16. Disclosure of Complications and Error

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Communication with patients about medical error is one of the most difficult issues which confront the surgeon. While surgeons strive to care for patients without mistakes, the complexity of the care process allows for the possibility of surgeon error, systems error, or error committed by any member of the care team. Given the complexity of the modern care process, most errors are the result of human rather than technical failures [1]. The current movement to enhance patient safety and improve health care quality will certainly reduce error, but medical error will unfortunately continue to occur. Human fallibility can be limited by robust systems, but will never be completely eliminated.

The definition of error which was adopted by the Institute of Medicine in the seminal report *To Err is Human* [2] was proposed by James Reason in 1990: "occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome" [3]. This definition includes errors that may not result in an adverse event, the concept of the "near miss." The Harvard Medical Practice Study defined adverse events as "an injury that was caused by medical management (and not the disease process) that either prolonged the hospitalization or produced a disability at the time of discharge or both" [4]. This definition is not only precise, but also includes significant errors which might not result in disability or prolonged hospital stay. These errors may not result in an adverse event but can still be troubling to patients or the health care team.

Toward a Taxonomy of Error

The traditional taxonomy of error employed by most surgeons is the model of the morbidity and mortality conference. This approach recognizes the time-honored concepts of technical error, judgment error,

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error of omission, and error of commission [4]. The morbidity and mortality conference analyzes all adverse events on a surgical service – deaths and complications – and the formal structure recognizes that some adverse events are preventable, others are not. This taxonomy of error is incomplete because it is unduly focused on the actions of the surgeon. While the surgeon may, indeed, commit a technical error or make an error in judgment (such as a delay in diagnosis), this approach does not recognize the myriad other kinds of medical error: medication errors, nursing care errors and system errors and latent errors. Latent error refers to the injury which can result from a complex chain of events in the care process – any one of the events might not result in injury, but taken together, an adverse event occurs. A more inclusive categorization of error is useful because it may provide guidance in changing systems of care to prevent future error (Exhibit 16.1).

Reason's definition of error is more broad and helpful as surgeons consider what to disclose to patients when errors occur. From a pragmatic and ethical standpoint, any error which reaches the threshold of the Harvard Medical Practice Study, resulting in prolonged hospital stay, death or disability, must be reported to the patient. However errors recognized by Reason must also be reported at times, specifically those which do not result in injury but may come to the patient's attention. These errors, the "near misses," must be discussed with the patient to avoid a loss in confidence in the caregivers.

Exhibit 16.1. Taxonomy of error.

Traditional surgical paradigm
Technical error
Judgment error
Delay in diagnosis
Error in diagnosis
Error of omission
Error of commission
Practical taxonomy of error
Technical error
Systems error
Latent error
Medication error
Device failure

Regulatory Aspects of Error Disclosure

The modern climate of health care now requires that errors be disclosed. This has resulted from the patient safety movement and increasing demands for transparency and public accountability in health care. In the past, the culture of medicine was to withhold admission of errors. Physicians commonly withheld the disclosure of errors from patients. Errors were only disclosed when the mistake was obvious or significant injury resulted. At times, adverse events were ascribed to the patient's disease rather than to error. The prevailing wisdom was that admission of error would increase the risk of malpractice litigation. Physicians also were embarrassed and unsure of disclosure strategies when confronting error. Patients now expect to be fully informed and involved in their care.

The momentum for the disclosure of error has developed as a result of the patient safety and quality movement. In the United States, the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) issued the first nationwide disclosure standard [6]. This standard requires that patients be informed about all outcomes of care including "unanticipated outcomes." The importance of the Joint Commission in the realm of hospital care gave great impetus to the movement to disclose errors. The National Quality Forum (NQF), an organization that operates at the federal level with strong ties to CMS, has developed standards for the disclosure of unanticipated outcomes [7]. The NQF safe practice standards are used by the Leapfrog Group, a coalition of 29 large healthcare purchasing organizations. A total of 1,300 hospitals currently report information about these standards, including disclosure, to the Leapfrog Group.

The Institute for Healthcare Improvement, the Agency for Healthcare Research and Quality, and numerous medical specialty societies have all called for policies of disclosure. Unfortunately, the medical society recommendations for transparent disclosure of error are somewhat vague and lack specificity. The AMA Code of Ethics, for example, states that "a physician should at all times deal honestly and openly with patients" [9].

On the international level, initiatives in Australia and the United Kingdom have been notable. In 2003, Australia initiated an "Open Disclosure Standard" in pilot programs across the country. In the United Kingdom, the "Being Open" initiative has been put in place with an extensive educational campaign. These programs have advocated

transparent communication and provided tools for enhancing communication with patients. These efforts have been voluntary and have not specifically addressed poor outcomes which have occurred as a result of medical error [8].

As the regulatory agencies have established standards for the disclosure of error, governmental authorities are beginning to mandate disclosure. Although there are no laws requiring disclosure at the national level, in 2005, Senators Hillary Rodham Clinton and Barack Obama sponsored a bill, the National Medical Error Disclosure and Compensation Act (MEDiC) calling for full disclosure of errors [9]. The bill did not pass, but it linked disclosure, quality and the medical liability system. The recognition at the federal level that issues of quality, openness, and liability are all closely related is important and suggests that these initiatives are likely to continue as health care reform becomes increasingly important as a national issue.

Several states have passed legislation mandating disclosure of serious unanticipated outcomes. Laws are now in effect in Nevada, Florida, New Jersey, Pennsylvania, Oregon, Vermont, and California [8]. The most stringent law is in place in Pennsylvania which requires that hospital notify patients in writing within 7 days of a serious event. The Pennsylvania law also prohibits the use of these communications as evidence of liability. These laws share in common an approach which requires that hospitals develop mechanisms for disclosure, rather than individual physicians. Forty-five states have enacted "apology laws" which protects certain information transmitted in disclosures, especially expressions of regret or other forms of apology [8]. Enforcement of these laws is only stipulated in the Pennsylvania law. Many of the laws are sufficiently vague that regulation of disclosures seems difficult, at best.

Error Disclosure and Risk of Litigation

Physicians have been most concerned that disclosure will increase the likelihood of a malpractice action. These concerns have done much to impede the flow of information to patients and families. Despite this, it is now clear that patients want to know about all errors that cause them harm. A large survey of emergency department patients revealed that 80% wanted to be informed immediately of any medical error. A large majority also supported reporting errors to government agencies, state medical boards, and hospital committees [11]. This study also

demonstrated that patients wished to be informed not just about error resulting in injury, but of "near misses" also. A large survey of health plan members reported increased patient satisfaction, trust when presented scenarios in which full disclosure was advocated. The study also indicated that patient felt that they would be less likely to seek legal advice with full disclosure [12].

American and Canadian physicians appear to embrace the soundness of disclosing errors. These attitudes have changed significantly during the last 20 years. In a 1991 survey of house officer, three of four said that they had not reported an error to a patient, largely because of concern about litigation [13]. By 2006, in a survey of 2,637 physicians, 98% supported disclosing serious medical errors to patients. Seventy-four percent thought that disclosing errors would be difficult, and 58% actually reported disclosing a serious error. Physicians who supported disclosing error were more likely to believe that disclosure made patients less likely to sue [14]. Physicians were more likely than hospital risk managers to support providing a full apology for error while the risk managers were more likely to support disclosing error in the first place [15].

The relationship between disclosure and risk of litigation is not at all clear. In 1987, the Veterans Affairs Hospital in Lexington, VA introduced a disclosure program years before any other. An analysis of the results in 1999 showed that the number of claims during the 12-year period was up, but payments made decreased [16]. Nonetheless, there is a paucity of data which relates the likelihood of a lawsuit to a policy of complete disclosure of error. Despite the lack of solid data, most experts believe that disclosure of error and apology likely reduce the risk of litigation. Based upon the University of Michigan experience, Boothman, Campbell et al. have demonstrated that forthright disclosure and a willingness to apologize is associated with a reduced risk of malpractice actions [17].

Strategies for Disclosing Error to Patients

Gallagher and his colleagues have observed that surgeons are more inclined to disclose error than their medical colleagues [14]. This may result in part from the fact that surgical errors are often more clear and unambiguous. In additional work, they documented better ability of surgeons to disclose error using a standardized set of patient scenarios [16]. Surgeons are probably better at disclosing error because of their greater familiarity with transmitting information about complications.

Surgeons tend to be direct in describing adverse events and are good at providing details about the consequences of medical error. However, surgeons are reluctant to state that and adverse event was a "mistake" or "error" [16]. Although surgeons may be better than their colleagues in other specialties, until recently there was very little guidance about how to communicate error. The lack of guidance contributes to the tendency of surgeons to avoid the use of the word error or mistake.

When an error occurs, it is necessary to disclose it forthrightly to the patient. The first decision centers on who should be present when the error is disclosed. This should be discussed prior to meeting with the patient and family. Often, other members of the team should be present to fully address the patient's needs – this may include nursing, hospital administration, risk management, or other physicians, The meeting should take place in a private setting and all participants should be introduced. The conversation with the patient should take place using clear, simple language.

The surgeon must provide all of the facts about the event. The source of the error must be identified, paying particular attention to whether it is a technical error, human error, or system failure. It is entirely appropriate to express regret for the adverse outcome and to offer a formal apology if the outcome is the result of system failure or error. These conversations should be carried out with empathy and sensitivity. It is very important to accept responsibility for the adverse outcome and to avoid the use of the passive voice. During these conversations, it is important to not attribute blame to others or to claim a lack of understanding of the events.

Following a discussion of the error and resulting injury, the surgeon should review its implications with the patient. The consequences of the error should be reviewed and the surgeon should explain what will be done to mitigate the problem. The emotional needs of the patient and family should be remembered at this time and any necessary support should be offered. The patient should also be told what measures will be taken to ensure that a similar error does not occur in the future to another patient.

From an institutional standpoint, the disclosure should be part of a response which includes patient safety and risk management activities – ensuring that a similar event does not occur again and that system problems are addressed. Coaching of physicians in appropriate communication strategies should be available. Given increasing regulatory requirements for disclosure, these events should be tracked using performance improvement tools (see Exhibit 16.2).

Exhibit 16.2. Key elements of the safe practice for disclosing unanticipated outcomes to patients.

Content to be disclosed to the patient
Provide facts about the event
Presence of error or system failure, if known
Results of event analysis to support informed decision making by the patient
Express regret for unanticipated outcome
Give formal apology if unanticipated outcome caused by error or system failure
Institutional requirements
Integrate disclosure, patient safety, and risk management activities
Establish disclosure support system
Provide background disclosure education
Ensure that disclosure coaching is available at all times
Provide emotional support for health care workers, administrators, patients and families
Use performance improvement tools to track and enhance disclosure

Surgeons have been leaders in the patient safety movement because of a historically longstanding commitment to analyzing and remediating error. Grounded in the tradition of the morbidity and mortality conference, this commitment is no surprise that surgeons are at the forefront of the movement to disclose error.

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