Medical Errors in Surgery

by David Emmott

Researchers at the Institute of Medicine have reported a staggering number of medical errors, that is, of adverse effects as a result of treatment, in healthcare in America. This article argues against a no-faults systems view as a corrective for these events and calls us instead to trust the motivations of providers and the peer review process to bring about the needed cultural revolution. It sees healthcare as an honorable profession rather than an off-the-shelf commodity, and calls on providers to be courageous leaders who make safety their priority.

Quality of Health Care in America, at the Parequest of the Institute of Medicine, published To Err Is Human (Kohn, Corrigan, and Donaldson 2000), an initiative to improve patient safety by calling for a reduction in medical errors. Adopting and embracing this comprehensive work will demand years of work, focused effort, and the development of a self-effacing attitude. It may, in fact, require nothing short of a cultural revolution among healthcare workers, perhaps especially physicians (Leape and Berwick 2000).

If healthcare providers expect to meet the challenges of new diseases, more sophisticated technology, and increasing populations of frail elderly patients, we must make our care safer, more effective, and more humane. We must, that is, decrease the number of complications resulting from treatment. Nevertheless, we must simultaneously resist allowing the pendulum to swing too far in the direction of oversight and suspicion.

Our ability to help patients will always depend on our ability to instill trust; therefore, in the pages that follow, I will argue that professional integrity and a reliance on individual responsibility should be preferred over a no-blame systems approach to acknowledging and reducing medical errors. Safety is a critical first step, and *To Err Is Human* (2000) rightly calls for a comprehensive approach. However, the same report notes the importance of "the intrinsic motivation of healthcare providers, shaped by professional ethics, norms, and expectations" (p. 6).

Primum non nocere

"First, do no harm" is axiomatic among healthcare workers, but it may have been easier to observe before the advent of invasive and sophisticated technology. Comfort care, after all, entails little risk; but it also offers little hope for success, if cure is the objective. Modern medicine is a relatively young science. On some accounts, its beginning is tied to Alexander Fleming's discovery of penicillin in 1928. In the seventy-five years since, we have developed numerous techniques for "invading" and altering the human body. We can enter bodies surgically, intravenously, sonographically,

magnetically, and radiographically — and each of these techniques allows us to treat disease or traumas that were once considered impossibilities. Moreover, now that we can perform these intrusions for purposes of removing, manipulating, or refining bodily functions, we can also tailor them to be less morbid and more tolerable.

Laparoscopic cholecystectomy (i.e., gallbladder surgery by scope), an out-patient procedure, has replaced an operation that once required an average length of stay in the hospital of five days with an additional four-to-six weeks for complete recovery. Extra-corporeal shock wave lithotripsy (the use of shockwaves to break up kidney stones), percutaneous coronary angioplasty (the balloon technique for expanding arteries), and arthroscopic joint surgery (knee or other joint surgery by scope) are a few of the modern adaptations that have improved outcomes and dramatically shortened or eliminated hospital stays. Modern medicine has obviously made tremendous gains in only a few decades.

Why, then, are we so concerned about medical mistakes? Can we not say that mistakes are necessary casualties for the sake of "progress"? Some, perhaps, but the majority of medical mistakes are not attributable to the learning curves of new procedures or techniques. They are, according to experts on the subject, the result of latent flaws in our system.

Defining and Quantifying Medical Error

The Harvard Medical Practice was the first key study to quantify and stratify "medical mistakes" (See Brennan, Leape, Laird et al. 1991 and Leape, Brennan, Laird et al. 1991). Powered by large numbers, this study sheds objective light on a problem each of us must face. In it, more than 30,000 randomly selected records from fiftyone acute-care hospitals, were examined, and a 3.7 percent incidence of adverse events was documented. Another large study, this time of 14,732 hospital charts from twenty-eight hospitals

in Utah and Colorado (Thomas, Studdert, Newhouse et al. 1999), though undertaken to determine the cost of preventable errors, corroborated the Harvard Study. In the Utah and Colorado hospitals, the incidence of adverse events was 3.1 percent, of which over half were deemed by the investigators to have been preventable.

Though imperfect, these studies are significant. Extrapolating their data to the 33.6 million yearly admissions to U.S. hospitals, suggests that the number of deaths attributable to medical errors is comparable to the number of Americans who die (annually) from breast cancer or motor vehicle accidents: 43,458 and 42,297, respectively (Kohn, Corrigan, and Donaldson 2000). Further, the

Can we not say that mistakes are necessary casualties for the sake of "progress"? Some, perhaps, but the majority of medical mistakes are not attributable to the learning curves of new procedures or techniques.

national cost of adverse events in the United States is in excess of \$37 billion annually. The implication that our system is not only wasteful but also needlessly harmful cannot be ignored.

Since the publication of *To Err Is Human*, several investigators have pointed to the dangers inherent in extrapolating these numbers (McDonald, Weiner, and Hui 2001). Both the Harvard Medical Practice Study and the Utah and Colorado study were designed to glean data on medical mistakes for the purpose of calculating the magnitude of medical expense and legal exposure. Both studies lacked the input of specialty physicians in the review process and acceptable complication rates for comparison, and both studies overemphasized minor adverse events.

Thus, for example, in the preventable or "negligence" category, the Harvard Medical Practice Study included wound infections (12.5%), nontechnical complications (20.1%), and surgical failures (36.4%). The same study also had an oversampling of patients in several high-risk, low-volume specialties, as it was designed to assess extent of injury that might lead to malpractice exposure. In the Harvard study, 56.8 percent of the adverse events resulted in minor impairment with complete recovery in one month. In the Utah and Colorado study, 84.1 percent of adverse events caused temporary disability, and the "preventability" of the events was judged intuitively by two study investigators."

Further, a study of 4,198 patients who died at seven Veterans Administration medical centers from 1995 to 1996 suggests that only 5 percent of patients who experienced adverse effects (one

The government's and medical leaders' important task is not simply to encourage reporting but also to protect the peer review process from discovery so that providers can tackle the remaining problems and make necessary adjustments.

out of every 10,000 admissions) would have lived longer than three months had care been optimal. This finding suggests the difficulty of establishing causal relationships between medical error and patient outcomes. Taken in context, the adverse events may be minor and the determination of negligence, or preventability, largely a subjective decision (Hayward and Hofer 2001).

It is, then, dangerous to accept the findings of these studies without further review, and dangerous or misleading to apply their data to the entire nation. It should also be noted, however, that Leape's (2000) response to these criticisms of data that have been largely unquestioned for ten years does much to contextualize this debate and much to dispel the notion that *To Err Is Human* erred by exaggeration.

The argument is not, however, over the exact number of errors that occur, but whether we should accept these figures as a rationale for implementing more bureaucratic regulation. I take it as granted that we who pride ourselves on having the best healthcare system in the world must also recognize that the structure of our delivery system may be seriously flawed. We may be among the most technologically progressive care providers in the world, but we also have apparent deficiencies that demand our consideration and attention.

At the same time, our technology and know-how provide us with unparalleled resources to facilitate improvement; and, indeed, we have been steadily improving (Brennan 2000). We have a peer review process and reporting requirements that are more likely than bureaucratic regulation to protect patients from adverse effects. Therefore, the government's and medical leaders' important task is not simply to encourage reporting but also to protect the peer review process from discovery so that providers can tackle the remaining problems and make necessary adjustments.

Protecting the Peer Review Process

Most states have statutes requiring acute care hospitals, skilled nursing facilities, home health agencies, primary care clinics, chemical dependency recovery hospitals, and correctional treatment centers to report certain adverse events to the proper agency. Standard-of-care determinations are, for instance, reportable to the state if they are found to reflect deficient quality of care. In return, states provide peer reviewers and risk managers protection from discovery, that is, from having to disclose the contents of their investigations and reports. The content of the risk management process is entirely confidential. In most instances, the details are restricted to

members of the Quality Improvement team, and the documented results are also accessible to only a few people.

This control and confidentiality are necessary to ensure the reporting of error, its objective evaluation, and the functioning of the entire process. Risk management and quality review will succeed only if nurses, physicians, psychologists, and other healthcare professionals are willing to cooperate and trust the process. Therefore, states must continue to protect the contents of peer review from discovery. The Institute of Medicine recognizes the significance of this concept and recommends that Congress "pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organiza-

Knowing that a peer review committee will examine and question their actions and management decisions raises the performance bar for most physicians.

tions for internal use or shared with others solely for purposes of improving safety and quality" (Kohn, Corrigan and Donaldson 2000).

Failure to ensure a safe haven for performing serious peer review and quality improvement work would deter proper reporting and compromise the ability of committees to analyze errors for the improvement of care and prevention of mistakes. It is imperative that these safeguards be kept in place, strengthened if necessary, and protected from judicial compromise.

In the State of Kansas, a dangerous pinhole has already been made in the confidentiality shield. The Kansas Supreme Court in 1998 held in *Adams vs. St. Francis Regional Medical Center* that peer review forms and documents containing factual accounts and witnesses' names were discoverable.

It also held that information generated by the peer review committee detailing the committee's decision-making process, the peer review officer's or committee's conclusions or final decisions was not discoverable. In other words, evidence and the identification of witnesses may be extracted, but the decision-making action and rationale are still protected. Peer review committees in Kansas must now navigate a precarious path on the slippery slope of discoverability. Those who accept the voluntary role of chairing Quality Improvement Committees must be legally prepared as well as medically versed to adequately serve their respective medical staffs without exposing them to potential medical-legal risks.

The peer-review process, by its mere presence, deters mistakes even when its investigative efforts do not disclose clear-cut errors. The vast majority of physicians, by virtue of their personal drive for flawlessness, take personal pride in their work and are extremely sensitive to external scrutiny. Knowing that a peer review committee will examine and question their actions and management decisions raises the performance bar for most physicians. The committee functions much like a patrolman with a radar gun on the median of a highway. Even if he does not "catch" anyone speeding, he succeeds if his presence makes every driver who passes by check the speedometer and adjust his or her speed. The short-term goal is to weed out offenders; the mid-range goal is compliance with the speed limit; the long-range goal is to make everyone safety-conscious, 100 percent of the time.

Reporting Near Misses

In connection with the peer review process, we have other opportunities to improve our system that we do not always recognize. We ought, for example, pay careful attention to "near misses," to situations that are recognized as potentially harmful but in which no harm materializes. Until recently, "near miss" was not even included in our medical terminology because we have operated from the traditional concept of "if no harm,

then no foul." Focusing on injurious situations after the fact creates anything but a tension-free atmosphere for quality-of-care reviewers. By not investigating incidents until harm has been done, the parties involved and the Quality Improvement team are frequently at an immediate disadvantage. Their inquiries are met with defensiveness and reluctant participation in the improvement

Meaningful change in healthcare can occur only if we raise the consciousness of physicians and other health workers and restore emphasis on providing safe care in an educational and cooperative environment.

process. Instead of examining a "near miss" that is potentially harmful, they find themselves examining an incident that is harmful — and one that may have uncontrollable repercussions.

Studying "near misses" would encourage healthcare workers to report potentially dangerous situations and provide neutral subject material for improvement-minded healthcare workers. Since underreporting of mistakes is cited as one of the deficiencies of the current system, stressing the investigation of "near misses" would also encourage healthcare workers to identify and correct any potentially harmful practices. In a sense, emphasizing "near miss" reporting is like taking a free throw — it has only an upside potential for physicians, nurses, support personnel, and especially patients.

Strengthening the peer review process and reporting near misses helps us understand why a mistake is possible in a given situation and what we can do to prevent errors, rather than who we can blame for a particular adverse effect. No matter how highly trained and conscientious the provider; he or she is still human, and mistakes happen. We may forget something, or let our

attention flag under pressure or in hurried cases. We may be overworked or emotionally distraught. Redesigning work or changing a particularly difficult environment will do much to prevent errors. This model is the one that Leape describes in an interview with Peter I. Buerhaus (1999). In it, systems — not individuals — are the source of errors. But even this "systems" model will only work if we also recognize that providers, for example, doctors, nurses, medication aides, and technicians, are persons of integrity and accountability for whom punitive measures are unnecessary and may even erode the person's desire to function at the highest level.

Conclusion

Meaningful change in healthcare can occur only if we raise the consciousness of physicians and other health workers and restore emphasis on providing safe care in an educational and cooperative environment. We have certainly come to an important crossroads in medicine. Propelled by an explosion in technology and fueled by massive profit-seeking companies, the healthcare delivery system needs conscientious guidance.

Patients need advocates who will educate them, shepherd them through difficult problems, and safeguard them from unnecessary pitfalls. Viewing healthcare not as an honorable profession but as a "system" ultimately downgrades the product to a store-shelf commodity. It may work for the airline industry, but I have doubts that it will work in healthcare where the functional unit of delivery takes place in a private room between a single patient and a professional. The culture will change if the deliverers of care make safety their priority and have the courage to lead.

References

- Adams vs. St. Francis Regional Medical Center. 1998 WL 95228 (Kansas).
- Berwick, Donald M., and Lucian L. Leape. 1999. "Reducing Errors in Medicine." Editorial. *British Medical Journal* 319:136-137.
- Brennan, Troyen A. 2000. "The Institute of Medicine Report on Medical Errors - Could It Do Harm?" New England Journal of Medicine 342(15): 1123-1125.
- Brennan, Troyen A., Lucian L. Leape, Nan M. Laird, Liesi Hebert, A. Russell Localio, Ann G. Lawthers, Joseph P. Newhouse, Paul C. Weiler, and Howard H. Hiatt. 1991. "Incidence of Adverse Events and Negligence in Hospitalized Patient's: Results of the "Harvard Medical practice Study I." New England Journal of Medicine 324(6): 370-376.
- Buerhaus, Peter I. 1999. "Lucian Leape on the Causes and Prevention of Errors and Adverse Events in Health Care." Interview. *Journal of Nursing Scholarship* 31(3): 281-286.
- Hayward, Rodney A., and Timothy P. Hofer. 2001. "Estimating Hospital Deaths Due to Medical Errors — Preventability Is in the Eye of the Reviewer." *JAMA* 286(4): 415-420.
- Kohn, Linda T., Janet M. Corrigan, and Molla S. Donaldson, editors. 2000. *To Err Is Human: Building a Safer Health System*. Report from the Institute of Medicine Committee on the Quality of Health Care in America. Washington, D.C.: National Academy Press.

- Leape, Lucian L. 1994. "Error in Medicine." Special Communication. *JAMA* 272(23):1851-1857.
- ———.2000. "Institute of Medicine Medical Error Figures Are Not Exaggerated." *JAMA* 284(1): 95-97. Leape, Lucian L., Troyen A. Brennan, Nan M. Laird, Ann G. Lawthers, A. Russell Localio, Benjamin A. Barnes, Liesi Hebert, Joseph P. Newhouse, Paul C. Weiler, and Howard Hiatt. 1991. "The Nature of Adverse Events in Hospitalized patients: Results of the Harvard Medical Practice Study II." *New England Journal of Medicine* 324(6): 377-384.
- Leape, Lucian L., Ann G. Lawthers, Troyen A. Brennan, and William G. Johnson.1993. "Preventing Medical Injury." *QRB* (May): 144-149.
- Leape, Lucian L., David D. Woods, Martin J. Hatlie, Kenneth W. Kizer, Steven A. Schroeder, and George D. Lundberg. 1998. "Promoting Patient Safety by Preventing Medical Error." Editorial. *JAMA* 280(16): 1444-1447.
- McDonald, C.J., M. Weiner, and S.L. Hui. 2000. "Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report. *JAMA* 284(1): 93-95.
- Rosner, Fred, Jeffrey T. Berger, Pieter Kark, Joel Potash, and Allen J. Bennett for the Committee on Bioethical Issues of the Medical Society of the State of NewYork. 2000. "Disclosure and Prevention of Medical Errors." *Archives of Internal Medicine* 160:2089-2092.
- Thomas, Eric J., David M. Studdert, Josseph P. Newhouse, Brett I.W. Zbar, K. Mason Howard, Elliot J. Williams, and Troyen A. Brennan. 1999. "Costs of Medical Injuries in Utah and Colorado." Inquiry 36: 255-264.