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Adverse event disclosure: benefits and drawbacks for patients and clinicians

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Introduction

Since the Institute of Medicine (1999) published *To Err is Human* in 1999, many publications have discussed the need for different approaches to disclosing adverse events to patients, and the need to create a culture of safety within the healthcare system. Many of these articles begin with a clinician discussing an adverse event in which they were involved (Richards, 2000; Wu, 2001; Payne, 2002). Each individual story provides the medical and policy communities with an isolated view of an adverse event and the disclosure or non-disclosure of that event to the patient. There have also been research papers in the legal and medical literature that are designed to address specific areas of disclosure (Popp, 2003; Wu, 2000). Error disclosure is now required by ethicists, professional organizations and increasingly by regulatory bodies.

The goal of this chapter is to combine these accounts, stories and recommendations into a coherent roadmap for guidance in the field of disclosure. To accomplish this goal, we will begin by defining key terms, and will provide evidence that disclosure is a central part of fostering a safety culture. We will examine physician report cards and their relationship to disclosure policies. We will address the significant gap that exists between the principle of error disclosure and actual practice. Although most of the literature on disclosure is based on in-patient adverse event occurrences, most of healthcare occurs in the ambulatory setting. We believe that the principles outlined below apply equally well to the ambulatory setting, but clearly require adapting the actual process of disclosure to accommodate the different time and location of outpatient care. This chapter will then examine the ethical, legal, and regulatory frameworks governing disclosure, and the benefits and drawbacks of disclosure.

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Definitions

The literature is full of different and conflicting definitions for the same terms, but in this chapter the term 'disclosure' is defined as *any time a member of the clinical team reveals to a patient or the patient's surrogate the occurrence of an adverse event, whether or not this includes an apology and information about causation and responsibility for the event*. An adverse event is defined as 'an event in which preventable harm was caused to the patient' (Jackson Memorial Hospital, 2002). This includes incidents that may or may not be subject to mandatory reporting, such as decubitus ulcers and hospital-acquired infections.

Defining the process of disclosure

Disclosure of adverse events requires a process that will enable clinicians and health care organizations to disclose the occurrence of an adverse event, apologize if warranted, and work to redress the harms suffered by the patient. A detailed discussion of such a process is beyond the scope of this chapter, and there are examples of policies and procedures for disclosure of adverse events in the literature (Devita, 2001; Kraman and Hamm, 1999; Cantor, 2005). However, there are a few key principles that should guide how disclosure is managed.

Criteria should be developed that determine what types of adverse events need to be disclosed, when the disclosure will occur, who will make the disclosure, and how it will be done. Not every adverse event needs to be disclosed: only those that caused significant harm, were not foreseen prior to the care being provided, and require a change in care must be disclosed. One successful approach is a multi-step process similar to that developed at the Lexington, KY, VA Medical Center (Kraman and Hamm, 1999), where a *clinical disclosure* is usually done, firstly, by the clinicians involved in the case, and which only provides basic information about what happened, and advises that an investigation is being launched. The *institutional disclosure* occurs later, includes the leadership from the healthcare organization, and provides an opportunity for an apology if warranted, an explanation of what happened, and advises what will be done to reduce the risk of similar harm to future patients. It is also used to offer compensation to patients for the harm they have suffered. This process also uses a carefully managed approach to create the right environment and to communicate effectively, similar to the approach developed by Buckman (1992) for use in breaking bad news to patients.

Why disclosure?

A major adverse event due to medical errors happens in 3 per cent of all hospitalizations. A 2003 study found that 18 specific human error injures resulted

in 2.4 million extra hospital days and $9.3 billion in extra costs alone (Penson *et al.*, 2001; Rice, 2002). Disclosure of adverse events is justified because of ethical and legal obligations (see below) and, in addition, it fulfils an important need in the realm of patient safety and medical liability. Disclosure has the potential to significantly promote patient safety and improve error prevention. Much research has focused on the narrative of the event as key to defining and sustaining safety in high risk industries.

Obviously, the optimal solution to safety problems is to prevent all errors. However, safety science research demonstrates that humans make errors even when vigilant and that the answer lies in creating safer systems that help to expose errors and to stop them from resulting in adverse events (Reason, 1997). Preventive systems, such as nuclear reactor safety systems, are known as front-end solutions because they are designed to prevent the event from occurring (Apostolakis and Barach, 2003). The danger of another Chernobyl or Three-Mile Island meltdown occurring has stopped all new nuclear power plant construction in the US. Unfortunately, no matter how carefully designed a front-end system is, there is still the possibility that it will fail. This happens because either the system was not comprehensive enough to capture all possibilities or because a 'work-around' (a way of getting around the procedural regulations) was created (Amalberti *et al.*, 2005). While it is true that higher levels of automation tend to reduce errors by decreasing human input into the system, technology creates its own potential cascade of errors, which can be more difficult to identify than human errors.

Ethical rationale for disclosure

There is widespread recognition that disclosing adverse events to patients is the ethically proper response (Cantor *et al*, 2005; Rosner *et al*, 2000; Sweet and Bernat, 1997; Wu *et al.*, 1997). Clinicians, however, face a difficult dilemma when deciding whether and how to disclose a harmful error to a patient. For healthcare professionals, there are three basic ethical rationales for this: utilitarian ethics, which argues that the approach that produces the most good is the proper course to follow (Mill, 1971); deontological, or duty-based ethics, that recognize that professionals have obligations to patients because of their special relationship with patients; and professional standards, that require members of that profession to put the needs and interests of patients ahead of the interests of the individual (Beauchamp and Childress, 2001). Similar reasoning applies to healthcare organizations, with utilitarian ethics supporting disclosure; deontological ethics pointing out that healthcare organizations have duties to patients for whom they provide care; and instead of professional standards, organizational codes of ethics that state organizational values and commit the institution to truth-telling and putting the needs of patients first.

Utilitarian ethics

Utilitarians argue that the process which produces maximum benefit and minimal harm is the proper approach. In the case of disclosing adverse events to patients, it is clear that the benefits of disclosure outweigh the harms. There is even an interest group now pushing for active disclosure of adverse events – a consumer-led group called the *Sorry Works! Coalition* (www.sorryworks.net) has brought together experts in law and medicine with patient representatives, to advocate for changes in organizational policies and state laws that would encourage disclosure of adverse events. Disclosure can result in several benefits to patients, including peace of mind because of increased knowledge about what happened, and better communication and a more trusting relationship with their healthcare providers. For healthcare professionals, disclosure results in relief from the emotional burden of making a mistake; opportunities to learn from errors and improve care in the future; opportunities to improve communication skills and strengthen the clinician–patient relationship; and potential reduction in litigation costs. For institutions, the major benefits are improvement in quality of care because of greater availability of data on errors; increased transparency and trust from the community served; and potential reduction in litigation costs.

Benefits for the patient

Patients may gain the most from the disclosure of adverse events. The first benefit for the patient is that disclosure can put the patient's mind at ease, though this may not always be the case. Surveys of patients and anecdotal evidence suggest that they want three things out of a disclosure: an explanation of what happened and why; an apology; and reassurance that something is being done to keep this from happening to the patient and other patients again (Mazor, Simon and Gurwitz, 2004). Research demonstrates that most patients want to be kept informed about the plan of care (Popp, 2003). Providing *consistent* information to the patient about an adverse event can be the sole factor that determines whether or not the patient pursues legal action. One noted physician has published a story recounting an incident where a patient was upset because the physician missed a digit fracture on an X-ray. Initially the patient threatened to sue their physician. The doctor quickly apologized to the patient and admitted the mistake. The patient then returned a few days later to apologize for his reaction and to state that he was not going to sue (Ryan, 1999). This story describes how an incensed patient was 'talked down' by his doctor admitting her mistake and apologizing for it. If we make the reasonable assumption that satisfied patients do not sue, this evidence supports the theory that proper disclosure to patients is reassuring (Hilborne and Kwon, 2000).

Early disclosure helps put the patient's mind at ease, and potentially reduces the likelihood that a patient will sue the doctor (Hiatt *et al.*, 1989).

The second benefit of disclosure for the patient is the improved physician–patient relationship that usually results. An improved physician–patient relationship makes the patient a more active participant in their healthcare and reduces some of his or her anxiety (Martyn and Fox, 2004). Lape (1998) has stressed the importance of the physician–patient relationship after adverse events occur. When a mistake is made, the 'physician becomes a patient', which requires that this relationship be trusting and open. Lape suggests that trust is one of the most important aspects of this relationship, and in the long run denial (or lack of disclosure) may cause the physician–patient relationship to deteriorate.

It has also been suggested that there is inherent mistrust between the physician and the patient (Tolstoy, 1960).Coulter has gone one step further suggesting that physicians must earn their patients' trust by treating them respectfully, answering all questions honestly and involving the patient in their healthcare plan (Coulter, 2002). Evidence such as that provided by Lape (1998) and Coulter (2002) suggests that open lines of communication with the patient are important at all stages of the health care process, and especially when things go awry. Occurrence of an adverse event should not change this basic assertion, rather, an adverse event should only increase the importance of open communication with the patient.

Benefits for the clinician

The first, and probably most important clinical benefit the clinician gains is that disclosure eases their conscience. A physician who caused an adverse event will have to cope with the fact that she may be responsible for that event. This moral weight can be heavy depending on the clinician and the type and outcome of the event. Some clinicians, such as Wu *et al.* (2000) have even called the clinician 'the second victim'. Other clinicians have admitted that they have felt better after disclosing an adverse event to a patient (Richards, 2000; Penson *et al.*, 2001). Failure to manage adverse events properly has led to some clinicians, including nurses, leaving the healthcare field.

The second benefit for the clinician is that disclosure allows clinicians to learn from their mistakes and improve their communication skills. There have been many personal accounts given by clinicians of how disclosure has benefited their careers. Dr Eric Anderson, for example, claims that '[I] never make the same mistake [ten] times.' (2001) He discusses how he learned from patients, and his mistakes, and over the years became a better physician. There are many similar accounts in the published literature. For example, evidence demonstrates that a better understanding of the causes of error will lead to more prevention (Ely *et al.*, 1995; Hebert *et al.*, 2001; Croskerry, 2000).

The literature, however, also indicates that physicians and/or hospitals sometimes cover up adverse events and never report them to the patient (Calman, 2000; Singer 2001). Examining the root causes of the event and drawing lessons for future care can lead to improved, safer, higher quality health care. Not disclosing an adverse event, or even covering it up, destroys a learning opportunity for clinicians and organizations. An effective form of disclosure involves disclosing to the patient how and why the error and adverse event occurred. This, in turn, helps clinicians understand the cause of the error and may lead to prevention of similar errors in the future.

Another benefit stems from the fact that disclosure requires some form of communication with the patient and their family. Thus disclosure serves as a 'forcing function' and increases the amount and frequency of communication with the patient. Research indicates that physicians with good communication skills identify patients' problems more accurately, have greater job satisfaction and less work stress (Maguire and Pitceathly, 2002). Clinicians, as well as their patients, suffer from an unmet need for communication about adverse events (Barclay, 2003). Both the patient and the clinician can benefit: the patient benefits through improved physician–patient relationships; the clinician benefits through increased patient trust and closure. Disclosure may also result in a decrease in potential liability.

Physician report cards

Interest in quality measurement of physician performance is increasing. Patients and regulators seek ways to identify superior and inferior clinicians. Physician clinical performance assessment, also known as report cards, is gaining interest around the world. These programme focus on capturing quality of care as measured by patient outcomes, process measures and patient satisfaction surveys (Kesselheim and Studdert, 2006). The pay for performance movement in the US and elsewhere is struggling to find robust and reliable measures by which to judge more effective process and outcome initiatives. Surgical incentive systems are being piloted to incentivize cardiac surgeons to produce safe outcomes, with the threat of public embarrassment and financial losses if not heeded. The New York State Cardiac Surgery Registry has perhaps the longest track record. After many years of contentious debate as to the real impact of this very public report card system, there is growing consensus that with the improved data collection and assessment methods, the process has become more reliable and the measurement metrics are valid. However, there is also a dark side to this issue, with some claiming that there is creep of patient severity, out-sourcing of sick patients to other states and a bottom-line risk avoidance approach ingrained into the surgical mindset that has eroded ethical decision-making. Further, some claim that procedures are being done

unnecessarily to allow opting out of the limited scope of the registry, such as adding a mitral valve plasty when doing a routine coronary bypass surgery (Werner and Asch, 2005).

Several obstacles confront these report cards, including technical measurement challenges, resistance to use these data tools, malpractice litigation concerns, and wariness with the reliability of these tools. The bar for admission of these data into the malpractice litigation appears at present too high and thus seems of limited concern. However, recent efforts in Florida, for example, in which all peer review has been undermined by public vote, are examples in which this data has and will be used against physicians in addressing patient adverse outcomes. This includes non-legal proceedings, such as hospital and state licensing and credentialing boards and other adjudicatory bodies, with more relaxed rules of evidence.

The future of physician performance reports suggests using aggregate patient encounters while focusing on the entire microsystem outcome – that is, the patient journey – and less on individual providers. By doing this, regulators and insurers will help make these tools truly patient-centered and alleviate the physician concerns. By going down this path, report cards on individual clinicians would be more consistent with, or in the spirit of, adverse event disclosure, given that the latter tends to emphasize systems (in order to encourage greater openness and so promote safety), whereas report cards emphasize individual clinicians. The next few years will need to address this key tension to ensure wider acceptance of physician performance report cards.

Benefits for the healthcare organization

Healthcare organizations may benefit from disclosure, as liability can pass through from the clinician to the hospital or healthcare organization under operation of the common law. Thus, any of the legal benefits that accrue to the clinician will also transfer to the health care organization. This does not take into account the fact that there is a fiduciary duty that exists between the health care organization and the patient (Stewart, 2002; Horton, 1999). Because of this duty, non-disclosure not only prohibits the healthcare organization from gaining the potential legal benefits discussed above, but it might actually *increase* the potential liability of the healthcare organization.

Healthcare organizations should also consider the value of transparency and growing evidence that disclosure cuts litigation costs. Society is increasingly placing a high value on being honest and forthcoming with information, especially when it is adverse. This generalization is based on the evidence that, while some legal experts have predicted that more disclosure would result in increased liability, the empirical evidence demonstrates that overall liability will likely decrease. The Lexington, KY, Veterans Administration Medical Center

(VAMC), has had a policy of 'extreme honesty' and active disclosure of adverse events since the mid-1980s (Kraman *et al.*, 2002; Lowes, 1997). After introducing the disclosure programme, the Lexington VAMC decreased its total payouts for medical negligence cases. Interestingly, even though the total number of payouts increased, the amount per payout decreased, largely because the medical centre worked with an injured patient or family member to arrive at a sum of money that would provide restitution for additional costs, and avoided punitive damage awards.

More recent evidence has come from medical negligence insurers. COPIC, a major medical malpractice insurance carrier in Colorado, has the '3Rs' programme where physicians participate in a programme to 'Recognize, Respond to and Resolve' adverse events. According to COPIC's 3Rs programme newsletter, in the first 3 years of the programme, there were 435 qualifying incidents, and 153 payouts, with an average cost of $1820 (Copic, 2004). This amount is in contrast to the average cost of all COPIC claims, which was $78 741 per claim, including claims where nothing was paid. The average cost of a typical case where payment was made was in excess of $250 000, in contrast to the 3Rs claims, where the maximum payout was $26 566 and the minimum was $100. Overall, claims have dropped 50% since the programme started, and settlement costs have declined 23% (Kowalczyk, 2005). Similarly, at the University of Michigan Healthcare System, a programme of active disclosure has cut claims in half and reduced attorneys' fees from $3 million a year to $1.25 million per year (Shapiro, 2000).

Society values and will reward a healthcare organization that is transparent and forthcoming with adverse event data. There is evidence that media and regulators are much less hostile to a healthcare organization when a medical error is admitted, and the general public does not have to find out about the error from secondary sources (Pietro *et al.*, 2000). This approach allows the healthcare facility to be proactive and control the narrative, and make it a story about recovery from an adverse event rather than the adverse event itself.

Overall, disclosure of adverse events can lead to increased patient satisfaction, increased trust in the physician, more positive emotional support for patients and professionals, and a decreased chance that the patient will change physicians after the event is disclosed (Mazor *et al.*, 2004). Given that there are multiple benefits to disclosure, why is it still not done universally?

The risks and costs of disclosure

While the potential benefits of a system of disclosure are great, there are also drawbacks. Although disclosure can be beneficial, it appears that most people are so concerned with the potential drawbacks that they fail to act in a way that would capture the benefits of disclosure. Thus, in order to form an effective

model system of disclosure, the drawbacks to such a system need to be understood so that their potential effects can be contained or mitigated.

Drawbacks for the patient

The first drawback to disclosure is that not all patients want to know everything, and some are unable to handle the information. There are cases in the literature that describe incidents where the clinician has disclosed to the patient, but the patient did not want to know. Studies have shown that similar results could be seen in the disclosure of adverse events to patients because most, but not all, patients want to know about the occurrence of an event. Disclosing an adverse event could be as traumatic as a diagnosis of a medical condition. For a few patients, disclosure may cause more harm than good. Not telling these patients about the adverse event is called the 'therapeutic exception' to the general rule that all patients should be informed about all aspects of their health (Berg, 2001).

There are rare exceptions to the general rule that adverse events should be disclosed. The major exception is when the patient does not want to be told about the adverse event (this can be determined by asking the patient what they know and whether they want to learn more about why things have not gone as well as they were supposed to), or if the disclosure will harm the patient. In cases where disclosure may cause harm to the patient, the 'therapeutic exception' allows for the information to be withheld. This position was nicely summarized by Rosner *et al.*, who correctly observe that '[f]ull and honest disclosure, including an apology to the patient, is generally the most appropriate action following a medical error; however, if the error is inconsequential or disclosure would cause undue harm to the patient, nondisclosure may be ethically appropriate' (Rosner *et al.*, 2000, p. 2091). It is important that the therapeutic exception be limited to rare cases where disclosure would clearly be harmful.

Drawbacks for the clinician

Disclosure probably presents the greatest number of drawbacks for clinicians. Many of these drawbacks have their genesis in the fact that the clinician is responsible, or is perceived to be responsible, for the adverse event. The first problem is that a clinician who discloses an adverse event faces several possible punishments. As discussed above, clinicians may face financial costs that are needed to make restitution for the suffering caused by the adverse event; possible disciplinary action by state licensure agencies and reporting to the National Practitioners Data Bank; reprimand from the healthcare organization and potential loss or limitation of clinical privileges; shame and humiliation in

front of the patient and colleagues; and, in very rare cases, criminal liability. Additionally, being forced to disclose errors to patients may shake the confidence of the clinician, leading to dangerous second-guessing in future cases.

Not disclosing adverse events may permit clinicians to act as if an adverse event never occurred. Bosk has documented this phenomenon, noting that there is almost an above the fray 'fighter pilot mentality' amongst surgeons (Bosk, 1979). They do not want to admit to mistakes or adverse events because their mentality tells them that they cannot make mistakes (Tasker, 2000). There is also the potential of ridicule from peers or loss of reputation and income (Small and Barach, 2002). Even if all clinicians were admitting their medical errors, there would still be a tally of who had to make the most disclosures, which could be a source of stigma against one clinician.

Further embarrassment and loss of reputation might result from the combination of disclosure and a physician report card. It is possible that the disclosure of an adverse event would go onto a clinician's scorecard for the general public to see. The argument has been made that scorecards would unfairly damage a clinician's reputation by penalizing only a clinician who makes one major error while letting the clinician who makes many smaller errors go free without accruing any marks against them (Kluge, 1999; Robson, 1999). While a full system of disclosure may mitigate this (through forcing all small and large events into the open), it would depend on how this information is conveyed to the public. It must be stressed, however, that since patients will generally not go to a physician who has a 'poor' reputation, maintenance of reputation is one of the primary reasons why clinicians will decline to disclose the occurrence of an adverse event. This may explain why it has been noted that fear can prevent physicians from being honest (Horton, 1999). Until societal attitudes change to make it safe for healthcare providers to admit mistakes, the negative repercussions to disclosure may pose the most significant problem (Brazeau, 1999).

There is also the potential for disciplinary action being taken against the clinician. Hospitals are willing to not only hide or cover up events, they might also punish the physicians who bring the events to light. Unfortunately, a disciplinary action from a hospital is not the only official action that clinicians have to worry about when disclosing an adverse event. There is also the possibility of liability through admission and a potential increase in the number of claims (Singer, 2001).

Drawbacks for the healthcare organization

The doctrine of institutional negligence, from *Darling v Charleston Community Memorial Hospital* (1965), not only allows the benefits for disclosure to pass through to the healthcare organization, it also allows the negatives to pass through as well. Thus, all of the potential costs to disclosure for the clinician

discussed above could pass through to the healthcare organization, either through operation of the common law, or as part of societal beliefs that the physician and team are part of the hospital. Additionally, the healthcare organization needs to consider a potential 'conflict of obligations', since it has a duty to help and protect its patients, and a similar responsibility to its staff and clinicians.

The balancing of the healthcare organizations' conflict of obligations is an interesting challenge (Stewart, 2002; Nowicki and Chaku, 1998). The difference between clinicians and the healthcare executives is that the clinician's self-interest affects only the clinician, while the executive's duty affects all employees and patients of the organization. If one accepts the legal arguments that disclosure reduces malpractice payments, it would appear that the healthcare organizations may benefit from full disclosure. However, there are some cases where disclosing the adverse event will harm the organization, whether it is through financial costs, bad publicity, or increased regulatory scrutiny and required corrective actions. Organizational leaders managing such cases face a conflict of obligations – what is best for the patient (disclosure), is harmful to the organization. Upholding both duties is not possible – if disclosure takes place, the organization suffers, if it does not take place, then the patient suffers.

The other drawback that healthcare organizations could face from disclosure is an increase in scrutiny from regulators. Just as clinicians have been reprimanded for being forthcoming about flaws in the system, healthcare organizations can be punished if they fully disclose what is happening within the organization. For example, Duke University Medical Center in the US has recently become a favorite target of regulators after they disclosed an adverse event in which a 17-year-old patient died after receiving a lung transplant from a donor with a different blood type, a known cause of rejection of implanted organs (Campion, 2003). This places healthcare organizations in a difficult position: if they disclose they might be punished, but whether and how they are punished may depend on the severity of the incident. It is also possible that organizations that foster a culture of transparency and disclosure will ultimately be rewarded for this by regulators who recognize the benefits of that approach.

Duty-based ethics

Clinicians and organizations have obligations because of their special relationships with patients that require them to act as fiduciaries and put the needs of the patient ahead of their own. This duty comes from several sources: respect for patient autonomy, and the recognition that patients need complete information in order to make treatment decisions; the need to act as a fiduciary; and because truth-telling enhances and supports patient trust (Cantor *et al.*, 2005). The implication of this duty is that professionals and the organizations they

work for are obligated to disclose adverse events, even if it is not beneficial for them to do so, which is in some ways a stronger argument than the utilitarian model, since the duty-based model does not require balancing of harms and benefits (Greely, 1999).

Professional ethics and organizational values

Healthcare professionals are also bound by the values of their profession to tell patients the truth and put the interests of patients ahead of their own. Professional codes of ethics for physicians, nurses and other healthcare professionals uniformly require truth telling, and by extension, disclosure of adverse events. Healthcare organizations are bound by analogous statements of organizational values and mission. For example, the mission of the Veterans Health Administration (2005) is to 'Honor America's veterans by providing exceptional health care that improves their health and well-being.' Embedded within this statement are the core values and beliefs that support provision of high-quality care that helps veteran, and the willingness to disclose and provide for redress when adverse events occur.

Conclusions

Disclosing adverse events is a complex process, but it is increasingly recognized as an important aspect of providing care of patients. Clinicians and organizations have clear ethical obligations to tell the truth about what happened, and to do it in a way that is sensitive, yet informative and clear. A growing body of evidence demonstrates that the benefits of disclosure outweigh the burdens, and that effective disclosure can improve patient safety, quality of care, and reduce costs. Although the ultimate goal is to avoid and eliminate adverse events, it is important to have mechanisms to mitigate the damage caused by these events, and disclosure is an important strategy for mitigation and improvement.

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