

Opportunities and responsibilities in pharmaceutical care

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Abstract: Pharmacy's opportunity to mature as a profession by accepting its social responsibility to reduce preventable drug-related morbidity and mortality is explored.

Pharmacy has shed the apothecary role but has not yet been restored to its erstwhile importance in medical care. It is not enough to dispense the correct drug or to provide sophisticated pharmaceutical services; nor will it be sufficient to devise new technical functions. Pharmacists and their institutions must stop looking inward and start redirecting their energies to the greater social good. Some 12,000 deaths and 15,000 hospitalizations due to adverse drug reactions (ADRs) were reported to the FDA in 1987, and many went unreported. Drug-related morbidity and mortality are often preventable, and pharmaceutical services can reduce the number of ADRs, the length of hospital stays, and the cost of care. Pharmacists must abandon factionalism and adopt pa-

tient-centered pharmaceutical care as their philosophy of practice. Changing the focus of practice from products and biological systems to ensuring the best drug therapy and patient safety will raise pharmacy's level of responsibility and require philosophical, organizational, and functional changes. It will be necessary to set new practice standards, establish cooperative relationships with other health-care professions, and determine strategies for marketing pharmaceutical care.

Pharmacy's reprofessionalization will be completed only when all pharmacists accept their social mandate to ensure the safe and effective drug therapy of the individual patient.

Index terms: Health care; Health professions; Patient care; Pharmacists; Pharmacy; Pharmaceutical services; Rational therapy; Toxicity
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The profession of pharmacy has experienced significant growth and development over the past 30 years. To critically reflect on pharmacy's future opportunities and responsibilities as a clinical profession, it is instructive to briefly examine the three major periods in twentieth-century pharmacy: the traditional, transitional, and patient-care stages of development. Within each stage we can discern different conceptions of pharmacy's functions and obligations, that is, different models of the social role of pharmacy. These stages are somewhat arbitrary but are consistent with the sequence de-

scribed by Hepler.¹

Pharmacy entered the twentieth century performing the social role of apothecary—preparing and selling medicinal drugs. During this traditional stage the pharmacist's function was procuring, preparing, and evaluating drug products. His^a primary obligation was to ensure that the drugs he sold were pure, unadulterated, and prepared *secundum artem*, although he had a secondary obligation to provide good advice to customers who asked him to prescribe drugs over the counter. The traditional role began to wane as the preparation of

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pharmaceuticals was gradually taken over by the pharmaceutical industry and as the choice of therapeutic agents passed to the physician. The pharmacist's professional role was narrowly constrained. On one side, the American Pharmaceutical Association (APhA) code of ethics of 1922–1969 prohibited the pharmacist from discussing "therapeutic effects or composition of a prescription with a patient." On the other side, the 1951 Durham-Humphrey amendment to the Food, Drug and Cosmetic Act, which introduced prescription-only legal status for most effective therapeutic agents, relegated the pharmacist to the role of dispenser of prefabricated drug products.

Clinical pharmacy practice was born in the mid-1960s. There began a period of professional transition in which pharmacists sought self-actualization—the full achievement of their professional potential. The transitional stage was a time of rapid expansion of functions and of increased professional diversity, driven by individualistic, sometimes zealous, pioneers.² Pharmacists not only began to perform functions that were new to pharmacy, they began to innovate functions and to make original contributions to the literature.¹ It seemed that by moving to the bedside, pharmacy might finally be restored to its erstwhile importance in medical care.

The popular motto of "patient-oriented practice," however, had many different meanings. Moreover, some proposed definitions of clinical pharmacy practice placed drugs at the forefront and only mentioned the patient. Brodie's³ call for "drug-use control" appears to have been understood by many to advocate the profession's preoccupation with product rather than person, while his presentation of these ideas in terms of social responsibility for patient care seems to have been overlooked. In addition, new pharmaceutical services (e.g., clinical pharmacokinetics) evolved, which, while moving pharmacy closer to the patient, continued to focus on the drug and its delivery to abstract biological systems rather than to individual patients.

This introspective transitional stage, in which pharmacy pursued professional identity and legitimation, was perhaps both an unavoidable response to the disappearance of the apothecary role and a necessary forerunner of professional maturation. Many pharmacists had to develop new, socially necessary functions and then test their competence to perform them. Unfortunately, these new, self-actualizing clinical functions have been slow to penetrate the profession. Although many pharmacists fervently express their desire to perform them, others seem to prefer the status quo. Likewise, some pharmacy organizations support expanded functions and others oppose them. Pharmacy today appears as a collection of disputatious factions and splinter groups, still "a profession in

search of a role," but now a profession unable to choose from a bewildering variety of functions and unable to overcome a variety of "barriers to clinical practice."⁴

We will not solve this problem by introspection. It will not help to clarify, list, or debate more functions for pharmacy. The element that is missing as we define our role during this period of transition is our conception of our responsibility to the patient. Some pharmacists have not yet identified patient-care responsibilities commensurate with their extended functions, and the profession as a whole has made no clear social commitment that reflects its clinical functions. Some pharmacists will remain mired in the transitional period of professional adolescence until this step is taken.

Pharmaceutical services like pharmacokinetic dosing, therapeutic monitoring, and drug information may extend functions, legitimate competence, and generally enhance professional status, but unless they are carried out in a context of professional responsibility for patient welfare, they cannot constitute a professional role. In Cipolle's⁵ words, drugs do not have doses, patients have doses. Pharmaceutical practice must restore what has been missing for years: a clear emphasis on the patient's welfare, a patient advocacy role with a clear ethical mandate to protect the patient from the harmful effects of what Manasse^{6,7} termed drug misadventuring.

Pharmacy's leaders are correct in seeking pharmacy's fundamental role. Certainly, a profession with a well-defined identity and a clearly articulated purpose has more to offer the commonweal than one that continues to be encapsulated in introspective factionalism. Pharmacy's social and professional purpose should be clearly delineated as first and foremost clinical. This must be its essential *raison d'être*, for, in our view, there is no viable alternative. In addition to supporting the functionalist conception of clinical pharmacy, however, pharmacists must be prepared to assume responsibility for pharmaceutical health care writ large. To do otherwise is to abdicate the ethical imperatives that go hand in hand with pharmacists' educational and professional preparation.

Many pharmacists are standing at the threshold of professional maturation; indeed, many have crossed over that threshold into the patient-care stage. Professional maturity has much in common with maturity as a person. One attribute common to both is a world view, an expectation that one thrives best by using one's power to serve something bigger than oneself. Another attribute common to both is acceptance of responsibility for one's actions. Some pharmacists understand both of these concepts but have been unable to cross the threshold because they cannot see opportunity. There are limits to what individual professionals can accomplish in our corporate and collectively

controlled world. The great majority of pharmacists need the support of pharmacy organizations, educational institutions, and corporate employers to advance into professional maturity. If these institutions and organizations should continue to look inward, asking only what is good for them or the profession, the majority will surely continue to experience the pain of arrested development. If, on the other hand, these institutions and organizations are ready to ask what pharmacy can do to serve a higher good, the answer is waiting for them. There exists today a dire problem in medical care that urgently requires expert attention—namely, that of preventable drug-related morbidity and mortality.

Drug-Related Morbidity and Mortality: Incidence and Cost

Talley and Laventurier⁸ estimated that 140,000 patients died and 1 million were hospitalized in the United States in 1971 because of adverse drug reactions (ADRs). More recently, Manasse^{6,7} reviewed the literature on drug misadventuring and concluded that a serious problem exists. Some 12,000 deaths and 15,000 hospitalizations due to ADRs were reported to the FDA in 1987, but the reported number of adverse reactions may be a small fraction—perhaps only 10%—of the true number.^{6,7} The cost of drug-related morbidity in the United States has been estimated to be as high as \$7 billion annually.⁹

Why should the incidence and cost of drug-related morbidity cause pharmacists to make dramatic changes in their attitudes and behavior? Because pharmacists are seeking a new professional mandate and a new professional mission. The concept of a professional mandate requires that we understand what society needs from pharmacists, and our mission is our commitment to meeting that need. Given that drug-related morbidity represents a costly social problem, several questions must be answered before pharmacy is ready to claim its mandate and state its mission. What exactly is the phenomenon of drug-related morbidity and mortality, and what does it have to do with pharmacy? Can some drug-related morbidity and mortality be prevented at an acceptable cost? Can pharmacists help to prevent these incidents?

Causes and Definitions

Drugs are administered for the purpose of achieving definite outcomes that improve the patient's quality of life. These outcomes are (1) cure of a disease, (2) reduction or elimination of symptoms, (3) arresting or slowing of a disease process, and (4) preventing a disease or symptoms. However, whenever drugs are given, the potential for outcomes that diminish the patient's quality of life

is always present. These less than optimal outcomes can result from the following causes:

1. Inappropriate Prescribing
 - Inappropriate regimen (inappropriate drug, dosage form, dose, route, dosage interval, or duration)
 - Unnecessary regimen
2. Inappropriate Delivery
 - Drug not available when needed because of (1) economic barriers (e.g., pharmacy does not stock drug, patient will not or cannot purchase it), (2) biopharmaceutical barriers (e.g., inappropriate formulation), or (3) sociological barriers (e.g., institutional drug distribution system or patient caretaker fails to administer drug)
 - Dispensing error involving (1) incorrect or inappropriately labeled prescription or (2) incorrect or missing patient information or advice
3. Inappropriate Behavior by the Patient
 - Compliance with inappropriate regimen
 - Noncompliance with appropriate regimen
4. Patient Idiosyncrasy
 - Idiosyncratic response to the drug
 - Mistake or accident
5. Inappropriate Monitoring
 - Failure to detect and resolve an inappropriate therapeutic decision
 - Failure to monitor the effects of the treatment regimen on the patient

Of the five basic causes of suboptimal patient outcomes, inappropriate monitoring may be the most important and least appreciated. Many causes of unsatisfactory outcomes can be detected by careful monitoring.

Drug-related morbidity is the phenomenon of therapeutic malfunction or miscarriage—the failure of a therapeutic agent to produce the intended therapeutic outcome. The concept includes both treatment failure (e.g., failure to cure or control a disease) and production of new medical problems (e.g., an adverse or toxic drug effect). Drug-related morbidity is the clinical or biosocial manifestation of unresolved drug-related problems and may be recognized by the patient, a caretaker, or a clinician. If not recognized and resolved, drug-related morbidity (manifested as either treatment failure or a new medical problem) can lead to drug-related mortality, the ultimate therapeutic miscarriage.

Drug-related morbidity is often preceded by a drug-related problem. A drug-related problem is an event or circumstance involving drug treatment that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care. Strand et al.¹⁰ identified eight categories of drug-related problems:

1. *Untreated Indications.* The patient has a medical problem that requires drug therapy (an indication for drug use) but is not receiving a drug for that indication;
2. *Improper Drug Selection.* The patient has a drug indication but is taking the wrong drug;
3. *Subtherapeutic Dosage.* The patient has a medical

problem that is being treated with too little of the correct drug;

4. *Failure To Receive Drugs.* The patient has a medical problem that is the result of his or her not receiving a drug (e.g., for pharmaceutical, psychological, sociological, or economic reasons);
5. *Overdosage.* The patient has a medical problem that is being treated with too much of the correct drug (toxicity);
6. *Adverse Drug Reactions.* The patient has a medical problem that is the result of an ADR or adverse effect;
7. *Drug Interactions.* The patient has a medical problem that is the result of a drug-drug, drug-food, or drug-laboratory interaction; and
8. *Drug Use without Indication.* The patient is taking a drug for no medically valid indication.

Preventability of Drug-Related Morbidity and Mortality

Some drug-related morbidities that result from the drug-related problems described above are unpredictable, often because the morbidity is idiosyncratic (i.e., occurs for some unrecognized, patient-specific reason). The first occurrence of an allergic ADR in a patient is an example. Patient idiosyncrasy, however, is only one of the five basic causes of drug-related morbidity listed earlier. Other drug-related morbidities are quite predictable and may therefore be preventable. For example, many drugs have well-recognized dosage ranges, and if a patient has a toxic reaction while receiving a dose much higher than usual, one might be justified in judging the toxicity to have been preventable.

There is a large gray area of possibly preventable drug-related morbidities, as suggested by four of the five possible causes. Of these, inappropriate monitoring appears especially important. For example, one might judge the second occurrence of an idiosyncratic drug reaction to have been preventable if the first could have been discovered by proper patient interviewing or appropriate use of records.

There are three logical elements in defining the concept of preventable drug-related morbidity. First, the drug-related problem must be recognizable and the likelihood of an undesirable clinical outcome must be foreseeable. Second, the causes of that outcome must be identifiable. Third, those causes must be controllable. Therefore, the actual classification of a drug-related morbidity as preventable depends on one's standard of care. That is, under more stringent standards of care, more drug-related morbidities would be classified as preventable.

In the studies described below, experts reviewed medical records to identify drug-related morbidity and mortality and, with one exception, to classify them as preventable or not preventable. These investigators did not define a standard of care or

provide criteria for preventability.

In 1976 McKenney and Harrison¹¹ reported that 59 (27%) of 216 admissions to a general medical-surgical unit involved drug-related problems. Of these, 24 admissions involved ADRs and 35 involved noncompliance, overdosage, or inadequate therapy. Stewart et al.¹² reported that 20% of admissions to a psychiatric service were attributable to noncompliance, adverse effects, or overdosage. Neither report described the admissions as preventable, but most hospital admissions for noncompliance, overdosage, and inadequate therapy, and many admissions for the treatment of adverse effects of psychiatric drugs, would seem preventable by relatively simple drug therapy-monitoring arrangements.

Burnum¹³ identified 42 ADRs in a series of 1000 patients (724 office patients and 276 hospital patients). He classified 23 of the ADRs as avoidable and commented that six avoidable reactions directly involved pharmacy.

In two studies in French hospitals, Trunet and his coworkers examined admissions from acute care to intensive care. Their first (1980) report¹⁴ showed that 4.3% of 325 admissions were due to preventable ADRs or therapeutic error, while their second (1986) report¹⁵ on a separate series of 1651 admissions showed that 2.6% were preventable and drug related. Preventable admissions accounted for about half (61% for the 1980 study and 44% for the 1986 study) of all the drug-related admissions.

Lakshmanan et al.¹⁶ studied 834 admissions to the medical service of an Ohio hospital for July and August 1984. They identified 35 drug-related admissions (4.2%), of which 17 (2% of the total) were deemed preventable. Again, about half of all the drug-related morbidities were judged preventable.

Ives et al.¹⁷ looked at patients who were enrolled in a family practice center and affiliated practices. Of 293 admissions to a family medicine unit, 17 involved ADRs; only two of these were considered preventable. The family practice residency in which this study was done uses clinical pharmacists as an educational resource. The authors made no claim in this regard, but it is possible that the educational efforts explain in part the low incidence of preventable drug-related admissions in this study.

In 1977 Porter and Jick¹⁸ reported a drug-related death rate in the United States of 1.2 deaths per 1000 hospital admissions—a close second to the drug-related death rate in New Zealand. The study showed that about 1% of hospital admissions led to drug-related deaths, of which about 25% were preventable. The authors were quite conservative and may have omitted some drug-related deaths. More recently, Dubois and Brook¹⁹ studied preventable deaths in 12 hospitals. A majority of the medical reviewers classified 17 of 70 deaths in patients with

pneumonia as preventable; about half of the preventable deaths were due to inadequate fluid management or improper choice of antimicrobials. Nine of 50 deaths in patients with cerebrovascular accidents were preventable, and two of the nine deaths were attributed to inadequate fluid management or inadequate management of sepsis. There were 23 preventable deaths in patients with myocardial infarction. Of these, four were judged to be due to inadequate fluid management, two were due to inadequate control of cardiac arrhythmias, and one was due to inadequate management of sepsis.

There were basic methodological problems with most of these studies. None of the investigators fully defined the concept of preventability; rather, they left the decision up to one or more medical record reviewers. Treatment failure²⁰ appears to have been excluded or underrepresented relative to ADRs, adverse effects, and toxicities. Incidences in particular samples were not adjusted for a typical age, sex, or diagnostic mix of patients. For these and other reasons, it is difficult to generalize about the prevalence of preventable drug-related morbidity or mortality in a typical patient population. Nonetheless, in four studies, about half of all drug-related morbidities were judged preventable. Even if treatment failures are ignored, the preventability of half of all ADRs points out a serious medical-care problem.

Costs of Preventable Drug-Related Morbidity and Mortality

It is also difficult to generalize about the cost of preventable drug-related morbidity and mortality. Common sense suggests that drug-related morbidity that results in physician office visits or hospital admissions, or that prolongs hospital length of stay (LOS), is quite expensive, and some studies confirm this.

Knapp and coworkers²¹ showed that the appropriateness of drug therapy might be related to LOS. They used explicit appropriateness criteria to evaluate the drug therapy given to patients with pyelonephritis. Patients whose antimicrobial therapy met appropriateness criteria had an average LOS two days shorter than patients whose therapy did not satisfy those criteria ($p < 0.05$).^b In a similar study by Knapp et al.,²² the mean difference in LOS between patients whose therapy met appropriateness criteria and patients whose therapy did not was 2.2 days for patients with pneumococcal pneumonia ($p < 0.05$) and 1.2 days for patients with pyelonephritis ($p < 0.05$). In these studies it was found that inappropriate prescribing often constituted undertreatment.

Drug toxicity increases the costs of care. Eisenberg et al.²³ reviewed the medical records of 1756 patients who had received aminoglycosides and

found that 7.3% of them developed aminoglycoside nephrotoxicity. The mean total additional cost was \$2501 per patient with aminoglycoside-associated nephrotoxicity, or \$183 per patient receiving aminoglycosides.

The prevalence of drug-related morbidity, the evidence that much of it is preventable, and the evidence that preventing it may actually decrease total costs while improving quality of care clearly establish the element of social need. Much of the problem is not inherent in the drug products themselves but in the way they are prescribed, dispensed, and used by patients. The next question, then, is whether pharmacists have the skills and knowledge to decrease this problem in our society.

Impact of Pharmaceutical Services

We are aware of no study directly relating the prevalence of preventable drug-related morbidity and mortality to the type of pharmaceutical services provided. There is, however, research showing that pharmaceutical services can greatly reduce the total cost of care and the length of hospitalization. Connecting this literature and the literature on preventable drug-related morbidity requires some interpolation. First, there are many papers documenting that pharmaceutical services can contribute to improved clinical outcomes.²⁴ Second, one early study does support a theoretical connection between preventable drug-related morbidity and LOS.

McKenney and Wasserman²⁵ reported on a study done as part of the Boston Collaborative Drug Surveillance Program. Nurse observers monitored ADRs and collected LOS data for two 20-bed study units during three 30-day observation periods (October 1973, February 1974, and September 1974). In the first period drugs were distributed to inpatients according to an inpatient prescription procedure, with limited "floor stock." There was no pharmacist review of drug therapy. In the second period the drug distribution system was continued, and four pharmacists regularly evaluated the appropriateness of drug therapy and routinely consulted with nurses or prescribers to resolve any problems they detected. In the third period the pharmacist evaluations and consultations continued, and the drug distribution system was changed to a unit dose procedure.

Mean \pm S.D. LOS was 12.0 ± 8.7 , 7.6 ± 5.9 , and 8.3 ± 7.0 days in periods 1 ($n = 77$), 2 ($n = 64$), and 3 ($n = 73$), respectively, and ADR incidence was 21%, 16%, and 8%, respectively. The decline in LOS and in ADR incidence is consistent with the finding that patients who experienced an ADR stayed in the hospital 50% to 80% longer than patients who did not have one. The primary importance of these data is that they suggest a relationship between ADRs and LOS. They may also suggest that phar-

maceutical services affect LOS by affecting ADR rates, but other explanations are also plausible because of the time-series design of the study.

Other studies have also suggested an association between changes in pharmaceutical services and reductions in LOS. Herfindal et al.²⁶ evaluated the effect of pharmacists' interventions on prescribing in orthopedics. They collected data on prescribing, drug costs, and length of hospitalization for orthopedic units in two hospitals over a 27-month period. In one hospital pharmaceutical services were implemented and in the other they were not. At the first hospital average LOS differed by 0.7 day between the period before implementation and the period when services were being provided. After the services were discontinued, average LOS rose to a value slightly higher than the preimplementation mean. The decline in LOS was not statistically significant and was smaller than the concurrent change in LOS in the hospital that was intended to serve as the control. However, the two hospitals do not appear to have been comparable, and the lack of significance of a moderate (10%) reduction in LOS may have been due to the large standard deviations of the dependent variable. As with the McKenney and Wasserman study, the Herfindal study suggests that pharmaceutical services might reduce LOS, but the time-series design can admit other explanations.

Kelly et al.²⁷ evaluated the impact of clinical pharmaceutical services on intravenous fluid use in a study with a randomized controlled design. Their data showed a significant difference in LOS between the pharmacist-monitored (study) group and the control group; the mean LOS for the study group was 2.4 days shorter than for the control group.

Clapham et al.²⁸ evaluated three drug-use-control systems in a teaching hospital. They conducted a controlled trial comparing LOS, total cost per admission, and drug and pharmaceutical service costs per admission among patients receiving care from three rounding teams. One team's patients received unit dose services in which a pharmacist reviewed drug therapy as part of a unit dose drug-cart check, while another team's patients received services through a drug-use-control system that included pharmacists in the patient-care unit. (The drug-use-control system for the remaining team was not much better than the control's, so that team is not discussed here.) Patients in the drug-use-control system had an average LOS 1.5 days shorter and an average total cost per admission \$1300 lower than patients in the unit dose system after corrections were made for age, severity of illness, and diagnosis. When the approximate cost of providing the extra pharmaceutical services was subtracted, the mean total cost per admission for experimental system patients was \$1238 less than for the unit dose-only group. The authors could not randomize

patient assignment to groups, but those assignments were made by the admitting department of the study hospital, which did not know about the study and which followed its own independent patient-assignment procedures.

Kidder²⁹ reviewed the literature on the effect of pharmaceutical consultation services on nursing home patients. The leading study in this area was the Thompson et al.³⁰ study of the effect of pharmacist management of long-term patients in a California skilled-nursing facility. From February 1981 through January 1982, two pharmacists managed the drug therapy of 67 patients. They performed patient assessment and problem identification, prescribed new medications, adjusted dosages, and discontinued medications. Patients in the control group were cared for by an internist in private practice. During the study year, patients in the pharmacist-managed group had significantly fewer active prescriptions, significantly more discharges to lower levels of care (e.g., home care), significantly fewer deaths, and fewer hospitalizations than the control group ($p = 0.06$). The difference in estimated net savings between the two groups was \$7000 per patient.

Our literature search uncovered only one study relating pharmaceutical services to total costs in ambulatory care. Cummings et al.³¹ conducted a one-year retrospective case-control study of the effect of pharmacist assessment, monitoring, and education of 129 adult male outpatients receiving extensive drug therapy (more than six active prescriptions). Improved pharmaceutical services were associated with significantly lower hospitalization rates and average number of days of hospital care. The investigators may have selected the subjects arbitrarily, so it is impossible to determine if the groups were equivalent.

Pharmacy's Mandate and Mission for the Twenty-First Century

To summarize, the literature suggests the following propositions:

1. Drug treatment involves risks. In some medical-pharmacy systems these risks are not properly controlled, and drug therapy causes substantial preventable morbidity and mortality (toxic and adverse reactions and perhaps treatment failures).
2. The cost of such morbidity may be substantially greater than the cost of the drug treatment itself.
3. Pharmaceutical services can improve outcomes and reduce costs of care. This can be done by preventing or detecting and resolving drug-related problems that can lead to drug-related morbidity and mortality, both by increasing the effectiveness of drug therapy and by avoiding adverse effects.

We believe that the literature on preventable drug-related morbidity and the potential of pharmacy to prevent it justify pharmacy's claim of a

mandate to help the patient obtain the best possible drug therapy and especially to protect the patient from harm. If the public knew what we know about drug-related morbidity and mortality, it would not just ask that pharmacists institute preventive measures, it would demand such action. We think that this has always been pharmacy's mandate but that many pharmacists have been refusing to accept it in its modern, nontraditional meaning. In the day of the apothecary it may have been enough to dispense the correct drug, correctly labeled. Today, more is required from us. The first principle of medical care is *primum non nocere* (first, do no harm). The APhA code of ethics adopted in 1969 states that "a pharmacist should hold the health and safety of patients to be of first consideration and should render to each patient the full measure of professional ability as an essential health practitioner."³²

Accepting this mandate will greatly increase the pharmacist's level of responsibility to patients, and discharging that responsibility will require philosophical, organizational, and functional changes in the practice of pharmacy. We can begin to implement these necessary changes by first understanding the basic concepts associated with our mandate to prevent drug-related morbidity and mortality—that is, by defining a mission of pharmacy practice consistent with our mandate.

The mission of pharmacy practice is not only what we have come to call clinical pharmacy. The research discussed here, and other studies published in the past 20 years,^{23,33} suggest that clinical knowledge and skills by themselves are not sufficient to maximize the effectiveness of pharmaceutical services. There must also be an appropriate philosophy of practice and an organizational structure within which to practice. We term the necessary philosophy of practice *pharmaceutical care* and the organizational structure that facilitates the provision of this care the *pharmaceutical-care system*. The mission of pharmacy practice, which is consistent with its mandate, is to provide pharmaceutical care.^{1,34}

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes, which were mentioned earlier, are (1) cure of a disease, (2) reduction or elimination of symptoms, (3) arresting or slowing of a disease process, and (4) preventing a disease or symptoms. Pharmaceutical care involves three major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug-related problems, and (3) preventing potential drug-related problems. (The eight categories of drug-related problems were listed earlier.) Problem resolution and prevention lead to the design, implementation, and monitoring of a therapeutic plan that the pharmacist be-

Definition of Pharmaceutical Care

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are (1) cure of a disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing of a disease process, or (4) preventing a disease or symptomatology.

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 potential drug-related problems.

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.

lieves will optimally accomplish the therapeutic objective.

Pharmaceutical care should be integrated with the other elements of health care. It is, however, provided for the direct benefit of the patient, and the pharmacist accepts direct responsibility for the quality of that care. Pharmaceutical care is based on a covenant between the patient, who promises to grant authority to the provider, and the provider, who promises competence and commitment (responsibility) to the patient.^{1,35-37}

It is time for each pharmacist to decide whether he will accept society's mandate and whether he will adopt pharmaceutical care as his professional mission. There are limits, however, to what individuals can accomplish alone. Therefore, it is also time for pharmaceutical organizations, educational institutions, and patient-care corporations to decide whether they want to be a part of the problem of drug-related morbidity and mortality or part of the solution. We all must establish the prevention, identification, and solution of drug-related problems as pharmacy's first priority. If we can turn from self-examination of professional well-being toward greater responsibility to the public, we can advance into professional maturity.

Issues and Proposals

Issue 1. Who Is Capable of Providing Pharmaceutical Care and Who Will Choose To Provide It?

Assuming that we achieve a consensus on pharmacy's mandate, the first issue concerns who may provide pharmaceutical care. Professional permission—licensure—is different from a mandate because the profession by itself cannot claim license. Rather, society must grant license. The issue is why state legislatures and other regulators should give pharmacists permission to provide pharmaceutical care.

Four criteria must be met before pharmacists should be granted the authority to provide pharmaceutical care and before pharmacists should accept that responsibility: (1) the provider must have adequate knowledge and skills in pharmaceutics and clinical pharmacology, (2) the provider must be able to mobilize the drug distribution system through which drug-use decisions are implemented, (3) the provider must be able to develop the relationships with the patient and other health-care professionals that are needed in the provision of pharmaceutical care, and (4) as a practical matter, there must be a sufficient number of providers to serve society. No occupation today can claim a number of competent practitioners sufficient to meet society's need for pharmaceutical care. However, pharmaceutical education comes closer than any other program of professional education. In general, there are enough pharmacists to meet society's need.³⁸

Some people may not agree that every practicing pharmacist fulfills the first three criteria to the necessary extent; therefore, the main issue at hand concerns which pharmacists shall provide pharmaceutical care. Organized pharmacy has tried to address this very sensitive issue of competence to provide pharmaceutical care through the traditional structure of professional specialization. It was proposed, and eventually accepted, that clinical pharmacy (also referred to as pharmacotherapeutics) could be treated as a specialty practice. Thereby, competence to provide pharmaceutical care would be considered to be a special level of competence—one that not every pharmacist was expected to achieve. This avoided the politically dangerous necessity of clearly stating the problem, namely that pharmacy needs a way to identify pharmacists who are fully competent to provide pharmaceutical care. It would be regrettable indeed if this strategy tends to reduce some pharmacists' obligation to be professionally competent.

Professional competence and responsibility are all the pharmacist has to offer the patient and are the primary ethical obligations. If pharmacy's mandate is pharmaceutical care, then it is time for organized pharmacy to say clearly that competence to provide pharmaceutical care should be the mini-

imum acceptable level of competence. If this conference agrees with this logic, it should address the question of how to achieve widespread competence in the shortest possible time. Over the next 5 to 10 years (if circumstances will give pharmacy that much time), it should be required that every new pharmacist and every practitioner meet minimum competence criteria for providing pharmaceutical care. This will in turn require the development of (1) appropriate competence criteria, (2) an examination or other measurement method for applying the criteria, (3) legal or economic status (e.g., licensure or relicensure) for those who can pass the examination, (4) an educational (re-educational) program that prepares pharmacists to pass the examination, and (5) a recruitment program that convinces both prospective pharmacists and existing practitioners that clinical education or re-education is worth their investment of time, effort, and money. This conference should consider strategies and methods for achieving these objectives.

Issue 2. What Standards of Practice Are Appropriate for Pharmaceutical Care? A closely related issue is how acceptable practice can be defined, identified, maintained, and rewarded. Pharmaceutical care may be manifested in a variety of economic and organizational settings—from private solo or group practice to practice as an employee of a corporation, from outpatient care to inpatient intensive care. The fundamental goals, processes, and relationships of pharmaceutical care, however, exist independent of the practice setting, although the specific content of the standards may vary from setting to setting.

Pharmacy practice standards have traditionally been promulgated and enforced by state pharmacy boards. This conference should consider alternative mechanisms. For example, some professional organizations have developed practice standards that they use as prerequisites for membership (or for continued certification). The American Academy of Family Physicians, for example, requires 150 hours of accredited medical continuing education every three years for re-election to membership, while the American Board of Family Practice requires self-assessment of office practice and a day-long re-examination every six years, among other requirements.

Beyond the standards enforced by a regulatory board or voluntary association, a health-care organization can create the necessary professional goals, processes, and relationships through its management system. These should include (1) a clear statement of commitment to the provision of pharmaceutical care; (2) an external organizational environment that welcomes that mission, expects the pharmacist to provide pharmaceutical care, and facilitates the exchange of information among physicians, pharmacists, and nurses; (3) appropriate methods for recognizing, evaluating, and reward-

ing effectiveness in the provision of pharmaceutical care, both inside and outside the pharmacy program; (4) an internal organizational structure that allows professionals to focus on individual patients and that allows easy communication of patient-care information; and (5) a rational, consistent approach to pharmaceutical care that integrates drug distribution and decision making.³³

An example of a consistent, rational approach to the provision of pharmaceutical care is the procedure called the Pharmacist's Workup of Drug Therapy (PWDT).³⁹ This procedure directs the pharmacist's decisions about the use of drugs and demonstrates how the concept of pharmaceutical care can actually be realized for any patient in any practice setting. The PWDT helps the pharmacist evaluate his success at identifying and solving a patient's drug-related problems.

The PWDT comprises seven major steps that must be performed (and appropriately documented) for each patient receiving pharmaceutical care (i.e., each patient receiving medical care). The steps are listed below. Steps 1 through 5 and step 7 organize and operationalize pharmaceutical and pharmacological competence, and step 6 organizes and operationalizes the drug distribution system.

1. Collect and interpret relevant patient information to determine if the patient has drug-related problems.
2. Identify drug-related problems.
3. Describe the desired therapeutic goals.
4. Describe feasible therapeutic alternatives.
5. Select and individualize the most appropriate treatment regimen.
6. Implement the decisions about drug use.
7. Design a monitoring plan to achieve desired therapeutic goals.

Issue 3. Relationships with Other Professions.

The third issue concerns how pharmacists who provide pharmaceutical care can relate their services to the other health-care professions. The goal is effective cooperation by providers of pharmaceutical care with physicians and nurses as professional equals. Perhaps family medicine group practice could provide guidance.

Successfully addressing this issue requires mutual cooperation with other professions that yet maintains professional autonomy for the pharmacist. Pharmaceutical care is a necessary element of medical care. Pharmaceutical care must be integrated with the other elements of care if it is to benefit the patient fully. Cooperation is complicated by the possibility that pharmaceutical care represents an expansion into the traditional roles of physicians and nurses. It is important that we understand how the drug-use process became so incapable of protecting patients from injury or suboptimal therapy and why pharmacists must become more involved in the total care of the patient.

Pharmaceuticals are distributed by manufactur-

ers, prescribed by physicians, dispensed by pharmacists, and consumed by patients—all under the (one hopes) watchful eyes of the FDA and state professional licensure boards. Some people may trust those processes to prevent drug-related morbidity. Some may think that the problem can be solved by adjusting one or another step in the process. For example, perhaps manufacturers promote drugs too vigorously, and the prevalence of drug-related morbidity would diminish if they changed their promotional and educational activities, if the FDA changed its rules, or if physicians received more than a smattering of pharmacology in medical school or were kept more informed about pharmacotherapeutics through continuing education.

We think it is more likely that the source of the problem lies within the drug-use process itself. Drug therapy has become so complex that one professional should no longer be expected to control the entire process alone. Pharmaceutical care, as a cooperative activity, would not detract from the other actors in the drug-use process. It would in fact add to their effectiveness by improving the quality of patient care.

As a professional service, pharmaceutical care is provided directly to the patient, and the provider accepts responsibility for the quality of that care. Therefore cooperation cannot be achieved by professional subordination, or the patient will lose some of the advantages of independent professional service. The essential element is the pharmacist's acceptance of direct responsibility to the patient. Professional autonomy flows naturally from professional responsibility and competence.

Rather than letting practitioners work out these problems for themselves, organized pharmacy could develop models of practice that achieve the necessary economic and professional relationships. The faculty members in the Department of Pharmacy Health Care Administration at the University of Florida have already begun this work, but much remains to be done.

Issue 4. Marketing Pharmaceutical Care. The empirical bases of pharmaceutical care suggest that there may be a substantial overlap between clinical effectiveness and cost-effectiveness. The clinical purpose of preventing and solving drug-related problems avoids drug-related morbidity and mortality and their financial consequences. The size of the overlap depends on how much money would be spent on treating preventable drug-related morbidity (e.g., on physician visits, hospitalizations, or prolonged hospital stays) and to a lesser extent on how much can be saved in lowering drug costs per se. Pharmaceutical care allows us to reconcile, to some extent, these two classes of outcomes, which are often thought to be antithetical.

A pharmaceutical-care marketing strategy based on this logic would differ fundamentally from the usual strategy developed for selling drug products.

The strategy would be directed at whoever would have to pay for preventable drug-related morbidity because those persons should willingly pay to prevent it. The marketing message, for example, might be directed primarily at the insurer, who has to pay for extra hospital days or physician visits caused by preventable drug-related morbidity. This should not preclude sending similar messages to patients, health professionals, or managers of health-care organizations, however. The messages should be supported by evidence demonstrating that integrated patient-specific pharmaceutical services can reduce the total cost of care. The evidence exists in the literature and could be used in presentations to specific providers and purchasers. Each message should specifically describe the purpose of the service and the procedures to be carried out for patients.

Pharmaceutical care is not a standard commodity, like a drug product, that can be purchased from the lowest bidder. Pharmaceutical care can be offered at a price that reflects its value to those who benefit economically from it. If pharmaceutical care can prevent treatment failure or other drug-related morbidity or mortality, it is much more valuable than the services incident to selling a drug product. However, health-care providers who themselves are paid by capitation or other fixed-dollar methods might insist that the provider of pharmaceutical care, who is basing his argument on total cost reduction, share some of the financial risks. Some pharmacists have found a way to negotiate fees for pharmaceutical care, but this remains an unresolved issue for many others.

Conclusion

Motive and opportunity for pharmacy's re-professionalization now coincide.^{1,34} This conference is an excellent opportunity for the leadership of pharmacy's national professional organizations to prepare for the future—first by deciding pharmacy's public mandate, second by defining a mission that reflects that mandate, and third by beginning to explore the issues that arise from that mission. We ask only that this be done in a manner that will foster pharmacy's professional maturation by helping pharmacists to meet society's great unmet need for safe and effective drug therapy.

^aMasculine pronouns denote both genders throughout this article.

^bThe observed difference in LOS was approximately equal to the difference in unexplained "extra" hospital days (hospital days after major symptoms had subsided), but the authors did not establish any plausible connection between extra days and the appropriateness of antimicrobial therapy. Extra days could be random events or a result or concomitant of inappropriate therapy.

References

1. Hepler CD. The third wave in pharmaceutical education: the clinical movement. *Am J Pharm Educ.* 1987; 51:369-85.
2. Angaran DM, Hepler CD, Bjornson DC et al. Career patterns of pioneer clinical pharmacists. *Am J Hosp Pharm.* 1988; 45:101-8.
3. Brodie DC. Drug use control: keystone to pharmaceutical service. *Drug Intell Clin Pharm.* 1967; 1:63-5.
4. Anon. Directions for clinical practice in pharmacy. Session II workshops—removing barriers to clinical practice. *Am J Hosp Pharm.* 1985; 42:1332-5.
5. Cipolle R. Drugs don't have doses—people have doses. *Drug Intell Clin Pharm.* 1986; 20:881-2.
6. Manasse HR Jr. Medication use in an imperfect world: drug misadventuring as an issue of public policy, part 1. *Am J Hosp Pharm.* 1989; 46:929-44.
7. Manasse HR Jr. Medication use in an imperfect world: drug misadventuring as an issue of public policy, part 2. *Am J Hosp Pharm.* 1989; 46:1141-52.
8. Talley RB, Laventurier MF. Drug-induced illness. *JAMA.* 1974; 229:1043. Letter.
9. Southwick K. A prescription for trouble: drugs to counteract drugs. *Health Week.* 1988; 2(Aug 8):1,12.
10. Strand LM, Cipolle R, Morley PC. Drug related problems: their structure and function. *DICP.* In press.
11. McKenney JM, Harrison WL. Drug-related hospital admissions. *Am J Hosp Pharm.* 1976; 33:792-5.
12. Stewart RB, Springer P, Adams J. Drug related hospitalizations to an inpatient psychiatry unit. *Am J Psychiatry.* 1980; 137:1093-5.
13. Burnum JF. Preventability of adverse drug reactions. *Ann Intern Med.* 1976; 85:80-1.
14. Trunet P, LeGall JR, Lhoste F et al. The role of iatrogenic disease in admissions to intensive care. *JAMA.* 1980; 244:2617-20.
15. Trunet P, Borda IT, Rouget A-V et al. The role of drug-induced illness in admissions to an intensive care unit. *Intensive Care Med.* 1986; 12:43-6.
16. Lakshmanan MC, Hershey CO, Breslau D. Hospital admissions caused by iatrogenic disease. *Arch Intern Med.* 1986; 146:1931-4.
17. Ives TJ, Bentz EJ, Gwyther RE. Drug-related admissions to a family medicine service. *Arch Intern Med.* 1987; 147:1117-20.
18. Porter J, Jick H. Drug-related deaths among medical inpatients. *JAMA.* 1977; 237:879-81.
19. Dubois RW, Brook RH. Preventable deaths: who, how often, and why? *Ann Intern Med.* 1988; 109:582-9.
20. Noyes M, Polk RE. Norfloxacin and absorption of magnesium-aluminum. *Ann Intern Med.* 1988; 109:168-9.
21. Knapp DE, Knapp DA, Speedie MK et al. Relationship of inappropriate drug prescribing to increased length of hospital stay. *Am J Hosp Pharm.* 1979; 36:1334-7.
22. Knapp DA, Speedie MK, Yaeger DM et al. Drug prescribing and its relation to length of hospital stay. *Inquiry.* 1980; 17:254-9.
23. Eisenberg JM, Koffer H, Glick HA et al. What is the cost of nephrotoxicity associated with aminoglycosides? *Ann Intern Med.* 1987; 107:900-9.
24. Black BL, ed. Resource book on progressive pharmaceutical services. Bethesda, MD: American Society of Hospital Pharmacists; 1986.
25. McKenney JM, Wasserman AJ. Effect of advanced pharmaceutical services on the incidence of adverse drug reactions. *Am J Hosp Pharm.* 1979; 36:1691-7.
26. Herfindal ET, Bernstein LR, Kishi DT. Effect of clinical pharmacy services on prescribing on an orthopedic unit. *Am J Hosp Pharm.* 1983; 40:1945-51.
27. Kelly KL, Covinsky JO, Fendler K et al. The impact of clinical pharmacist activity on intravenous fluid and medication administration. *Drug Intell Clin Pharm.* 1980; 14:516-20.
28. Clapham CE, Hepler CD, Reinders TP et al. Economic consequences of two drug-use control systems in a teaching hospital. *Am J Hosp Pharm.* 1988; 45:2329-40.

29. Kidder SW. Cost-benefit of pharmacist-conducted drug-regimen reviews. *Consult Pharm.* 1987; 2:394-8.
 30. Thompson JF, McGhan WF, Ruffalo RL et al. Clinical pharmacists prescribing drug therapy in a geriatric setting: outcome of a trial. *J Am Geriatr Soc.* 1984; 32:154-9.
 31. Cummings DM, Corson M, Seaman JJ. The effect of clinical pharmacy services provided to ambulatory patients on hospitalization. *Am J Pharm.* 1984; 156:44-50.
 32. Smith MC, Knapp DA. Pharmacy, drugs and medical care. Baltimore: Williams & Wilkins; 1987:226-7.
 33. Phillips JO, Strand LM, Chesteen SA et al. Functional and structural prerequisites for the delivery of clinical pharmacy services. *Am J Hosp Pharm.* 1987; 44:1598-605.
 34. Hepler CD. Unresolved issues in the future of pharmacy. *Am J Hosp Pharm.* 1988; 45:1071-81.
 35. Veatch RM. A theory of medical ethics. New York: Basic Books; 1981:110-38.
 36. May WF. Code and covenant or philanthropy and contract? *Hastings Cent Rep.* 1975; 5:29-38.
 37. Hepler CD. Pharmacy as a clinical profession. *Am J Hosp Pharm.* 1985; 42:1298-306.
 38. Manasse HR Jr. Pharmacy's manpower: is our future in peril? *Am J Hosp Pharm.* 1988; 45:2183-91.
 39. Strand LM, Cipolle RJ, Morley PC. Documenting the clinical pharmacist's activities: back to basics. *Drug Intell Clin Pharm.* 1988; 22:63-6.
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