical pharmacy. My goal is to unite, not divide, and I offer these ideas as topics for discussion as a professional colleague. Our patients urgently need us to cooperate rather than compete, and our profession would benefit from increased intraprofessional cooperation.

Philosophy

The philosophic relationship of pharmaceutical care and clinical pharmacy depends on specific definitions. Many definitions of each term exist. Further, there is no persuasive argument for
choosing or ignoring many of them. I have arbitrarily chosen definitions that I think have been the most influential and that would be most useful.

Pharmaceutical Care

The concept of pharmaceutical care in its modern sense was introduced in 1980: "Pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only of the drug required but also the necessary services (before, during or after treatment) to assure optimally safe and effective therapy. It includes a feedback mechanism as a means of facilitating continuity of care by those who provide it."[4]

In 1989, my colleague (Linda Strand) and I emphasized the importance of an orientation toward outcomes, which had been implicit in the earlier definition. Our definition also addressed

responsibility within relationships: "Responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[5]
Based on other writings, the respective authors intended the word "care" to invoke analogies to medical care and nursing care.[6, 7] Responsibility was defined in its prospective sense as moral trustworthiness (i.e., behaving, to the full extent of law and custom, as if one expected to be accountable for one's actions).[8] This concept of responsibility does not presume full authority over patient care.
In 1998, another group defined pharmaceutical care as "a practice in which the practitioner takes responsibility for a patient's drug-related needs and is held accountable for this commitment. In the course of this practice, responsible drug therapy is provided for the purpose of achieving positive patient outcomes."[9]

Similarities and Differences
The comparisons show that clinical pharmacy and pharmaceutical care are compatible, mutually complementary ideas. They seem to have similar goals; however, these goals are expressed in different language frameworks and emphasize different aspects of practice. One way to sort them out would be to say that clinical pharmacy describes a practice of pharmacy that would contribute, within a larger pharmaceutical care system, to achieving pharmacotherapeutic and quality-of-life therapeutic objectives.
Although the idea of pharmaceutical care was developed mainly by pharmacists, pharmaceutical care is not "about" pharmacists. It is funda- mentally an idea about a system for the delivery of patient care. It requires cooperation by a variety of hospital and community pharmacists, physicians, nurses, and other professionals. Clinical pharmacy is an essential component in the delivery of pharmaceutical care. Understanding clinical pharmacy can improve the technical quality of pharmaceutical care. Understanding pharmaceutical care can enrich and broaden the philosophy and practice of clinical pharmacy.
According to these definitions, clinical pharmacy clearly comprises processes carried out by pharmacists without specific reference to outcomes. In contrast, the first previously mentioned definition of pharmaceutical care[4] strongly implies an orientation toward patient outcomes by mentioning feedback, which is "control" information about outcomes. The second and third definitions of pharmaceutical care[5, 9] explicitly mention outcomes.
None of the definitions of pharmaceutical care explicitly name a specific profession to provide care. The authors of these definitions surely had pharmacists in mind, but they also envisaged cooperative systems. By mentioning "services before, during or after treatment," the first definition[4] surely meant to include physician services. In our discussion, my colleague and I made this point explicitly.[5] Pharmacists cannot provide drug therapy without cooperation from prescribers and patients. Pharmaceutical care is often discussed as a system. None of the defini- tions of clinical pharmacy mentions systems.

The two concepts also seem to differ in their philosophic bases. The ACCP definition of clinical pharmacy says it is a health science and enumerates academic disciplines.[9] None of the definitions of clinical pharmacy specifically mentions values or responsibilities. Two definitions of pharmaceutical care mention responsibility, but none mentions academic disciplines. Evidently, the basis for clinical pharmacy is more in science than in relationship ethics, whereas the basis of pharmaceutical care is more in relationship ethics than in science.

These are not "black and white" distinctions. They do not suggest that clinical pharmacy, in practice, completely lacks any element that is present in the definition of pharmaceutical care, or vice versa. Certainly, clinical pharmacy practice is meant to be an ethically mediated practice involving responsibility for clinical and quality-of-life outcomes. However, it was not defined as such. Undoubtedly, pharmaceutical care should depend on correct processes and should require academic knowledge. However, its definitions do not require these elements. The semantic

comparisons show that both concepts are incomplete and that they support and complete each other.

Practice Implications

Some clinical practices may meet both a definition of clinical pharmacy and a definition of pharmaceutical care. For example, many clinical pharmacy practitioners carry out specific clinical functions, direct their practices at specific out- comes, and act as if they would share responsi- bility for those outcomes. That was the original idea of clinical pharmacy. The definitions, however, seem to allow for divergent practices that meet one definition but not the other.

Clinical Pharmacy Practices

Consider the following examples, which would not violate the definition of clinical pharmacy. Suppose that a pharmacist provided clinical pharmacy services regardless of whether a therapeutic objective had been explicitly stated; limited his or her responsibility to the per- formance of the function rather than a patient's outcome and was evaluated on performance instead of effect on results (e.g., whether pharmacokinetic analyses were correct rather than whether the patient's clinical status or quality of life was improved); chose (or was assigned) functions without clear reference to patients' needs; limited service to advising physicians without follow-up, even to the point that the physician, rather than the patient, became the clinical pharmacist's actual client; or limited service to managing certain therapies or diseases rather than the "whole" patient.

Certainly, the innovators of clinical pharmacy would have seen such practices as incompletely satisfying the definitions given above, but such examples are not uncommon. Fragmented clinical pharmacy functions could become ends in themselves and lose their meaning. We know that scientifically correct therapy can fail from lack of appropriateness to a specific patient need or from inadequate management toward a therapeutic objective.

For example, according to the definition of clinical pharmacy, a clinical pharmacist could carry out pharmacokinetics for one drug that a patient was receiving, such as an aminoglycoside antibiotic. That fits all the definitions of clinical pharmacy. The pharmacist, however, could ignore the indication for the drug or whether the prescribed aminoglycoside was the right choice for the patient. He or she could ignore the management of other drugs the patient was receiving and ignore any significant untreated indications for therapy, even if he or she were the only clinical pharmacist caring for that patient. None of these facts would violate the definition of clinical pharmacy.

Whether patients receiving aminoglycosides are better off with such a limited service is not the point here. This type of practice is self- contradictory. It argues, on the one hand, that clinical pharmacists add value to drug therapy management and then, on the other hand, withhold that expertise except for highly specialized, perhaps arbitrarily chosen, functions. To continue the example, a patient receiving optimal pharmacokinetic dosing, nutrition support, oncology therapy, and so forth may still have other, more mundane problems.

Medical subspecialists (e.g., transplant surgeons) can reasonably focus on one aspect of care because they work with generalists (e.g., internists) who take care of the patient's overall needs. Has clinical pharmacy defined specialties (or subspecialties) without providing for expert bgeneralists? (A reading of the Board of Pharma- ceutical Specialties Web site [http://www.bpsweb. org/Recognized.Specialties/ Recognized.Specialties. Pharmacotherapy.shtml] would tell anyone that pharmacotherapy is a specialty recognized by the board on the same level as oncology, etc.) Is it within the definition of clinical pharmacy if specialists provide specific clinical functions without a clinical pharmacy generalist to coordinate?

Pharmaceutical Care Practices

Likewise, a pharmaceutical care provider could satisfy a definition of pharmaceutical care but not a definition of clinical pharmacy. To me, the greatest difficulty with the definition of pharma- ceutical care is its potential ambiguity about what functions should be carried out by which participant, about which processes must be in the repertoire of each participant, and about the level of competence required.

This ambiguity could allow pharmaceutical care to comprise a much more limited range of professional services than the framers intended. The definition implies (but does not require) due regard to what the patient needs vis-à-vis what others are providing.

The definitions require that the provider act responsibly or be held accountable, but do not provide an explicit basis for responsibility, such as scientific knowledge. For example, a practitioner may be able to meet the definition of pharma- ceutical care even though his or her technical and scientific proficiency may not meet normal standards for clinical pharmacy (I do not advocate this, but it follows from the published definitions).

A pharmacy practice that is fully consistent with the definition of pharmaceutical care would be holistic and general (i.e., encompass the whole patient and comprehend a wide scope of patient problems). It could also be more shallow or superficial than a specialized practice of clinical pharmacy.

A pharmacist might not recognize the need to perform a necessary clinical function or might not recognize some clinically significant drug therapy problems that a (presumably) well- trained clinical pharmacist would have caught.

A practitioner may be competent at one time but lack the academic background for sustained competence over a longer interval.

A pharmacist could have difficulty under- standing the appropriate balance of shared responsibility and cooperation. A well-meaning but unsophisticated pharmacist, while attempting to improve outcomes, while taking personal responsibility, could unintentionally complicate the physician-patient relationship.

The framers of the definitions of pharmaceutical care, I believe, intended it to be an extension of, not a substitute for, clinical pharmacy. That was certainly the spirit in which I approached my contributions to the topic. Unfortunately, over more than a decade, this interpretation has become partially submerged in a sea of invidious and divisive contrasts. Most of the ambiguity about function is a problem only when people try to understand pharmaceutical care without reference to clinical pharmacy. There is one major exception to this, which depends on the needs of individual patients and care populations.

The Needs of Patients

These practice comparisons show that a practice that meets only one type of definition may fall short of what patients need from pharmacists. The concept of clinical pharmacy is clearer about the need for technical competence but a bit vague about whom it serves, how much it is really committed to patient outcomes, and the scope of its responsibility. Pharmaceutical care is quite clear about its responsibilities to patients and its orientation toward outcomes but is vague about how this will be accomplished and about technical competence. Our understanding will be improved by integrating the ideas, but how should we do that?

We should emphasize the needs of various types of patients rather than our own assump- tions, practice preferences, or organizational loyalties. Certainly, extensive, specialized academic knowledge and skill are often prerequisites for a pharmacist to add value in some environments (e.g., tertiary hospitals). Such environments already include many specialists in other professions. According to research data, inappropriate prescribing is the leading cause of preventable drug-related morbidity (PDRM) among hospitalized patients.[11] (A PDRM is an injury caused by drug therapy [an adverse drug event] or is an injury caused by nontreatment of a valid indication.) Improving their drug therapy outcomes would require improvement in prescribing more than, say, improvement in monitoring. Hospital-based clinical pharmacists have access to patient data needed to prescribe and access to physicians. So, clinical pharmacists are surely not far wrong when they emphasize prescribing and other technical processes of drug therapy, or when they emphasize technical competence.

In other environments (e.g., in some ambulatory care environments), however, patients have different needs. They may need a generalist who knows them and their drug therapy, who can cooperate with them and their physician(s) over long periods of time, who can coordinate drug

therapy (when necessary) from assorted specialists, and who can help to keep therapy on track over long periods of time.

According to research data, failure to monitor patient progress adequately is a frequent failure point in ambulatory care drug therapy, especially if one includes nonadherence that would be detectable by follow-up and mild adverse drug reactions that were allowed to become severe.[11–13] Most community pharmacists practice separately from community physicians. They lack timely access to patient data and to prescribers, which they would need to influence prescribing prospectively. However, community pharmacists are highly accessible to patients (and vice versa) and may have fewer organizational constraints against talking to patients. The time interval between physician visits is rarely dictated by the rhythms of drug therapy. Community pharmacists can, and often do, see patients in the pharmacy between physician visits. This is a natural opportunity to monitor the progress of therapy. Therefore, clinical pharmacy in a community practice requires a different skill set than that of clinical pharmacy in a hospital. It may require unusual attentiveness, interpersonal and problem-solving skills, and a sense of shared responsibility for drug therapy outcomes, more than advanced knowledge of pharmacology, toxicology, pharmacokinetics, and therapeutics. Community physicians tend to have more general practices than do hospital physicians and to value practical more than technical competence. Furthermore, research studies show that the most prevalent and significant drug-related emergency room visits and hospitalizations involve therapeutics that are well within the comprehension of most pharmacists.[11] With minimal training, most pharmacists can learn to recognize common yet very troublesome drug therapy problems in heart failure, hypertension, post–myocardial infarction care, diabetes mellitus, asthma, and oversedation. They can detect nontreatment of valid indications, especially untreated or undertreated pain; inappropriate prescribing (noncompliance with prescribing guidelines); inadequate monitoring and follow-up; and patient nonadherence.

Pharmaceutical care is an idea about cooperative systems, not pharmacists, per se. (Pharmacists cannot provide drug therapy by themselves. Pharmacists and physicians cannot improve a patient's quality of life without the cooperation of the patient or a family caregiver.) Pharmaceutical care, by definition, assumes cooperation among people who have different sets of skills, privileges, and responsibilities. When a pharmacist finds a possible drug therapy problem that he or she cannot resolve, that pharmacist is expected to refer it to a more specialized clinical pharmacist or physician.

Politics

Many issues involving the relationship of clinical pharmacy and pharmaceutical care are political, in the broad sense of public advocacy of ideas by groups of like-minded people. Pharmacists who identify with clinical pharmacy tend to have organizational affiliations different from those of pharmacists who identify themselves with pharmaceutical care. Perhaps these organizations have been slow to appreciate that both clinical pharmacy and pharmaceutical care complement each other from a public health perspective. Personal experience surely shapes assumptions and attitudes. Each should recognize the other's potential contributions to patient care and to a complete practice of pharmacy. Each should be willing to contribute to making the other whole. In the eyes of the world, we are all pharmacists. I think we will succeed or fail together, based not only on the accomplishments of the best and brightest, but also on our overall contribution to the public good.

Those Who Forget History Are Doomed to Repeat It Clinical pharmacy was one of the most important developments in pharmaceutical practice and education of the 20th century. Clinical pharmacy was clearly an idea whose time had come, pharmacy's long overdue response to the information revolution. It promised to make pharmaceutical education patient centered and whole again, and to improve the quality of drug therapy for millions of people.[7] I once called clinical pharmacy, metaphorically, "a gene pool for the future of pharmacy."[14]

The emergence of clinical pharmacy education was, nonetheless, a story of interprofessional and intraprofessional struggle. I know how hard clinical pharmacists have worked to reach their present

status. Clinical pharmacists had to prove themselves worthy of professional parity on hospital staffs and within faculties of pharmacy.[7] I see echoes of this struggle in the ACCP definition of clinical pharmacy.[9] It presents clinical pharmacy as a "health science" and offers its scientific and disciplinary credentials. By the way, that definition does not stand alone. The ACCP has led in the movement to legitimize clinical pharmacy academically and in clinical pharmacy credentialing by examination. That has revolutionized some practice environments but has missed the mark in others (e.g., community practice).

Now, in the United States at least, clinical pharmacy is well established. It has become the unifying principle of an American pharma- ceutical education. It would be ironic, indeed, if the established leaders of clinical pharmacy would actually resist a movement like pharma- ceutical care, which intends mainly to recall clinical pharmacy to its original ideals of patient- centered pharmacy and to extend clinical pharmacy to larger, mainly community, populations. It would also waste energy that we need to spend on planning our professional futures. Perhaps pharmacy's leaders, remembering that bit of history, will help our profession to avoid repeating it.

This is a classic moral choice. Each practitioner or practice philosophy can emphasize its superiority over the others. The question is whether the most accomplished individuals in either group act like an elite corps or like an aristocracy. I think the distinction is important but recognized too seldom. The real question is what they do with their accomplishments. An elite corps is necessary because it shows others the way to greater accomplishment and service. It provides models of excellence to others who are less accomplished. Elites are not worth much, however, if they do not use their virtuosity in the service of others. Such an elite is merely an aristocracy. It no longer matters how hard its members (or their progenitors) worked to get there or how much fun being an aristocrat may be for a while. The history of the modern world shows that elites go on serving as long as they have a purpose bigger than they are. Aristocracies eventually meet their nemeses.

It Takes a System

The current care systems cannot do the job. Trying harder will not work. Changing systems of care will.[2] We can improve the quality of drug therapy by improving the organizational structures through which we deliver drug therapy, specifically by creating medications use systems and by regularly evaluating their performance.[15] As envisaged by the Institute of Medicine, these systems must be patient centered, cooperative, and interprofessional. In community practice, such systems may have to be formed ab initio, perhaps by using formal practice collaborations between community pharmacies and general practices, perhaps by incorporating practice pharmacists in primary care group practices, as is done in the United Kingdom.

To maximize pharmacists' participation in such systems, basic change is necessary in pharmaceutical education and practice. Pharmacists need to understand the importance of a system's design and operation, whether they practice within or manage a medications use system. Pharmacy education should include courses in medications use systems, as necessary counterparts to courses in pharmacotherapeutics (an example is available from http://www.cop.ufl. edu/safezone/ hepler/pha5255/index.htm; also available on CD.) Teaching therapeutics and systems theory together seems most effective and would challenge faculties to work together in new ways. In practice, we must stop speaking of and thinking of clinical pharmacy as a specialty. Our minimum goal should be for every pharmaceutical practice to be a clinical practice, not just in name but in reality. The ability to design, manage, and work within such systems will be prerequisites for success.

One basic prerequisite for creating collaborative practice systems is an appreciation of the potential contributions of pharmacists to safer and more effective drug therapy, patient welfare, and the good of society. Society has recognized that the provisions for drug therapy (as well as other parts of health care) are often unsafe and ineffective. This presents pharmacists with an unprecedented window of opportunity to increase their service to society and their significance in health care. The Institute of Medicine has proposed changes at every level of the delivery system, with the patient at

the center of it all. To be relevant, pharmacy should begin to describe how it can help to improve the system for providing drug therapy, given the present realities.

Mainstream pharmacy practice must be seen as committed and able to improve the quality of drug therapy. The official positions of our pharmacy organizations are inspiring. Behind the scenes, however, our present divisions, and petty squabbles (clinical pharmacy vs pharmaceutical care especially), do not show the world that we are ready. Our elite clinical pharmacists are all but invisible to politicians and payers, and even to most practitioners and patients. How will they all learn, as they must, about pharmacy's potential? I happen to believe that managed care has largely failed to improve the quality of health care, although there are some outstanding exceptions. If the market has failed, we should next consider higher voluntary or compulsory standards.[15, 16] Our present divisions impede development of higher practice standards.

Detecting and resolving drug therapy problems should no longer be an optional enhancement of the distribution function in any practice site. Isolated clinical services should not constitute a satisfactory level of clinical pharmacy. The concepts of clinical pharmacy and pharma- ceutical care are too limiting. Pharmaceutical care has the larger scope. It basically describes a cooperative system for providing drug therapy within which pharmacists would have a major part. Pharmaceutical care describes the original purpose of clinical pharmacy, from when it was thought of as a professional practice rather than a health science. It describes a way that clinical pharmacy, especially specialists and subspecialists, could coordinate their work more effectively.[17]

The concept of clinical pharmacy adds essential clarity about the process component of pharmacists' participation in, and strengthens the academic basis of, pharmaceutical care. Clinical pharmacists, under the banner of the ACCP, have led the way in establishing higher standards for clinical practice through the specialty certification process.

None of pharmacy's organizations can do it alone. Now it is time for all of pharmacy to raise its practice standards. Before others will expect more from us, we must expect more from ourselves. The experience of clinical pharmacy specialist certification should be invaluable for describing and certifying a pharmaceutical care generalist. Adherents of both concepts should contribute to improved practice standards.

The clinical, humanitarian, and economic case for preventing PDRM is strong. Pharmacy's case for major participation in pharmaceutical care systems, although not unequivocal, is much stronger than that of any other profession's. Pharmacy has much to offer. It is, again, time to work together as a profession to plan our common future.

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