Medical Errors

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Following the 2000 report of the Institute of Medicine, *To Err Is Human*, which documented that as many as 98,000 people in this country die of medical errors every year, medical, hospital, and governmental agencies began to consider changes in hospital systems. The report had found that errors were much more likely to result from systemic problems than from inept health care providers. Progress in re-inventing hospital systems has been very slow, although some institutions have made great gains.

"Medical errors" may be of several types. Some lead to malpractice claims, many do not. Many people who have been severely injured by errors never file claims. Making a medical mistake is not necessarily "malpractice."

There are six elements a patient must prove in order to win a malpractice case: a physician-patient relationship must exist, the care provider must owe the patient a duty of care, evidence (usually expert testimony) must be presented that there was a failure in some part of the duty of care, there must proof that the lack of care was the proximate cause of harm, and proof of evidence that harm occurred. The patient must also prove his or her assessment of damages.

Solutions to the problem of patient injuries are suggested.

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In 2000, the Institute of Medicine published *To Err Is Human*,[1] a study which demonstrated that as many as 98,000 people in this country die every year as the result of medical errors. It called upon leadership in medicine and in government to begin to make the medical environment safer. Its chief finding was that most serious medical errors are systemic—and are not caused by health care providers making egregious mistakes. Although approaching the problem of medical errors as a systemic one has many critics, including those who believe that not blaming individuals for errors will weaken accountability for physicians,[3] the report has increased the efforts of organizations such as the Agency for Healthcare Research and Quality, the Joint Commission for the Accreditation of Hospitals (JCAHO), and other health care leaders to seek improvements.

It has now been five years since the original report was published. In reviewing progress since that time, a very recent article[2] questions the national commitment to changing the hospital environment. Many approaches to preventing and dealing with medical errors have been attempted, with varying success. Where systems changes have been made, many of the most common injuries, including some with very serious consequences to patients, have become much less common. For example, many fewer patients die from accidental injections of potassium chloride now that the drug has been removed from readily accessible nursing unit shelves. Properly reclining the beds of patients on ventilators is associated with fewer cases of pneumonia. Where there have been vigorous campaigns in hospitals to require handwashing, there are many fewer infections from IV lines.

The Veterans' Administration (VA) system has probably advanced most quickly in this area, since it has far more control over physicians' behaviors than either community hospitals or academic medical centers do. In particular, in 1998 the VA created the National Center for Patient Safety (NCPS) to evaluate adverse events and "close calls" and then implement changes for patient safety across the VA system.[4] The VA uses electronic medical records, computerized order entry, and bar-coded medications.[5] Examples also abound outside of the VA system. One academic hospital made changes in both physical plant and procedures after studying the Toyota assembly line. Those changes resulted in improvements in patient care, patient satisfaction, and fiscal savings.[6]

However, in some circumstances, changes have been implemented without adequately studying whether errors have in fact been prevented without incurring other unintended, and equally adverse, effects on delivery of medical care. For example, one recent article suggested that computerized order entry can decrease erroneous orders (errors of commission) but had the unintended consequence of deleting necessary orders (errors of omission) such as antibiotics and pain medications.[7] In another provocative study, infection control procedures that isolate patients decreased the degree of monitoring of those patients and increased their dissatisfaction, suggesting that their personal care was compromised for the greater good of preventing infectious spread.[8]

What is "a medical error?" (and not all errors cause injuries, in medicine or in any other field). "Error" can be defined as "mistake." The IOM report defined error as "the failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an

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aim (an error of planning.)" If the error injures the patient, it is known as an "adverse event."

Adverse events fall into three categories:[9]

(1) Overuse: The patient receives treatment of no value and which in itself may have risks. For example, a patient is diagnosed as having a pulmonary embolus, is treated, has a life threatening bleeding episode as a result of the treatment, and the diagnosis is later demonstrated to have been wrong.

(2) Underuse: The patient fails to receive needed treatment. For example, a patient is followed only by physical examination for months of new onset progressive adenopathy, which is later shown on biopsy to be an aggressive lymphoma. When the diagnosis is finally made, the patient has advanced disease and organ dysfunction, and rapidly dies of his disease.

(3) Misuse: Errors and defects in treatment. This category is what most physicians think of as "malpractice." For example, a hematologist misinterprets cytogenetic and pathology reports and treats a patient with CML with high-dose induction chemotherapy for AML.

Malpractice

While no one doubts that prevention of medical errors is necessary for good care, another more personal reason for preventing errors is to avoid malpractice suits.[10] In fact, reluctance to report personal errors and discuss reasons for errors in a public setting due to concern about lawsuits is probably one of the more difficult and entrenched physician behaviors impeding faster progress in medical error reduction.[11] While all medical errors do not constitute "malpractice," a poor outcome is usually the impetus for a lawsuit. Many studies have indicated (and any in-house lawyer at a university hospital can tell you) that hospital record reviews show an amazing disconnect between injured patients and people filing malpractice suits—many of those seriously injured never sue, and many people who do sue have no cause for doing so.[12] Finding a method of fairly compensating those injured by true malpractice and rejecting compensation for those who don't deserve it is the question we struggle to answer. Defense attorneys who believe they are unlikely to win usually settle before a case comes to court. Because of this selection bias, once a malpractice case goes to court, the verdict is likely to be favorable for the physician defendant (> 80% of cases) although the personal toll may be extremely high.

There are very, very few malpractice suits against hematologists and of those that are, a very high percentage deal with systemic errors—for example, a chemotherapy drug ordered by a hematologist was given incorrectly in the clinic. Efforts such as computerized order entry, triple checking chemotherapy doses, armbands for patients receiving outpatient therapy or procedures, and other safeguards can decrease the likelihood of these errors. The other types of errors made by hematologists are likely to be miscellaneous errors of diagnosis or treatment that are harder to address systematically.

If an error (regardless of cause) occurs, the physician's response is critical to sorting out the situation. Discussions with the patient or the patient's family and other interventions can materially decrease the likelihood of a claim. There have been several excellent studies documenting that there are two basic reasons why patients make the decision to sue for malpractice.[13] First, the cause is the patient's or family's conviction, in the face of an obviously bad outcome, that the medical team is lying to them, covering something up, will not talk to them at all, or simply will not provide a credible story about what had happened. Most of them also feel that the physicians had not listened to them before the bad result. Second, in serious cases, the cost of caring for the patient or repairing the damage far exceeds the family's available financial resources and the only way care can be provided is with the proceeds of the malpractice case.

To appropriately deal with errors expeditiously and decrease the likelihood of a malpractice suit, all hospitals have procedures for reporting errors to a risk manager, hospital in-house counsel, or other entity, and those should be followed as soon as possible. The earlier discussions or interventions take place, the less likely the patient is to feel that no one cared about what happened. The situation can be discussed honestly with the patient without using language (such as "that was the dumbest thing I ever did") that might provoke a visit to a lawyer. "I'm sorry it happened" is NOT an admission of fault. It may be counterintuitive to physicians that admission of error accompanied by sincere apology can help avert a malpractice suit, but such acknowledgment may mollify a dissatisfied patient.[14] Any discussions about what happened and what was done about it should be documented in the patient's chart.

Elements of a Successful Malpractice Case

In order for a patient to succeed in bringing a malpractice suit, he or she must prove the existence of six elements of his or her case, and it is never the duty of the defendant physician or hospital to disprove them:

1. Existence of physician-patient relationship

The patient must prove the existence of a physician-patient relationship with the defendant physician. While this is usually obvious, in some cases, it may not be. Suppose a specialist at a medical center receives a call from a primary care physician in a remote town asking advice on the care of a patient. The patient's name is never mentioned, just that she is a female aged 26. The specialist listens to the physician's description of the patient's problems and what he plans to do about it, and the specialist says the plans seem reasonable to her. She never reviews a medical record, never examines the patient, and never speaks or writes to the patient. She never again discusses the case with the physician.

The patient files a malpractice suit against both the primary care physician and the specialist. The court would dismiss the case against the specialist since no physician-patient relationship was established.

2. Duty of care

The patient must prove that the defendant physician owed him or her a duty of care. The duty of care to a patient by any health care provider entails the use of skill, care and knowledge that a person with the same training would have used under the same or similar circumstances.

The use of skill means basically manual dexterity in the execution of a medical procedure—for example, the hematologist/oncologist knows how to perform a bone marrow aspirate.

The use of care means that one is careful while executing the procedure or making the diagnosis—one is paying attention to what one is doing. Failure to pay attention causes more legitimate malpractice claims than any other cause. When things become routine (except, of course, for the patient) attention slips, distractions enter, and harm is done. For example, a young patient with no known risk factors is admitted with a deep vein thrombosis. The patient has the appropriate workup, but the results demonstrating a hypercoagulable state are never checked. The patient has a recurrent life-threatening clot.

The use of knowledge means one knows what one is doing—the "book learning" part of the care of patients.

All of these elements must be performed at the level of a physician with the same training and within the same circumstances.

3. Evidence

In order to prove that the defendant physician was negligent in some part of the duty of care, the patient must present at least one expert witness, except for the rare instance in which the alleged malpractice involved something a lay jury can understand on its own.

The expert witness must be qualified in the same field as the defendant. He or she must testify quite specifically about the applicable standard of care and in what manner the defendant breached that standard. Unfortunately, there are many doctors who make their living as "hired gun" expert witnesses, almost always for malpractice plaintiffs. Little, if anything, is ever done by their own profession to restrain these physicians.

4. Cause of harm

There must also be proof that the lack of due care was the proximate cause of harm to the patient. Some horrendous errors don't hurt the patient and thus cannot sustain a malpractice suit, although they should certainly result in system changes. For example, a hospital patient in a two-bed room is given a blood transfusion intended for the other patient because the patient's arm band is not appropriately checked. Fortunately for all concerned, the two patients have the same blood type, and the error is discovered before any other harm occurs.

5. Evidence that harm occurred

In any case, proof of harm is required and there can be no finding of malpractice without it. Hurt feelings are not enough. For example, in one anecdote, a man had an allogeneic stem cell transplant and made a full recovery. A year later, his nephew, the medical student, came to see him. The nephew told him that he had had a 40% chance of dying with that procedure and was very lucky he hadn't. The patient did not remember any conversation with his doctors about the risk of death, was furious, and sued the doctors for failure to obtain his informed consent. The court dismissed the claim on the ground that the patient suffered no harm—he was manifestly not dead (the allegedly nondisclosed risk had not occurred) and he had recovered from his problem for which the transplant was performed.

6. Assessment of damages

Once harm and the elements of the patient's damage have been proved, the jury assesses damages. Damages—the amount of money assessed against the losing party—are of three types in any sort of personal injury case:

- "Actual damages" are those that are proven losses: the cost of repairing the damage, the cost of protracted institutional or nursing home care for the patient, lost wages, and other items that can be assessed economically. For children, the elderly, and those who do not have jobs, "actual damages" can be very small if nothing can be done to alleviate the problem.
- "Pain and suffering" damages are those awarded to compensate the patient for limitations on his or her life and the elements of suffering that cannot be economically assessed.
- "Punitive" damages are damages awarded for deliberate infliction of harm or "callous disregard" of the patient's welfare and are awarded only in a tiny number of cases. Punitive damages are not covered by malpractice insurance, so must be paid out of the defendant's own pocket.

Many "mistakes" are not considered "malpractice." For example, a patient comes with symptoms that could be either disease A or disease B. All the appropriate diagnostic tests are done and the results are inconclusive. The physician says, "I think you have B, but it could be A" and treatment for B proceeds. Several months later it becomes evident that the patient actually has A. That would not be considered "malpractice" by anyone. The standard of care for diagnosis has clearly been met. On the other hand, if the same patient comes in and the physician says "I am sure you have B and there is no need for tests, so we can just begin treatment," malpractice has probably occurred.

Almost all physicians have malpractice insurance, and much has been made of the high costs of coverage. One

suggested solution is simply to cap malpractice awards. Caps on awards, which already exist in some states, have not resulted in lower premiums.[15] and have hurt the most grievously injured. Suppose a young child sustains a severe brain injury due to malpractice. In a state with a $250,000 cap, his rehabilitation and lifetime care will exhaust that sum well before he grows into a normal life expectancy in which he will never care for himself.

If the object is to reduce the rise in malpractice premiums, then application of the Sherman Anti-trust Act to malpractice insurers has been suggested as a possible solution. Including insurers within the same competitive regulations required of all other industries in the country could help control prices since most states currently only have one dominant insurer so there is little incentive to compete on rates.

While much of the focus in the media on the "malpractice crisis" refers to high premium costs and some allegations of loss of practitioners in key areas (such as rural obstetricians),[16] other studies do not show such losses of physician power.[17] Another hidden cost may be the practice of defensive medicine (changes in physician behavior driven by fear of malpractice suits rather than delivery of good medical care). There is some evidence that costs of defensive medicine may drive overall costs up in areas and specialties with the highest malpractice premiums.[18]

Summary

The Institute of Medicine report stated that by 2010 (in 5 more years) there should be a 90% reduction rate in nosocomial infections, a 50% reduction in medication errors, and a 90% reduction rate in errors associated with high-harm medications such as chemotherapy. We appear to have much work ahead to achieve these goals, since many of the easier, more obvious solutions already are part of current practice. Whether a decrease in actual error rate through systems approaches and better handling of medical errors when they do occur improves the malpractice climate also awaits further experience.

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