

A New Leadership Role for Pharmacists: A Prescription for Change

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Objective: Pharmacists can play an important role as leaders to reduce patient safety risks, optimize the safe function of medication management systems, and align pharmacy services with national initiatives that measure and reward quality performance. The objective of this article is to determine the actions that pharmacists can take to create a visible and sustainable safe medication management structure and system in the health care environment.

Methods: An evidence-based literature search was performed to determine what actions successful pharmacist leaders have taken to improve patient safety.

Results: There is a growing number of quality and patient safety standards, as well as measures that focus specifically on medication use and education. Health care organizations must be made aware of the valuable resources that pharmacists provide and of the complexity of medication management. There are steps that pharmacist leaders can take to achieve these goals.

Conclusions: The 10 steps that pharmacist leaders can take to create a visible and sustainable safe medication management structure and system are the following:

1. Identify and mitigate medication management risks and hazards to reduce preventable patient harm.
2. Establish pharmacy leadership structures and systems to ensure organizational awareness of medication safety gaps.
3. Support an organizational culture of safe medication use.
4. Ensure evidence-based medication regimens for all patients.
5. Have daily check-in calls/meetings, with the primary focus on significant safety or quality issues.
6. Establish a medication safety committee.
7. Perform medication safety walk-rounds to evaluate medication processes, and request front-line staff's input about medication safe practices.
8. Ensure that pharmacy staff engage in teamwork, skill building, and communication training.
9. Engage in readiness planning for implementation of health information technology (HIT).
10. Include medication history-taking and reviews upon entry into the organization; medication counseling and training during the discharge process; and follow-up after the transition to home.

Key Words: medication safety, medication management, pharmacist leadership, National Quality Forum safe practice

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Pharmacy leadership is the core of a successful medication safety program. Pharmacy leaders can play an enormously important role in performance improvement. They can be part of the senior leadership team's DNA because their impact and view go far beyond the walls of the pharmacy.

Pharmacy leadership structures and systems ensure a multidisciplinary focus and a streamlined operational approach to achieving organization-wide safe medication use. Adverse drug events (ADEs) are at a critical level, continuing to cause significant harm and death to patients. This increased awareness of ADEs, the lack of care coordination among providers, and the advancements in health information technologies have prompted calls for an enhanced role for pharmacists, to ensure effective drug use and patient safety. This enhanced role for pharmacists may require some changes in the views of the pharmacists' role, responsibilities, and contributions to the medication management process. Furthermore, there is a need to recognize pharmacists as health care providers for the purposes of practice liability and billing.

Senior administrative management and governance leaders must recognize the critical role that pharmacists can play in reducing patient safety risks, optimizing the safe function of medication management systems, and aligning pharmacy services with national initiatives that measure and reward quality performance.¹ Great leadership is infectious. It is critically important that governance, administrative, and medical leadership put pharmacy leaders more at center stage. If they do, and if pharmacy leaders rise to the occasion and contribute to the performance improvement of the organization, the new entrepreneurial energy will cascade contagiously through the entire pharmacy workforce and will create a new and more positive self-identity that can only spell safer care for all patients who are served.²

As drug spending continues to rise at double-digit rates for hospital expenditures, hospital leadership must ensure that pharmacists have a central role in medication management strategies. Pharmacy leaders should be included in the organizations' leadership teams and involved with integral system decisions. Because of the manpower burden of managing this complex integrated system, adequate resources should be allocated to support the comprehensive pharmacy structure and system. Recognizably, there is palpable tension about the lack of rigorous evidence in the realm of medication management solutions; however, these system failures are real and have resulted in human suffering and death.

ADVERSE DRUG EVENTS

Adverse drug events are the most frequently cited cause of significant harm and death among hospitalized patients³ and are leading cause of readmission after discharge. The Institute of Medicine Committee on Identifying and Preventing Medication Errors estimated that at least 1.5 million preventable ADEs occur each year in the United States.^{4,5} A staggering rate of 10%, or 1 ADE per 10 inpatients, was revealed during a community hospital study in Massachusetts.⁶ As technology evolves to

provide a more sophisticated tracking mechanism for ADEs, this number will likely be a gross underestimation. With approximately 90% of Medicare beneficiaries reporting that they take prescription medicines, and nearly half of those individuals reporting the use of 5 or more different medications, the probability of an ADE is extremely high.⁷

Many preventable ADEs result from a problem in medication ordering.⁸ A recent evaluation of community hospital ADE rates was performed using an adaptation of a trigger instrument developed by the Institute for Healthcare Improvement.⁹ A rate of 15 ADEs per 100 admissions was discovered; 75% were preventable. Adverse drug events were rated as serious in 49.4% and life threatening in 11.7%. Of the preventable ADEs, 81.5% were judged potentially preventable by computerized physician order entry.¹⁰ A direct observation study found that medication bar code technology significantly reduced the rate of target dispensing errors leaving the pharmacy by 85% and the rate of potential ADEs due to dispensing errors by 63%. Therefore, in a 735-bed hospital where 6 million doses of medications are dispensed per year, this technology is expected to prevent approximately 13,000 dispensing errors and 6000 potential ADEs per year.¹¹ Involving a pharmacist in medication history-taking has been reported to reduce medication errors by 51%.¹² It has also been demonstrated in inpatient settings that having a pharmacist review medication orders before administration is associated with a significant decrease in preventable ADEs.^{13–15} Similar findings have been found in ambulatory settings.^{16–18} A recent study showed that pharmacists intercepted or intervened in potential medication errors at a rate of 3 per 100 medication orders in the emergency department. Ninety percent of errors were intercepted before reaching the patient.¹⁹ In addition, the presence of a pharmacist on a clinical team conducting inpatient rounds resulted in a 66% to 78% reduction in preventable ADEs.^{20,21}

The severity of harm attributed to ADEs has been estimated at a mortality rate of 1% to 2.45%.^{22–25} Heparin, a high-alert medication, remains in the consumer spotlight as a medication commonly involved in medication errors and ADEs that have led to death. Adverse drug events contribute to 2.5% of emergency department visits for unintentional injuries and to 0.6% of all medical visits.²⁶ Twenty-two percent of hospitalizations have been attributed to patient medication nonadherence.²⁷ Health care systems, including pharmacy leaders, must learn from each other's mistakes and use proactive risk mitigation strategies to prevent the past harm from repeating itself.

The estimated cost to a health care system for a preventable ADE is \$8700, using the consumer price index for medical care adjusted to 2009 dollars. The cost of suffering to patients and health care providers is incalculable.

The continuance of preventable ADEs, the cost to our health care organizations, and the harm to patients is not new information. Then, the question is, "Why do these medication errors and events still occur?" Our systems are perfectly designed to achieve exactly the results they get.²⁸ Pharmacy leaders must begin to look at medication management with a systems view. Pharmacists are no longer simply responsible for delivering the right medication to a patient and managing issues within the 4 walls of the pharmacy. They must step into an active role on the organization's administrative leadership team and reflect authority and accountability for medication management systems performance across the entire organization.

Structures and systems should provide a continuous flow of information to leaders from multiple sources about the risks, hazards, and performance gaps that contribute to medication management patient safety issues. The governance board, senior

administrative management, midlevel management, physician leaders, and front-line caregivers should be directly accountable for closing certain performance gaps and for adopting certain patient safety practices. Capacity, resources, and competency are critical to the ability of organizations to make changes in their culture and in patient safety performance. On a regular basis, determined by the organization, governance boards and senior administrative leaders should assess medication management systems for the adequacy of funding and should document the actions taken to adjust resource allocations to ensure that a comprehensive medication safety program is adequately funded.^{29,30}

NATIONAL QUALITY FORUM PHARMACIST LEADERSHIP STRUCTURE AND SYSTEMS PRACTICE

The National Quality Forum (NQF) Pharmacist Leadership Structures and Systems safe practice 18³⁰ highlights medication management practice gaps that have resulted in patient harm, and encourages proactive risk mitigation and a strong foundation of pharmacist leadership, teamwork, and safety culture. "With Safe Practice 18, the NQF is acknowledging the value of having pharmacists involved, not only in the delivery of safe health care of individuals but also in helping to create systemic changes in health care organizations that can both drive safety and reduce costs," said Mary Andrawis, PharmD, MPH, ASHP's director of clinical guidelines and quality improvement. (Oral communication, December 16, 2009)

FOUNDATION OF A SUCCESSFUL MEDICATION SAFETY PROGRAM

The foundation of a successful medication safety program is a dedicated, willing pharmacist leader. There has never been a more critical time for pharmacy leaders to take their rightful ownership of medication management structures and systems within health care organizations. Financial constraints, health care reform, mediocre quality of care, and continued preventable harm to patients should be enough motivation for pharmacy leaders to ensure their seats at the executive table.

Leadership failure is one of the most frequent causes of sentinel events.³¹ Failure of middle managers to execute the strategies of the organization is also a major contributor. To be successful, pharmacist leaders must have the authority in the organization to institute a change when one is suggested and to overcome barriers when they arise. As a system leader, he or she understands both the implications of the proposed change for the system and the cause-and-effect relationships that such a change may trigger. Successful improvement models make the status quo uncomfortable and the future attractive by leveraging will, ideas, and execution.³²

Frank Federico, RPh, a director at IHI said, "Medications are the most common intervention in health care. They can be a financial burden to a hospital, as well as a way to decrease costs when used appropriately. Pharmacists possess clinical and process-oriented skills. They must manage budgets, resources, and understand how to use data. It is this combination that makes them candidates for leadership of medication-related and other improvement projects." (Oral communication, December 10, 2009)

There is a growing number of quality and patient safety standards, as well as measures that focus specifically on medication use and education. Health care organizations must be

made aware of the valuable resources that pharmacists provide and the complexity of medication management. As Karla Miller, PharmD, director of pharmacy services for HCA, explained, “Pharmacists are playing an integral role in assuring the Centers for Medicare & Medicaid Services’ (CMS) core measure and regulatory safety compliance. It is critical that senior leaders understand the role of the pharmacist in providing evidence-based care by incorporating appropriate medication use into workflow and documentation.” (Oral communication, December 14, 2009) In 2008, CMS recognized the pharmacist’s role of documentation for medication contraindications in the core measures specifications manual.³³

Pharmacy leaders must evolve and build their skills to comply with the demands of health care organizations. Outlined below are 10 actions that pharmacist leaders can implement to create a visible and sustainable safe medication management structure and system. The *NQF Safe Practices for Better Healthcare* — 2009 Update has been revised, and the 10 actions outlined in this section are part of the 2010 practice recommendations of Safe Practice 18 — Pharmacist Leadership Structures and Systems³⁴:

1. **Systematically identify and mitigate medication management risks and hazards to reduce preventable patient harm.**^{35,36} Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors. However, research has established that only 10% to 20% of errors are ever reported, and of those, 90% to 95% cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients and to allow for rapid changes to reduce harm.⁹ High-performing organizations have implemented real-time electronic trigger tools to alert pharmacists and prescribers about potential ADEs. Performing self-assessments to identify clinical, operational, and communication opportunities is vital to proactively prevent harm caused by system breakdowns and by communication/handoff failures.^{37–39} Despite the widespread increase in patient safety activities in the past decade, the importance of proactively reducing the risk of some of the most tragic medication errors has been minimized too often because the events have occurred infrequently or the corresponding error reduction strategies have not been quantified scientifically. Yet from the perspective of both patient safety and credibility in the eyes of patients who place their trust in our hands, the urgency for eradicating these “rare” events should be given highest priority. Prevalence should be one of many considerations when prioritizing patient safety efforts, but certainly not the only determinant of whether proactive steps must be taken. Moreover, consumers are unlikely to understand our tolerance of “rare” but harmful events when, rightfully, they should be considered “never” events in health care. We would not understand if the risk of an airplane crash were considered low priority because it happens infrequently, especially if it had been caused by untrained or intimidating pilots, or a refusal to avoid dangerous abbreviations or to repeat verbal commands to ensure understanding.
2. **Establish pharmacy leadership structures and systems to ensure organization awareness of medication safety gaps.**^{40–42} This will require direct accountability of senior leadership for those gaps, with adequate budget available for performance improvement. Some organizations have created a Chief Pharmacy Officer as a position in the senior administration in recognition of the value pharmacists bring as system experts. Pharmacy leaders must have access and direct involvement with senior leadership to ensure accountability of the organization for medication management gaps. Medication management dashboards with outcome, process, structural, and patient-centered measures should be shared with senior leadership and the governance board, at a minimum, quarterly.
3. **Support an organizational culture of safe medication use, measure pharmacy staff safety culture, and provide feedback to leadership and staff.**^{43–46} It is important for pharmacy leaders to exhibit behaviors that are core to the organizational mission and values. A culture of safety is built on trust and execution.⁴⁷ Each employee’s input must be coveted and valued for everyday improvement and skill building. To maximize safety, many hospitals have also created a Medication Safety Officer (MSO) position in the organization. Medication error reduction efforts would be more productive if we employed specially trained and dedicated pharmacy practitioners to serve as MSOs to identify medication safety issues through a variety of sources, follow the safety literature, and disseminate information to all those who need to know, including the safety committee. The MSO supports error detection efforts with analysis of the data, review of the literature, implementation of system-based error reduction strategies, and capture of ideas from sources external to the hospital. We should open our eyes to the evidence provided by infection control efforts in the United States and recognize the immense value of employing trained, dedicated practitioners for the sole purpose of medication error surveillance and proactive error-control planning.⁴⁸
4. **Work with the interdisciplinary team to ensure evidence-based medication regimens for all patients.**^{21,49–51} There are many ways by which pharmacists can affect appropriate medication regimens. Three influential methods include formulary management, pharmacist proactive review, and pharmacist rounding at the point of care with the interdisciplinary team. Medications are powerful weapons that can be expensive and harmful when used inappropriately. Pharmacists are well-trained to critically evaluate the literature and make informed, evidence-based decisions with their medical staff for formulary additions and deletions. Medication errors are often associated with situations in which clinicians are not knowledgeable about the potential harms or correct utilization of new medications. A formulary that guides the appropriate use of medications could serve the organization well, not only in safety but also in reducing health care waste. Pharmacists who participate in interdisciplinary rounds with the clinical care team, including input from the patient as a team member, not only improve the communication within disciplines but also allow intervention and education before the prescription creation. The pharmacists’ clinical interventions should be documented, trended, and reported to the medication safety committee.
5. **High-reliability organizations have daily check-in calls/meetings with the primary focus on significant safety or quality issues from the last 24 hours or last shift; anticipated safety or quality issues in the next 24 hours; and follow-up on critical issues for accountability of resolution.** These daily meetings are intentional, purposed conversations among the senior leaders and middle managers of the organization with an end point of issue prioritization, ownership, and resolution of potential harm to patients or staff. These meetings are limited to 15 to

30 minutes with an expected attendance of all department directors and are facilitated by a senior leader.⁵² Similarly, pharmacy leaders should be directly engaged daily with frontline managers and staff to reassess the organization's goals and strategy. Execution is integral to strategy, it is a major responsibility of the leader, and it needs to be core to the pharmacy's and organization's culture and behaviors. If the strategy is not achievable—that is, not mapped to skills, resources, and assets of the organization—success is unlikely. The leader must be engaged in the execution of the strategy to adjust goals and priorities or to make available additional resources to overcome barriers in a timely manner.^{53,54}

6. **Establish a medication safety committee to review medication errors, ADEs, and near misses with respect to medications; and report data and prevention strategies to senior leadership and the patient safety officer.**^{55–59} Creating an interdisciplinary medication safety committee to evaluate issues, prioritize performance improvement initiatives, and establish accountability for execution of the action items is an important part of the overall medication safety program. Ideally, a pharmacist would lead the committee with a minimum of nursing, medical staff, senior leadership, and patient involvement. Engagement of laboratory, radiology, and specific unit leaders as necessary, based on the committee agenda, are important considerations for improving communication. The Institute for Safe Medication Practices (ISMP) encourages organizations to be proactive, to look outside their environments, to monitor harmful events, and bring this information into their improvement model. The ISMP Medication Errors Reporting Program offers a window on the world of hospital and community medication management issues, having the opportunity to recognize critical patterns for both success and failure. The ISMP offers a source of connectedness for pharmacy leaders to make valuable system insights and to position themselves further as a worthy resource investment.
7. **Perform medication safety walk-rounds to evaluate medication processes and request front-line staff input about medication safe practices.**^{60,61} Seek to understand the needs of your customer (i.e., your patients, families, health care colleagues, and senior administration). To truly create a visible medication safety program, the pharmacist leader should engage regularly in dialogue with front-line staff, physicians, patients, and senior leaders about ways to improve safe medication delivery and use. Opening the lines of communication broadly will also begin to create a culture of safety and improve medication issue reporting. The observational method of medication-error detection may be valuable in detecting medication safety-related issues, but even more so, it helps to identify what is really happening on the nursing unit, to identify the needs of nurses, and to identify the workarounds the nurses feel they need to go through on a regular basis. Much of this will remain invisible unless pharmacy regularly observes medication administration and storage of medications.
8. **Ensure that pharmacy staff engage in teamwork, skill building, and communication training, at a minimum, annually.**^{62,63} Establish an organization-wide approach to developing team-based care through teamwork training and team-led performance improvement interventions that reduce preventable patient harm. Incorporating performance improvement models of change, as part of

skill-building training for pharmacists and pharmacy technicians, allows all staff members to be part of the medication safety solution. Pharmacy leaders should have, in place, core competency programs and continuing education in place to ensure that all pharmacy staff can adequately and successfully fulfill the requirements of their positions. High-performing pharmacist leaders limit their time in meetings and staffing in order to grow the talent of their staff through coaching and feedback.

Lack of communication or poorly communicated information is often the root cause of medication errors. The use of role-playing exercises for “crucial conversations” in the workplace empowers staff to “stop the line” when patient safety is at stake.

9. **Establish a central role in the readiness planning for implementation of computerized physician order entry, medication and patient bar-coding, smart infusion technology, and other health information technologies that have an impact on medication management systems and medication use safety.**^{64–66} A systematic approach to developing the foundational elements of evidence-based care reengineering, assurance of health care provider readiness, and integrated technology infrastructure cannot be done efficiently without pharmacy leaders' direct involvement during product selection, education, and implementation of such complex technologies. Pharmacy practice models should be adopted to place pharmacists in their best position to promote the safe and effective use of medications, whereas technologies and technicians are used for preparation and dispensing processes.^{67,68} Also, reevaluating and redesigning the medication-use system to improve error-prone steps through the use of technology will optimize efficiency when carefully implemented.⁶⁹
10. **Pharmacists engage in the continuum of patient care to include medication history-taking and reviews upon entry of each patient into the organization; medication counseling and training during the discharge process; and follow-up after the transition to home.**^{70–74} Medication errors and ADEs are common during patient admission and transitions of care, including discharge from the hospital. Pharmacist involvement during these times of transition, to prevent errors of omission, duplication, and drug interactions, is integral to harm reduction.

The pharmacist workforce is changing dramatically. The 2006 American Society of Health-System Pharmacists' workforce survey showed an increasing pharmacist manager shortage. Hiring managers and experienced front-line pharmacists continues to be a challenge. Only 25% of pharmacy directors surveyed agreed that their organization was adequately preparing for the changing demographic trends in the workforce.⁷⁵ Current pharmacy leaders must prepare and train their staff for the demands of complex medication management systems. The future of pharmacists as an integral part of the organization's leadership and safety program will require that we quickly adapt to performance improvement models and streamline our operational processes to allow emphasis on clinical care services, technology integration, and medication safety programs. Pharmacy schools must incorporate into their curricula and training the skill set needed for future pharmacists to be vital assets in the health care workforce.

Dr. Brian Robson stated, from his experience as the Medical Director for e-Health in the National Services Scotland (NSS), “Pharmacist leadership has been instrumental and

inspiring at the front-line of care with individual patients and in coordinating multidisciplinary teams in small tests of change to workflow and processes. Our pharmacists have created will for improvement, worked using local staff ideas to improve care, and supported execution of improvements. Adoption of measurement strategies to monitor and demonstrate impact of improved processes of medication management and a willingness to share results of successes and failures are a feature of our Scottish program, and pharmacists have been leading in this area also.” (Oral communication, December 12, 2009)

According to the 2009 Gallup Honesty and Ethics of Professions poll, nurses, pharmacists, and medical doctors are all well regarded for their honesty and ethics by more than 6 in 10 Americans.⁷⁶ We health care professionals have a moral obligation to commit ourselves to their safety while they are under our organizations’ care. This sacred trust cannot be broken.

The ISMP has used the power of stories as a vehicle to communicate the critical concepts through their medication error reporting data and pattern recognition. Stories can breathe life into cold statistics of harm and also can ignite action. Great leaders use them to engage the heart and the mind so that they can put the hands to work.

“Fail to honor people, they fail to honor you. But of a good leader, who talks little, when his work is done, his aims fulfilled, they will all say ‘We did this to ourselves’...”Lao Tzu⁷⁷

The NQF pharmacy leadership practice is, indeed, a prescription for change, and pharmacy leaders who want to make a real difference can fill that order. It is time for them to have a conversation with the future, step up, and make the dialogue their own personal success story.

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