

Levels of pharmaceutical care: A needs-based approach

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It is not thy duty to complete the work, but neither art thou free to desist from it.

—Talmud: *Ethics of the Fathers*, 11, 12

The concept of pharmaceutical care is capturing the attention of a growing number of practitioners. Indeed, to remark that the issues involved are controversial should come as no surprise to anyone who has reflected on the future of pharmacy. Present discourse reveals an urgent need to clarify a number of issues, however, and to delineate conceptual frameworks that can both shape and direct practice.

The purpose of this article is to describe pharmaceutical care as it relates to the patient, the pharmacist, and pharmaceutical services. Once these relationships are described, we will argue that the criterion on which to base the distinction of levels of pharmaceutical care is patient need, not the functions, activities, or services of the pharmacist. One important reason for this discussion is that pharmacists require a clear, shared vocabulary for communicating their role and functions, for stating their need for resources to practice that role, and for describing the benefit derived from their practice.

Defining Pharmaceutical Care

Before levels of pharmaceutical care can be discussed, it is necessary to have a very clear understanding of what is meant by pharmaceutical care. Pharmaceutical care is that component of pharmacy practice that directly involves patient care. Our definition of pharmaceutical care begins with that of Hepler and Strand¹:

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

Moreover:

Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This in turn

involves three major functions: (1) identifying potential and actual drug-related problems, (2) resolving actual drug-related problems, and (3) preventing drug-related problems.

Hepler and Strand emphasized the patient's quality of life and the necessity of adopting a patient focus with a cooperative "working relationship" in which both patient and pharmacist strive to resolve complex issues¹:

Pharmaceutical care is a necessary element of health care, and should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accepts responsibility) to the patient.

The fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice setting.

Of particular importance is the idea that pharmaceutical care is the component of pharmacy practice that is provided for the direct benefit of the patient and that the pharmacist is responsible directly to the patient for the effectiveness and quality of that care. When we examine pharmaceutical care in the light of more traditional pharmacy practice activities, we note the variable distances between pharmaceutical services offered (functions performed) and the patient. Too often this "patient" remains abstract in the taken-for-granted sense of "everything we do is for the patient." In this sense, the patient remains faceless. Thus, when the focus is on products and their timely distribution, pharmacists responsible for this service remain distant from the patient and rarely, if ever, establish relationships such as those called for in pharmaceutical care. Similarly, when we critically examine the functions of a drug information center, the coordination of a pharmacokinetic dosing service, or drug-use evaluation activities, we also find that the patient is often removed from the decision. The patient is not necessarily central to the task of information retrieval, the calculation of a drug dose, or the evaluation of how drugs are used in the institution as a whole. Extrapolated data, abstract patient profiles, and "faceless" charts can and do legitimize the distance between the practitioner and the patient.

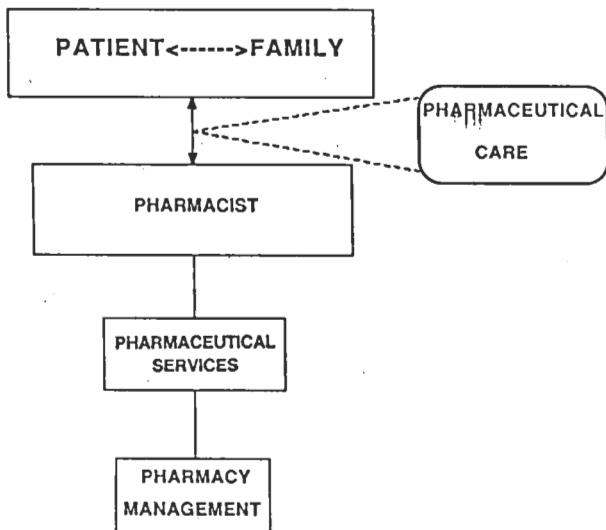
Figure 1 illustrates our conceptualization of pharmacy practice. It identifies the components of pharmacy practice and illustrates the relationships among pharmaceutical care, pharmaceutical services, and pharmacy management. Pharmaceutical care serves as the interface between the patient and the pharmacist.

It is important to recognize that traditional pharmaceutical services, while not by themselves constituting pharmaceutical care, do provide important information and products deemed indispensable to the rules,

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Figure 1. Components of pharmacy practice.



roles, and relationships of pharmaceutical care. Without them, pharmacists would be unable to meet their entrusted responsibilities.

To provide further clarification, consider the following examples. When we interview a patient, review his or her medical record, and take a medication history with a view to determining the need for pharmacotherapy, we are practicing pharmaceutical care. However, the creation of a drug profile is essentially a supportive service, a useful resource that helps the pharmacist to practice pharmaceutical care. The determination of an appropriate dosage of cyclosporine for a patient, a cognitive function, is part of providing pharmaceutical care. However, the manipulation of a computerized dosing program represents a supportive function that assists the pharmacist in determining the appropriate dosage. Making certain that the patient is able to adhere to the pharmacotherapeutic regimen is part of the provision of pharmaceutical care, but making certain that the lot number is recorded on the package label at the time of product preparation is part of the supportive function of drug distribution. In each of these examples there is a clear distinction between "technical" functions and the cognitive functions of the practitioner. If we examine the cognitive functions of the patient interacting with the pharmacist to define the needs of the patient, then we will have defined the characteristics of the patient-pharmacist exchange necessary for pharmaceutical care.

In essence, pharmaceutical care is that component of pharmacy practice that can be performed by no one other than a competent pharmacist committed to establishing a reciprocal relationship of truthfulness, confidentiality, and loyalty with patients whose pharmacotherapeutic needs are met through the application of knowledge and humanistic principles.

Pharmacist Functions Common to All levels of Pharmaceutical Care

What, we may ask, is it that pharmacists do that is specifically pharmaceutical care, regardless of the level of care needed by the patient? A description of these common pharmacist functions should help to explain why it is patient need and not specific pharmacist activities that should be used to differentiate one level of care from another.

The six major functions that are basic to pharmaceutical care are described below.² These major functions allow the pharmacist to identify and resolve, or prevent, a patient's drug-related problems.³

1. *The pharmacist collects and documents relevant information in a systematic, structured manner for the purpose of determining if the patient is experiencing potential or actual drug-related problems.* To begin to deliver pharmaceutical care, the pharmacist must "get to know" the patient. Through this process the patient ceases to be a case, a number, or a physiological system and becomes a person. If we (as experts with the best of intentions) unilaterally conclude that we are confronted by a drug-related problem without a human face, we may continue to see only a collection of organs and neglect the humanness of the patient. On the other hand, if we begin by assigning a patient the status and role of a human being experiencing a drug-related problem, we can work toward a relationship that has humanizing consequences. Medicine has begun to explore the philosophical issues surrounding this issue; pharmacy must do no less. Once the rapport between pharmacist and patient has been established, data collection is facilitated. The acquisition of information on a disease, its symptoms, current and past drug therapy, and other clinical variables can depend to a large extent on the communicative process between pharmacist and patient. Poor communication may mean inadequate data collection, which may translate into flawed decisions and inadequate care.

2. *The pharmacist identifies and lists the drug-related problems the patient is experiencing or is at risk of experiencing.* Here the pharmacist decides if the patient has an actual or potential drug-related problem requiring attention.³ If the patient does have an identified drug-related problem requiring the creation of a pharmacotherapeutic plan, then the pharmacist must be prepared to document that evidence, make decisions based on that evidence, and initiate action. If the patient does not have a drug-related problem, then it is reasonable to assume that the pharmacist has provided all the pharmaceutical care needed. But it must be kept in mind that, should the patient undergo other clinical interventions (e.g., surgery), then pharmacotherapy may at some point be necessary.

3. *The pharmacist establishes and lists the desired therapeutic outcomes for each drug-related problem that has been identified.* For each drug-related problem, the pharmacist must identify a successful outcome. The question of "desirable outcome" cannot be decided paternalis-

tically by the pharmacist alone. Patient input is essential and may be entirely based on subjective preferences and expectations. Family involvement is also frequently requested. Thus, while the pharmacist assumes responsibility for knowledge, the patient should be respected as a major participant in treatment decisions. What the patient lacks in pharmacologic knowledge is, with adequate communication, balanced by personal experience, sensations, emotions, and values—self-knowledge. While difficult to quantify, these subjective phenomena are crucial to the complete rendering of pharmaceutical care and adherence to pharmacotherapeutic plans.

4. *The pharmacist considers and ranks all the therapeutic interventions that might be expected to produce the desired therapeutic outcomes for each problem.* A decision is made as to the most appropriate alternative available for resolving the problem in question. Again, patient input should be encouraged and given serious consideration.

5. *The pharmacist decides which therapeutic alternatives to select and records the dosage regimen for each medication for each patient.* Each patient must receive individualized treatment not only because of information derived from scientific knowledge but also because he or she must be consistently respected as a unique individual with specific needs.

6. *The pharmacist formulates and documents a pharmacotherapeutic monitoring plan to verify that the drug-related decisions implemented have resulted in the outcomes desired and not in undesirable adverse reactions or toxicities.* The solution agreed on by both the pharmacist and the patient must be implemented and monitored to ensure that the desired outcomes are successfully achieved. Throughout any evaluative exercise, the pharmacist must continue to involve the patient rather than revert to the role of a distant "objective" observer relying solely on pharmacokinetic and other "hard" measures of outcome. Also, the pharmacist must be aware of the importance of critical re-evaluation of the therapeutic plan. Thinking must not be allowed to slip into the "drug of choice" mode, in which a false sense of security all too often replaces active monitoring and the idiosyncratic is forgotten.

Distinctions among Levels of Pharmaceutical Care

The preceding discussion may be considered a summary of the functional prerequisites of pharmaceutical care. Each of these functions must be in place for every patient if patients can truly be said to receive comprehensive pharmaceutical care. Since the pharmacist's primary functions remain constant whenever pharmaceutical care is given, regardless of the setting and other environmental factors, then it should be logical to look to something other than the pharmacist's functions to distinguish among levels of pharmaceutical care.

It is our view that *patient need* must differentiate the level of care required by and provided to a patient. In

the case of pharmaceutical care, distinctions can be expressed in terms of the risk associated with the patient's pharmacotherapy. When we consider the element of risk in pharmacotherapy we can, to some extent, understand the nature of patient need and pharmacist responsibility. For example, when the risk associated with an individual's pharmacotherapy is considered low, then it may reasonably be concluded that a primary level of pharmaceutical care is appropriate. Conversely, when the risk is high, then some higher level of care is required. Once we define the extreme levels of care, other levels of pharmaceutical care may be delineated.

To determine the type and magnitude of pharmacotherapeutic risk experienced by a patient, it is necessary to delineate the factors that place the patient at risk. We identify three categories of risk factors that can affect the type and level of pharmacotherapeutic risk: (1) risk factors associated with the patient's clinical characteristics, (2) risk factors associated with the patient's disease, and (3) risk factors associated with the patient's pharmacotherapy. The interaction of these three types of risk factors ultimately determines the level of risk associated with a patient's pharmacotherapy and therefore the level of pharmaceutical care required of the pharmacist.

Risk Factors Associated with the Patient's Clinical Characteristics. A number of factors contribute to the vulnerability of a patient if he or she does not receive the appropriate pharmacotherapy. These include, but are not limited to, the patient's age, gender, ethnicity, race, pregnancy status, immune system status, kidney function, liver function, cardiac function, nutritional status, and expectations for outcome. These factors act either independently or dependently to help define pharmacotherapeutic risk levels. However, these factors represent only a portion of the equation that determines the level of pharmaceutical care needed.

Risk Factors Associated with the Patient's Disease. Three risk factors contribute to the disease risk associated with a patient's pharmacotherapy. These are the rate (in units of time) at which the disease will harm the patient, the extent (in terms of severity) of the harm caused by the disease, and the patient's perception of the rate and severity of the harm caused by the disease. The latter is an important but often overlooked factor in pharmacotherapy.

Risk Factors Associated with the Patient's Pharmacotherapy. Four risk factors help to define the patient's pharmacotherapeutic risk: (1) the toxicity profile of the pharmacotherapy being undertaken or needed, (2) the adverse drug reaction profile of the pharmacotherapy, (3) the route and technique used for administration, and (4) the patient's perception of the toxicity, adverse reactions, and appropriateness of the pharmacotherapy. For this discussion, toxicity is defined as the extension of the pharmacologic action of the drug; in most cases, it is a dose- or concentration-related phenomenon. Adverse drug reactions are defined as all other negative consequences of the drug,

both preventable and nonpreventable. The toxicity and adverse drug reaction profiles include not only the frequency of the effects but also their severity.

Determining the Level of Pharmaceutical Care Needed

To determine the level of pharmaceutical care needed for a patient, the pharmacist performs the functions described above by collecting data on the patient's clinical characteristics, diseases, and pharmacotherapy. The pharmacist then transforms these data into relevant information through the application of knowledge, judgment, empiricism, heuristics, values, and experience. The result of this cognitive activity is a decision about the relative risk associated with the patient's pharmacotherapy, which will range from slight to significant (with a sense of urgency about the care required). In the practice environment, where the judgment, experience, and values of pharmacists vary, the decision as to what level of care is needed may vary for a given patient. This should not be alarming, since practitioner-to-practitioner variability underlies most "second-opinion" and "utilization review" processes in our health-care system.

The risk associated with the patient's pharmacotherapy, as we have used it to represent the need for pharmaceutical care, is a continuous variable with extremes of no risk and high risk. If we choose to reduce this risk to a nominal or ordinal variable and report patient need on the basis of discrete levels of pharmaceutical care (for example, primary, secondary, and tertiary), then we will lose information about the patient and his or her needs. This should serve as a warning to those who wish to group patient needs into discrete levels of pharmaceutical care. The loss of information about the patient's pharmaceutical-care needs reminds us that there are limitations to creating discrete levels of pharmaceutical care. Perhaps part of our motivation to create levels of pharmaceutical care at this stage is our lack of familiarity with actual patient needs. Defining discrete levels of pharmaceutical care with our current knowledge base interferes with our need to understand the original data from which the levels are constructed and does not ensure that patient needs are met.

Meeting Patient Needs at Different Levels of Pharmaceutical Care

We believe that pharmacists who respond to the needs of patients at minimal risk are providing "primary" pharmaceutical care. Care of such patients may involve, for example, recommending a nonprescription drug, determining a pharmacotherapeutic regimen with an unauthorized protocol, and helping the patient to choose between a generic and a therapeutically equivalent product. Patients at highest risk are often located in a critical-care unit, where the close monitoring of drug therapy is essential. In such situations the pharmacist is a member of a very sophisti-

cated care team working to solve complex and urgent medical and drug-related problems. There are obviously many patients whose risks lie on a continuum between these extremes.

It must be emphasized that since risk is on a continuum, the level of pharmaceutical care is likewise on a continuum. The knowledge, skills, and values required to provide pharmaceutical care increase with the degree of risk and are also on a continuum. The greater the risk, the higher the probability that a pharmacist will become dependent on colleagues for information and support to enable him or her to provide optimal care.

Conclusion

We have argued that patient need is the criterion on which levels of pharmaceutical care should be grounded. Since patient need lies on a continuum, distinguishing among levels of pharmaceutical care is a complex exercise. This discussion has allowed us to clarify the definition of pharmaceutical care, especially as it relates to more traditional pharmaceutical services, and to focus on the cognitive portions of pharmacists' responsibilities for patient care. It shows how technical functions serve to support the important decision-making activities in pharmaceutical care. The difficulty encountered in differentiating among levels of pharmaceutical care shows how comfortable we have become with defining pharmacy practice according to what pharmacists do instead of what the patient needs. It seems evident that we have accumulated very little hard information that describes pharmaceutical-care needs, patient risks related to pharmacotherapy, and the drug-related problems present. Before the concept of levels of pharmaceutical care can be developed any further, this information needs to be collected and evaluated.

Substantially more discussion, research, and critical thinking will be necessary before specific levels of pharmaceutical care should be defined.

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