

ASSESSING MEDICAL ERROR IN HEALTH CARE

Controversy, Challenge, and a Culture of Safety

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A Rhode Island hospital performed a tonsillectomy on the wrong patient because staff confused her and another girl with a similar last name.¹ Neurosurgical instruments used by Tulane University on a patient later found to be infected with Creutzfeldt-Jakob disease may be the cause of transmitting that illness to eight other patients.² Even more shocking, the *Chicago Tribune's* review of 3 million patient records concluded that since 1995, at least 1,700 hospital patients had been accidentally killed and another 9,584 injured because of nursing mistakes.³

These and other headlines of medical errors found much attention in the popular media in 2000. Increased concern by the public about the safety of hospitals heightened last year after the Institute of Medicine (IOM) published the report "To Err is Human" in November 1999. This report described, in great detail, the magnitude of medical error in U.S. health care institutions. The report maintained that if data from studies in Utah and New York were extrapolated to the more than 33.6 million hospital admissions in 1997, then at least 44,000 Americans—possibly up to 98,000—die each year as a result of medical errors. In addition, the report stated that "total national costs (lost income, lost household production, disability, and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one half."⁴ It concluded that medical error is the eighth leading cause of death in the United States.

EROSION OF PUBLIC TRUST

A recent study of 2,000 adults by the Kaiser Family Foundation reported that a surprising number of individuals were "very concerned"

about an error resulting in injury to them or a family member in the following situations:

- 47 percent when receiving health care in general
- 47 percent when going to the hospital for care
- 40 percent when going to a physician's office for care
- 34 percent when filling a prescription at a pharmacy
- 30 percent when eating food purchased at a supermarket⁵

The loss of confidence regarding the quality of health care in the United States and the huge amount of wasted dollars entrusted to the industry's stewardship represent a serious problem for health care institutions. The U.S. health care system is based on the Hippocratic oath and the commitment to "above all, do no harm." Can hospitals continue to espouse mission statements that profess to deliver high-quality care?

Catholic health care in particular is based on a ministry of caring for its patients and improving the quality of their health and lives. Clearly, each Catholic hospital administrator and physician leader must commit to addressing the problem of medical errors—patients demand it.

So where do we begin? Focusing our energy on why errors happen is more productive than disputing the number and frequency of medical errors. The delivery of health care is complex, involving multiple providers and components and including various degrees of specialization, all of which have a high degree of interdependency.

Overall, errors themselves are complex and occur in complicated systems. But other highly complex industries, such as space exploration, nuclear power, and aviation, have done substantial work in studying errors, many of which occurred after catastrophic events. We can learn from the

work done to analyze these accidents, such as the Three-Mile Island accident and the Challenger crash. The Challenger failed because of a combination of brittle O-rings, unexpected cold weather, reliance on the seals in the design of the booster, and a change in the roles of the contractor and the National Aeronautics and Space Administration. No one factor alone caused this crash, but the combination lead to disaster. An accumulation of seemingly insignificant events can cause large systems to fail.

Setting a goal of "zero defects"—or no errors—in a health care organization is unrealistic. Errors will always occur; the same systems that produce success also produce failure. However, we can reduce their frequency and severity by understanding the causes and building recovery into our procedures. Procedures depend on time and sequence, and often no buffer or margin for error exists. The best we can hope for is to build in more checks and balances (slices of "Swiss cheese"*) to catch errors before they reach the patient.

Health care has come late to the study of errors on an industry-wide level. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) put in place requirements for "sentinel event" reporting and investigation just a few years ago to encourage hospitals to investigate errors and to begin a central system for collecting and analyzing the information. Reporting of such events—defined as an unexpected occurrence involving death or serious physical or psychological injury—has led to issuance of "sentinel event alerts" from JCAHO regarding common errors or

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procedures that have caused patient harm. The most notable alert recounted the misadministration of concentrated potassium chloride in nursing units, including neonatal and intensive care units. The alert recommended removal of this compound from nursing units, which, because of packaging similarities, can be mistaken for more commonly administered pharmaceuticals. No subse-

quent patient deaths related to concentrated potassium chloride have occurred since this alert was published. The study of sentinel events and the completion of the JCAHO-required "root cause analysis" (an examination of underlying organizational systems and procedures) force hospitals to attempt to identify causative factors for error, which can then be addressed. JCAHO's latest recommendation is to apply this method to identified near misses as well.

TYPES OF ERRORS

Although Catholic health care acknowledges the complexity of systems and the fallibility of human beings, leaders still must work to prevent as many errors affecting patients as possible. Our goal should be to rekindle confidence in health care and develop the trust of our patients and physicians. Prevention of error begins with understanding the four types of error:

- Execution error, which involves a planned action that was not completed as intended
- Planning error, in which the intended action is incorrect
- Active error, which is error by the frontline staff
- Latent error, which involves procedural flaws that led to operator error

According to the first IOM report, most responses to error tend to focus on active error. Scrutinizing the person closest to the error is the most obvious approach. However, examining latent error is a more effective way to make the system safer. JCAHO's requirement of a credible root cause analysis was implemented to attempt to force health care institutions to look past the

*James Reason's work on the latent failure model of complex systems is commonly known as the "Swiss cheese" model of error. In this model, many different factors come together in time and space, resulting in an error that affects the patient. The slices of Swiss cheese represent parts of the process and often serve to deflect an error, creating a near miss. An error occurs when the holes in the "Swiss cheese" slices line up (failures in multiple parts of the process) and the error reaches the patient.

active error and investigate further to find any applicable latent error.

Many other factors contribute to medical error, including some acute health care delivery systems that developed after World War II and have not changed since inception. *Organizational factors* include the institution's culture, workflow design, staffing levels, reliance on mandatory overtime, and overall resources allocated for patient care delivery. *Ergonomic factors*, such as lighting, noise, design of equipment and furniture, legibility of labels, positioning of controls, and confusingly similar designs, also contribute to error. *Human vulnerabilities* of poor planning ability, poor short-term memory, poor problem-solving ability, and limited attention span are also complications. *Situational factors* abound in health care and include fatigue, stress, illness, and sensory overload. (How can hospitals require a registered nurse to work mandatory overtime when the Federal Aviation Administration grounds pilots who have not have at least eight hours of rest after a 10-hour shift?) *Cognitive lapses* contribute to error in the form of overconfidence, overgeneralization, reversion to the familiar when under stress, and confirmation bias (looking for something that confirms what one believes). *External factors* that may contribute to error include regulations, litigation, payors, and consumers.

THE CURRENT CULTURE OF BLAME

Hospital and physician leaders will confront many barriers in their attempt to study medical error. Identifying and addressing these barriers is the first step in the process. The first is admitting that errors occur; the second is resistance to change. Others include resistance to "cookbook" medicine and guidelines, fear of discipline or retaliation, failure to appreciate the complexity of health care, hindsight bias, and financial limitations. Other types of barriers are societal: the growing lack of trust in the health care system, the need to blame someone, and the need to rationalize a negative event.

Last, but certainly not the least, are legal and political barriers. Health care providers are caught up in a civil legal system (involving fault-finding under tort law), a regulatory system, and a criminal justice system, all of which create an unusual and burdensome context in which to address medical errors. Moreover, concerns about liability of medical errors in the tort system are, frankly, not the most compelling in the day-to-day health

care environment; professional liability exposure is usually not determined until years after an incident occurs. More important is the increasingly aggressive approach of federal and state surveyors from agencies such as Centers for Medicare and Medicaid Services and the Department of Health. These agencies respond immediately to notification of medical errors by conducting multiple surveys and finding numerous faults in the quality of care. Deviations from standards are noted as deficiencies by governmental agencies, thus subjecting health care providers to loss of licensure and reimbursement.

The criminalization of health care, as shown by recent selective and successful criminal prosecutions of health care providers for errors in judgment, has raised the specter of personal exposure. Legislating corrective action to address medical error is not the most effective way to handle this issue and clearly will not resolve the errors. Indeed, creating more regulatory and criminal exposure might well drive the reporting and discussion of medical errors underground, thus having a negative effect on performance improvement.

THE 2001 IOM REPORT

On March 1, 2001, The IOM released a second report on its investigation into the safety of health care in the United States. "Crossing the Quality Chasm: A New Health System for the 21st Century" focused on 13 specific recommendations in four general themes designed to provide a road map for organizations to use in their efforts to improve patient safety.⁶ The themes are vision, redesign of the delivery system, building organizational support for change, and environmental change. The report stated that health care should be:

- Safe—avoiding injuries to patients from care intended to help them
- Effective—providing services based on scientific knowledge to all who can benefit and refraining from providing services to those not likely to benefit
- Patient-centered—providing care respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions
- Timely—reducing wait times and sometimes harmful delays for those who receive and those who give care
- Efficient—avoiding waste, including waste of equipment, supplies, ideas, and energy
- Equitable—providing care that does not vary

in quality because of personal characteristics such as sex, ethnicity, geographic location, or socioeconomic status⁶

The Catholic health care ministry focuses on a common vision, which includes patient-centered care with attention to stewardship and a commitment rooted in the human dignity of all persons. The efforts to address what health care "should be" will be easier to achieve as Catholic leadership reminds staff and medical partners about this special focus.

Although many health care leaders are uncomfortable with the increasing scrutiny of their organizations by non-medical professionals, they will come to see that the attention can be positive if actions are taken to reduce the frequency and severity of medical error. Catholic health care professionals, physicians, and administrators persevere in this complex and very difficult environment of patient care because of their commitment to continuing Jesus' healing ministry. Health care organizations uniquely grounded in a religious commitment have an advantage in addressing the barriers and issues that contribute to medical errors. The Catholic values of preserving human dignity, focusing on the common good, and advocating care of the needy are reflected by system leadership. Catholic health care is thus well positioned to improve patient safety.

On the heels of the second IOM report, U.S. Health and Human Services Department Secretary Tommy G. Thompson announced the formation of a patient safety task force to coordinate a joint effort among several federal agencies to collect data on patient safety. The secretary has charged the Agency for Health Care Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services to identify the data that health care providers, states, and other agencies need to collect to improve patient safety. The announcement included a statement that this plan will provide "those who must submit reports an opportunity to learn," suggesting a mandatory reporting structure.

NEW JCAHO STANDARDS IN 2001

New JCAHO standards that focus on medical error reduction in hospitals and patient safety were implemented July 1, 2001. They were added to the JCAHO-named areas of leadership, improving organizational performance, and management of information. A new emphasis on patient safety was added to patient rights, educa-

tion of patients and families, continuity of care, and management of human resources. The major focus of these new standards is on organizational leadership and the development of a culture of safety. The standards state that hospital leaders are to create an environment that:

- Encourages error identification and remedial steps to reduce the likelihood of future or recurring errors
- Minimizes individual blame or retribution to those involved in or who report an error
- Establishes an organization-wide patient safety program that uses both internal and external knowledge and experience to prevent errors

One of the most controversial new standards challenges the way hospitals currently address errors that result in patient injury. This requirement, in the JCAHO category of patient rights, states that the patient and/or the patient's family must be informed about results of care, including unanticipated outcomes. In the past, health care organizations have had to consider liability and resultant legal actions when investigating medical errors, often choosing not to fully inform the patient or family. This standard forces organizations to work toward a culture of safety and full disclosure of medical error to those affected.

As the IOM report states, "It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives and meet the challenges ahead." Harnessing this motivation and recapturing the public's trust and confidence that each organization will provide high-quality treatment is a special challenge to Catholic health care. □

NOTES

1. *Patient Safety Monitor*, December 27, 2000, vol. 1, no. 51.
2. *Patient Safety Monitor*, November 3, 2000, vol. 1, no. 48.
3. *Chicago Tribune*, <http://chicagotribune.com>, September 10-12, 2000.
4. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, editors, *To Err Is Human*, Institute of Medicine, National Academy Press, November 1999.
5. K. Hallam, "An Erosion of Trust: Survey Finds Consumers Fear Medical Errors and Want Better Protection From Such Mistakes," *Modern Healthcare*, December 18, 2000, pp. 30-31.
6. Committee on Quality Health Care in America, *Crossing the Quality Chasm: A New Health System for the 21st Century*, Institute of Medicine, National Academy Press, March 2001, pp. 5-20.
7. *Crossing the Quality Chasm*, pp. 5-20.

JOURNAL OF THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES

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