News and Views

Law and Ethics in Medicine

Medical Error - Cautionary Tales that Leave Us Wondering About the System

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Abstract
This section of the UTMJ addresses issues in medical ethics and their legal implications. The following article describes two high-profile cases involving medical error at a prominent Toronto hospital. Both cases have gone to a coroner's jury, and one was ruled a homicide—the killing of one person by another. The fact that these cases could occur, with such consequences, calls into question our methods of dealing with medical error. This paper seeks to outline current thinking about the mistakes that can occur as healthcare workers do their jobs, with a focus on how the system can be changed.

Cases
In October of 1998, a little girl named Lisa was admitted to hospital. She needed help to relieve a severe burning pain caused by reflex sympathetic dystrophy, a rare disorder that can occur after trauma. The ten-year-old was given morphine. An order was placed in the computer system asking nurses to check her vital signs including blood pressure, every hour, to ensure she was not too sedated from the drug. For reasons that remain unclear, the orders were not followed. Lisa was supposed to be on a monitor to measure her breathing and heart rate, but the alarm on the monitor never went off. Less than 12 hours after her admission, Lisa Shore died in respiratory failure while her mother slept in the same room. More than a year later, a coroner’s jury ruled Lisa’s death a ‘homicide’.

In September of 1999, a teenager named Sanchia died after routine surgery in the same hospital. Although she had severe sickle cell disease, the usual pre-operative assessments were not done. The surgery went smoothly, but afterwards she received morphine, a drug to which she had known sensitivity. Her return to the ward was delayed, and during that time, no staff took her vital signs. Incredibly, Sanchia bled to death. The nurse who was monitoring her vital signs was junior and had never looked after a patient in shock before. While she noticed that Sanchia’s vital signs were changing, she did not alert other staff. The surgeon on rounds stopped in the 17-year-old’s room, but did not assess her vital signs. He later admitted that had he done so, Sanchia Bulgin might have lived. The coroner conducted an inquest into her death, and released a report containing 31 recommendations for systemic changes at the hospital.

Medical Error
Both these cases took place at Toronto’s Hospital for Sick Children. They are not described here to point the finger of blame or to suggest that this hospital is particularly error-prone. Rather, they are recounted to show that bad mistakes can happen in generally good institutions, where the staff cares very much about providing high quality care for their patients. When a terrible thing happens, such as the death of a child, we instinctively look for someone or something to blame. Blaming is understandable, emotionally satisfying and very human, as human as making the mistakes that can lead to such events in the first place. As a result of cases like these, there is a movement to make some changes in the ways that hospitals, and the healthcare system in general, approach human error.

A report released by the Institute of Medicine in the United States estimates that between 44,000 and 98,000 people die in hospitals every year, partly as a result of preventable medical errors. Those figures are higher than the numbers of people who die in motor vehicle accidents or who have breast cancer or AIDS. The magnitude of the problem is similar in Australia and the United Kingdom, where such studies have been replicated. Comparable studies estimating the total number of deaths due to preventable adverse events in Canada have not yet been done, although studies are under way at the Canadian Institute for Health Research. If the American figures are accurate, one can estimate that 10,000 Canadians die every year as result of hospital errors, and a further 10,000 die from hospital-acquired infections and the unanticipated complications of medication. Studies from Britain indicate that teaching hospitals may have higher rates of error because of the complexity of the cases they handle and perhaps because of poor supervision of junior doctors. Although the exact size of the figures has been debated, it cannot be denied that medical error is a significant problem and one that requires further discussion.

The Institute of Medicine defined medical error as “failure of a planned action to be completed as intended,” or “the use of a wrong plan to achieve an aim.” Typical medical errors include: mistakes in diagnosis, failure to act on abnormal test results, errors in drug dosage or method of drug use, inadequate monitoring, equipment failure, surgical injuries and many more. The Institute estimated that all these errors cost between 17 and 29 billion US dollars annually in additional care, lost income and disability. And this is merely the cost that can be calculated. In addition, there is a public loss of trust in medical institutions, to say nothing of needless pain and suffering. The families of children like Lisa and
Sanchia are understandably angry because they have lost their child at the hands of the people they turned to for help. They want to know what happened, they want someone to be accountable, and at the very least, they want something to change so as to prevent future errors of the same type. At the same time, there can also be frustration and loss of morale on the part of the healthcare workers. There are certainly a few people who are frankly incompetent or negligent, and hopefully even fewer who intend to cause harm. However, surely there are virtually no nurses and doctors who go to work intending to commit deadly mistakes.

Changing the System
Ethically, iatrogenic harm—harm created by medical intervention—goes against the oldest moral rule in medicine as found in the Hippocratic oath: primum non nocere (“above all, do no harm ...”). Medical error also conflicts with the principles of beneficence and justice. And that is why the Institute of Medicine (IOM) declared its estimated error rate unacceptable and, in 1999, launched a plan to reduce preventable medical error by 50% in the following 5 years. The plan was endorsed by former U.S. President Bill Clinton and has gone on to be widely publicized. Some U.S. employer groups (who pay employee health insurance) are encouraging employees to only choose healthcare facilities who have adopted certain patient safety initiatives.10

The IOM plan is based on the premise that most medical errors are systemic and are only rarely caused by incompetent or reckless individuals. Their approach is to change the system—improve scheduling, computerize drug orders, and even change technology so it can only be used correctly. For example: the connectors for oxygen masks should be designed so they only fit onto oxygen tanks, and medications which are toxic at full strength should only be stored in diluted form. The IOM plan is to design the system so it is safer thus making it “harder for people to do something wrong and easier to do it right.” That does not mean there is no personal responsibility for error. Individuals must maintain their credentials, keep up to date in their field, and avoid carelessness. But the overall idea is to recreate the system so it encourages a culture of patient safety.

In Canada, no such national plan exists, but new efforts are underway. An Institute for Safe Medication Practices (http://www.ismp-canada.org) has been established, following an American model. The College of Physicians and Surgeons in various provinces are working on ways to create more openness in the reporting of error, an important aspect of patient safety.11 In Ontario, the legislation governing professional bodies is being reviewed and the College of Physicians and Surgeons has made submissions suggesting that the process of examining medical error should look towards systemic changes rather than the punishment of individual physicians.12 The Canadian Medical Association (CMA) is currently considering the issue of medical error and the Royal College of Physicians and Surgeons has struck a national patient safety committee which has very ambitious goals.13

Greater Openness
Advocates of patient safety believe attitudes need to change if significant changes are to be made in medical error rates. James Reason advocates rejecting the current culture of “naming, shaming and blaming and move towards a just and open culture, where appropriate lines are drawn between blameless and blameworthy actions.”14 Reason’s theory of medical error states that individual actions come at the end of a chain of events, and only when several defensive layers, including alarms, physical barriers, automatic shutdowns and administrative process have failed, can the errors of an individual have any effect. The U.S. Department of Veterans Affairs has done a lot of work on patient safety issues (www.patientsafety.gov) and they recommend mandatory reporting of all errors, so that organizations can work through and learn from their mistakes. Of course there are many concerns among healthcare workers about this type of system. They fear retaliation, in the form of public criticism, litigation, losing jobs, losing their chances for promotion and even losing their licenses to practice. These types of fears continue to reinforce the existing culture, where cover-up of mistakes occurs all too frequently. While the fears are not unfounded, they may be exaggerated. Most medical errors never result in complaints or lawsuits. Complaints where filed, however, can result in a variety of outcomes, ranging from cautioning the physician in writing to referring the problem to the discipline committee or initiating other actions consistent with the law.15 In Ontario, the CPSO discipline committee can revoke a physician’s license, after due process, but such situations have typically involved sexual impropriety. Most mistakes in clinical medicine are more characteristically handled by mediation and re-education. However, as part of the current legislative review, the CPSO has asked for emergency powers to suspend a license immediately, specifically for cases where a physician is considered a danger to patients. The suspension would be followed by an expedited hearing process.16

There are work cultures which are more open and less blaming than medicine; they include the aviation industry, some nuclear power plants and the military. One study quotes that in aviation maintenance, some 90% of quality lapses were judged as blameless.14 There are some interesting studies that compare the attitudes of physicians and pilots—for example, physicians are more likely to deny the effects of fatigue on their performance than pilots. In contrast, pilots are more likely to reject work settings where there are steep hierarchies and senior staff are not open to input or correction from junior team members. Surgeons are more comfortable with such situations.17

Greater openness about error within the medical system also means greater honesty with patients. The literature recounts many instances in which neither the patient nor their family were ever informed of error. There is one story of an elderly woman with abdominal pain. She died 5 days after admission to hospital, undiagnosed. After her death, the resident in charge of her care discovered an ECG strip he had forgotten to read. It was taken on the day of her admission and clearly showed an acute MI. The resident admitted his error to a senior physician who tore the date off the ECG and rewrote the date of the woman’s death. The senior physician said “making a fuss over this won’t bring her back,” and “let this be a lesson to us.”18

Commentary published about this case suggests that the response was inappropriate on a number of levels. First of all, the physicians lied; secondly, they did not treat the woman’s family with respect; and finally, they missed an opportunity for the whole team to learn from a mistake made by one of them.19,20,21

Personal Responsibility
Of course it is difficult to face patients and admit mistakes. Physicians fear their anger, worry about legal liability, and just have
trouble admitting when they are wrong. But hiding mistakes is deceptive, and as Philip Hebert says “can be seen as a breach of professional ethics – a lapse in the commitment to act solely for the patient’s best interests.”

Telling the truth to patients is a sign of respect and it is owed to them. After all, these are people who seek out doctors’ help with the problems in their lives, not simply cases that rotate in and out of the hospital doors. Hebert also makes the point that although Canadian law allows physicians to make mistakes without considering them negligent, the courts have frequently ruled against physicians who deceived their patients about serious error. It is also interesting to note that the literature shows victims of medical error want to know the truth about even minor error.

In fact, some people sue because they are upset or angry about the lack of information they are given. This is certainly why the Shore family asked the coroner to conduct an inquiry into their daughter’s death. They were never told why she died and they needed to know. In some cases, it is indeed difficult to know when and how to approach families with news of a medical error. Medical trainees receive little training in the art of disclosure and professional bodies have not, until recently, taken this on. The CMA does not address disclosure of error in its code of ethics. However, the Canadian Medical Protective Agency (CMPA) now advises openness with patients about poor outcomes of care but they prefer that allegations of responsibility are not made.

The Future

It has been more than 2 years since Lisa Shore died at the Hospital for Sick Children. The two nurses responsible for her care have been charged with criminal negligence and as this paper goes to press the matter is before the courts. The Hospital for Sick Children is working on creating a culture of open reporting of error and a climate of patient safety. Prior to the coroner’s inquest regarding Sanchia Bulgin’s death, the hospital, with the leadership of the Quality and Risk Management Department, conducted a review and generated a list of 24 recommendations for systemic changes within the hospital. The recommendations include such things as an external review of surgical procedures, a review of nursing practice, more support for junior nurses, physician “hand-over” rounds, and changes to the formatting of the computer system used to file orders and prescribe medications.

The hospital is also working on trying to increase overall communication so that staff are talking to each other more about procedures on the wards, confirming and reconfirming that tasks that have been done, and attempting to create a culture where junior staff feel comfortable questioning the actions of their seniors. They are also working on the reporting of medical errors so that the attitudes of the staff shift from the traditional fear of admitting mistakes to a new way of thinking where people say “let’s learn something here.”

But changing people’s attitudes is a challenge. And Sharon Shore, Lisa’s mother, is skeptical. She understands that in the vast majority of cases of medical error, people do not intend to cause harm. But she feels that: “there is a big distinction between medical error and gross negligence.” And she is worried that as healthcare agencies “get on the system’s bandwagon,” it gives them an excuse to avoid dealing with the cases where true negligence exists. Systemic error is a critical issue. It remains to be seen how it will be balanced with personal responsibility.

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