Accepting accountability for the medication-use system

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In March 2010, the United States achieved a landmark in health policy with the passage of the Patient Protection and Affordable Care Act (PPACA). The urgency of a reform of the health care delivery system and its financing has never been more pressing, with the costs of health care rapidly escalating and the quality of care trailing behind. A lack of accountability due to the fragmentation of the health care system is one well-known barrier to promoting the prudent use of resources to provide high-value services. Fragmentation of our health care system has had a significant negative impact on patient outcomes. Poor patient handoffs due to a lack of communication among clinicians are not only a major contributor to errors but also undoubtedly a root cause of suboptimal health care. Preventable hospital readmissions are widely recognized as a major consequence of the lack of accountability prevalent in the current health care system. In 2006, nearly 4.4 million U.S. hospital admissions were identified as potentially preventable; the two most common reasons for readmission were congestive heart failure and bacterial pneumonia.

Whose responsibility is it to keep patients from requiring readmission after a hospitalization? The nation confronted this issue through a subsection of the PPACA that calls for the testing of a variety of innovative ways to deliver health care that focus accountability on one entity with broad responsibility for many aspects of care. Through payment reforms, hospitals, clinics, and other providers are to be incentivized to assemble into systems that accept accountability for the care of patients. To encourage the formation of these “accountable care organizations” (ACOs), the new law enables payment to organizations or other entities and provides economic rewards based on their performance on outcome measures. The key elements of an ACO include local accountability of providers across the continuum of care, standardized performance measurement, and payment incentives based on performance.

Defining accountability. Accountability was a keyword in health policy long before the health reform action in 2010. Accountability is a concept with broad applicability in ethics and law, and it is also a key aspect of the sociologic basis of the health professions. In ethics, accountability is often associated with standards of responsible behavior or responsibility; in law, it relates to the First Amendment of the Constitution, which holds the government accountable through the constituents’ right to petition for the redressing of grievances. Within the health care professions, accountability is exemplified by the covenant between a patient and a provider. “Accountability refers to the obligation of one party to provide a justification and to be held responsible for its actions by another interested party.” Accountability has been a major issue among physicians and the professional associations representing physicians.

Initiatives by organized pharmacy. In the pharmacy profession, discussions of accountability have been limited; however, there have recently been several prominent calls for increased accountability of the profession. In 2010, the National Quality Forum (NQF) identified the critical need for accountability of medication management systems in a consensus report presenting 34 specific safe-practice recommendations in all areas of health care. NQF-endorsed Safe Practice 18 states: “Pharmacy leaders should have an active role on...
the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.” Through the creation of this safe practice, pharmacy has become the first and only profession to be singled out in the NQF safe practices as having compiled a body of scientific evidence demonstrating a significant impact on patient safety when accountability is taken by the profession.

The Joint Commission of Pharmacy Practitioners in 2004 issued a consensus vision statement on the future of pharmacy practice: “Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.” By 2015, the statement envisioned, “pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients’ therapeutic outcomes.”

In 2007, the American Society of Health-System Pharmacists (ASHP) Council on Pharmacy Practice discussed the concept of accountability in pharmacy practice, concluding that there was a strong need to change the mindset of hospital and health-system pharmacists to one that takes responsibility for patient outcomes from medication use. ASHP identified the promotion of pharmacists’ accountability for medication therapy outcomes as a top professional priority in its 2010–11 Leadership Agenda. This past fall, the ASHP Council on Pharmacy Practice and Council on Therapeutics both recommended policies affirming that pharmacists are accountable for patients’ medication therapy outcomes and are obligated by their covenantal relationship with patients to provide medication therapy that results in desired outcomes. In response to the passage of health care reform, the Pharmacy Practice Model Initiative (PPMI) was begun in the summer of 2010, an effort led by ASHP and the ASHP Research and Education Foundation. The goal of the initiative is to improve the care of patients through the creation of a forward-thinking hospital and health-system pharmacy practice model that supports the most effective use of pharmacists as direct patient care providers. As part of the PPMI, a two-day invitational summit was held in November 2010; among the significant themes to emerge was the concept of accountability—specifically, accountability for the development and documentation of the medication-related components of the patient care plan and, ultimately, for patient outcomes.

**Historical perspective.** The concept of accountability in pharmacy is not a new idea. The 1977 Harvey A. K. Whitney Award recipient, Herbert Carlin, noted that “the question of accountability is crucial to the provision of comprehensive pharmaceutical service and to the survival of pharmacy as a profession making a full contribution to health care.” In 1985, ASHP and the ASHP Research and Education Foundation hosted an invitational conference at Hilton Head Island, South Carolina, to address directions for clinical practice in pharmacy. The issue of accountability indirectly arose when Charles D. Hepler discussed the professionalization of clinical pharmacy, observing that in order for pharmacy to advance as a profession, it needed to “define its services in terms of responsibility for the total drug-use control process.” In order to do this, Hepler outlined the need for achieving consensus within pharmacy, developing valid standards, and demonstrating the commitment and the ability of the pharmacy profession to serve society. He also noted a major barrier to defining responsibility was a lack of time, citing the time-consuming nature of drug distribution. Other barriers identified included the lack of a widely agreed-on philosophy of practice and the lack of consensus on what the standards of practice in pharmacy ought to be. Despite those challenges, conference attendees were in strong agreement that pharmacists should continue to have the ultimate responsibility for both drug distribution and drug-control activities. The conference reaffirmed pharmacists’ obligation to other health care professions, to patients, and to the public to provide authoritative and usable drug information. In addition, the conference identified the need for pharmacists to be diligent in cultivating a public image of pharmacists as the foremost advocates for patients in all matters related to medication use.

In 1993, ASHP and the ASHP Research and Education Foundation again convened an invitational conference to discuss the implementation of pharmaceutical care. One of the primary objectives of the conference was to identify the full implications of pharmacists’ assumption of responsibility for drug therapy outcomes—an essential aspect of the concept of pharmaceutical care. Among the statements issued from the conference, the highest ranking included the following:

- In order for pharmaceutical care to be provided, pharmacists must be genuinely interested in and committed to the well-being of the patients they serve.
- Pharmacists must relinquish ownership of their traditional roles through the use of technical support or automation to effectively focus their energy on the care of the patient.
- A challenge to pharmacy will be to convince external audiences, including the public, legal and regulatory bodies, third-party payers, and administrators, that pharmaceutical care is not a self-serving interest of pharmacists.
- Objective determination of the success of pharmaceutical care requires patient outcome measurement and
monitoring techniques more sophisticated than those typically used in pharmacy at present.

- Assuming responsibility for drug therapy outcomes dictates that the pharmacist should have an opportunity for initial input into the overall therapy care plan for the patient that can only be achieved by the pharmacist having a more prominent role on the health care team.

**Slow transformation.** Although the issue of pharmacists’ accountability has been addressed historically, the profession has not made significant progress in claiming full accountability for the medication-use system. Areas of accountability for pharmacists have traditionally been perceived by patients, physicians, and society at large as being limited to the acquisition, storage, and accurate preparation and dispensing of medications. In 1968, Denzin and Mettlin concluded that pharmacy had achieved “incomplete professionalization” based on the characteristics they identified as necessary for an occupation to be a profession. Most notably, the authors identified a “failure to gain control over the social object which justified the existence of its professional qualities in the first place.” It could be argued that the profession of pharmacy has evolved significantly in the past four decades and should now be recognized for its “ownership” of drug information as a social object. However, the results of a 2006 study indicated that patients still perceived physicians, not pharmacists, as the primary provider of medication risk-management services. Even the current court system has imposed the primary duty to warn patients of drug interactions and adverse effects not on the pharmacist but rather on the prescribing physician in an effort to “protect the sanctity of the doctor–patient relationship.” In one case in which a patient died due to a drug interaction, the pharmacy was dismissed from a wrongful-death action. The court found that because the pharmacist had notified the physician of the interaction, the pharmacy was discharged from any additional duties to warn the patient. Although the outcomes of similar legal cases have been inconsistent due to differences in interpretations of law and in standards of practice applied in civil versus administrative proceedings, collectively these cases threaten the professionalization of pharmacy by devaluing the pharmacist–patient relationship and stripping pharmacists of accountability for patient outcomes.

While pharmacy has made great strides in the past several decades, the profession has yet to gain control of comprehensive, scientific medication information as a social object or, hence, accountability for patient outcomes, including direct accountability to the patient. As Smith et al. succinctly noted, “Pharmacists need to improve their credibility with physicians by accepting greater personal responsibility for patients’ drug therapy outcomes.”

**Far-reaching implications.** In order to be accountable as a profession, it is critical that the profession of pharmacy and its constituents accept responsibility for drug therapy outcomes and then demonstrate that accountability to society and our colleagues in the prescribing professions. Such accountability can be defined by high-quality core services and actions that are provided by pharmacists to all patients in a consistent and reliable manner. Based on criteria for accountability measures, we believe that health care providers should be accountable for all care processes that have been demonstrated, with strong evidence, to consistently result in significantly improved outcomes. Therefore, pharmacy providers should be accountable for care processes that have been deemed to consistently and significantly improve outcomes.

With regard to medication use, several care processes have been identified as having a consistent and significant effect on patient outcomes. These processes include participation in interdisciplinary patient care rounds, performance of medication histories on hospital admission, management of adverse drug reactions, provision of drug information, and drug protocol management.

The positive effects of the provision of pharmacy services have been widely reported in community, hospital, and other settings. Pharmacists’ interventions improve patient outcomes, satisfaction, and quality of life; reduce medication errors and costs, avoidable hospital admissions, adverse events, and length of stay; and, ultimately, reduce morbidity, mortality, and overall health care costs. Essentially, pharmacists improve health, promote the rational use and prescribing of medicines, and increase access to health care. As a recent report noted, “Because pharmacist-related patient care activities are evolving, clear expectations and accountabilities should be established to ensure recognition by national health care organizations, the government, and other health care professionals.”

As scientific and technological advances continue to revolutionize the scope and depth of health care services and delivery, they also create mounting challenges for the health care system. For example, the exponential expansion of the pharmaceutical armamentarium in recent decades requires greater competence and more time to optimally use and manage those therapies. With enhanced understanding of diseases, new and targeted therapies are increasing the complexity of pharmaceutical care, which now encompasses the use of medications and other medical products created through biological rather than chemical processes. Coupled with patterns of increased medication use
related to longer life spans and the rising prevalence of chronic diseases, already strained health care resources will be increasingly stressed; consequently, the need for high-quality medication management services will continue to grow.

In recent years, the development and use of technology such as electronic order entry, bar-code scanning, mail-order delivery systems, and dispensing robotics, as well as the expansion of the training and responsibility of pharmacy technicians, have reduced the amount of time pharmacists spend on order-entry and dispensing functions, freeing them to devote more time to providing comprehensive medication management services.

In the practice of pharmacy, the profession should be held accountable for the entire medication-use process, including the achievement of optimal patient outcomes. Pharmacy must be accountable for the quality and safety of medications, which means taking responsibility for the integrity of medication products by ensuring the integrity of the drug supply chain. Accountability for the medication-use process also encompasses responsibility for the quality and safety of the use of medications by ensuring the appropriateness of drug therapies. Pharmacists are equipped with in-depth clinical, technical, and scientific training, and it is incumbent on the profession to be accountable for optimizing patient outcomes, which, in turn, entails accountability to the patient—a direct covenantal relationship between the pharmacist provider and the patient. As Altilio observed,

The pharmacist’s responsibility is, as it states in the Oath of a Pharmacist, to “assure optimal drug therapy outcomes.” There is no reference here to the physician’s responsibility for the patient, nor is there a qualification that the drug therapies be optimal in the eyes of the physician. Instead, the pharmacist has a direct obligation to the patient to ensure that he or she gets as much as possible out of his or her drug therapy.

As the patient increasingly becomes a key player in shared health care decision-making, it is crucial that pharmacists work with patients in a collaborative manner to identify any problems with therapy (e.g., adverse drug reactions, interactions) and to evaluate adherence and efficacy of therapy. In addition, as the health care system moves from autonomous provider relationships to a more collaborative team culture, pharmacists must maintain this covenantal relationship while contributing and performing as part of the health care team caring for the patient. As described in the “Common Principles of Team-Based Care” adopted by ASHP and other member organizations of the Hospital Care Collaborative (HCC), pharmacists and all other members of the health care team are accountable not just for their own performance but also for the performance of the entire team.

One aspect of accountability includes ensuring and maintaining professional and scientific competence. For pharmacy, a self-regulated profession, this brings forth discussions of continuing-education requirements and, more controversially, credentialing issues. Competence in the provision of basic patient care services and drug distribution is generally accepted to be ensured through completion of a doctor of pharmacy (Pharm.D.) curriculum and state licensure requirements. However, discussions continue on the expansion of and requirement of board certification or other postgraduate credentials for the provision of medication management to various patient populations. The future of postgraduate credentialing is being debated but will likely include residency training and board certification in maintaining a required standard of competence among pharmacist providers.

Essential steps to greater accountability. In order for pharmacists to assume increased accountability, they must secure access to pertinent medical information, in all settings, to optimize patient outcomes. The HCC common principles state, “Appropriate information must be readily available to all team members, at the right point of decision making, and in a format that allows for ongoing updating and communication to the team.” Currently, there is wide variation in pharmacists’ access to medical information (e.g., laboratory test results, medical histories, daily assessments) in hospitals and health systems; there is even wider variation in pharmacists’ ability to communicate to the health care team any recommendations or assessments of medical therapies and to document any interventions made. Addressing these issues is a crucial first step in laying a foundation for increased accountability.

Secondly, the cost and provision of medication management services must be separated from the costs of products and product preparation and the costs associated with the dispensing process; at the same time, pharmacists’ authority over and accountability for those components of the medication-use process must be maintained. This will allow for payment for high-quality medication management services that reflects the value brought to patients and the health care system, accurately accounting for differentiation in the types and quality of such services.

Thirdly, the profession of pharmacy must work to incorporate a culture of accountability—to patients, to the health care team, and to society—through a continued emphasis on the scope and quality of pharmacy education and training programs. As noted by the International Pharmaceutical Federation’s Pharmacy
Education Taskforce, “Having a clinically competent, scientifically based profession [of pharmacy] will lead to better health care outcomes on a wide variety of variables.”

Finally, pharmacists must play an active role in identifying and promoting the use of performance standards and measures that support the achievement of optimal medication therapy outcomes. Such quality-assurance tools include the use of metrics to ensure the pharmacist’s active contribution to and participation on the health care team, supported by evidence that demonstrates improved performance when pharmacists are part of that team. Currently, a significant barrier to the formal adoption of specific clinical measures by pharmacies and pharmacy departments is the concern that because pharmacy is not solely responsible for the patient’s care, it would be inappropriate for pharmacy to take accountability for that measure. That mentality should be transformed to a willingness to take accountability. Even if the care process is not entirely within pharmacy’s purview, the profession must take responsibility to drive the process to ensure that pharmacists are champions of optimal patient care wherever medications are used.

Meeting a critical need. The accountability of pharmacists for drug therapy outcomes will be a transforming concept for a profession that is publicly perceived as “dispensers.” Moving toward an accountability model of pharmacy practice will, in our opinion, assure the continued relevance of the profession in a health care system that critically needs its unique talents, skills, and competencies.

References