Annals of Health Law

Volume 19
Issue 1 *Special Edition 2010*

Article 19

2010

A Review of the Patient-Safety Improvements since IOM Report: How the Healthcare Delivery System Progressed and the Challenges That Remain

Jennifer Groszek
Northwestern Memorial Hospital

A Review of the Patient-Safety Improvements Since the IOM Report: How the Healthcare Delivery System Progressed and the Challenges that Remain

*Jennifer Groszek**

It has been ten years since the Institute of Medicine (IOM) released the report *To Err Is Human: Building a Safer Health System* which referenced studies that analyzed medical errors and extrapolated that at least 44,000-98,000 deaths each year are a result of generally preventable medical errors.[1] The report concluded that, in 1999, costs associated with these medical errors were estimated to be between $17 and $29 billion.[2] The IOM report served as the catalyst for the patient safety movement in health care. Furthermore, the report discussed the complex nature of our current health care system; the frequency and type of medical errors; the development and protection associated with error reporting systems; analyzed why and how errors occur; and proposed a comprehensive approach for reducing errors and improving patient safety. The purpose of this article is to describe different error perspectives, the human factors in engineering concepts that are relevant in health care, to identify noteworthy advances and accomplishments from the past ten years, and present the challenges and remaining priorities.

James Reason, a British psychologist, believed the causes of such errors could be viewed through either one of two different perspectives as person failures or system failures.[3] The person failure perspective acknowledges that errors occur due to a human component, such as forgetfulness,

* Jennifer M. Groszek, R.N., B.S.N., M.J., CPHRM has a bachelor of science in nursing from Saint Mary's College, Notre Dame, IN and a master of jurisprudence in health law from Loyola University Chicago School of Law. She is a Certified Professional in Healthcare Risk Management (CPHRM). Currently, she is a risk manager at Northwestern Memorial Hospital in Chicago.

1. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYS., (Linda T. Kohn, Janet M. Corrigan, & Molla S. Donaldson eds., 1999).

2. *Id.* at 2.

3. James Reason, *Human Errors: Models & Management,* 320 BRITISH MED. J. 768, 769 (2000).

distraction, or reckless behavior. Unfortunately, the medical and health care profession environments have traditionally viewed medical errors as the responsibility and fault of the health care clinician. On the contrary, the system perspective recognizes that while humans are fallible and errors will occur, the situation and/or current process has contributed and even "set-up" the individual to fail. The IOM report was instrumental in bringing forth this perspective within the health care environment.

Another error-management concept that is applicable to health care and its patient safety initiatives can be found in the error philosophies of high-reliability organizations in other fields, such as aviation and nuclear power. High-reliability organizations are defined as industries which continuously perform in hazardous conditions or environments, have little to no margin for deviation or error, and for whom errors can be catastrophic. As such, these organizations have implemented practices, standards, and human engineering theories that promote the following: redundancy and standardization, reduction of reliance on memory through utilization of checklists and tools, instill a culture of preoccupation with failure, promote transparency and disclosure, and a non-punitive approach towards error prevention and reporting. Such high-reliability organization theories have been the foundation for many of the patient-safety changes regarding error analysis and system improvement.

In response to the IOM report, the government initiated an evaluation of the health care delivery system and its outcomes. It challenged administrators, leaders, and providers to comprehensively change vulnerable, error prone, and inefficient health care processes. New and existing private and public sectors responded to the challenge. The following are a select few of the many efforts and changes that resulted. One example from the private sector was the development of the Leapfrog Group. The Leapfrog Group was founded by a group of large employers whose goal was aimed at mobilizing employer purchasing power to alert the health care industry that big leaps forward in healthcare safety, quality, and customer value would be recognized and rewarded.[4] They focused on three care practices: implementation of computerized prescriber order entry (CPOE), application of evidence-based hospital referrals, and staffing of critical care medicine specialists in the intensive care unit. Hospitals are implementing the recommendations, but often struggle with their costs and resource requirements.

Congress responded to the challenge by giving the Agency for Healthcare Research and Quality (AHRQ), a public health services agency within the Department of Health and Human Services (DHHS), $50 million

4. The Leapfrog Group, About Us, http://www.leapfroggroup.org/about_us.

in 2001 to develop patient safety and improvement programs.[5] Federal, state and local policymakers, as well as public and private groups, associations and societies have since been able to implement changes based on AHRQ's research and recommendations, as well as find supportive grants and partnerships.

In regards to the accreditation and standard-setting bodies, The Joint Commission (TJC), a voluntary accreditation program for hospitals and health care organizations, established the Patient Safety Advisory Group. This group developed recommendations for the National Patient Safety Goals (NPSG) that included improving the use of medications, creating a safe environment, implementing fall prevention tactics, and establishing effective communications and teamwork strategies amongst caregivers. These goals were established to help organizations respond to patient safety concerns and are now a part of the respective accreditation process. Each year new goals are approved and added to the list of requirements that organizations must meet to be deemed accredited. Subsequently, two other well known national patient safety initiatives were established by the TJC: the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery, and the Speak Up Campaign which encouraged consumers to be active participants in their health care.[6]

As a public and private resource based organization, the National Quality Forum (NQF) released the report *Serious Reportable Events (SRE's) in Healthcare*, which identified 27 serious, preventable adverse events, commonly referred to as a "never events," that occur in hospitals. The intent of this report was to establish agreement on the definitions of these events and the expected accountability and systematic improvements that should occur. The report was updated in 2006 and is now due for review with possible additions in 2011.

Medical education and training programs were impacted by the patient safety movement as well. In 2003, the Accreditation Council for Graduate Medical Education (ACGME) set the "cap hours for physicians in training at 80 hours per week; limit continuous duty time to 24 hours; required rest periods between shifts; and one day to be free of program responsibilities."[7] These guidelines were set in response to evidence that sleep deprivation and long hours can have a significant impact on physician performance,

5. Lucian L. Leape & Donald M. Berwick, *Five Years After To Err IS Human: What Have We Learned?* 293 JAMA 2384, 2385 (2005).

6. The Joint Commission, Facts About Patient Safety, http://www.jointcommission.org/PatientSafety/facts_patient_safety.htm.

7. Accreditation Council for Graduate Medical Education, The ACGME's Approach to Limit Resident Duty Hours: Common Program Requirements for Duty Hours, http://www.acgme.org/acWebsite/dutyHours/dh_dhSummary.pdf.

learning, and well-being.[8] The program also contains a process for investigating non-compliance and complaints.

As the industry continued to address the goal of improving the quality of care and reducing errors and patient harm, Congress passed The Patient Safety and Quality Improvement Act of 2005. Some of the main advantages within this statute are privilege and confidentiality protections associated with information collected, shared, and analyzed by covered entities. The final rule authorized the development of patient safety organizations (PSO) to encourage error reporting, data analysis, and facilitate learning.[9] However, implementation was delayed until the final guidelines were released in 2008. Healthcare entities continue to develop strategies for implementation.

As the health care industry and its stakeholders progressed with system improvements and the reduction of medical errors, the Centers for Medicare and Medicaid Services announced incentives for hospitals to improve the quality of care, payment provisions to reduce never events, and began identifying hospital-acquired conditions which are preventable. Most recently, a component of the economic stimulus legislation of 2009 allocated approximately $19 billion for health information technology services and the continued development of the electronic health record.

The impact of patient safety improvement is clearly evident. Administrators have recognized the need for executive leadership and support as well as accountability. Disclosure of adverse events and medical errors is no longer a question or issue to debate. Physicians and providers seek guidance and assistance in responding to such events. Every year, TJC releases new National Patient Safety Goals which continue to provide patient safety improvements. But despite many promising efforts, challenges still remain.

One of the main barriers to improving overall care and quality is the financial component. There are multiple demands and incentives from payers, purchasers, and regulatory bodies, yet there is no universal standard. Other challenges are the costs and resources associated with these changes and their implementation. For example, CPOE has demonstrated benefits and error reduction components but has simultaneously introduced new system failures and contributed to medical errors. Staffing resource shortages, certainly not a new hindrance to health care, continue to experience cyclical changes in medical, nursing, and ancillary health care professional school enrollments. Last, the continued debate over tort reform and the current malpractice system creates ongoing challenges.

---

8. *Id.*

9. Patient Safety & Quality Improvement, 73 Fed. Reg. 70,732 (proposed Nov. 21, 2008) (to be codified at 42 C.F.R. pt. 3).

Another challenge is the cultural aspect within the domain of patient safety. As the health care industry embraces and facilitates a "no-blame" culture and system failure perspective, administrators and professional licensing boards must distinguish between individual accountability, process break-downs, and a clear violation of rules. Consumer demands and increased expectations are other components of the cultural challenges that remain. Traditionally, the physician was not challenged by the patient. Now, consumers have more information available to them, expect improvements in the delivery system, and are taking a more active role in their health care.

Over the past ten years, previously unrecognized areas and issues have been identified, which has consequently facilitated prioritization of efforts. It should be acknowledged that opportunities for error exist, medical errors still occur, new changes will affect the system, and patients will continue to experience preventable adverse events. Fortunately, dedicated health care providers, researchers, and patient safety leaders continue to accept these challenges and work toward the ultimate goals of promoting shared learning opportunities and better health care outcomes.