Surgical Error

Ethical Issues of Adverse Events

Thomas J. Krizek, MD

We all recognize and accept that adverse events occur with some frequency in surgery and that all departments meet regularly to review them. Since adverse events and “mistakes” have the potential for delaying recovery and injuring surgical patients, an ethical mandate exists to do all that can be done to prevent harm. This article suggests that there are 5 issues within the practice of surgery that have inhibited improvement in quality: (1) inadequate data about the incidence of adverse events, (2) inadequate practice guidelines or protocols and poor outcome analysis, (3) a culture of blame, (4) a need to compensate “injured” patients, and (5) difficulty in truth telling.

The opening quotation is a widely published and discussed claim that made me think of W. Edwards Deming. When I composed my list of the most influential persons of the 20th century, I included Deming. It was he who introduced many important quality controls into the manufacture of automobiles, electronics, and televisions, first in Japan and later in the United States. His fundamental belief was that the people doing the work were the best able to recognize and correct error. Accordingly, he empowered those at the site of production where errors occurred to correct the identified problems. He proved that with proper protocols, ongoing data collection, and early identification of problems, defect-free products could be produced. If these recent data from the Institute of Medicine1 on the occurrence of between 44000 and 98000 fatal errors per year were applied to auto makers, they would be out of business. Although we in medicine have come to expect defect-free televisions and automobiles with 100000-mile warranties, we have been loathe to accept the same processes into our delivery of surgical care.

I would like to present an illustrative case:

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units. We both, along with colleagues, began to multiply the number of recognized errors by the number of patients in our hospital. We obtained a grant from the Robert Wood Johnson Foundation (Princeton, NJ) to study error in surgical units. The results of that study are briefly presented.

Suggestions for change, in addition to the 5 issues within the practice of surgery that have inhibited improvement in quality are addressed in this article: (1) inadequate data about the incidence of adverse events, (2) inadequate practice guidelines or protocols and poor outcome analysis, (3) a culture of blame, (4) a need to compensate “injured” patients, and (5) difficulty in truth telling.

Data about the frequency of adverse events related to inappropriate care have traditionally been obtained from retrospective review of written medical records, and yet we know how reluctant health care workers are to record adverse events in the official medical record. In addition, there is an acceptance on the basketball floor and in the intensive care unit of “no harm . . . no foul,” which in both places is an ineffective prevention tool. This was important to us since even a thorough review of my medical record would not have triggered any effort to correct a flawed process that as yet could not be identified, one that repeatedly offered me the very agent that had caused my hospitalization.

The reluctance to document error in the official medical record, largely because of legal liability issues, is one of the major limitations of all previous studies of the incidence of adverse events. The most widely accepted and quoted study on adverse events was the Harvard Medical Practice Study of 30,121 written medical records of patients in the New York hospital system. The data collected were directed largely toward a possible change in legal policy. The researchers hoped to determine whether a “no-fault” approach to error would be feasible. Using fairly stringent criteria, they found errors in the care of approximately 10% of patients, of which approximately 3.7% were considered critical. The 10% incidence was considered high. Recognizing how reluctant people are to enter anything in the medical record that could later be interpreted as negligence, we felt that these study results vastly underestimated the incidence of error.

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Table 1: Major Hospital Areas and Categories Involved in the Study

<table>
<thead>
<tr>
<th>Major Areas</th>
<th>Specific Categories</th>
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</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>38</td>
</tr>
<tr>
<td>Surgery</td>
<td>48</td>
</tr>
<tr>
<td>Treatment</td>
<td>25</td>
</tr>
<tr>
<td>Monitoring/daily care</td>
<td>97</td>
</tr>
<tr>
<td>Drugs/medications</td>
<td>20</td>
</tr>
<tr>
<td>Nutrition</td>
<td>5</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>11</td>
</tr>
<tr>
<td>Complications</td>
<td>112</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>368</strong></td>
</tr>
</tbody>
</table>

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Published studies on medication errors, surgical complications (such as infection rates), and most current approaches to “quality improvement” continue to depend largely on self-reporting (incident reports) or on similar retrospective analyses of hospital records. These are exactly the methods of data collection that Deming attempted to change. Disturbed by a high incidence of defective products, like the automobiles known as “lemons,” Deming suggested that it would be better to identify problems before a defective product rolled off the assembly line. His process was to collect ongoing rather than retrospective data and to obtain the data in a nonpunitive manner. Our study demonstrates that (1) ongoing data collection in the surgical care of patients is feasible and (2) when data are obtained in a nonjudgmental context, the incidence of error is far greater than other studies have suggested.

We conducted a prospective study of patients admitted to 3 surgical units, a surgical intensive care unit, a burn unit, and a surgical floor. We used trained observers who attended all day-to-day activities during which adverse events were likely to be discussed by nurses and physicians, such as nurses’ reports, physicians’ rounds, morbidity and mortality (M&M) conferences, quality-assurance meetings, and many other less official gatherings of staff in the 3 units. The observers became marvelously attuned to what health care workers were discussing and recognized when something adverse was being discussed. We wryly developed our own red flag that we called “eyebrow-raising events,” so named when that part of the face expressed concern or surprise. Their observations were carefully reviewed and matched against other available data from meetings, medical records, or incident reports. Generally, there was agreement among the observers, surgeons, and other investigators.

We attempted to observe the process fairly; we did not include errors that were averted, such as my not eating the eggs, the wrong blood sent but not transfused, or the incorrect medication order not followed. We used our judgment to determine whether error really occurred or whether there was only a misunderstanding. We did not include errors without consequence or those with no measurable adverse effects. It was, of course, necessary for us to categorize and itemize error, and we did so by identifying the 9 major problem areas depicted in Table 1. Each of the 9 problem areas had its own set of categories, so that we arrived at 368 specific categories.

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Table 2

A total of 1047 patients were admitted to the 3 study units during the course of the study. One or more adverse events or errors occurred in 480 patients (45.8%). A total of 2183 errors were identified, of which 462 (21.2%) were considered serious (ie, a potentially life- or limb-threatening event). One hundred seventy-five patients (17.7%) had at least 1 severe event.

These errors were distributed among all 9 problem areas (Table 2). The most common problem areas in which error occurred were daily patient care (29.3%) and management of other complications (19.5%). Among the more serious errors, most were related to the manage-
ment of complications (38.1%) or to surgery itself (19.7%). It is noteworthy that diagnosis was responsible for fewer than 10% of errors, and anesthesia, the involvement of which is often invoked in our surgical M&M conferences, accounted for a small percentage of errors; however, when they occurred, they tended to be serious and accounted for 2.4% of all serious errors.

An analysis of the 40 most frequently encountered categories of adverse events showed that a single individual who might be considered responsible for the error could be identified in only 37.8% of the cases, and in more than one third of these cases, it was simply not possible to assign any responsibility. Much like airplane mishaps, the errors are often individually small and seemingly insignificant but seem to cascade to compound the problem. Patients who had already experienced a complication or adverse event were the most likely to experience additional problems. Gertrude Stein observed that, “A difference, to be a difference, must make a difference.” These data seemed to confirm that adverse events make a difference. The patients who experienced no identifiable adverse events had an average length of stay of 8.8 days. Those who did experience adverse events spent an average of 23.8 days in the hospital, and those with “serious” adverse events were hospitalized for an average of 32 days.

A legitimate concern for all health care providers is that of litigation. Of the 1047 patients in this study, 13 filed claims against the physicians or hospital. Of 13 claims, 11 occurred among 480 patients whom our study had identified as having experienced an error. For the 2 patients who were not in the error group, an unfortunate outcome was judged to not be the result of error. Of all claims, 3 resulted in compensation, 8 were dropped, and 2 were favorably resolved.

These observations were made under strict university and hospital research protocols. Except in the most obvious and serious observed errors, the observers were empowered neither to intervene and change the course of events nor to officially report to the hospital or university staff. As reported, some of the errors were officially recognized and became the subject of conferences and reviews. There were varying degrees of action in the various categories, ranging from official action in 2.6% of cases that involved surgery, and to identify a medication error in 5.3% of cases. An additional 15% to 20% of cases involved some form of unofficial action, such as discussion at M&M conferences or a report to those who oversee quality assurance. Almost 80% of the adverse events or errors that we observed were not officially recognized and recorded, and the events resulted in no identifiable action on either a personal or institutional level.

Although our patients were perhaps more seriously ill than those in other published series, to our knowledge, the incidence of error was substantially higher than any previous report. A 45.8% incidence of error and a 21.2% incidence of serious error is many times larger than the reported 10% error (3.7% serious error) published elsewhere. Although the data were collected as concurrently as we could devise, it is probable that errors were missed in our study as well, suggesting strongly that the probable incidence of error involves a staggering half of all patients admitted to surgical intensive care units. Traditionally, we have approached error by attempting to identify and then correct or punish the person(s) responsible. Our data show that such persons held responsible could be identified less than 40% of the time, and we believe that the patient was more often the victim of one of the other types of error explained in the following section and presented in Table 3. It became clear that errors could be categorized in several different ways. This is important since each type of error would lead to a different type of individual or institutional response.

### TYPES OF ERRORS

#### Judgmental Errors

Judgmental errors are usually discussed at conferences and are referred to as “errors” that are the result of inadequate knowledge or failure to employ knowledge. These errors include failure to obtain appropriate consultation and failure to order the proper tests or to interpret them improperly. The seemingly obvious way to correct these deficiencies is education. We as surgical educators spend inordinate amounts of time in such educational pursuits. If there are unhappy consequences that are predictable, such as the death of terminally ill pa-

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### Table 2. Problem Areas

<table>
<thead>
<tr>
<th>Problem Area</th>
<th>No. (%) of All Adverse Events</th>
<th>No. (%) of Serious Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>164 (7.5)</td>
<td>24 (5.2)</td>
</tr>
<tr>
<td>Surgery</td>
<td>230 (10.5)</td>
<td>91 (17.9)</td>
</tr>
<tr>
<td>Treatment</td>
<td>293 (13.4)</td>
<td>42 (9.1)</td>
</tr>
<tr>
<td>Monitoring/daily care</td>
<td>693 (29.3)</td>
<td>79 (17.1)</td>
</tr>
<tr>
<td>Drugs/medications</td>
<td>204 (9.3)</td>
<td>27 (5.8)</td>
</tr>
<tr>
<td>Nutrition</td>
<td>51 (2.3)</td>
<td>2 (9.4)</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>27 (2.1)</td>
<td>11 (2.4)</td>
</tr>
<tr>
<td>Complications</td>
<td>452 (19.5)</td>
<td>176 (38.1)</td>
</tr>
<tr>
<td>Other</td>
<td>150 (6.0)</td>
<td>10 (2.2)</td>
</tr>
</tbody>
</table>

### Table 3. Types of Adverse Events

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Examples</th>
<th>Traditionally Corrected by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judgmental</td>
<td>Inadequate knowledge</td>
<td>Education</td>
</tr>
<tr>
<td>Technical</td>
<td>“Slip of the knife”</td>
<td>Supervision</td>
</tr>
<tr>
<td>Expectation</td>
<td>Inappropriate delegation of responsibility</td>
<td>Awareness</td>
</tr>
<tr>
<td>Systems</td>
<td>Inadequate staffing</td>
<td>Administrative</td>
</tr>
<tr>
<td>Mechanical</td>
<td>Failure of equipment</td>
<td>Administrative</td>
</tr>
</tbody>
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tients, we spend relatively little time in discussion. Similarly, we do not frequently discuss good results since these are also expected. Unexpected adverse consequences are discussed at M&M conferences, and unexpected successes are presented at grand rounds. Perhaps we should reexamine how we direct our energies.

Our data show that diagnosis and treatment decisions in surgery resulted in fewer than 20% of all errors. Even among those that seem to be errors of judgment, the fault was more often found to be systemic. In Tampa, Fla, for instance, a surgeon removed the wrong leg. Despite wide national publicity and subsequent punishment of the surgeon, 2 other surgeons in the same year operated on the wrong finger. They also were disciplined, but are these truly judgment errors or are they matters of system failure? I believe that a class of high school students could design a system of finger identification, which if the system worked, would make it impossible for anyone to operate on the wrong digit, limb, or patient.

Conferences improve information and knowledge. Deming's experience in industry and our data show that adverse events are frequently neither the result of a lack of knowledge, nor reflective of "bad" surgeons. Deming showed that well-designed protocols minimize defects in industry and that well-defined protocols based on objective outcome standards and analysis would accomplish the same in surgery.

Technical Errors

Technical errors are part of surgery and are often referred to as "tricks of the trade." Technical errors do occur and are accepted as part of a learning process in a residency, but they may also be the result of defective equipment or the use of equipment in an inappropriate fashion. Audiences roll their eyes when I ask them whether they had ever observed an intensive care unit patient monitor with the alarm shut off so as not to disturb patients or nurses. The previously mentioned amputation performed on the wrong leg was often referred to as a technical error, but I believe that the operation was performed in a technically satisfactory way. It may not have been the fault of the surgeon not knowing which leg to operate on, and it does not take M&M conferences to demonstrate that operating on the wrong limb, lung, or eye should be avoided. Despite widespread attention, the same type of error occurred twice in the same city within months of the initial error. Publicity, education, and discipline all failed to correct the problem. We found that technical problems were involved in our list of adverse events in fewer than 10% of cases.

Expectations Errors

Misplaced expectations are an often-ignored cause of error. In most medical practice, there are no strict guidelines as to the process for performing or the individual expertise required for a given task. It is an unspoken tenant of surgical residencies that young surgeons are to be supervised and given graduated responsibility as their abilities expand. However, in most residencies, the milestones to be achieved are vague, poorly established, and rarely confirmed by any objective measure. Rarely is there an established checklist, or at least one that is actually followed. Several years ago I attended an M&M conference where a discussion involved a junior resident's inadvertent division of a central line that resulted in tubing entering the patient's body. Much of the discussion was devoted to the question of discipline, and whether this particular house officer should be discharged from the program. The house officer had never been supervised in this task, and though it was early in the year, it was mistakenly assumed that the resident possessed the requisite skill. We all know that residents seem to be more capable after the sun goes down and when the attending physician's personal supervision is most inconvenient. The resident who cut the line, some years later now, is among the best and the brightest. The tragedy was revealed by our finding that this same error had previously been made by other residents in the same program, yet no effort was made to change either the educational program or the system for managing catheter changes.

In the broader hospital system, the error of expectation in the face of dwindling resources is more egregious and relentless. On recent rounds during a weekend at the burn center I directed, it became clear to me that I did not recognize a single nurse, therapist, or technician; discussion confirmed that no single person on duty had ever worked in the burn unit before. Even if all are assumed to be exceptionally qualified for surgical care, the special protocols of the burn unit were not known to them, and they could not have been expected to perform at a high level in an emergency.

Systems Errors

Deming documented that most errors in industry are within the system itself and are usually not generated by individual failure. He strongly argued for the introduction of meticulously designed protocols at every step of the production. Additionally, these were to be monitored meticulously and continuously so that deviation would be immediately identified and corrected. Our study confirms that an analogous situation and opportunity is present within the hospital. More than 60% of all errors were identified as being in the system, and even among those for which an individual was identified, the person was also acting within the system. The tradition of identification and discipline of the person responsible is not sufficient to change the system.

Mechanical Errors

The final and most infrequent cause of error is from the mechanical failure of equipment. The maintenance of equipment is, in most hospitals, outside the mainstream of medical hierarchy and follows strict protocols, schedules, and criteria established by other industries.

IDENTIFICATION OF PRACTICE PROTOCOLS AND OUTCOME ANALYSIS

The first part of this article presents the situation as we identified it by the concurrent observation of adverse
events in surgical patients. This offered us the opportunity to examine some of the intrinsic problems within surgical practice and to make some recommendations for change.

Other industries have long demanded meticulous adherence to well-defined protocols. My brother-in-law has retired from a position as a senior pilot for a major airline. He flew the most modern planes in the world and was one of the earliest pilots certified to fly the Airbus. He and his copilot followed meticulous checklists and protocols. He occasionally reminisced about and longed for some of the thrills and freedom of his earlier days as a freelance pilot. However, as he settles into his single-engine plane, he and his copilot wife meticulously follow a checklist similar to what he followed with the airline.

It is arrogant to think that each surgeon’s approach to a given problem is as good as any other surgeon’s approach. It is inexcusable to ignore the fact that there are documented approaches to some conditions that are demonstrated to be superior to others. In one city, early breast cancer in a certain hospital is treated most of the time by lumpectomy and radiation with lymph node sampling. Across town, it is treated 80% of the time by modified radical mastectomy with complete lymph node dissection. Among the surgeons at all hospitals, there are a variety of approaches to drains, dressings, antibiotics, and other approaches that are idiosyncratic and not subjected to objective evaluation. Is everyone correct? Our beginning efforts to develop consensus approaches are laudatory and sensible. Studies on left colon surgery demonstrate that with meticulous attention to protocol, hospitalization can be reduced to a few days, and complications and adverse events can be all but eliminated.5

Many senior surgeons have spent the bulk of their professional careers working in the same operating room with the same nurses and anesthesiologist for decades. In such a situation, an unspoken practice protocol evolves, which may or not be as up-to-date as some others but is dependable and reproducible. Under such circumstances, judgment is second nature to all involved, technical and mechanical problems are probably rare, and there are few problems regarding expectations. In short, a good system would be developed almost intuitively by those involved.

That is rarely the situation in major hospitals today, particularly in the major teaching hospitals. The surgeon who sees the same anesthesiologist or nursing team every day is fortunate. Certainly, if emergency surgery is required during “off hours,” a group of highly trained strangers is gathered, rather than a highly trained and experienced team. Even though everyone involved may be talented, they are not a team (even the worst professional football or basketball team will usually beat a team of “all-stars”). The absence of strict protocols, not just “doctor preference cards,” denies the patient a critical safety factor. Pilots can fly with copilots whom they have never met only because they are assured that they are going to follow the same procedures. Patients, too, have a right to expect that surgeons provide them the same assurance of comparability and skill.

CULTURE OF BLAME

Charles Bosk conducted a seminal study at the same institution where I ate eggs, to determine how surgical faculty members evaluate the progress of young residents and to determine who among them are to be surgeons.6 While Bosk was observing surgeons at work, he also identified error and response to error. He noted that some types of errors made by residents are forgiven and remembered, whereas other errors are deterministic and not forgiven. He divided the errors into 4 categories: judgment, technical, normative, and quasi-normative.

Judgment errors are much as described earlier and they refer to situations in which lack of knowledge or experience is believed to have led to the error. We surgeons have devoted much of our educational efforts to expanding knowledge by conducting didactic grand rounds and journal clubs that are traditionally informational. Walking rounds with residents and students and operating room activities are largely devoted to sharing technical expertise and the value of previous experiences. Surgical M&M conferences have traditionally had the slightly different focus of reviewing adverse events and outcomes. The format has usually involved a resident presenting and attempting an explanation of the case. Although the attending physician is tacitly known to be responsible, the resident is expected to accept blame for whatever occurred. Much of the criticism may be based on “off-the-cuff” comments by senior surgeons and may reflect their own, sometimes idiosyncratic approaches to similar cases. The considerable time and effort devoted to such case reviews is presumably based on the assumption that error can be ascribed to the individual actions of people or groups of participants. It is further tacitly implied that perfect knowledge would lead to perfect judgment and elimination of error. Our data show that this belief is ultimately false and more than two thirds of all adverse events have nothing to do with judgments as such.

Bosk named a second type of error: technical. This type was infrequent and unless repetitive, was forgivable.

The third and most critical error was called normative and had to do with personal behavior. It involved assumption of responsibility relating to patients, staff, and faculty. Errors in this category (such as failure to visit a patient when called at night) are interpreted as character flaws and suggest that the resident does not have the “right stuff” to be a surgeon. Character flaws are still identified among surgeons and require courage to address.

The final category was intriguingly titled quasi-normative. It referred to a failure of the resident to identify, acknowledge, and follow the desires of a faculty member. These desires were often idiosyncratic and not based on any common practice or science that might be learned from the literature. The resident’s failure to observe these practices was evidence of hubris, considered insulting to the attending physician, and generally unacceptable. Since the activity was not dictated by any known protocol but rather as “just the way he does things,” residents could not accurately predict the practice pattern. It is hard to imagine a situation more prone to error. It is compa-
rable to the airline pilot having his own way of flying and the copilot having to guess how to assist.

NEED TO COMPENSATE THE VICTIM

Workers’ compensation legislation is designed to be a “no fault” approach to injuries on the job. Workers are cared for and compensated without having to prove who was at fault when an injury is sustained. It was felt that tort law could not handle this situation; companies and unions would wrangle endlessly while the injured worker was not being covered. A similar problem has developed within the medical field. The patient who has experienced an adverse event is, at present, charged with the expensive effort of finding the responsible person in the institution. Since all health care workers fear being singled out for blame and litigation, we are not eager to come forward when error occurs, sometimes even to help correct the situation. We in the system have responded by handling adverse events with silence, disapproval, and fear of liability. One of the observations in our study was that the more egregious and serious the error, the more eager people were to talk about it. Actually, risk management teams and lawyers usually strongly urge great care in discussing the issues of a serious adverse event. There is in our educational system a tendency to blame residents, and the more senior or popular the surgeon, the more he or she is protected by the system. Those who would attempt to discipline more senior surgeons may be isolated as whistleblowers, and the colleagues of the individual, no matter how ill-informed they may be, rally around the accused. The culture of blame is a difficult 2-edged sword in our profession. We seem to know no other approach than blame. Even workers’ compensation laws are fading as the no-fault approach to injury fails to serve the needs of plaintiffs. Litigation based on medical error also leads to circling wagons against an outside threat. The threat of litigation makes public discussion of the systemic problems almost impossible. The fact that the tort system is not very efficient (of 480 patients in our study, only 3 with adverse events received compensation) does not take away the awesome fear of litigation.

DIFFICULTY IN TRUTH TELLING

Telling the truth continues to be a difficult issue for physicians and surgeons. To my knowledge, all patients and medical students, without exception, believe that professionals have a responsibility to tell the truth. Truth telling has not long been part of the culture of medicine. Hippocrates advised us to do good and to protect our patients from harm; both of these are to be found in the oath that we take in his name at graduation. Regarding truth telling, Hippocrates was notably silent. He advised that we should “treat patients calmly and adroitly . . . concealing most things from the patient.” When I survey medical students on their second or third week on a surgical rotation about whether they have heard surgeons lie to their patients, they respond with a rather blank look. All of them have heard surgeons (and other physicians) withhold information and lie about some aspect of the patient’s care.

Truth telling does not have to be brutal and unkind. Leveling with patients and delivering truth in an artful fashion does not have to be a lie. In what circumstance are we most likely to participate in deception? It surely isn’t when we have just performed an imaginative and dexterous life-saving procedure. Rather, it is during the situations of adverse events and medical errors when we are individually and as a profession most challenged.

RECOMMENDATIONS

I would like to offer the premise that the health care industry, hospitals, and the practice of surgery are not so different from other industries that they can afford to ignore the wisdom of W. Edwards Deming. We have every reason to believe that there is a real, tangible, measurable incidence of error in the practice of surgery. It is an ethical imperative for all surgeons to attempt to minimize these errors. We cannot claim that errors are either unavoidable or not preventable. The analogy to airline pilots and airplanes is applicable; none of us would readily accept a 43.8% (our data) or even a 10% (Harvard data3) error rate in the cockpit. How can we accept such an egregious rate of error in the operating room and the other units where our patients are treated? Let us apply some of the wisdom of Deming.

Collect Data

The retrospective collection of data from the medical record is simply inadequate. Any quality assurance program that purports to be effective but collects its data after the fact is doomed. Workers do not record errors for all the understandable reasons described. Deming showed that the people who should collect the data are the workers on the line. We must allow nurses, technicians, pharmacists, therapists, residents, and secretaries to collect data at the point of care. I have worked with a software company (Safety-Centered Solutions, Tampa, Fla) that has used essentially the same problem areas and categories that we used in our study, and have introduced these to several hospitals. They have confirmed that such a process of data collection can be conducted. They can demonstrate dramatic reduction in adverse events with resultant cost savings.4

Develop Practice Protocols and Outcome Measurements

Unless there is a specified protocol, those at the point where the care is being delivered may not even be sure whether there has been a deviation from accepted standards of care. How can we correct error when those involved may be unaware that error has occurred? Accurate data collection, even retrospectively, requires that those involved have an understanding of correct procedure. As reluctant as physicians are regarding health maintenance organization and other cost-conscious third-party payers, the outside insistence on protocols and efforts to document that certain outcomes can be anticipated from various therapeutic
approaches is appropriate. Almost belatedly, surgeons are required to arrive at a consensus on the best approach to any given situation. Procedure protocols are nothing more than logical algorithms and outcome analysis requires only that results be objectively measured. One of Bosk’s most insightful observations was the pervasive presence of quasi-normative behavior among surgeons, idiosyncrasies that are lacking in scientific basis. That this is confusing to residents and other members of the health care team is self-evident; that it should predispose to error is obvious.

Eliminate the Culture of Blame

There are bad surgeons and their faults are usually what Bosk referred to as “normative” (i.e., the result of character flaws). The culture of silence in our profession should no longer protect them. That persons in authority abrogate their responsibilities and participate in cover-up has recently been emphasized in the case of Dr. Swango who seems to have actually murdered persons during surgical services but was able to move from institution to institution because those in responsibility failed to take principled stands. The culture of silence should not lead to the punishment of those who are legitimately trying to maintain quality, even when it involves disciplining or removing a popular surgeon.

Adverse events and medical errors occur when good surgeons are doing their best. They involve good residents doing their best. They involve good health care workers trying to do their best. True negligence is unusual. This is important since the system will change only when all of these people, doing their best, redirect their efforts toward the system. Our data clearly demonstrate that the problems are most often systemic, that is, within the system. Attempts to find the parties responsible when the system itself is at fault is fruitless. It makes it most difficult for good people to volunteer information when they become victims of blame, silence, disapproval, or liability.

Those who are involved at the scene of the error are the ones who are most likely to identify the error and, most importantly, are in the best position to correct it. Those at the scene should be empowered to enter data about the error at the time and place of the error and, as part of the ongoing quality improvement, be the team that fixes it. Only when we stop blaming individuals will workers voluntarily enter the data and allow the Deming process to lead to continuous improvement.

Compensate the Patients Who Are Injured

The workers’ compensation model worked when workers and industry agreed to a “no fault” approach to injury. The tort system failed to protect the workers and as tort has begun to displace no fault, we encounter more workers for whom the possibility of a large tort judgment becomes a disincentive to successful rehabilitation. Those of us who treated burns and other injuries became adept at marking the date that the patient hired an attorney; progress in recovery often stopped. Surgeons have spoken long and emotionally about tort reform but almost always in terms of protecting our own interests. The recognition that error is frequent may lead to increased litigation, but not all of these errors are negligence nor should litigation ultimately occur with increased frequency, at least for a period of time. Adherence to standardized protocols protects surgeons. As we recognize the incidence of adverse events, and begin gathering more data and taking action at the point of care, the incidence of error can drop dramatically. In the meantime, we need to work with industry, third-party payers, and the government to explore other ways to fairly compensate the injured. We can use as a starting point the fact that the profusion of malpractice litigation has not eliminated error; it has only made it desirable to hide and thus that much more difficult to correct.

Tell the Truth

We are not infallible, but we are not nearly so fallible as we appear to be; surgeons rarely “botch” the case. The medical profession needs to take the leadership in correcting the system. It is hard to maintain the posture that we are rendering elegant and safe care when we lack protocols that would allow us to compare processes; when we lack strict outcome criteria, which would allow us compare results; and when we continue to fail to address systemic problems. We cannot resist change in the face of data that show that 45.8% of our patients experience an adverse event and that 21.2% of these patients experience a “serious” adverse event. We must tell the truth. First, we must tell the truth to each other, then to our patients, and finally to the public, since the culture of silence will not serve us or allow us to change. The medical students who rotate on our services know when they hear lies. We must tell the truth.

ETHICAL CHALLENGES

Ethical decisions are not a separate part of life. There are, in our pluralistic society, dominant religious determinants of what is ethical behavior. There are certain values on which we can agree. We all believe that murder, slavery, and genocide are wrong. We all believe that there are certain virtuous characteristics that surgeons should possess. Surgeons should possess prudence, which implies knowledge and skill in our profession. Surgeons should possess temperance, maintaining our own health and having an awareness of chemical dependency in our colleagues and patients. Surgeons should possess fortitude, which is the courage to perform when we are tired, scared, or not getting paid, and the courage to speak out even if it means loss of income or friendships. Surgeons, finally, should possess a sense of justice for our society and for those in our society who are least able to speak for themselves: the poor, those who suffer discrimination, and those who may be contagious or even dangerous to our own health. These virtues of prudence, temperance, fortitude, and justice must be exhibited by us in addressing the issue of surgical error. The ethical imperative is to exhaust our efforts in correcting the processes and situations that lead to error. Almost all reli-
regions have adopted this last tenet as a true virtue; some call it love, some call it charity, and all describe it as a willingness to “to welcome the stranger.” In a sense, all our patients are strangers and we should welcome them, respect them, and keep them from harm.

In this article, I referred to the company Safety-Centered Solutions, Tampa, Fla (formerly Management Prescriptions Inc), established by David and Carolyn Spencer. The company has recently been acquired and is in partnership with Thomson Healthcare Information Group, Montvale, NJ. I have no financial interest in either of these companies.

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REFERENCES


ARCHIVES OF INTERNAL MEDICINE

Association Between Nonsteroidal Anti-inflammatory Drugs and Upper Gastrointestinal Tract Bleeding/Perforation: An Overview of Epidemiologic Studies Published in the 1990s

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Background: In the last decades, studies have estimated the upper gastrointestinal tract bleeding/perforation (UGIB) risk associated with individual nonsteroidal anti-inflammatory drugs (NSAIDs). Later analyses have also included the effect of patterns of NSAID use, risk factors for UGIB, and modifiers of NSAID effect.

Methods: Systematic review of case-control and cohort studies on serious gastrointestinal tract complications and nonaspirin NSAIDs published between 1990 and 1999 using MEDLINE. Eighteen original studies were selected according to predefined criteria. Two researchers extracted the data independently. Pooled relative risk estimates were calculated according to subject and exposure characteristics. Heterogeneity of effects was tested and reasons for heterogeneity were considered.

Results: Advanced age, history of peptic ulcer disease, and being male were risk factors for UGIB. Nonsteroidal anti-inflammatory drug users with advanced age or a history of peptic ulcer had the highest absolute risks. The pooled relative risk of UGIB after exposure to NSAIDs was 3.8 (95% confidence interval, 3.6-4.1). The increased risk was maintained during treatment and returned to baseline once treatment was stopped. A clear dose response was observed. There was some variation in risk between individual NSAIDs, though these differences were markedly attenuated when comparable daily doses were considered.

Conclusions: The elderly and patients with a history of peptic ulcer could benefit the most from a reduction in NSAID gastrotoxicity. Whenever possible, physicians may wish to recommend lower doses to reduce the UGIB risk associated with all individual NSAIDs, especially in the subgroup of patients with the greatest background risk. (2000;160:2093-2099)

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