

ASHP Statement on the Role of the Medication Safety Leader

Position

The American Society of Health-System Pharmacists (ASHP) believes that medication safety is a fundamental responsibility of all members of the profession of pharmacy. For a medication safety program to succeed, however, it is essential that there be an innovative leader to set a vision and direction, identify opportunities to improve the medication-use system, and lead implementation of error-prevention strategies. The medication safety leader's role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education. ASHP believes that because of their training, knowledge of the medication-use process, skills, and abilities, pharmacists are uniquely qualified to fill the roles and meet the responsibilities of the medication safety leader in hospitals and health systems.

Background

Hospital and health-system pharmacists have improved pharmacy systems over the past 60 years to reduce the risk that medications could harm patients. Medication safety was at the heart of such historic innovations in pharmacy services as unit-dose systems, decentralized clinical pharmacy services, and intravenous admixture services. The crucial leadership role of pharmacists in medication safety has been summarized as follows:

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 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.¹

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The landmark Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System*² generated major patient safety initiatives by government agencies, regulatory and accrediting bodies, professional and organizational associations, and health care organizations. The Joint Commission National Patient Safety Goals (NPSGs)³ are an example of a response to the original IOM report. The Practice Advancement Initiative (PAI)⁴ and the National Quality Forum (NQF) Safe Practice 18: Pharmacist Leadership Structures and Systems⁵ incorporate medication safety principles to ensure optimal patient safety and outcomes.

The medication safety leader (also referred to as a medication safety officer, medication safety manager, or medication safety coordinator, among other titles) is a clinical practitioner designated by an organization to serve as the authoritative expert in safe medication use. Traditionally, the medication safety leader has been a clinical pharmacist or manager within the department of pharmacy, although the position is sometimes filled by a nurse or physician. The medication safety leader may report to the organization's pharmacy, risk-management, or quality departments, or to senior administration. The medication safety leader should be positioned on the organizational chart where it will best enhance his or her "ability to affect change and advocate that the position remains targeted on medication safety."⁶ Medication safety leadership may encompass a single hospital or a group of organizations (e.g., spanning a health system or at a corporate level of a larger organization). Regardless of organization size, it is critical that the fundamentals of medication safety are the central component of the medication safety leader's job function. Although medication safety leaders may have other responsibilities in smaller institutions, medication safety should remain their core responsibility, and they must be strategically positioned and empowered to lead efforts to reduce the risks of medication use.

The characteristics of a medication safety leader include

1. A strong understanding of the facility's internal systems and processes developed through firsthand experience, observations, medication-use evaluations, interviews, and data analysis for the spectrum of patient populations treated in their organization

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- (e.g., pediatric, geriatric, cardiac, oncology).
2. Clinical expertise and a broad understanding of health care systems and processes to facilitate accurate interpretation of clinical events.
 3. Knowledge of and experience with all aspects of the medication-use system, including procurement, prescribing, transcribing, preparation, distribution, administration, documentation, and monitoring.
 4. Strong analytical skills and an understanding of statistics, population data, and the concepts of risk and prioritization.
 5. Knowledge of performance-improvement methodology and tools, including root cause analysis (RCA), failure mode and effects analysis (FMEA), cause-and-effect diagramming, process-flow mapping, and methods for monitoring projects and measuring the progress of performance-improvement initiatives.
 6. Post-graduate specialized training (e.g., medication safety residency or fellowship) or three or more years of health-system practice experience.
 7. Demonstrated leadership skills.
 8. Excellent small- and large-group presentation skills.
 9. Excellent oral communication skills, especially the ability to communicate to all types of health care providers as individuals as well as in small and large groups.
 10. Excellent writing and editing skills.
 11. Strong personal belief that resolving the problem of medication errors is a systems issue and not an individual health care provider issue.
 12. Ability to function proactively rather than reactively.
 13. Strong personal belief in the concept of a “just culture”⁷ that enhances transparency, opens participation to all health care professionals, and fosters a “lessons learned” environment in an organization’s medication error reporting system.
 14. Understanding of concepts and application of safety principles, continuous quality improvement, and human factors engineering.

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15. Appropriate assertiveness.
16. A passion for medication safety and improving patient outcomes.
17. Proven success in working with interdisciplinary teams and engaging diverse groups.
18. Strong personal belief in engaging patients as part of the health care team.
19. Eagerness to learn from events outside one's own facility (e.g., through external sources of information) to apply learning about what went wrong in order to identify and remedy possible system weaknesses to prevent patient harm.

The scope of a medication safety leader's responsibilities reaches into every corner of the health care system and encompasses many roles, such as educator, preceptor, mentor, detective, compliance officer, risk manager, engineer, accountant, statistician, computer analyst, and counselor. A typical day may include attending safety rounds, precepting pharmacy students and residents, writing policies, reviewing adverse drug events and medication error reports,⁸ developing error-prevention strategies, leading process-improvement teams, implementing action items, reviewing smart pump libraries, ensuring safe use of automated medication dispensing systems, assessing the safety of replacement drug products during drug shortages, orienting new professional staff, designing and optimizing the medication reconciliation process, conducting tracers to ensure compliance with accreditation standards (e.g., Joint Commission medication management standards and NPSGs), working with practitioners to resolve acute events, attending medical staff meetings, and educating staff and leaders across the system on the culture of safety. Most medication safety leaders quickly find themselves involved in many projects and committees as well as serving as the contact person when nursing, pharmacy, or medical staff have questions or problems. The medication safety leader needs a solid understanding of patient safety principles and must have the ability to prioritize work activities to have a positive impact on the safety of patient care. The medication safety leader should strive to acquire additional skills crucial to success, such as presentation and communication skills, as well as expertise in process-improvement methodologies such as

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Six Sigma and Lean. Formalized training in medication safety can be achieved through residency, fellowship, and certificate programs and other methods of continuing education. ASHP supports the expansion of pharmacy education and postgraduate residency training to include an emphasis on medication safety.⁹

Responsibilities of Medication Safety Leaders

Medication safety leaders must collaborate with all types of health care professionals, support staff, and management and consider all components of the medication-use process in all settings of healthcare (e.g., inpatient, clinic, community pharmacies, drug distribution centers) in order to improve medication safety. The medication safety leader's role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education.

Leadership. To provide leadership, the medication safety leader will

1. Develop a vision of an ideal safe medication-use system for the organization.
2. Oversee the planning, creation, review, and refinement of a medication safety plan.
3. Proactively develop and lead implementation of error-prevention strategies based on practice standards, best practice guidelines (or recommendations), literature review, external error reports, medication safety tools, and analysis of the organization's medication safety data.
4. Ensure medication management and patient safety are core components of overall organization quality and outcomes initiatives.
5. Participate in the planning, design, and implementation of the organization's medication-use technology and automation systems.
6. Build a culture of safety through "lesson learned" education and communication across the entire organization.
7. Oversee processes to collect information on the organization's medication errors and system failures to ensure that they are captured and barriers to reporting are

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8. Ensure compliance with state and federal regulatory and legal requirements relating to medication safety and assist in the accreditation process by ensuring that the organization's medication-use processes meet applicable medication management standards and NPSGs.
9. Support the development and implementation of a second victim/care-for-the-caregiver program.

Medication Safety Expertise. In the role of medication safety expert, the medication safety leader will

1. Serve as an authoritative resource on medication safety for the organization.
2. Contribute the medication safety perspective for technology initiatives.
3. Contribute the medication safety perspective to internal and external emergency-preparedness planning.
4. Serve as an internal consultant to investigate medication safety events or issues and develop recommendations for action.
5. Serve as the chair of the medication safety committee, whose duties may include setting the agenda, reviewing general and specific error reports, and examining the progress of projects and initiatives assigned to the medication safety team.
6. Be knowledgeable in the application and use of a variety of quality-improvement methodologies and tools (e.g., FOCUS-PDCA or Lean methodologies, RCA, FMEA).
7. Collect, review, and analyze the organization's medication-use process, medication errors, adverse drug reactions, and continuous quality-improvement data (e.g., markers of adverse drug events, smart pump event data, triggers and surveillance information, automated dispensing system and bedside bar-code scanning reports) and use appropriate data analysis techniques to identify needed improvements and develop high-leverage error-reduction strategies.

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8. Predict and prepare to manage medication safety issues caused by potential or actual drug product shortages and the use of replacement drug products.
9. Maintain knowledge of trends and developments in the patient safety field through continuous professional development: reading articles, journals, and related material; attending appropriate seminars, conferences, or educational programs; and using information from the Institute for Safe Medication Practices (ISMP) National Medication Error Reporting Program, the Food and Drug Administration (FDA) MedWatch program, and similar programs.
10. Participate at local and national levels in patient safety and medication safety organizations and initiatives. Medication safety leaders are also encouraged to seek and share best practices with other regional safety leaders and practice sites.

Influencing Practice Change. To influence practice change, the medication safety leader will

1. Collaborate with other departments (e.g., pharmacy, risk management, patient safety), hospital or health-system senior leadership, frontline staff, and nursing and medical staff leadership to identify and prioritize safety issues and develop risk-reduction strategies using the methods listed above to identify opportunities to improve medication safety.
2. Manage changes in the medication-use system to enhance medication safety, ensure that appropriate measures are taken to address and resolve medication safety issues, and see that hospital staff and faculty are supported in providing safe care for patients.
3. Work closely with others (e.g., the patient safety officer) to integrate medication safety into the overall strategic plan for patient safety and coordinate medication safety initiatives with organizational patient safety initiatives.
4. Participate in or lead multidisciplinary hospital and health-system committees concerned with medication errors, adverse drug events and reactions, near misses, policy review, safe medication use, new product review, and patient safety to identify

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risk points and prioritize system improvements to reduce the potential for medication error and patient harm.

5. Consult with and advise specific clinical teams and the hospital and health system generally on opportunities and strategies to improve patient care.
6. Encourage organization wide medication error reporting through an established and accepted error reporting system that utilizes appropriate error detection methods (e.g., trigger tools) and through other appropriate avenues such as the pharmacy and therapeutics committee, medication safety committee, and patient safety committee.
7. Develop effective methods for spreading best medication-use practices throughout the organization.
8. Use continuous quality-improvement principles to assess and report on the status of efforts to improve medication safety.
9. Periodically review and update clinical decision-support tools to alert staff to high-risk situations and educate staff as needed.

Research and Education. To further research and education regarding medication safety, the medication safety leader will

1. Design and assist in the implementation of education and orientation programs in safe medication use, including
2. Development of competency assessment for
 - staff tasks related to medication safety (e.g., use of smart pumps and automated medication dispensing systems);
 - Education of health care providers, other pertinent staff, and (as possible) patients to ensure they are competent in safe medication-use practices; and
 - Provision of effective ongoing programs and presentations related to safe medication use to diverse audiences (e.g., nursing, pharmacy, respiratory care, and medical staff).

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3. Share information about actual or potential medication errors or harm with safety organizations such as ISMP, FDA, drug or product manufacturers, and state error reporting programs.
4. Conduct medication-use safety research through well-designed, externally validated studies and implement evidence-based practices for medication safety.
5. Contribute to the literature on medication safety.
6. Provide medication safety education to pharmacy colleagues, students, and residents, as well as other health care professionals.
7. Integrate medication safety into orientation and training for all health care providers who participate in the medication-use process.

Conclusion

ASHP believes that pharmacists, as experts on medication use, are uniquely qualified to serve as medication safety leaders. Medication safety leaders articulate the vision and direction for improving the safety of the medication-use system to prevent patient harm. The medication safety leader's role includes responsibility for leadership through direction and prioritization, medication safety expertise, influencing practice change, research, and education. Through analysis of the organization's medication safety data and literature review, the medication safety leader will lead development and implementation of proactive error-prevention strategies and build a culture of safety across the organization.

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Suggested Readings

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Web Resources

www.ashp.org

www.ismp.org

www.safemedication.com

www.medsafetyofficer.org

www.asmsso.org

www.ahrq.gov

www.fda.gov/cder/drugSafety.htm

www.ihl.org

www.jointcommission.org/standards_information/npsgs.aspx

www.leapfroggroup.org

www.qualityforum.org

www.nccmerp.org

www.usp.org

www.patientsafety.gov

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www.npsf.org

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This statement was drafted by Stacy L. Carson, Pharm.D., BCPS, FISMP; Sophia Chhay, Pharm.D.; Michael Dejos, Pharm.D.; Michael O'Connor, Pharm.D., M.S.; and Krystal Moorman, Pharm.D., BCPS; the drafters declared no potential conflicts of interest.

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