

FROM BIRTH TO DEATH AND BENCH TO CLINIC THE HASTINGS CENTER BIOETHICS BRIEFING BOOK

for Journalists, Policymakers, and Campaigns

CHAPTER 21

Medical Error

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medical error

by Nancy Berlinger

Framing the Issue

In November 1999, the Institute of Medicine released a report titled To Err Is Human that made front-page news. It revealed that 44,000 to 98,000 patients were dying each year in the United States due to medical errors. Deaths from medical error were exceeding deaths from breast cancer or motor vehicle accidents. The report estimated that deaths and injuries from preventable medical errors cost the nation from \$17 billion to \$29 billion in health care, lost income, and other expenses. Although the report reflected several decades of ongoing research into the problem of medical error, it succeeded in attracting far more attention from the media, the public, and policymakers than previous studies of the issue.

Since the release of the IOM report there have been notable efforts to prevent medical errors and to improve the care of patients, families, and clinicians affected by mistakes. A cultural shift is taking place in the medical profession, with hospitals and other institutions changing from "blame and shame" practices in dealing with medical errors toward a more nuanced understanding of them. Hospitals now frequently offer workshops, grand rounds, and public lectures on topics related to medical mistakes. In response, physicians appear more willing to talk about their own mistakes and even to write about them, both in medical journals and in articles and books for a general audience, although fears of liability continue to make it difficult for them to be fully candid.

Major developments include:

- Campaigns led by the nonprofit Institute for Healthcare Improvement and other patient safety advocacy groups to work with hospital trustees and staff on ways to avoid lifethreatening errors.
- Recognition of a list of "never events": medical harms that should never happen because they are preventable when patient safety protocols are followed. Medicare, Medicaid, Blue Cross and Blue Shield, and several other major private insurers now refuse to reimburse hospitals for costs associated with some never events, while hundreds of hospitals have agreed not to bill injured patients for these costs (see box, "Never Events").
- The requirement by The Joint Commission—which accredits 5,000 hospitals and other health care institutions in the United States—for accredited institutions to have policies

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HIGHLIGHTS

- As many as 98,000 patients die each year in the United States due to medical errors.
- Preventable medical errors cost the nation \$17 billion to \$29 billion in health care, lost income, and other expenses.
- A cultural shift is taking place, with hospitals and other institutions changing from "blame and shame" practices in dealing with medical errors to a more nuanced understanding of why they occur and how to prevent them.
- Hospitals and insurers recognize a list of "never events"-medical harms that should never happen because they are preventable with safety protocols.
- Medicare, Medicaid, and several private insurers refuse to pay for costs associated with never events.
- The tort system is not a good remedy for resolving most cases of medical injury.
- Contrary to widely held belief, most injured patients never sue their doctors.
- Efforts are under way to find more effective alternatives to malpractice litigation to compensate victims of medical error.

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ALTERNATIVES TO LITIGATION

Swift and fair compensation should be part of an ethical process of disclosing medical errors. But malpractice lawsuits are anything but swift—they take about three to five years. And they appear to be an inefficient means of awarding compensation. A study of settlement payments from 1990 to the present, published online in Health Affairs in 2005, found that jury awards of any size constituted just 4% of payments to injured patients: 96% of malpractice claims resulting in payments were eventually settled outside of court. These findings suggest that improving hospitals' ability to negotiate settlements with injured patients is a more productive use of resources. Several nonadversarial approaches are in use in the United States, and others are being tested.

- The Lexington model, developed at a Veterans Administration hospital in Kentucky, is a comprehensive approach to disclosure, apology, and fair compensation.
- The COPIC, or 3Rs, model, developed by COPIC, a Colorado-based insurer of physicians and hospitals, provides no-fault compensation for certain out-of-pocket expenses associated with adverse events.
- The University of Michigan model, developed by the risk managers of the university's health care system and based on the Lexington model, has greatly reduced lawsuits and cut legal costs.
- The **health courts model**, being piloted in several states, uses administrative courts with judges trained in evidencebased medical practice.
- and procedures for disclosing medical mistakes to patients and families.
- A trend in state government to enact "I'm sorry" laws, which prevent expressions of sympathy, remorse, or-in some cases-fault from being used as evidence against physicians in medical malpractice lawsuits.
- Development of alternatives to malpractice litigation in compensating patients and families harmed by medical error.

Medical Error and Patient Safety: Assessing Progress

Are patients in U.S. hospitals safer today than they were when To Err Is Human was released? Are they more likely to be told the truth if they are harmed by medical mistakes? Are they more likely to receive fair compensation if their injuries have medical or financial consequences? The consensus is: maybe.

In 2005, patient safety leaders Lucian L. Leape of the Harvard School of Public Health and Donald M. Berwick of the Institute for Healthcare Improvement concluded that the IOM report had dramatically expanded conversation and concern about a major but poorly understood health care problem. It had also prompted many safety improvements as hospitals and professional groups worked to reduce specific medical errors. Among the improvements noted were the identification of never events and subsequent data on the effectiveness of changing practices in avoiding these injuries. A visitor to any U.S. hospital will see some evidence of greater awareness of patient safety as a shared responsibility of health care professionals. Hospital staff wear buttons inviting people to ask if they have washed their hands. Computer screen savers sport images of germ-laden unwashed hands. Posters in the elevators remind staff to avoid using abbreviations that could be misread or misheard when writing prescriptions or giving instructions.

However, greater awareness and changes at the margin still do not always translate into systemic adoption of verifiably safer practices. Leape and Berwick gave several explanations. First of all, health care is more complex that any other contemporary system in terms of its technology and human factors: there are more things to improve, and more ways to fail. In addition, the culture of medicine prizes individual identity, skill, and authority; encouraging a culture of safety means persuading strong-willed individuals to conform to safe practice standards and to think of themselves as part of "systems." Finally, board members and CEOs of health care institutions may be reluctant to make patient safety an ongoing priority, perhaps because talking about improving safety suggests that an institution is not already safe.

Turf issues can also stymie efforts to make health care safer. Some institutions still tolerate "work arounds"—adaptations to poorly-designed systems—rather than showing frontline staff how to distinguish between safe and unsafe practices and how to challenge system flaws that put patients at risk. Ironically, the growth of "patient safety" and quality improvement, or QI, as relative-

ly new professions within health care along with continuing efforts to improve error disclosure can actually lead to new systems flaws. When responsibility for patient safety, QI, and disclosure training is "siloed" into different departments rather than integrated into organizational priorities, the system may be serving turf interests rather than patients' interests.

No physician can responsibly argue that lying or concealing the truth about medical mistakes is an acceptable option. The American Medical Association's Code of Ethics stipulates that patients are owed truthful and complete information about their health, including the aftermath of known or suspected errors. However, culture change is slow. The "hidden curriculum" in teaching hospitals may undermine what residents are taught about their truth telling obligations: if they never see senior colleagues acknowledge and disclose mistakes, residents may conclude that to do so is not in their career interests, either. And some institutions still react to adverse events by communicating with their lawyers rather than their patients, even though both hospital defense counsel and insurers may argue for full, frank, and fast disclosure as the soundest defense strategy.

Although we may finally have reached a consensus that injured patients are owed the basic truth about how they were harmed, we have not reached consensus about what else they may be owed, nor how this will be provided to them. There is increasing awareness of alternatives to the undeniable burden of litigation, such as health courts and other nonadversarial approaches (see box, "Alternatives to Litigation"). But in the absence of a universal health care system in the United States, compensation for medical harm varies from one state to the next. In states where there is no history of cooperation among physicians, hospitals, insurers, and plaintiffs' attorneys, starting a conversation about nonadversarial approaches can be hard.

Continuing Ethical and Policy Challenges

Medical harm is a health care problem that usually has a health care solution. One of the persistent difficulties in finding a health care solution is the longstanding tendency for health care professionals and the general public to associate medical injuries with the tort system, especially with "frivolous" lawsuits filed by people who do not have

"NEVER EVENTS"

This is a sampling of the 28 medical errors that should never occur-known as "never events"—as compiled by the National Quality Forum. The list is widely recognized by hospitals and insurers.

- Artificial insemination with the wrong donor sperm or donor egg
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Patient death or serious disability associated with a medication error
- Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a health care facility
- Patient death or serious disability associated with a fall while being cared for in a health care facility

Source: The National Quality Forum.

legitimate claims. However, most injured patients never sue their doctors, and the tort system is not a good remedy for resolving most cases of medical injury.

The tort system is not—and was not designed to be—a fairness-based system. It was designed to affix blame and award damages. As award formulas are based on lost income or earning potential, and as plaintiffs' attorneys are paid out of awards, these attorneys have little financial incentive to take on clients with low incomes or earning potential, including women who do not work outside the home. Empirical research has found that lowincome, uninsured, and elderly patients are much less likely to file malpractice suits than are other patients with equivalent medical injuries. Elderly patients in particular fear disrupting their relationships with health care providers and tend not to pursue compensation for injuries.

Lucian Leape has noted that the lack of a universally accessible fair-compensation alternative to the tort system, as exits in Scandinavia and New Zealand, means that injured patients have little choice but to use a system that does not meet their needs: there is simply no other place for them to go. Judicial reform efforts such as health courts may provide some relief, particularly for major injuries. However, reformers should not neglect the health care system itself as the place where injured patients can either receive or be denied justice.

Just as physicians and hospitals can learn how

to tell injured patients the truth about how they were harmed, so hospitals and insurers can learn how to provide fair compensation for these injuries. Mindful of the maxim "to permit is to promote," policymakers and insurers who want to reduce malpractice lawsuits can encourage hospitals in their states to adopt successful models of fair compensation, such as the University of Michigan's risk management strategy of early settlement or the no-fault "3Rs" approach (see box, "Alternatives to Litigation"), or to develop and test new models that have the potential to be both fair and efficient.

Reducing the variation in how institutions prevent and respond to medical errors is another continuing challenge with ethical and policy dimensions. Policymakers can help by removing impediments to sharing data on successful patient safety efforts and malpractice settlements. Such impediments include the common practice of sealing malpractice settlements, which makes studying the details of harmful incidents or identifying patterns of similar injuries across institutions in the same region difficult. The movement by insurers to use the lever of reimbursements to prohibit hospitals from recovering the costs of never events is another innovative way to compel them to remain vigilant about patient safety. Leape and Berwick argue that for preventable injuries to become true "never events," leaders will need to be as focused on patient safety as they are on the bottom line.

We are not sure how many patients are still being killed by medical mistakes each year. In 2005, Leape and Berwick concluded that, despite progress on various fronts, it was as yet "hard to see" evidence of national, systemic impact: some patients, in some units, at some hospitals, were certainly receiving safer care, but other patients, in other units, at other hospitals, were certainly not. We do know that there is not nearly enough funding dedicated to research on medical error as a health care problem, relative to other major causes of death in the United States.

Leape and Berwick note with concern that by 2004 the already tiny budget of the federal Agency for Healthcare Research and Quality (AHRQ) had been largely restricted through earmarks, making it impossible for the agency to support ongoing research programs on patient safety. Understanding medical error as a health care problem and bringing safety from the margins to the center requires a serious and sustained commitment to funding research on its causes and on how

RESOURCES

Web sites

- www.ihi.org Institute for Healthcare Improvement. Includes books, videos, reports, and white papers resulting from IHI's programs and strategic initiatives.
- http://psnet.ahrq.gov Patient Safety Network of the Agency for Health Care Research and Quality. Includes links to frequently cited books, articles, and resources by subject, as well as a newsletter and a glossary.

Recent news

- · Kevin Sack, "Doctors Start to Say 'I'm Sorry' Long Before 'See You in Court," New York Times, May 18, 2008.
- · Susan Brink, "It's Never Just One Thing' That Leads to Serious Harm", Los Angeles Times, January 28, 2008.
- "Medicare Against Mistakes" (editorial), Boston Globe, August 22, 2007.
- Judith Graham, "Doctors Try New Word: Sorry," Chicago Tribune, August 19, 2007.
- · Barron H. Lerner, "Doctors Examine Themselves," Washington Post, March 20, 2007.
- · Nicholas Bakalar, "Medical Errors? Patients May Be the Last to Know," New York Times, August 29, 2006.

Further reading

- Nancy Berlinger, After Harm: Medical Error and the Ethics of Forgiveness, Johns Hopkins University Press, 2005.
- · Virginia A. Sharpe, ed., Accountability: Patient Safety and Policy Reform, Georgetown University Press, 2004.
- · Atul Gawande, "When Doctors Make Mistakes," in Complications: A Surgeon's Notes on an Imperfect Science, Macmillan, 2003.
- Thomas H. Gallagher et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors," Journal of the American Medical Association, February 2003.
- Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, To Err Is Human: Building a Safer Health System, National Academy Press, 2000.



See online-only campaign appendix at www.thehastingscenter.org/briefingbook

to help patients, families, and clinicians recover from these devastating incidents.

Talking about mistakes—"to err is human"—is only the first step in the slow work of culture change. Preventing patients from being harmed in the course of seeking help, and treating harmed patients not as adversaries but as the most vulnerable persons in our health care system, continue to be challenges. T