Medical Errors Continue To Be Problematic

Alan C. Horowitz

Between 210,000 and 400,000 preventable deaths occur annually in U.S. hospitals, according to an article in the current issue of the Journal of Patient Safety.[1] If the findings are correct, they represent a sobering increase over the 44,000 to 98,000 preventable hospital deaths estimated in the landmark Institute of Medicine (IOM) report published in 2000, "*To Err is Human: Building a Safer Health System*."[2] Indeed, medical errors would represent the third leading cause of death in the U.S. if the recent article's conclusion is correct. According to the Centers for Disease Control and Prevention, only heart disease and cancer have a higher mortality rate.

The author of the article, John T. James, is a toxicologist at the National Aeronautics and Space Administration (NASA) who examined four published studies, each of which used the Global Trigger Tool to identify preventable adverse events (PAE). Two of the studies relied upon were undertaken by the U.S. Department of Health and Human Services' Office of Inspector General (OIG). In those studies, the OIG measured adverse events among Medicare beneficiaries using the Global Trigger Tool as one method of detection. The Global Trigger Tool was developed by the Institute for Healthcare Improvement and is used by hundreds of hospitals in many countries to monitor adverse event rates. It relies in part on a systematic and retrospective review of medical records by trained individuals who look for "triggers" or clues that enable researchers to identify adverse events.

It comes as little surprise that adverse events in hospitals have remained a problem as resistant as the latest strain of MRSA. However, the magnitude of the problem demands attention. A decade after the IOM report, a recent analysis of Medicare data revealed that from 2009 through 2011, there were 287,630 serious potentially preventable patient safety events among Medicare patients in U.S. hospitals.[3] (Note: those preventable adverse events represent only the Medicare patient population.)

The precise number of deaths related to medical errors is unknown. The primary reason, as many patient safety experts point out, is that 50 – 96% of adverse events are not reported. Regardless of the actual number of preventable deaths, there is cause for continued concern and further action.

The IOM report prompted many health care organizations to create and implement new patient safety initiatives. It also caused a groundswell of legislative activity at the state and federal levels and inspired the Patient Safety and Quality Improvement Act (PSQIA) of 2005.[4] The regulation implementing the PSQIA was published on November 21, 2008, and became effective on January 19, 2009.

Hospitals and other providers should appreciate (and utilize) the fact that the PSQIA is the first

1 *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, John T. James, PhD, Journal of Patient Safety, 122-128, September 2013.

2 According to the IOM Report, "At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies." IOM (Institute of Medicine). To Err is Human – Building a Safer Health System, Washington, DC: The National Academy Press; 2000.

3 Statistics are based on HealthGrades application of QI Windows® Software (version 4.4), developed by the Agency for Healthcare Research and Quality (AHRQ), for MedPAR data for years 2009 through 2011 and represent 3-year estimates for Medicare patients, available at https://www.cpmhealthgrades.com/index.cfm/portfolio/research-studies/.

4 Pub.L. 109–41, 119 Stat. 424 (2005) (codified at 42 U.S.C. §§ 299b-21-299b-26 (2006); *see* also Patient Safety Rule, 42 C.F.R. § 3 (2010) (implementing the Patient Safety Act).

federal legislation that created a privilege for information defined as "Patient Safety Work Product" (PSWP). According to the PSQIA, "patient safety work product shall be privileged and shall not be: 1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider; [or] 2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider." Thus, an important obstacle to disclosing and learning from serious adverse events was removed.

The PSQIA also created Patient Safety Organizations (PSO). The agency within HHS responsible for overseeing the PSQIA is the Agency for Health Care Research and Quality (AHRQ). According to AHRQ, "PSOs are organizations that share the goal of improving the quality and safety of health care delivery." Public or private entities, profit or not-for-profit entities, and provider entities such as hospital chains are eligible to become PSOs.[5]

By providing both confidentiality and a privilege that shields against discovery in lawsuits, PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data. Consequently, they improve quality by identifying and reducing the risks and hazards associated with patient care.

Not all responses to the lingering problem of PAEs have been welcomed with open arms. For example, the National Quality Forum (NQF) created a list of 28 Serious Reportable Events, commonly, if not fondly, referred to as "Never Events." In July of 2008, the Centers for Medicare & Medicaid Services (CMS) announced that effective October 1, 2008, it would no longer pay hospitals the additional costs associated with Never Events such as: a foreign object unintentionally retained after surgery; vascular-catheter associated hospital acquired infections; catheter-associated urinary tract infections; administration of incompatible blood, and air embolism.

Are the Numbers of PAEs Increasing?

For more than a decade, hospitals and other health care providers have undertaken significant attempts at reducing PAEs. Thus, the current report's conclusion that up to 400,000 PAEs occur annually seems counterintuitive. Indeed, that figure is four times higher than the number of PAEs cited in the IOM report. However, there may be a plausible explanation. The IOM report was based on two studies: the Harvard Medical Practice Study, which examined 30,000 discharge records from 51 New York hospitals in 1984; and a study that examined 15,000 medical records from Colorado and Utah hospitals in 1992. The researchers extrapolated their findings to the more than 33.6 million admissions to U.S. hospitals in 1997. The study in Colorado and Utah estimated that at least 44,000 Americans die each year as a result of medical errors while the results of the New York Study suggested the number may be as high as 98,000.

According to David Jackson, MD, PhD, Adjunct Professor of Geriatric Medicine, Johns Hopkins University School of Medicine, "American Medicine is at a crossroads with regards to the occurrence of medical errors. The numbers of lethal adverse events caused by these errors during acute hospitalizations are so large, that no matter what study one accepts as the most definitive, action must be taken to address this epidemic."[6]

James postulates that the bar for identifying PAEs in the New York/IOM study was higher than that in the four more recent studies he examined. He also suggests that the Global Trigger Tool is more precise than the methodologies used in the older studies. Other possible explanations for his estimate of 210,000 to 400,000 deaths per year include: the proliferation of antibiotic-resistant bacteria, the inappropriate use of medications, an increasingly aging population and the increased complexity of medicine and technology.

Lessons Learned and Successful Strategies

The IOM report ushered in broader acceptance of the systems theory of errors. Rarely is a medical error caused by a single individual. Systems theory explains that faulty systems account for and allow medical errors to occur. Where health care facilities and organizations have moved away from a "culture of blame" to an understanding of the role

5 Additional information about the PSQIA and PSOs, including a list of all AHRQ-certified PSOs may be found at http://www.pso.ahrq.gov/.

6 Email from David Jackson, MD, PhD, (Adjunct Professor of Geriatric Medicine, Johns Hopkins University School of Medicine) to Alan C. Horowitz (September 26, 2013) (copy on file with author).

systems play, reporting has increased, leading to identification of underlying system flaws and the implementation of effective preventative measures.

Dr. Jackson suggests that "We must re-teach health professionals about the need for a sense of urgency when treating acute bacterial infections (unnecessary delay in treatment can kill), tempered by the understanding that one should not over treat. Physicians must use the most selective, narrow spectrum drug that can effectively treat the infecting organism if we are to reduce the contribution of this problem to the rate of deaths each year caused by less than optimal prescription of these potentially life-saving drugs."[7]

According to Michael Cohen, RPh, MS, Sc.D., FASHP, a pioneer in the area of medication safety and the founder and president of the Institute for Safe Medication Practices (ISMP), "I think more emphasis is needed on the value of confidential adverse event reporting programs operated by federally recognized Patient Safety Organizations. Our focus at the Institute for Safe Medication Practices, one of the PSOs, is medication error prevention. I believe we've made some good progress in this area by giving practitioners a safe forum to communicate about actual medication errors through the National Medication Error Reporting Program that we operate. Practitioners also send us information about near misses and potentially hazardous conditions like poor labeling of certain drug products. In turn, we apply our expertise in analyzing and publishing information that provides evidence-based or peer-reviewed prevention strategies."[8]

Cohen notes, "We also advocate for changes in products and practices through our relationships with regulatory agencies, standards organizations and product manufacturers. This has led to many changes for safety reasons, including numerous products that have been removed from the market, changes in drug names and/or labeling, and practice changes as well. I believe that much of what we do is applicable to areas other than medications. More needs to be done to study, support and promote these programs as a major step in overall improvement of the numbers we see in this report [*Journal of Patient Safety*]."

Dr. Patricia Nay is the Executive Director of the Office of Health Care Quality for Maryland's Department of Health and Mental Hygiene. In her position, Dr. Nay is responsible for overseeing the care provided by 14,000 health care facilities in Maryland. Underscoring the role all stakeholders have in reducing medical errors, she notes that "Medication management is a team sport – all members of the interdisciplinary team, as well as the patient, share in this crucial process."[9] Dr. Nay recommends that systems have safety nets or built-in redundancies. "In a hospital, the systems governing medication management must be made fault-tolerant to include redundancies to compensate for inevitable human error."[10]

The reporting and analysis of data on adverse events is essential in reducing PAEs. Towards that end, being able to disclose and discuss medical errors and near misses candidly without fear of retribution further promotes the goal of patient safety. Overall, health care providers have made significant progress in the area of patient safety. However, as the article in the *Journal of Patient Safety* illustrates, opportunities for further improvement clearly remain. An overarching and bedrock principle of medicine is applicable in the context of patient safety; *primum non nocere* – first, do no harm.

7 Id.

8 Email from Michael Cohen, RPh, MS, Sc.D., FASHP (President and founder of the Institute for Safe Medication Practices) to Alan C. Horowitz (September 25, 2013) (copy on file with author). The IOM Report acknowledged the significant contribution of Michael Cohen and ISMP, among others, in helping the researchers understand the nuances of patient safety. A partial list of ISMP accomplishments can be found at: http://www.ismp.org/about/accomplishments.asp.

9 Email from Patricia Tomsko Nay, MD, CMD, CHCQM, FAAFP, FAIHQ, FAAHPM (Executive Director, Office of Health Care Quality, Maryland Department of Health and Mental Hygiene) to Alan C. Horowitz (September 26, 2013) (copy on file with author).

10 Id.

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