MONOGRAPH

PREPARED BY THE MONOGRAPHS TASK FORCE OF THE AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

The growing role of the **Patient Safety Officer**: Implications for risk managers

Published June 2004

ONE NORTH FRANKLIN, CHICAGO, IL 60606 ASHRM (312) 422-3980 WWW.ASHRM. ORG

TABLE OF CONTENTS

INTRODUCTION

A new health care role is emerging: the patient safety officer (PSO). The growth of the modern patient safety movement, a desire to bring recognition and leadership to new patient safety programs, the need for special skills to meet patient safety program requirements and reconfiguration of existing professionals' functions are among the catalysts for this new role.

Its ascent is a matter of vital interest for health care risk managers. The implications for them are huge when leadership restructures an organization to formalize PSO responsibilities. Importantly, this phenomenon gives risk managers (as well as other professionals, of course) an opportunity to highlight their current contributions to patient safety, develop additional skills and expand their profile.

The PSO role is a moving target, however, because the basic educational eligibility, required competencies, tasks and responsibilities and most effective organizational structure are not yet firmly established.

This monograph provides an overview of the current state of play for the PSO role including a brief history of the catalysts, broad dimensions of the role, ways in which the role may be structured, organizational prerequisites for PSO success, current educational pathways to the role and justifications for it. The monograph concludes with resources that may provide more understanding of the role.

The modern patient safety movement

The concept of patient safety is not new. It dates at least back to Hippocrates, one of the founders of medical ethics, with his precept of "first, do no harm."(1) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), medical professional groups, early theorists and professional liability insurers addressed patient care safety and iatrogenic injury rates in the 1970s and '80s in audit requirements, clinical guidelines, articles and research studies.(2)

Nonetheless, patient safety did not gain widespread attention in the medical profession and health care communities until the 1991 publication of the Harvard Medical Practice Study and its findings of higher-than-expected rates of preventable medical error in hospital admissions.(3) During the 1980s and '90s, certain well-publicized, preventable adverse events resulting in patients' deaths, such as the Betsy Lehman case, brought the medical errors issue directly to the public.(4)

The 1999 publication of the first Institute of Medicine Study, " To Err Is Human: Building a Safer Health System," reiterated and expanded on the Harvard study and other research. It also created national public pressure to address the patient safety issues identified in its report.(5)

By 2003, federal and state governmental entities, professional organizations, national business coalitions and JCAHO had entered the patient safety arena, establishing patient

safety standards and indicators, required sentinel/serious adverse event reporting and compliance with safe practices.(6)

The modern patient safety movement emphasizes certain values. These values include transparency or candor with patients and their families regarding unanticipated outcomes, a just or non-punitive health care environment where individuals are not automatically punished for reporting medical errors or near misses, an informed or data-driven culture, accurate reporting, a focus on system (not individual) failures, learning from errors and a flexible culture that can recover from crises.(7)

In recent years, health care organizations developed patient safety programs to respond to these external and internal pressures for improvement. Patient safety committees and/or specific professionals were designated to lead the day-to-day implementation of a culture of safety. Thus, the role of PSO was born.

EMERGENCE OF THE ROLE

Traditionally, patient safety activities have been largely retrospective or reactive; the focus has been on individual events or people rather than understanding the nature of human error and health care systems. "The problem of patient safety begins with a lack of a common definition, the disparate views of the topic, and the lack of a systematic process for collecting and analyzing scientific data from which to set an agenda objectively." (8) These issues are beginning to be addressed through more research on medical error and application of more formal analytic methods to patient safety issues such as root cause analysis, failure mode and effect analysis, Six Sigma and prioritization models. These tools have emerged as weapons in the patient safety armamentarium while the locus of attention shifts from a reactive to a proactive view of health care safety.

Meanwhile, the chasm is widening between the patient/family view on quality and that which is emerging from the patient safety field, and this dissonance is illustrated in National Patient Safety Foundation (NPSF) study findings: "75 percent of the [public] respondents to this survey felt that the most effective way to increase patient safety was to keep health care professionals with bad track records from providing care." (9) In contrast, some emerging patient safety theory postulates that it is not the individual but the system in which the individual works that needs attention. The person in the PSO role needs to understand this enterprise-wide view.

Ideally, the PSO's role is not merely a title change or a cosmetic change to an existing position because it is based on an emerging cultural change unlike anything that has occurred in health care. The PSO role and function should be purposefully structured to achieve the goal of a "culture of safety" and not as a fulfillment of some regulatory or accreditation requirement. A culture of safety is defined by the National Academies of Sciences as "an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the process of care delivery."(10)

PSO skill sets

What skill sets are needed to build the "model" PSO? Working from the description of a culture of safety, a few essential elements can be identified. These include:

- **Global perspective.** A big picture view of the inter-relatedness of health care practices is required. It is at these junctures (or handoffs) that the risk of patient injury remains the highest.

- **Communication skills.** The PSO must be able to clearly articulate ideas and concepts in non-judgmental and non-confrontational ways.

- **Integrity.** The integrity of the PSO is critical to maintain effectiveness and build the trust essential to a new program in health care's complex environments. Corporate honesty and transparency are also difficult concepts to implement unless there is a basis of integrity and trust.

- **Data fluency.** The PSO must have a data-driven mindset and must understand and use basic statistical methods and formal analytic methods. The PSO often has to work with a plethora of disconnected data from which decisions must be made. Without the proper tools and understanding of those tools, analysis will be weak and improper conclusions will be drawn. Gleaning information is only a part of the PSO's function. Analysis of data enables the PSO to prioritize action steps so that the project can be evaluated based on measurable criteria and placed within a financial construct to gain acceptance from the organization's administration.

- **Leadership and change management.** The PSO role calls for leadership and team-building skills. All members of the organization must participate in the work of patient safety if patient safety (not to mention the organization itself) is to thrive. The PSO must motivate and coordinate participation throughout the organization, including the governing body, administration, physicians, other clinicians and patients and family members. Understanding the local culture and how to successfully introduce change is a major issue. The PSO may well find a punitive mindset that must be dealt with along with resistance to other changes.

- **Knowledge base.** A current understanding of patient safety theory, methods, standards and regulatory requirements is essential along with a commitment to life-long learning to maintain expertise in a rapidly changing field.

What risk managers bring

In a complex health care environment, the ability to provide consistent quality is especially complicated because patients present for care in all sorts of conditions. Fortunately, risk managers possess the breadth of experience in identifying, managing and reducing risk required to support the delivery of safe health care for a variety of needs.

Risk managers' exposure to wide-ranging information sources in an organization also makes them uniquely positioned to identify risk (with claims and loss data); educate and train to avoid risks (conduct root cause analyses, failure mode and effect analyses, etc.) and manage and measure performance to reduce risk (through benchmarking, claims and loss data).

Enhancing these PSO skills may be critical for effecting change that can reduce risk and improve patient safety.

ORGANIZATIONAL STRUCTURE

The organizational approach used to fulfill the patient safety officer role varies. Small hospitals may charge one individual with wearing several administrative designations including patient safety, quality improvement, case management, risk management and even infection control. These individuals face an arduous task as they struggle to balance the requirements of these positions.

Other organizations may use an existing committee structure to fulfill the requirements of the patient safety role. Larger organizations generally have a dedicated PSO reporting to administrative levels including nursing, legal, corporate compliance, COO, CEO or the Board of Trustees.

Any organizational approach can be effective or non-effective depending on the support of the person to whom the PSO and other factors discussed below.

The PSO role needs to be integrated with all accountability programs such as quality/performance improvement and risk management as well as medical staff, nursing and other departments in the facility. There should be direct communication linkages between the PSO and these entities.

Sharing responsibility to achieve buy-in

It is important to note here that the PSO cannot stand alone either as the only authoritative source on patient safety in a true culture of safety or as the sole participant in patient safety activities. Buy-in for this function needs to occur at all levels of the organization. The PSO must be in the position to tap the collective expertise of the experts who are the primary caregivers of the patient, from physicians to patient care technicians. Likewise, the PSO needs to be able to work within the existing structures and culture to document the need for cultural change. PSO activities need to be reported throughout the organization to quality committees, medical staff committees, leadership committees and within the departmental structure of the facility.

For this reason, the use of a patient safety committee can be a great help – the greater the involvement, the greater the buy-in. By leading a patient safety committee, the PSO can successfully explore those interactions and interdependencies that exist at the juncture of increased risk of injury. A good committee can look at an issue from a 360°

perspective while attempting to select the correct intervention for the event.

Finally, as in any complex organization, a number of turf issues and other personal agendas come into play in the process of facilitating change. To face them, the PSO should possess a high degree of political savvy as well as courage.

ORGANIZATIONAL PREREQUISITES

Implementing and maintaining a culture of safety in a health care organization is a mammoth undertaking that not even the most competent PSO can complete alone. And while there must be a policy of individual and corporate accountability throughout the organization, that also is not enough to guarantee a successful patient safety program.

One critical and ongoing responsibility of the PSO is to inform and assist senior leadership to understand that their active commitment is essential to the success of the patient safety program. Governing board and senior management must make an overt and pervasive commitment to patient safety as a strategic goal. That commitment entails total staff involvement in the patient safety program, a defined program plan and objectives, ongoing support for a culture of safety, dedicated resources for required training, technology, personnel and other program needs, incentives for behavior that improves patient safety, willingness to make difficult decisions and oversight of program progress by key committees and the governing board.(11) Barriers to this level of organizational commitment are many. They include competing financial priorities, fear of increased malpractice litigation, resistance to change and misunderstanding of the nature of human error.(12)

EDUCATIONAL PATHWAYS

Currently, patient safety officers come from backgrounds including risk management, quality or performance improvement, medicine and nursing. Newly designated PSOs may or may not have had any formal training in patient safety.

Many venues are available to gain knowledge on patient safety theory and methods including journal articles, online materials, governmental and professional association resources and textbooks. Almost every state or national health care professional association meeting includes one or more lectures or workshops on patient safety topics. And, within recent years, more formal patient safety fellowships, core curricula and certification programs have emerged.

Health care professional associations and the federal government offer most of the current structured patient safety fellowship programs. Universities, professional liability insurers and consulting firms are also entering this educational marketplace, which has become quite competitive.(13) The existing fellowship programs vary considerably in time commitment, cost, instructional methods used and depth of the educational experience.

Instructional approaches include onsite residencies, distance learning via the Internet, self-study and combinations of brief intense face-to-face sessions with self-study or online learning. Topic areas usually included in the more in-depth fellowship programs are:

- Fundamentals and history
- Systems theory
- Human factors issues
- Reporting and assessing errors and near misses
- Disclosure of medical error
- Communication and teamwork
- Role of technology
- Culture of safety
- Change management
- Medication safety
- Evidence-based practice
- Tools for evaluation and improvement
- Legal, regulatory and ethical issues
- Business case for patient safety.

ASHRM patient safety initiatives

Through its numerous educational offerings and publications, ASHRM delivers many resources on which to build a patient safety program. ASHRM's Annual Conference & Exhibition offers a dedicated education track on patient safety (in addition to sessions on claims and litigation plus legal and regulatory issues). Audio conferences and monographs also tackle patient safety topics while building on risk financing and claims management concepts that are contributors to identifying risk and enhancing safety efforts.

ASHRM is a partner in the development of the Patient Safety Leadership Fellowship program, which is administered by the American Hospital Association's Health Forum. The ongoing yearlong intensive learning experience is aimed at senior leaders committed to advancing the science of patient safety in health care. The fellowship provides a highly participatory learning community (online and in retreats) in which individuals develop "action learning projects" that can be applied to their workplaces.

ASHRM is also completing a Patient Safety Curriculum to bring the latest in concepts and thinking to managers of risk while also building on many of the founding concepts of patient

safety. The course, to be introduced in 2005, is intended to deliver principles and applications with which participants may build or enhance their current safety work.

JUSTIFICATION FOR POSITION

Economic pressures in today's health care environment make the creation of a position a difficult task that must be thoroughly justified.

There are several potential justifications for a PSO, such as compliance with external requirements, management of organizational workload, reduction in costly errors through loss prevention activities and mitigation of damage to an organization's reputation through the creation of a patient safety program.

Regulatory agencies, accrediting bodies, third-party payors and patients are creating especially forceful new demands centered on patient safety initiatives. These demands require oversight in planning, implementation and measurement. JCAHO, for example, calls for implementation of seven National Patient Safety Goals for accreditation and estimates almost 50 percent of its standards are directly related to safety.(14) The Agency for Healthcare Research and Quality established 11 safe practices selected from 79 evidence-based safe practices, the National Quality Forum identified 30 safe practices and the Leapfrog Group identified three patient safety "leaps" for 2004.(15) (Additionally, the Leapfrog Group specifically calls for the creation of a PSO as "the single point of contact for questions about safety, for education and for deployment of system changes."(16))

The burden is on health care providers to demonstrate compliance with national safety standards and to meet state serious adverse event reporting requirements. Carrying that burden is no small task for any organization.

Assessments to determine needs

An assessment or inventory of current essential risk management responsibilities in combination with a listing of external patient safety standard and reporting requirements may help to demonstrate to senior leadership the new expanded demands upon the organizational workload and the need for additional resources. *ASHRM's Self-Assessment Tool for Risk Management Programs & Functions (2nd Edition),* for example, provides a list of core assessment measures most essential to the effective functioning of the risk management program that could be used in such an inventory.(17) Estimates of hours per week or percentages of full-time equivalents required to complete these tasks can be displayed next to each measure or external requirement on the inventory to demonstrate staff needs or to illustrate those risk management or patient safety program components which are not currently staffed.

Another way the patient safety role is justified is through identification of cost savings to the organization based on patient safety activities. And in coordinating patient safety activities, the PSO may assume responsibility for some areas of medication safety.

Adverse drug events (ADEs) are injuries resulting from the use of a drug. Setting the goal of reducing ADEs is one example of building a business case for the PSO role. The literature suggests there is financial evidence in supporting strategies to reduce errors.(18) It has been estimated that safety strategies for preventing adverse drug events can save $3,000 per event. As one study states, ADEs represent 6 percent of malpractice claims and are preventable in two-thirds of the cases.(19) Most commonly identified were system errors, poor team communication, inadequate handoffs, confused lines of authority and ergonomic issues.

A PSO may also bring added value in meeting the need for team training. Industries such as aviation and nuclear power have used the concept of team training, defined by Spath as a "cooperative effort by members of a group or team to achieve a common goal,"(20) to reduce errors related to communication, handoffs and confused lines of authority. In Army aviation, teamwork has demonstrated a 20 percent improvement in mission performance.(21) The PSO, with experience in team training and communication, can use teamwork tools to play an important role in reducing error.

Demonstrating savings related to prompt disclosure of unanticipated outcomes to patients, avoidance of claims or early and reduced settlements may be another way to show the need for the PSO role, considering that PSOs may be a key player in developing early disclosure policies and educating staff on these approaches.

Further justification of the PSO relates to public relations. A medical error with associated public disclosure and media attention can harm the reputation of an organization. While it may be hard to quantify the harm in lost earnings and expenses associated in damage control, it is not hard to imagine the overall negative impact on an organization. A credible patient safety program, with executive leadership support, can assist in mitigating loss of reputation. By continuous planning, implementing and monitoring, organizations can reduce risk associated with loss of reputation and improve the safety of patients.

CONCLUSION

The relatively new domain of patient safety is moving to the forefront of health care as a critical concern shared by health care providers as well as regulators, accrediting bodies and patients.

The need for research and scientific study in patient safety is paramount to achieve a more widely accepted definition of the role. Nevertheless, while there is no consensus on the most successful approaches and methods to enhancing patient safety, the new role of patient safety officer continues to gain acceptance.

The pool of professionals who may assume the patient safety officer role can come from risk management, quality or performance improvement, medicine, nursing and other backgrounds.

Whether the health care industry turns to risk managers to fulfill the role – or to become a subset of the role – depends in part on risk managers' ability to leverage their existing skill sets and enhance them with the skills required to lead a patient safety program.

The bottom line for the organization and the individuals providing health care services to patients and their families is "*primum non nocere* - first, do no harm." This is as true for everyone today as it was for Hippocrates centuries ago.

CONTRIBUTORS

Marva West Tan, RN, ARM, FASHRM
Consultant, M W Tan Communications, Marietta, GA

Paul Gutting, ARM, FASHRM, CPHRM
St. Joseph's/Candler Health System, Savannah, GA

Julie Gorczyca, RN, AHRMQ
Clinical Risk Manager, St. John Hospital, Grosse Pointe Park, MI

REFERENCES

1. Origin of the phrase is unknown although it is often described as a paraphrase of a Hippocratic aphorism. See also "The Hippocratic oath, 4th century, B.C." *Risk Management Handbook for Health Care Organizations (4th Ed.).* Roberta Carroll, editor. San Francisco: Jossey-Bass, 2004. Appendix 30.2. Page 805.

2. See archives at www.jcaho.org, California Medical Association, California Medical Insurance Feasibility Study, Sutter Publications, 1977; Jacobs, Christoffel and Dixon, *Measuring the Quality of Patient Care: The Rationale for Outcome Audit*, Ballinger Publishing, 1976; Donabedian, "Explorations in Quality Assessment and Monitoring," Ann Arbor, MI: Health Administration Press, 1980; Harvard Anesthesia Practice Standards, 1985.

3. Brennen, T.A., Leape, L.L. et al., "Incidence of adverse events and negligence in hospitalized patients (results of the Harvard Medical Practice Study)." *NEJM,* 324, 1991. Pages 370-76.

4. See www.boston.com/globe archives for articles on Betsy Lehman case.

5. Institute of Medicine. "To err is human: Building a safer health system." Washington, D.C.: National Academies Press, 1999.

6. See www.jcaho.org, www.ahrq.gov, www.leapfroggroup.com and www.qualityforum.org.

7. Reason, J. "Engineering a safety culture" in *Managing the Risks of Organizational Accidents*. Brookfield, VT: Ashgate Publishing, 1997. Pages 191-223.

8. "Agenda for Research and Development in Patient Safety," National Patient Safety Foundation, 2000. Page 1.

9. "How the Public Perceives Patient Safety," Focus on Patient Safety, National Patient Safety Foundation Newsletter, Winter 1997. Vol. 1, Issue 1. Page 3.

10. "Patient Safety: Achieving a new standard for care," National Academy of Sciences, Washington, D.C.: National Academies Press, 2004. Page 128.

11. Pennsylvania Patient Safety Collaborative, *Elements of a Patient Safety Culture: Patient Safety Is Our Top Priority*. The Hospital and Healthsystem Association of Pennsylvania, 2001.

12. Berwick, D.M. "Errors today and errors tomorrow," *NEJM*, 348, 2003. Pages 2570-2572.

13. See Institute for Healthcare Improvement's Merck Fellowships Program and PSO Executive Training Program (617-754-4800), Virginia Commonwealth University's Fellowship in Patient Safety (804-828-5460), National Patient Safety Foundation/ASHRM/Health Forum Patient Safety Fellowship (Health Forum: 415-248-8407), The Quality Colloquium's Patient Safety Officer training (206-628-7668), Harvard Risk Management Foundation online patient safety core curriculum for clinical trainers (877-763-2742), U.S. Department of Health and Human Services/Veterans Affairs/Agency for Healthcare Research and Quality Patient Safety Training Program (AHRQ: 301-427-1364), American Board of Quality Assurance and Utilization Review Physicians online patient safety course and certification (ABQAURP: 727-569-0190), VA National Center for Patient Safety pilot and ASHRM Patient Safety Core Curriculum for Patient Safety (312-422-3989).

14. See www.jcaho.org, 2004 National Patient Safety Goals and Patient Safety Related Standards.

15. See www.ahrq.gov, www.leapfroggroup.org and www.qualityforum.org.

16. Leapfrog Group 2004 Hospital Quality and Safety Survey. Page 27.

17. *ASHRM's Self-Assessment Tool for Risk Management Programs & Functions"(2nd Ed.)* Chicago: ASHRM, 2003.

18. Oetgen, W.J., Oetgen, P.M. "A business case for patient safety." *The Physician Executive,* 2003. September-October. Pages 39-42.

19. Rothschild, J.M., Federico, F.F., et al. "Analysis of medication-related malpractice claims." *Arch Intern Med,* 2002. 162, Pages 2414-2420.

20. Spath, P.L. *Error Reduction in Health Care: A Systems Approach To Improving Patient Safety*. San Francisco: Jossey-Bass, 1999. Page 235.

RESOURCES

Sample job descriptions
www.medpathways.info (Pathways for Medication Safety, Tools, Section 1 Attachments)
www.npsf.org (Patient Safety Officer section)

ASHRM online glossary of health care risk management terms. Access at www.ashrm.org.

Patient Safety Resources. Access at www.ashrm.org (Tools & Products)

Patient Safety Handbook. Boston: Jones and Bartlett, 2004. $84.95 for ASHRM members, $99.95 for non-members. Available at www.ashrm.org (Tools & Products) and (800) AHA-2626. (AHA catalog #178850).

Risk Management Handbook for Health Care Organizations (4th Ed.). San Francisco: Jossey-Bass, 2003. $135 for ASHRM members, $150 for non-members. Available at www.ashrm.org (Tools & Products) and (800) AHA-2626. (AHA catalog #178161).

Self-Assessment Tool for Risk Management Programs & Functions (2nd Ed.). CD-ROM. $99 for ASHRM members, $149 for non-members. Available at www.ashrm.org (Tools & Products) and (800) AHA-2626. (AHA catalog # 178933)

REPRINTING THIS MONOGRAPH

This monograph is part of a series of timely summaries on critical risk management issues presented by the American Society for Healthcare Risk Management. ASHRM monographs are published as PDFs at www.ashrm.org. Reproduction for distribution without permission is prohibited. Request permission via e-mail at ashrm@aha.org.