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Medical Errors, Patient Safety, and the Law: Ten Years Later

*Krishna Lynch**



In 1999 the Institute of Medicine (IOM) cited the lack of supportive systems as one of the leading contributors to errors in healthcare. Today many of those systems issues are being addressed. Upon release of the IOM's landmark 1999 report, *To Err is Human*, healthcare leaders and patient safety experts posited the following:

Imagine working in an environment in which all physicians routinely practiced crisis management skills in realistic simulations, using computerized dummies for patients; where all hospitals used electronic medical records, eliminating errors related to a doctor's illegible handwriting; where doctors and nurses worked collaboratively and respectfully in teams so they could understand how to support and help one another; and when mistakes did happen and patients were injured or killed, the first question asked was not, "Who did it?" but, "How did the system fail the provider and the patient?"¹

In 2001, the use of simulators began to gain acceptance and they increasingly were used for clinical care training. The Leapfrog group, a healthcare purchasing organization of Fortune 500 companies, endorsed computerized physician order entry (CPOE) to address the common problems associated with medication administration errors. In 2002, organizations including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) advocated that root-cause analyses and other techniques developed and routinely used in other high hazard industries be adopted in healthcare to promote understanding of the etiology of errors. In addition, in 2006, the Department of Defense (DoD) and the

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1. Janice Perrone, *Designing a Safer, Smarter Healthcare System* (Oct. 27, 1997), available at http://www.ama-assn.org/amednews/1997/pick_97/pick1027.htm.

Agency for Healthcare Quality and Research (AHRQ) released TeamSTEPPS, an evidence-based teamwork system designed to improve communication and teamwork skills amongst healthcare providers. Just last year, Congress passed the American Recovery and Reinvestment Act containing \$19 billion to advance healthcare information technology, including funds to develop integrated electronic health records (EHRs).²

Nearly ten years ago, I researched the epidemiology of medical errors and their impact on patient safety and the law. As a second-year student in Loyola University Chicago School of Law's Master of Jurisprudence (M.J.) in health law program, my journey began with curiosity about the intersection of medical errors, patient safety, and the law. *To Err is Human* first exposed me and my peers to medical errors and their impact on patient safety. You may recall the news headlines, "44,000 to 98,000 Americans die as a result of medical errors."³ The IOM asserted that medical errors rank as the 8th leading cause of death, citing that more people die from medical errors than from car accidents, breast cancer and AIDS.⁴ The costs associated with medical errors were estimated between \$17 billion and \$29 billion.⁵ The findings elicited a significant public and private response regarding the safe practices of the U.S. healthcare system, making patient safety a national issue. *To Err is Human* characterized the U.S. healthcare system as "decentralized and fragmented" with large, complex problems. Moreover, it emphasized the need to overcome legal and cultural barriers, while providing knowledge and tools necessary to promote patient safety. The IOM recommended a multi-faceted approach of system redesign for reducing medical errors and improving patient safety: (1) establish a national center for patient safety; (2) create voluntary and mandatory reporting systems; (3) encourage action by licensing and accrediting bodies, professional organizations and group purchasers; and (4) develop healthcare organization initiatives to improve safety.⁶ The government response came from the Quality Interagency Coordination Task Force (QuIC) in a report to former President Clinton entitled *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact* (QuIC report). The QuIC report endorsed all of the IOM's recommendations, including a specific plan to implement the recommendations and further actions to reduce medical errors and promote patient safety.

The QuIC report resurfaced the issue of medical error and its threat to quality healthcare in the U.S. The report did not contain new information

2. Pub. L. No. 111-5, 123 Stat. 115.

3. INST. OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 1-2 (1999).

4. *Id.*

5. *Id.*

6. *Id.*

but instead highlighted the need to focus on system redesign rather than individuals or incidents. Interestingly, the startling results generated by the IOM were compiled from previous research studies conducted in New York in 1984 (the Harvard Medical Practice Study) and in Colorado and Utah in 1992, which revealed that over half of all adverse events resulted from medical errors. The Harvard Medical Practice Study, led by Dr. Lucian Leape, is considered the benchmark study for estimating the extent of medical injuries resulting from medical interventions. Both studies reiterated that injury attributable to medical error was an inherent risk of hospital care. While the IOM's use of both studies was controversial, the report raised a significant level of interest from an array of stakeholders. It demanded a call to action.

The follow-up IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century in 2001* (2001 IOM report), focused on system improvements including implementing information technology, team based care, and redesign of reimbursement practices. More importantly, the 2001 IOM report espoused six aims for improving the quality of healthcare: safe, effective, patient-centered, timely, efficient, and equitable (STEEEP). The fundamental principles of the American Hospital Association's (AHA) platform, Hospitals In Pursuit of Excellence (HPOE), support STEEEP. The AHA adopted HPOE as a strategic platform to accelerate performance improvement in U.S. hospitals by focusing on healthcare-associated infections, care coordination, patient safety, medication management and health information technology.

In my research, I posited that errors in medicine, though multi-factorial, can be remedied and prevented through safety system improvements, a cultural shift toward patient safety, and an overall commitment at every level of the health delivery process. I examined definitions synonymous with medical error and the lack of standardized taxonomy or nomenclature for identifying and reporting adverse events or medical errors. Additionally, I researched the current practices in healthcare, both medical and legal, that impact the law and disclosure of medical errors on the provision of patient care—the tort liability system, ethical implications of disclosure, existing legal protections and their impact on error reporting systems. Finally, I examined the lessons learned, preventive strategies and patient safety initiatives undertaken by healthcare systems, the federal government, and patient safety advocacy groups.

I pondered how this nation would utilize the IOM's findings about medical errors and their deleterious impact on the healthcare system. My findings evoked a model that seeks to examine latent system failures and weaknesses, investigate beyond the individual or incident and implement mechanisms to reduce the likelihood of error, including standardization, double checks, information system technologies, checklists, protocols, and

training. Most importantly, my research demonstrated that the institutionalization of safety was critical for a viable healthcare system. I surmised that voluntary reporting systems and the creation of the AHRQ as a national center for patient safety and research in 2001 were noteworthy federal initiatives of promise. However, I perceived the burden of the tort liability system as a threat to patient safety improvement efforts. Larry Palmer postulated that safety is a goal choice that may be achieved by tort liability through adjudication, by regulation through the political process, or by transactions through the market process.⁷ He contended that the healthcare industry should assess its capacity to adopt new ways of viewing safety, which would require a shift in the way the industry views error prevention and the law.⁸ I agree.

More than ten years after the release of *To Err is Human*, many ask whether healthcare is safer today. Error prevention and patient safety remain at the forefront of national priorities in public and private sectors, legislative and regulatory bodies and healthcare organizations. Media outlets, professional associations and consumer advocacy groups recently revisited the myriad of issues uncovered in *To Err is Human* and attempted to evaluate the nation's progress in preventing medical errors and improving patient outcomes. The responses are mixed, yet the consensus is that there is much more to be done in reducing preventable medical errors and advancing quality and safer healthcare practices. The institutionalization of safety has not occurred. Successes have been fragmented while challenges remain incessant.

The anniversary of *To Err is Human* is marked by the promise of the passage of healthcare reform. Congress charged seventy-seven Patient Safety Organizations (PSOs) with conducting activities to improve patient safety in the Patient Safety Quality Improvement Act of 2005.⁹ As of November 2009, twenty-seven states plus the District of Columbia have passed legislation or regulation related to hospital reporting of adverse events to a state agency. Healthcare systems have begun to employ early settlement strategies and mediation to the adjudication of serious injuries causing harm, as well as effective disclosure practices.

Yet medication errors and healthcare-associated infections abound. The Food and Drug Administration estimates that 1.5 million preventable adverse healthcare events occur annually. According to the Centers for Disease Control and Prevention, healthcare-associated infections account for an estimated 1.7 million infections and 99,000 associated deaths each

7. Larry Palmer, *Patient Safety, Risk Reduction, and the Law*, 36 HOUS. L. REV 1609, 1615-17 (1999).

8. *Id.*

9. Pub. L. No. 109-41, 119 Stat. 424.

year. However, the healthcare community forges ahead to establish safe practices aimed at reducing healthcare-associated infections through projects such as the Michigan Health and Hospital Association/John Hopkins University Keystone Intensive Care Unit Project. The Institute for Healthcare Improvement's work through its Five Million Lives Campaign to protect patients from medical harm and technological developments such as the adoption of health information technology systems for medication orders and the use of barcodes and decision alerts for potentially harmful medications has raised awareness of medical errors and promoted best practices for patient safety.

How will the nation advance the quality and patient safety agenda to U.S. hospitals in the coming years? What is the next frontier of patient safety? There is growing concern of the impact of transparency and legal/regulatory mandates on quality and patient safety efforts. Medicare Hospital Compare, a public website that provides accessible information about hospital performance and efforts to improve quality, aims to improve care through information.¹⁰ Many states have adopted mandatory reporting laws modeling the National Quality Forum's Healthcare "Never Events." The Centers for Medicare and Medicaid Services (CMS) instituted a non-payment policy for Hospital Acquired Conditions (HACs) and some commercial insurance carriers have followed. In addition, in their quest for models of healthcare payment and delivery reform, CMS has launched a series of value-based purchasing demonstration projects to improve quality of care. Models of what patient safety can achieve are few and far between, nationally. The challenges lie in the availability of resources. There is still much to accomplish in reducing preventable errors and institutionalizing safety in healthcare.

10. See <http://www.hospitalcompare.hhs.gov/>.