

CHAPTER 1

The Legal Context for Disclosing Bad News

The health care industry is like a ship being tossed by high waves in the middle of a severe storm. It is being buffeted by angry and often distrusting patients, regulators, and legislators calling for rigorous scrutiny and payers demanding evidence-based quality care. At the same time, litigation-minded lawyers have fomented a wave of malpractice. The result has been a contracting of insurance carriers willing to write health professional liability insurance coverage. Those who are left in the field are demanding very expensive premiums for less coverage than was available only a few years ago. In the malpractice cases that go to trial, juries are sending a signal that the health care industry must transform itself into a quality-driven, accountable endeavor or be prepared to take the consequences in large damage awards.

To understand why there is so much emphasis on patient communication in the health care field, it is important to reflect on the drivers of this change: the change agents found in the government, accreditation, consumer, and payer sectors. Although many may not welcome this pressure for change, the result may be a health care system better prepared to partner with patients in the delivery of quality treatment and services.

THE FEDERAL PERSPECTIVE

In 1999, the Institute of Medicine (IOM) issued a landmark report that seemed to capture these shifting winds of dissatisfaction and distrust. In *To Err Is Human: Building a Safer Health System*, the IOM noted that the American health care industry kills an estimated forty-four thousand to ninety-eight thousand patients every year through medical error-related events.¹ The report pointed out that many of these deaths were preventable. Subsequently, a number of federal entities known as the Quality Interagency Coordination (QuIC) Task Force made their own recommendations in response to the IOM report. This QuIC report, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*, delineated one hundred action items for the federal government to take to rectify the situation.² In part, the government strategy focused on institutional accountability, leadership, and communication.

After the QuIC report, the Agency for Health Care Research and Quality (AHRQ; formerly known as the Agency for Health Care Policy and Research) took on a leadership role among federal authorities committed to patient safety. AHRQ has funded a variety of studies and research. One particular report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, reflects AHRQ's research commitment.³ Prepared by the University of California at San Francisco (UCSF)–Standard Evidence-Based Practice Center (EPC), it focuses on evidence-based patient safety practices.

Working with the National Forum for Quality Measurement and Report, better known as the National Quality Forum (NQF), a partnership of private and public sector entities, the EPC developed a definition for a patient safety practice: “a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.”⁴ This definition encompasses communication skills and consent to treatment. Indeed, the report contained a discussion about informed consent and the need for research on the topic in conjunction with patient safety practices.

The Food and Drug Administration,⁵ the Conditions of Participation for Hospitals in Medicare and Medicaid Patients Rights Standards,⁶ and

federally sponsored reports addressing the issue of patients rights⁷ all point to the need for strong communication processes. Involving the patient in the decision-making process is viewed as a key ingredient to successful medical treatment.⁸

THE STATE GOVERNMENT PERSPECTIVE

At the state level, the move toward patient safety has been demonstrated by legislative initiatives geared toward reporting serious adverse events or patient deaths to databases in the belief that collecting such information will be useful in holding health care entities accountable for their performance.⁹ As distinguished from voluntary reporting methodologies, the mandatory reporting procedures found in some states are at times linked to fines and penalties, and the format is tied to public disclosure.¹⁰

Some innovations have also occurred at the state level to facilitate reporting of adverse events without fear of disclosure of this information in medical malpractice litigation. The idea is to create an atmosphere conducive to the examination of adverse event information with a view to process improvement in patient safety. Examples of this approach include evidentiary use laws in Oklahoma,¹¹ Minnesota,¹² and Louisiana.¹³ However, these laws are more the exception than the rule.

In addition, at the urging of the IOM in *To Err Is Human: Building a Safer Health System*, consideration is being given to a rethinking of health professional licensure at the state level.¹⁴ The intent is to consider a variety of methodologies, including periodic relicensure.

The IOM report also emphasized the need for institutional accountability on the part of health care facilities. Indeed, *To Err Is Human: Building a Safer Health System* explored the idea of enterprise liability, that is, holding health care entities legally responsible for the errors and omissions of nonemployee health professionals who had been accorded staff privileges.¹⁵ According to this concept, the health care entity could not avoid liability even when it contracted out delivery of health care services to physician groups for such departments as radiology or emergency medicine. Following the

logic of this enterprise accountability theory, the hospital could be held negligent for a substandard consent to treatment on the part of a staff physician.

Thus far, only two states have clearly adopted the legal theory of enterprise liability.¹⁶ In neither instance was consent the issue. Rather, it was the matter of substandard delivery of emergency treatment. However, at least one court has examined the idea of enterprise liability for negligent consent.¹⁷ The point is that consent and the communication process underlying it may well be the basis for holding a hospital responsible for the negligence of a staff doctor. This type of liability exposure gives impetus to those who are trying to improve provider-patient communications and discussion of negative treatment outcomes.¹⁸

THE ACCREDITATION PERSPECTIVE

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the accrediting body for hospitals in the United States. In addition, it accredits nursing homes, integrated delivery systems, managed care organizations, and other health care organizations. The accreditation process is about quality of care, safe environments of care, and patient safety. It requires health care organizations to demonstrate compliance with standards developed for guiding health care services. Surveys are done to compare performance with the standards, and depending on the outcome, a health care entity may or may not receive a grade that is comparable to similarly situated facilities. Facilities that are in noncompliance will receive what are known as Type I or Type II findings, which require work to align the organization with the standards. In serious standards noncompliance situations, JCAHO may revoke or deny accreditation status.

Accreditation is a voluntary process. However, by becoming accredited, a hospital can host approved medical residency programs. Moreover, an accredited health care organization is automatically qualified to participate in Medicare and Medicaid. It need not seek separate approval from either the Centers for Medicare and Medicaid Services (CMS) or a state agency. Moreover, many health plans require JCAHO accreditation to be a partici-

pating provider for members, and many professional liability carriers look to JCAHO accreditation as a key indicator in deciding whether to offer insurance coverage.

At its best, the accreditation survey process is but a snapshot in time. In the interval between the previous survey and the subsequent evaluation, many things can happen that can result in a poor level of care or diminished patient safety. This fact was recognized in reports issued by the Government Accounting Office (GAO) and the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services.

Calling into question the value of the costly accreditation process, both the GAO and the OIG made several criticisms that went to the core of the JCAHO process.¹⁹ JCAHO responded by revamping many aspects of the accreditation model. The reformation is ongoing to make the accreditation process more efficient, practical, and directed to delivery of high-quality, patient-safe care.

As a result of publication of *To Err Is Human*, JCAHO ramped up its efforts in patient safety.²⁰ Indeed, it is noteworthy that prior to publication of this IOM report, JCAHO had embarked on a course of reducing risk-prone processes through the use of root cause analysis for what it termed reviewable sentinel events. Borrowing a page from industry, JCAHO set out to have accredited facilities drill down into the systems failures that gave rise to patient injury or death. The vehicle for this effort was root cause analysis, which would pinpoint the common, latent, and special causes of iatrogenic illness or death.²¹

After the IOM report, JCAHO stepped up its activity, introducing a set of so-called patient safety standards designed to address a variety of systemic concerns that contribute to patient injury. Among the many patient safety standards is one that mandates a discussion of the outcomes of care with patients. JCAHO requires that patients, and when appropriate their families, receive information about the outcomes of care.²² *Outcomes* here refers to both anticipated and unanticipated results, whether good or bad. However, JCAHO placed emphasis on the unanticipated outcomes of care, believing that doctors and other caregivers are reticent to share bad news with patients.

Many in the health care community interpreted the JCAHO requirement as compelling doctors and other health care professionals to make an admission of liability, although JCAHO adamantly denied this was the case. Others questioned how one could share bad outcome information with patients and their loved ones without leaving the implication of medical malpractice liability. The American Society for Healthcare Risk Management (ASHRM) issued a white paper on the subject that provided some perspectives on delivering such information without making an admission of culpability.²³ It has proved to be a good starting point for managing disclosure of unanticipated outcomes of care.²⁴ The ASHRM white paper emphasizes the need for frank and candid discussion of risks and benefits with patients prior to embarking on treatment. It views consent as laying the foundation for solid communications with patients and family members so that should unanticipated events occur, there is a preexisting relationship and framework for subsequent discussions.

JCAHO also has embarked on a new strategy to involve patients in their own care better. Termed “Speak Up: Help Prevent Errors in Your Care,” this public relations strategy was designed to motivate patients to become more involved and informed participants as members of the health care team. According to JCAHO, the new concept is based on research demonstrating “that patients who take part in decisions about their health care are more likely to have better outcomes.”²⁵ At the core of the initiative is the enhancement of professional-patient communications.

There is little doubt that the JCAHO’s patients’ safety standards are a key driver of change shaping the delivery of safe care to patients.

PRESIDENT’S ADVISORY COMMISSION ON CONSUMER PROTECTION AND QUALITY IN THE HEALTHCARE COMMUNITY

In 1999, a report was published on the findings and recommendations of the President’s Advisory Commission on Consumer Protection and Quality in the Healthcare Industry.²⁶ Not only did it address accessibility and

affordability of health care services, it stressed the needs to involve patients better in designing treatment plans and for patients to have sufficient communication with health care providers. Tying information to the quality of health care, the report reinforced the idea of a patient's right to information. As such, it became an important driver in the push for patient safety.

THE PAYER PERSPECTIVE

Payers have many interests in promoting quality-based health care. With so many employers paying ever-increasing premiums for health care coverage, there is an expectation that the money should be spent wisely in promoting wellness and curing illness. When employees complain that care is inadequate or shoddy or that they come away from a health care encounter injured, employers have reason to be concerned. Not only does this suggest that health care premiums are not being spent wisely, but employers may not be meeting their obligations under federally qualified health care plans. At the same time, employers worry about worker productivity if health care does more harm than good.

In January 2000, a group of the Fortune 500 from the Business Roundtable formed a coalition called "The Leapfrog Group" to respond to the situation.²⁷ With a mandate to alter the situation in terms of patient safety, Leapfrog has positioned itself to jump over government regulatory inroads and accreditation standards to effect change. In 2001, it published three standards for hospitals to meet: referrals to facilities that have a high volume of procedures, computerized order entry, and use of intensivists in intensive care units. The idea was that these three steps would start the health care industry down the road to effective change. In 2002, it completed a survey of hospital compliance with the standards. More standards are expected in future.

The payer is not going to remain silent. Increased health care costs, employee dissatisfaction, and perceived quality-of-care issues are driving the formation of so-called baby Leapfrogs, or state-based initiatives to compel change. Greater participation of employees in treatment planning is seen

as a key point, especially with the results of benchmark studies designed to inform consumers about how well hospitals compare with one another in the delivery of care based on the Leapfrog standards.

THE CONSUMER PERSPECTIVE

The President's Advisory Commission Report is a reflection of the concerns articulated by consumers. Many are afraid to seek health care. They fear becoming another medical error statistic. They want more information, not less, about their health care. Many want to know about the treatment or outcome results of a surgeon who proposes to perform a surgical procedure. Others want information about hospital performance, medication error rates, and infection control statistics before seeking treatment at an acute care facility.²⁸ Web site-based information is becoming available on disciplinary activity surrounding physicians, data made available through the auspices of some state boards of medicine.²⁹ JCAHO publishes "Quality Check" data on hospital performance, information that is easily accessible over the Internet.³⁰

The point is that consumers want to make informed choices about their health care. Knowing the "batting average" of a doctor or a hospital is important to consumers in deciding from whom to seek health care services. To consumer groups, making this information available to the public helps drive competition for the delivery of quality, patient-safe health care services.

THE INSURANCE INDUSTRY PERSPECTIVE

Beyond legislative, regulatory, accreditation, payer, and consumer-driven demands for greater disclosure of information, there are other key groups to consider. One group in particular is the medical malpractice or professional health care liability insurance carriers.

In many instances, insurance carriers have been seen as an impediment to disclosure of information about adverse outcomes of tests or treatment. It has been posited that physicians have been admonished by carriers *not to*

reveal such information voluntarily lest it be seen as an admission of liability. Should physicians reject such direction from their insurance carriers, they may face the prospect of a so-called reservation of rights letter, in which the insured is told that coverage may not be available for making disclosures that compromise the ability to properly defend any claims arising out of the unanticipated or adverse outcome.

To be sure, the insurance industry may be sending mixed messages. Some insurers have taken a very public stance in encouraging their insured physicians to communicate with patients about unanticipated outcomes of care.³¹

Perhaps there is a plausible explanation for the apparent disagreement, perceived or real, among liability insurance carriers. Insurers do not want to set the stage for an antagonistic battle between a staff physician and a hospital, an approach that could easily backfire in the course of building a joint defense strategy. Furthermore, liability carriers do not want hospitals to be forced to choose between listening to a “say nothing” approach from an insurer, on the one hand, and, on the other, facing accreditation repercussions if they do not abide by the patient safety standard on disclosure of unanticipated outcomes of care.

The middle ground in each instance focuses on disclosure of information about outcomes of care without making admissions of liability. Such an approach is plausible and achievable if a factual account is presented without making statements that point the finger of culpability in the direction of a specific caregiver or health care organization. In drawing a distinction between disclosure of adverse outcome information and a statement steeped in blame or fault, some liability insurance carriers do not exhibit any difficulty with their insured physicians’ meeting the expectation to reveal details about unanticipated treatment results.

RESEARCH ON DISCLOSURE OF ADVERSE OUTCOMES

Articles and study results have been published that suggest that in appropriate circumstances, disclosure of adverse outcomes may thwart rather than exacerbate the chance for litigation stemming from the event. In one

study, surveys mailed to 400 patients sought to obtain patients' reactions to three hypothetical scenarios involving medical error. Most of the 149 respondents wanted the doctor to disclose when a mistake occurred, with most wanting an acknowledgment that an error had taken place. Interestingly, the study showed that doctors were likely to be sued or be reported if they *did not* acknowledge that a mistake had occurred. As the study investigators indicated, based on the findings in this patient sample, the failure to report medical errors actually increases the risk of lawsuits and professional disciplinary sanctions.³²

An obvious concern about disclosure is the financial cost of acknowledging that an error has occurred. If a physician or a health care organization adopts a disclosure policy, will such revelations increase the ultimate cost of a malpractice claim or settlement? One study done at the Veterans Administration (VA) Medical Center in Lexington, Kentucky, suggests that the costs may actually decrease. Since adopting a disclosure policy, the Lexington facility has found that it has brought its claims or settlements down to the lowest amount paid for such events among a group of VA hospitals.³³

To be sure, such studies can be criticized as representing a very small sample. Also, in the case of the VA findings, physician-employees cannot be sued in their individual capacity, a key protective benefit from the Federal Torts Claims Act.³⁴ Nonetheless, the results point to an important finding: communicating with patients and sharing with them details about adverse events can diffuse a situation that might otherwise lead to onerous litigation, professional disciplinary actions, and regulatory entanglements. Furthermore, there is no guarantee that a person with a predisposition to sue will be placated by disclosure about an adverse event. What the discussion may do in such instances is trigger an early, just, and financially reasonable settlement. This may be a win for health care professionals and organizations alike that are increasingly burdened by either escalating premiums for medical malpractice and health facility liability insurance or limitations in coverage. At the very least, the timing, setting, and scope of disclosure of bad news merit further research.

PRACTICAL CONSIDERATIONS

Other groups have their own perspectives on why there is a problem today in the health care field. Among them are professional trade associations that represent the interests of hospitals, physicians, and nurses;³⁵ health care professional unions; group purchasing associations;³⁶ the plaintiffs' bar; and defense attorneys. There are also experts in the field of health care public policy who have their own views on the subject.³⁷

There are also a number of practical considerations—for example:

- A perception that doctors must see many more patients and spend less time with them than in the past due to the financial constraints imposed on them by managed care organizations and health plans
- A perception that consent is a form, not a process
- An absence of communications training for health care professionals that sets them up for failure in terms of successfully completing an effective consent process
- A lack of communications training for health care professionals that makes them incapable of dealing with disclosure of unanticipated outcomes

Many of these considerations are easily dispelled. For example, as noted in Chapter Two, consent is *not* a piece of paper; rather, it is a communications process. Similarly, even if caregivers never received formal training on the proper methods for communicating information to patients, they can learn to do so through continuing-education programs. Moreover, with tools such as checklists, it is possible to curtail the amount of time perceived as being required to complete a successful consent process.

Anyone can put up hurdles to thwart change. The old paradigm of silence about bad outcomes has begun to fall by the wayside. In its place is a practical framework guided by cogent legal advice and proper training for those who must deliver the bad news.

THE LEGAL PROBLEM: EVIDENTIARY PROTECTION AND DISCLOSURE

By far, one of the most challenging issues is the matter of evidentiary protection in situations in which health care professionals must disclose information regarding adverse outcomes. Given the state of evidentiary laws, this is a very real concern.

In the United States, there is not a single consistent legislative, regulatory, or case law approach to the issue of evidentiary protection for the review of adverse events. In many instances, the results of such reviews, including root cause analysis, could be subject to legal discovery or admitted as evidence in a professional liability claim. This is seen as having a chilling effect on health care professionals' taking part in such activities even though the purpose of such activity is to enhance quality patient care.³⁸

Some models do exist for creating a "protective zone" for reporting, discussing, and analyzing such information. Although some are found outside the health care field, most notably in the field of aviation safety, there are some models in the health care field.³⁹ For example, a limited peer review immunity was created by Congress in the Health Care Quality Improvement Act (HCQIA).⁴⁰ This law creates a limited immunity from damages for those who take part in peer review activities that may culminate in a health care facility's taking action against an individual's medical staff privileges. The HCQIA also affords protection to those who provide information to bodies that review data that lead to corrective action. However, even this protection has its limitations. It does not apply if the action was taken without granting the individual due process, such as a right to notice and a hearing. Moreover, if the action was not premised on the reasonable belief that it would further quality health care, such activity is not covered by the HCQIA.

The U.S. Food and Drug Administration (FDA) operates adverse event reporting systems:

The Vaccine Adverse Event Reporting System, a program cosponsored with the Centers for Disease Control and Prevention (CDC). This

system, which started in 1990, is used to collect and analyze data from reports of adverse events following immunization. The intent is to use the system to identify new safety concerns. It is important to note that anyone can report to this system.

The Special Nutritional Adverse Event Monitoring System, a voluntary reporting system established in 1993 to address adverse events associated with use of a special nutritional product: dietary supplements, infant formulas, and medical foods.

The Manufacturer and User Facility Device Experience Database, which aggregates information on medical device adverse events.

Other federal agencies also collect information that deals with adverse events, such as the CDC's National Nosocomial Infections Surveillance System, a voluntary effort that began in 1970 between the CDC and acute care general hospitals to collect information for a national nosocomial infections database. Under applicable law, information provided by participating hospitals that would link data with any individual or institution is held in strict confidence.

At the state level, a variety of laws are designed to provide evidentiary protection for data or activities geared to peer review. The basic premise of such legislation is to create a "protective zone" in which frank and candid discourse can occur without fear that the discussions of the data reviewed will be subject to legal process. In other words, those who take part in the proceedings, whether as members of a peer review committee or as a witness, are protected from legal recourse.⁴¹

Many state laws were created to facilitate implementation of the HCQIA. The scope of these laws is quite narrow, applicable to hospitals and other facilities with a peer review mechanism and a due process system focused on medical staff members.⁴² The laws were designed to encourage quality patient care. Written at a time when the focal point was peer review for purposes of credentialing, the laws were not designed to address root cause analysis or disclosure of unanticipated outcome information.

Although there are federal models in place for revealing adverse events without concern that such information will be used outside the scope of the reporting laws, the same cannot be said of disclosure of unanticipated outcomes of care. There are specific frameworks in place for voluntary reporting of medical device or vaccination issues. The same cannot be said for telling a patient or a family about an untoward event.

The legal concern is quite simple. If a hospital or a physician voluntarily discloses unanticipated outcome information, does this action signify a decision to give up evidentiary protection for other purposes, such as a legal proceeding for professional liability or disciplinary action before a regulatory body? Does it signify an admission of liability?

The plaintiffs' bar may well argue that by disclosing unanticipated outcome information outside the scope of peer review, the health care facility consciously relinquished evidentiary protection. The same kind of argument would be used with respect to a physician's sharing such news outside the realm of the peer review process. Although such disclosure may be required by JCAHO standards, the plaintiff may insist that such a step signifies voluntarily giving up any evidentiary protection.

The plaintiffs' bar is likely to go one step further, insisting that disclosure of unanticipated outcome or bad news is tantamount to an admission of culpability. Not only is this a specious argument, it flies in the face of the basic foundations of consent law (see Chapter Two).

The fact that a physician or a hospital spokesperson talks with the patient or family about an unanticipated outcome does not signify relinquishment of evidentiary protection. A patient and family expect to have closure in the communication process that begins with consent to treatment and ends with the outcome of a test or treatment intervention. It is curious that the plaintiffs' bar does not make such assertions when the outcome of care disclosure focuses on positive, not negative, results. Furthermore, it is expected that to complete the consent cycle, the patient and, when appropriate, the family will receive information about the tests or treatment. This is important for purposes of follow-up care, watching for side effects, or the recurrence of symptoms. Absent such information, the

patient could undertake activities or consume medication that may have a negative impact on his or her health. Without such details, important warning signals about changes in health status could be ignored, to the detriment of the patient's well-being. The failure of a physician to communicate such information could be seen as substandard care. Hence, the notion that outcomes disclosure is a special communication process that relinquishes evidentiary process is unrealistic. It is incongruent with the law of consent to treatment.

To be certain, steps should be taken to make sure that well-intentioned statements about the outcomes of care are not taken out of context or that such disclosures are not seen as voluntarily relinquishment of desired evidentiary protection. Such steps include delineating a thoughtful outcomes disclosure process. Thus, patients and families can receive cogent, factual outcomes information, without blame or fault attributed to someone. It means that outcomes information can be explained so that patients and families understand that some occurrences take place without someone being at fault.

Another solution is to look for a legislative answer, ideally at the national level, to make it clear that such information, if disclosed to patients and their families, does not signal relinquishment of evidentiary protection. Legislation would encourage greater discussion without fear of recrimination for doing so. Some federal legislators are considering such an approach with a view to encouraging greater internal review of bad outcomes to enhance patient safety.⁴³ Until such steps are taken, it is important for health care providers to obtain practical legal advice regarding their responsibilities in the disclosure of information about unanticipated outcomes of care.

CONCLUSION

Many complex factors have helped make it difficult for caregivers to disclose information about adverse outcomes of care. Some of these complexities stem from outdated laws and outmoded legal reasoning. Against this backdrop is a groundswell of demands from consumers, payers, and

accrediting bodies insisting that caregivers disclose such information. The problem is all the more difficult since most health professionals have not received training in how to interact with patients or their families in difficult circumstances.

The consent process, a topic discussed in the next chapter, provides a framework for delivering bad news or unanticipated outcomes of care. Fundamental to this process is a strong understanding of the physician-patient and physician-family relationships. The right set of skills for managing “how to say it” is essential.