SPECIAL FEATURES

Transitions, part 1: Beyond pharmaceutical care

ROSS W. HOLLAND AND CHRISTINE M. NIMMO

Abstract: A systems view of the amalgamation of existing pharmacy practice models is proposed.

Pharmacy's evolution is traceable as a series of stages. The stages in pharmacy's evolution have been manufacturing pharmacy, compounding, distribution, clinical pharmacy, and pharmaceutical care. Good pharmacy practice (GPP) represents an international attempt to unite various conceptualizations of practice, including pharmaceutical care. GPP in turn provides a foundation for a model to explain current and changing practice, the total pharmacy care (TPC) model. TPC combines five existing practice models: drug information, self-care, clinical pharmacy, pharmaceutical care, and distribution. TPC, as the sum of these models, asserts that there will be an ongoing need for all five existing models of practice, that the proportion of pharmacists employing each model will reflect the needs of a given health care environment at a given time, and that if changes in health care provide more opportunities for pharmaceutical care, pharmacists will shift increasingly toward that type of practice.

Total pharmacy care is the delivery of a comprehensive range of services that result in the maximum possible contribution to the health of a nation's population within the limits of the health care delivery structure.

Index terms: Clinical pharmacy; Compounding; Health care; History; Manufacturing; Models; Pharmaceutical care; Pharmacy; Pharmacy, community; Pharmacy, institutional, hospital; United States
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This article examines pharmacy practice as it has evolved in the United States and elsewhere. A model is presented that places current and future changes in practice in historical context and shows how the shift to the practice philosophy of pharmaceutical care enhances and optimizes pharmacy's contribution to the health and well-being of a nation's population. The review of the history of change in practice and the discussion of the current state of practice models provide necessary background for those who would make effective use of the Holland–Nimmo practice change model to be discussed later in the "Transitions" series.

The emergence of pharmaceutical care: An adaptive response

Stages in the evolution of pharmacy practice. A brief review of the evolution of pharmacy practice provides context for understanding the current desire for change. We begin with an examination of seminal events in the United States, because practice in this country is representative of the most advanced in the world and because documentation exists to trace its history. Higby[1] has described the evolution of pharmacy practice in the United States over the past 140 years, culminating in the development of pharmaceutical care. The story tells of frequent, dramatic changes in practice spurred by advances in technology, by economic alterations, and by legislation. Between 1860 and the late 1990s, the profession's preferred orientation has moved from manufacturing, to compounding, to distribution, to a more clinical role, and finally to pharmaceutical care. Seen in retrospect, these shifts seem so large as to represent a series of entirely different professions bound only by a common name and an association with a common product, medications.

Our discussion combines, condenses, and reinterprets work by Higby[1] and Hepler[2] to present a broad picture of the five major shifts in pharmacy practice. We acknowledge our subjective and reductionist interpretation of events, intending only to raise awareness of how frequently pharmacists have been required to

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significantly change what they do and the extent of these changes. Figure 1 shows a time line for the stages of practice.

In stage 1, the chief task of pharmacy was manufacturing. Pharmacy began as a cottage industry serving the individual; pharmacists created patent medicines according to their own recipes and prescribed and sold them from their own dispensaries. The apothecary was the equivalent of today's pharmaceutical industry, drugstore, and primary care provider all rolled into one. Both product and process were valued: Patients came to the pharmacist for the medication itself and for advice and guidance on its selection and use. At that time, pharmacy had a clearly defined social value.

In stage 2, with the emergence of the pharmaceutical manufacturing industry, increasing numbers of pharmacists ceased to manufacture drugs and moved to compounding—the mixing of already manufactured drugs according to a prescription—as their primary task. Patients still came to the pharmacist for medications and guidance on the use of patent medicines for self-care. Pharmacy continued to have clearly defined social worth.

In the third stage, the main task of pharmacists diverged, depending on the practice site. Change was most dramatic for pharmacists practicing in the community. Greater availability of manufactured medications and the 1951 Durham-Humphrey Amendment to the 1938 Food, Drug, and Cosmetic Act, which limited who could prescribe and who could advise on the use of medications, confined community pharmacy practice to dispensing. The shift in practice was reflected in the 1952 American Pharmaceutical Association Code of Ethics, which said that an ethical pharmacist does not discuss with patients the therapeutic effects or composition of prescriptions. Further constraints were imposed by community pharmacists' lack of access to the full scope of patient-specific clinical information, patients' caregivers, and drug literature. While focus on the product remained, process faded from the picture. The community pharmacist lost social purpose; "pharmacy became a channel of distribution for the pharmaceutical industry."[2] At the same time, hospital pharmacists functioned primarily in a support role for the management of drug products. Their daily activities were more varied than those of the community pharmacist and included distribution, management, large-volume compounding, teaching of nurses, and participation on pharmacy and therapeutics committees. As in community practice, the emphasis was on the product.

During the fourth stage, community pharmacists resumed providing drug information by way of advice and medication counseling, and hospital pharmacists added clinical pharmacy to the previous role of supporting distribution within the organization. Still product focused, community practitioners added to their dispensing function by providing consultations

on generic substitution and advice on the use of nonprescription medications. Although some community pharmacists moved toward patient-oriented self-care, the social value of community pharmacy as a whole remained weak. Hospital pharmacists, meanwhile, capitalizing on their direct access to patient-specific clinical information, patients' caregivers, and the drug literature, added clinical pharmacy as a means of enhancing the ability of physicians to make good decisions about medications. While physicians maintained responsibility for medication therapy outcomes, pharmacists provided a valuable supporting service founded in their specialized knowledge of the action and use of medications.

Adoption of the clinical pharmacy practice model may be viewed as the beginning of social value for hospital pharmacists. Observed Hepler: "The greatest social value seems to come from the synergy of the drug

Figure 1. Time line of the five stages of major change in pharmacy practice.
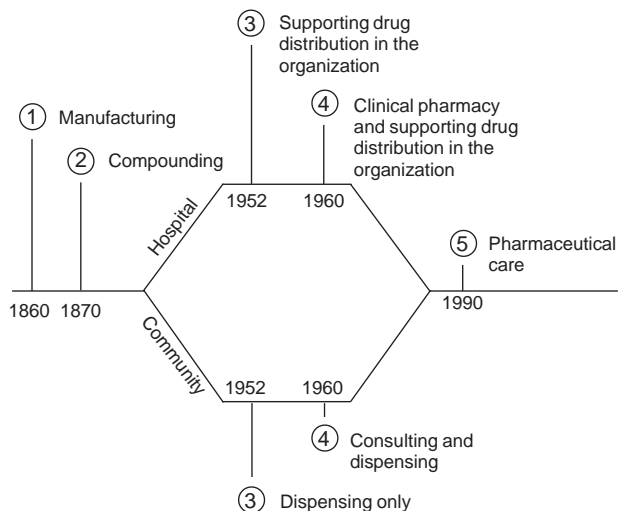
product itself and the intelligence to control its use."[2] A counterargument is that continued physician responsibility did not allow pharmacists to become autonomous, independent practitioners.

Stage 5, pharmaceutical care, is as much dream as reality. Implementation of pharmaceutical care suggests that the tasks associated with practice in the community pharmacy and in the hospital merge. Dispensing remains the foundation. The hospital pharmacist continues to perform the functions of clinical pharmacy, and the community pharmacist performs these functions through such activities as disease management. While the knowledge, skills, and abilities of the pharmacist remain the same as in clinical pharmacy, the orientation of professional attitudes and values is different. A pharmacist practicing pharmaceutical care assumes responsibility for the outcomes of medication therapy. Product remains a necessary and important component of practice, but its role is secondary to the main function, process. With the adoption of pharmaceutical care, one could conjecture that pharmacy would be in the position to fully implement Hepler's notion of "synergy of the drug product itself and the intelligence to control its use" and thus to fully realize the profession's potential for social value.

Higby[1] and Hepler[2] described an evolutionary process in which there is uneven adoption of a new practice model as opportunities for its exercise emerge, rather than a series of abrupt changes in practice occurring simultaneously throughout the profession. Thus, we see today a major proportion of pharmacists in both community and health-system settings who perform solely or primarily distributive functions, the uneven adoption since the 1970s of clinical tasks, and much talk about, but scant performance of, pharmaceutical care functions by either health-system or community pharmacists.[3,4]

Pharmaceutical care: Philosophy, practice, implications. Now that we have reviewed the pattern of significant change in practice that circumstances have required of pharmacists, it is important to define pharmaceutical care and how it differs from clinical pharmacy. In their 1990 call for a change in the mission of pharmacy, Hepler and Strand defined pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life."[5] Hepler further differentiated pharmaceutical care from clinical pharmacy by saying that the former "emphasizes the purpose of the functions over simply performing them . . . Professionals accept responsibility rather than merely provide functions."[2] Thus, the shift from clinical pharmacy to pharmaceutical care as a practice model focuses more attention than previously on the professionalization of the pharmacist. There is a need for pharmacists to assume new practice responsibilities in order to meet the new obligations of pharmacy for "drug use control

. . . governed by awareness of and commitment to the patient's interest."[2] For some pharmacists already embracing a clinical pharmacy practice model, the shift to pharmaceutical care is primarily a change in attitude.[6] For others, still in a distributive role, it signals a major change in knowledge and skills as well.

Change in the practice of pharmacy is taking place in an environment in which other health care professionals are similarly seeking to redefine their roles as systems for the delivery of care change. As in past transitions in practice, the reorganization of pharmacy under pharmaceutical care includes practice patterns that extend the pharmacist's role into some areas traditionally occupied by physicians. Central to this extension of territory into the management of drug therapy has been the emphasis by pharmacists on their stronger professional preparation than that of physicians in the area of drugs. This argument is the bulwark of the pharmacy profession's response to society's demand for better value for health care dollars: suggesting that pharmacists' contributions to care can improve outcomes and cut costs.[7]

Wertheimer, speaking at the international congress of the International Pharmaceutical Federation (FIP) foresaw potential physician–pharmacist conflict as pharmacists sought independent prescribing authority and the right to independently order laboratory tests.[8] Lambert[9] noted the turf-threatening professional-identity issues generated by pharmacy's new role definition. The 1997 position statement of the Infectious Diseases Society of America (IDSA) is but one example of predictions such as Lambert's coming true:

> Members of the IDSA wish to encourage a positive cooperative effort between infectious diseases physicians and pharmacists, but it is the opinion of the members that therapeutic decisions and recommendations should be made by physicians and that pharmacists who receive requests for such information should refer the requests to appropriately trained physicians.[10]

IDSA argued that selecting specific drugs and the route and setting of their administration requires competence in the practice of medicine, and that clinical pharmacists do not have this expertise and in particular lack the ability to "interpret the adequacy and significance of historical, physical, laboratory, and radiographic findings for individual patients."[10]

While some may view U.S. pharmacy as being at the forefront of practice evolution and, therefore, a model for pharmacy professionals in other nations seeking to advance their practice level, resistance by other U.S. health care providers to pharmacy's desired new role suggests that its achievement is not guaranteed. Part 3 of the "Transitions" series will offer a perspective on the role of leadership in facilitating acceptance of practice change.

Global perspective on the evolution of practice. Outside the United States, pharmacy practice has

also been evolving—sometimes in different directions. One major movement has been the emergence of self-care as a practice focus. This trend originated at a 1978 conference of the World Health Organization where enunciation of the concept of "health for all by the year 2000" included articulation of the idea that people must take charge of their own health through a process of self-care.[11] The idea was seen as having universal applicability, although at different levels in different cultures. Some countries, notably Australia, England, and New Zealand, have adopted the self-care approach.

Self-care includes activities associated with "advice about and, where appropriate, the supply of a medicine or other treatment for symptoms of ailments that lend themselves to self-treatment."[12] Like pharmaceutical care, self-care developed first as a philosophy of practice. Self-care diverges from pharmaceutical care in that the individual takes total control of and responsibility for his or her health care in a manner that may be characterized as self-reliant, self-directed, and discriminating in the use of health services.

In the implementation of self-care, pharmacy has an important role to play in facilitating individual choice, and self-care has gained a strong foothold as a pharmacy practice model. But the trend toward self-care has not been universal. In the United States, 1950s legislation categorizing all but the least potent of medications as prescriptive and to be recommended and discussed only by physicians delayed the appearance of U.S. pharmacists as major players on the field of self-care. Recent acceleration in prescription-to-nonprescription switches,[13] however, is effecting a predicted increase in self-care participation by U.S. pharmacists.[14]

Good pharmacy practice (GPP) represents an international attempt to bring various conceptualizations of practice together. Beginning in 1991, FIP began developing standards for GPP that embody a number of roles for pharmacy, including pharmaceutical care. The initiative reflected a worldwide response by pharmacy's leadership to the changes in health care delivery systems and the need for pharmacy to reorganize and redefine its role accordingly.

In the 1993 "Tokyo declaration" on GPP, FIP stated: "The mission of pharmacy practice is to provide medications and other health care products and services and to help people and society to make the best use of them."[12] The Tokyo declaration speaks to both product and process issues and includes not only the perspective of the individual patient but also that of society. It addresses prevention and responsibility for outcomes.

GPP, as endorsed by FIP, separates pharmacy practice into four distinct fields with associated practice responsibilities; one of those fields is pharmaceutical care. The four fields and the responsibilities are as follows:

1. *Health promotion and ill-health prevention.* The responsibilities are to ensure that facilities provided for counseling facilitate confidentiality, provide general advice to health care consumers on health matters in group and individual settings, contribute the pharmacy perspective to the design and delivery of public wellness campaigns, and ensure the quality of diagnostic equipment and advice given in diagnostic testing.

2. *Supply and use of prescribed medicines and other health care products.* The responsibilities are to ensure the integrity of a prescription; ensure that a prescription is appropriate for the individual and that it meets therapeutic, social, legal, and economic requirements; secure medications and ensure the quality and accuracy of medications dispensed; counsel patients on medication use; monitor the effects of medication use; and document professional activities.

3. *Self-care.* The responsibilities are to assess the individual's need, recommend efficacious and safe products, make needed referrals, and engage in appropriate follow-up activities.

4. *Influencing prescribing and medicine use.* The responsibilities are to contribute the pharmacy perspective to formulary decisions, educate prescribers regarding their individual prescribing patterns, evaluate patterns of medication use, evaluate materials promoting medication use, evaluate and disseminate medication-related information to health care professionals, and provide medication-related educational programs to other health care providers.

GPP was endorsed, but could it be implemented worldwide? Beginning in 1995, FIP's Community Pharmacists' Section acknowledged the need to address the wide variability in conditions of pharmacy practice by establishing the FIP Community Pharmacy Section Working Group II to provide guidelines for staged development of GPP. That group's work, "Draft Guidelines for Good Pharmacy Practice (GPP) in Developing Countries," will be considered by the section council in 1999. The working group's purpose was to address health care services in developing countries, as well as differences in services within countries. The preamble to the group's draft recommendations points out that some countries have few to no persons with formal training in pharmacy and that there may be significant differences in services between urban and rural areas. The document advocates a stepwise approach to raising the level of practice in some countries, since GPP standards may not be relevant there until practice has advanced to certain levels. In such countries, the practice of pharmaceutical care, as we define it, is a distant goal.

Total pharmacy care: A model for the future

Pharmacy's leadership is clear about the future direction of the profession: Pharmacy is to adopt the practice philosophy of pharmaceutical care. However, nations, regions within nations, and individual practice sites have widely varying levels of pharmacy practice, and adoption of new concepts like pharmaceutical care has

often been slow. Furthermore, technology, while a vital tool for pharmaceutical care, has not yet freed and may never completely free the pharmacist from responsibilities for drug preparation and distribution. Practicing pharmacists are being urged to change their practice, but many do not have a clear picture of how the new practice model is to fit into current reality. A problem for pharmacy's leadership, then, in the implementation of practice change is communicating the objectives and expectations of pharmaceutical care in a way that connects with the experience of the individual frontline pharmacist.

GPP has helped provide a worldwide perspective on pharmacy's role and contributions, but the initiative is focused on the development of national standards, and as such it neither accounts for ongoing shifts in practice nor speaks to the individual practitioner. In addition, GPP does not address the interrelationships among the four fields of practice it defines. Therefore, GPP can serve as a solid conceptual foundation but not as the building itself.

Pharmacy needs a descriptive model of practice that allows pharmacists to see not only the individual elements but also the big picture. Such a model must let individuals see how they fit into the larger scheme, accommodate individual differences in health care delivery systems and individual practice sites, account for ongoing change, and be applicable worldwide.

Total pharmacy care (TPC) is a model for pharmacy practice that addresses all the important communication issues from a system perspective (Figure 2). The model presents the current practice of pharmacy as an amalgam of five distinct practice models: drug informa-

tion, self-care, clinical pharmacy, pharmaceutical care, and distribution. The model shows all five submodels as concurrently operational. TPC, as the sum of the contributions of the five existing models, represents a comprehensive range of services that make the maximum possible contribution to the health and well-being of a nation's population within the limits of the country's current health care delivery structure.

Beginning with drug information and ending with either self-care or distribution, the positions in Figure 2 of the five existing practice models indicate their sequential contributions. There is feedback to drug information from the other forms of practice except self-care. The percentage of pharmacists in a given setting engaged in each model of practice will vary according to current needs. Figure 2 does not include the managerial role; it addresses only the practice models that provide direct services to patients. As with the five major shifts in pharmacy practice discussed earlier, the TPC model of practice is necessarily reductionist.

The TPC model assumes that each of the models on which it is based is defined by its own set of tasks. Three observations are necessary here. First, the five practice models follow the categories of GPP closely, but not identically. In particular, GPP does not single out clinical pharmacy and deals separately with the tasks of health promotion and influencing prescribing and medicine use; TPC, however, regards most of the associated tasks in these two GPP fields as falling within the drug information model of practice. Second, TPC focuses on practice itself and not on the management of practice. Third, the list of tasks associated with each model of practice is generalized. The tasks are as follows:

Figure 2. Total pharmacy care depicted as the synthesis of five existing pharmacy practice models. Solid lines show the flow of pharmacy services to patients, and dotted lines indicate feedback paths to the drug information practice model.
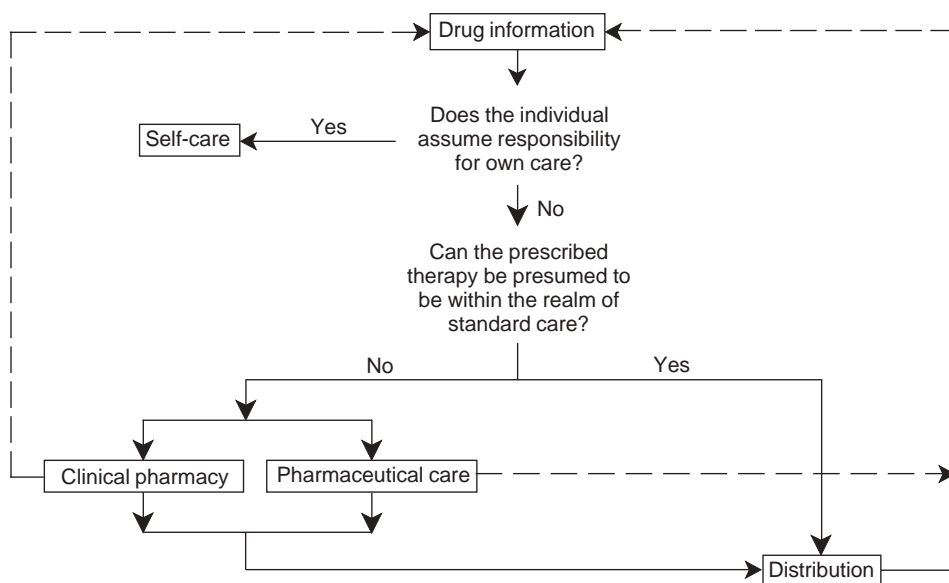
1. *Drug information practice model.* The tasks are to provide general advice to health care consumers on health matters in group settings, contribute the pharmacy perspective to the design and delivery of public wellness campaigns, contribute the pharmacy perspective to formulary decisions, educate prescribers about their individual prescribing patterns, evaluate patterns of medication use, evaluate materials promoting medication use, evaluate and disseminate drug information, provide education-related educational programs for other health care professionals, and provide patient-specific drug information.
2. *Self-care practice model.* The tasks are to provide general advice to health care consumers on health care matters in individual settings, assess the individual's need, recommend safe and efficacious products, and make needed referrals.
3. *Clinical pharmacy practice model.* The task is to contribute to the physician's therapeutic management of a patient by providing one or more clinical services, such as drug information, pharmacokinetic dosing, or taking a drug history or by modifying or designing, recommending, monitoring, and evaluating the patient's pharmacotherapy.
4. *Pharmaceutical care practice model.* The tasks are to assume responsibility, on the patient care team, for modifying or designing, recommending, monitoring, and evaluating a patient's pharmacotherapy, and to ensure the outcomes of the pharmacotherapy provided.
5. *Distributive practice model.* The tasks are to ensure the integrity of a prescription; ensure that a prescription is appropriate for the individual and that it meets therapeutic, social, legal, and economic requirements; secure medications and ensure the quality and accuracy of medications dispensed; counsel patients on medication use; and document professional activities.

Total pharmacy care accounts for ongoing change in the relative contributions of the five existing models as the time individual pharmacists spend practicing within the models changes with needs and opportunities. It is assumed that, if the philosophy of pharmaceutical care pervades the profession, individuals will influence their environments to allow the provision of this type of care. The proportion of pharmacists who practice pharmaceutical care will thus ultimately increase. TPC does not, however, suggest that pharmaceutical care will be the only acceptable practice model. Instead, it presents a view of all pharmaceutical services required to meet a population's needs that require pharmacists functioning in all five practice models. Hepler, too, recognized the need for a multiplicity of models: "The practice of pharmacy includes professional activities that do not fall within pharmaceutical care."[6]

TPC also accounts for the likelihood that pharmacists will continue to bear responsibility for the distribution of medications, although the pharmacist's tasks may change from hands-on duties to managing skilled personnel and implementing technology. Likewise, the model allows for a continuing need for pharmacists who operate primarily in the areas of drug information, clinical intervention, and self-care. In other words, TPC says that it is the sum of different practice contributions, and not the exercise of pharmaceutical care alone, that will maximize pharmacy's contribution to a nation's health and well-being. Remaining intact is the underlying hope that, over time, all pharmacists will adopt pharmaceutical care—the belief that the mission of pharmacy includes at least partial assumption of responsibility for the outcomes of patient care—and the belief that pharmaceutical care should influence every activity the pharmacist engages in, be it direct patient care or not.

TPC is based on the perspective of the individual receiving care. Pharmacists who wish to use the model to understand their present and future roles in practice must extrapolate from the model to accommodate the practitioner's perspective. Using the model as a communication device that will make sense to the individual pharmacist is a two-step process. First, pharmacists must be encouraged to view the model from their individual perspective and to identify the characteristics of their own current practice. Some pharmacists will identify their practice as using only one model; others will see it as employing two or more. In the second step, pharmacists should analyze their environment and reflect on what is needed to provide TPC and how the proportions of pharmacists using the various practice models would change if pharmacists were contributing maximally to positive patient care outcomes. For example, a pharmacist might conclude that his or her practice is a mixture of roughly 90% distribution and 10% clinical pharmacy. However, in a group discussion with all other members of the pharmacy department who had similarly analyzed the makeup of their practices, the consensus might be that the department would improve its contribution to patients' health care outcomes if there were a 10% across-the-board increase in all pharmacists' use of the clinical pharmacy model. The results of such individual analysis should generate a clearer understanding of personal necessity for practice change and the areas in which such change can be most effective in maximizing one's contribution to the overall picture. The TPC model can, therefore, serve as a useful tool for leadership in facilitating individual decision-making for changes in practice.

Simultaneously, the TPC model can be of use to leaders for determining the disposition of available pharmacists among the five practice models and thus for maximizing contributions to care in current and future environments. TPC can be an effective tool both for current decision-making and for long-range planning.

Looking ahead

In reviewing the TPC model, we can make predictions about coming shifts in the demands of practice.

First, provided that the responsibility for drug distribution remains with pharmacy, the distributive model will never completely disappear, although the nature of the work performed may alter dramatically as technology continues to mechanize the process. In addition to significant change in the tasks of the distributive model, the proportion of pharmacists engaged in this type of practice will predictably decrease dramatically. Second, for countries that move to managed care as the dominant health care delivery system, the proportional demand for pharmacists employing the drug information practice model is likely to increase. Third, as the treatment of patients shifts from the acute care to the ambulatory care environment and as consumers increasingly conditioned to managed care come to see themselves as the primary managers of their care, the proportion of pharmacists employing self-care as their practice model is likely to increase, even in the United States. Fourth, health care teams and patients who come to value pharmaceutical care may move away from wanting clinical pharmacy practitioners. Finally, if the demand for pharmaceutical care increases, more pharmacists will be required to shift to this practice model.

In "Transitions, Part 2," we will discuss the distinctions among the five practice models contributing to TPC with respect to knowledge, skills, and attitudes. This will provide a basis for examining the requirements for retraining as the profession engages in practice change.

Conclusion

Total pharmacy care is the delivery of a comprehensive range of services that result in the maximum possible contribution to the health and well-being of a nation's population within the limits of the country's current health care delivery structure. The TPC model incorporates five existing practice models—drug information, self-care, clinical pharmacy, pharmaceutical care, and distribution.

References

1. Higby GJ. American pharmacy in the twentieth century. *Am J Health-Syst Pharm.* 1997; 54:1805-15.
2. Hepler CD. The third wave in pharmaceutical education: the clinical movement. *Am J Pharm Educ.* 1987; 51:369-85.
3. Ringold DJ, Santell JP, Schneider PJ et al. ASHP national survey of pharmacy practice in acute care settings: prescribing and transcribing—1998. *Am J Health-Syst Pharm.* 1999; 56:148-57.
4. Odedina PT, Segal RS, Hepler CD et al. Changing pharmacists' practice pattern: pharmacists' implementation of pharmaceutical care factors. *J Soc Adm Pharm.* 1996; 13(2):74-88.
5. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990; 47:533-43.
6. Hepler CD. Philosophical issues raised by pharmaceutical care. *J Pharm Teach.* 1996; 5(1-2):19-47.
7. Johnson JA, Bootman JL. Drug-related morbidity and mortality and the economic impact of pharmaceutical care. *Am J Health-Syst Pharm.* 1997; 54:554-8.
8. Gebhart F. M.D.-R.Ph. cooperation called a matter of survival. *Drug Top.* 1997; 141(Oct 6):42.
9. Lambert BL. Face and politeness in pharmacist-physician interaction. *Soc Sci Med.* 1996; 43:1189-98.
10. Position statement from the Infectious Diseases Society of America: hospital pharmacists and infectious diseases specialists. *Clin Infect Dis.* 1997; 25:802.
11. Primary health care report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, jointly sponsored by the World Health Organization and the United Nations Children's Fund. Health for all series no. 1. Geneva, Switzerland: World Health Organization; 1978
12. Good pharmacy practice in community and hospital pharmacy settings: annex 7 to the thirty-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. WHO technical report series, no. 885. Geneva, Switzerland: World Health Organization; 1999:93-101.
13. Bachrach EE. The FDA's new over-the-counter drug office and advisory committee: an industry perspective. *Food Drug Law J.* 1993; 48:563-6.
14. Newton G, Popovich NG, Pray WS. Rx-to-OTC switches: from prescription to self-care. *J Am Pharm Assoc.* 1996; NS36:489-95.