



Patient Safety: Disclosure of Medical Errors and Risk Mitigation

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The question of whether surgeons should disclose medical errors to patients and their families has been the subject of much commentary since the 1999 report of the Institute of Medicine, “To Err is Human: Building a Safer Health System,” which brought to public attention the problem of hospital deaths due to medical errors [1]. There has always been a concern about the liability risk, both financial and reputational, that goes along with disclosure and truly revealing surgeon or system failures. A general consensus has been reached, however, among bioethicists and those within the medical profession: physicians and surgeons have an ethical obligation to patients to disclose errors made during their health care [2, 3]. In emphasizing candid conversations with both patients and clinicians, it is now fairly well understood that health care organizations can promote their leaders’ accountability for safer systems, better engage clinicians in continuous improvement, and engender greater patient trust. To date, many institutions have embraced the sharing of information on publicly reported performance measures, but transparency regarding medical errors has proved much more difficult to achieve. The leap from theoretic understanding of disclosure and actual performance is likely to still have persistent gaps.

Despite this generally understood best practice and ethical stance, U.S. health care organizations and surgeons, in particular, have not achieved a consistently and reliable culture in which all errors are openly identified, investigated, and disclosed to the patient in a timely fashion [4]. Importantly, fewer than two thirds of staff members reported having a favorable perception of their hospital’s openness in communication, and fewer than half reported that their hospitals respond to errors in a nonpunitive way [4]. Institutions and clinicians continue to be concerned about the financial risk and the impact on reputation if and when they admit to errors to patients, families, hospital administration, or payers. An institution or provider may fear that as the public becomes more aware of its gaps in patient safety, its reputation and clinical volumes may decline, and ultimately could be irreparable. Because the resultant data on disclosure and apology programs are limited to some key and high-performing organizations, surgeons and hospital leaders may worry that disclosure will also raise liability costs. As a result, if a patient is not aware of an

error, the incentives to keep surgeons from disclosure can be very powerful.

Health care organizations that aim to be transparent about errors and actively manage risk may initiate a number of steps to support and engage their clinicians in this endeavor. Institutions may attempt to allay surgeons’ fears over losing their jobs because of a human error. Embracing a “just culture” in which there is no blame but instead sustained accountability can help to accomplish this aim. Essentially, balancing accountability means that surgeons do not face blame or repercussions for human errors but are held accountable for intentional transgressions such as a willful violation of established policy or protocol [4–6]. When an institution chooses to reduce risk and address human errors by implementing better systems rather than by punishing its employees, effectively communicating this strategy to staff and all team members nonetheless can be challenging. For instance, many surgeons may continue to perceive these events primarily as an individual’s failure, rather than relating to systems, and therefore be disinclined to report or discuss such events. Health care organizations can foster greater openness from their staff by ensuring that simple human errors will not lead to punishment and likewise promoting increased awareness of their nonpunitive stance among the providers.

Greater sensitivity is needed regarding the emotional and psychological concerns of patients and providers, particularly among surgical disciplines. Even if a case is treated and discussed as a systems-related failure, the surgeon involved is readily identifiable and often feels accountable. The reality of “shame and blame” is not only perception; it also can be incredibly demoralizing. Similarly, patients and family members may want to put the event behind them but feel unable to do so if pertinent information continues to be circulated. Consequently, organizations may benefit from involving patients and surgeons in a structured communication process around disclosure, thereby addressing their concerns in real time. Without these steps, transparency efforts and risk mitigation may backfire if clinicians avoid discussion for fear of feeling exposed or if patients and families become aggravated by a perceived lack of information exchange [7–9].

To address liability-related concerns, there have been proposed potential legal reforms through which providers would still be held accountable for reckless or intentional behavior, but not for human or systems errors. Options have included modifying the National Practitioner Data Bank and state board requirements so

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that systems errors are not reported against or directed at specific persons, recognizing that such an approach will require a robust adjudication process. Another option is to enact “enterprise liability” legislation that allows or requires institutions to take sole fiscal and reporting responsibility for systems errors. A third is implementing a system of administrative health courts in which compensation for a claim does not result in the reporting of a particular clinician; under such a system, disciplinary investigations would have to be filed and investigated separately. Such reforms better align liability with modern patient safety principles; they could also cultivate greater openness and discussion among clinicians. In removing clinicians’ concerns from settlement discussions, organizations may also find themselves better positioned to resolve claims more quickly [10–12].

Health care institutions in the United States have begun promoting transparency to improve the safety of patient care and ultimately reduce risk at many levels. Their success will require a collective understanding of the importance of transparency as well as a strong commitment to open discussions. Institutions today are better positioned to foster a culture that balances accountability and addresses the emotional and legal concerns of patients and health care providers [13, 14].

An International Phenomenon

Efforts to improve patient safety remain an international focus in health care delivery. After the US Institute of Medicine report, England, Australia, New Zealand, and Canada also identified adverse events and errors as a major health problem [15–17]. Studies from these countries have revealed that as few as 30% of harmful errors are disclosed to patients [7, 18]. The medical culture of the United States is often compared to that of Canada; in particular, while being neighboring countries, the difference in the malpractice environment to date has been fairly disparate [13]. In a survey of more than 2,600 physicians in the two countries, 64% agreed that patient safety errors were a serious problem. However, 50% disagreed that errors were usually a result of a system failure. Interestingly, 98% endorsed disclosing serious errors to patients but only 58% actually completed this process. Sixty-six percent agreed that disclosing a serious error reduced malpractice risk. Therefore, the attitudes toward disclosure of Canadian physicians and those in the United States were similar despite different malpractice environments; however, overall there were mixed feelings regarding the impact of disclosure on malpractice claims.

Regarding error disclosure during medical training, in a sample of 269 German medical students who participated in an anonymous online questionnaire, 25% of respondents stated that they already had committed a medical error. Nearly half of the participants reported that they had been assigned to perform tasks for which they were not qualified (47%) or where medical errors could have happened easily (50%). Students in their final year of training showed less confidence in error

disclosure compared with younger students, and the majority of respondents (64%) expressed a desire for more education on these issues [14].

The medical profession has often regarded the malpractice environment as an important or primary obstacle to improving the process of error disclosure to patients. But given that similar attitudes and concerns are shared among providers in many countries with different malpractice and litigation histories and policies, one can propose that there are important factors, such as emotional and personal as suggested previously, beyond the malpractice environment that influence a provider’s willingness to disclose serious errors.

Training Our Next Generation

When a trainee is involved in a medical error, he or she, irrespective of the level of training, shares responsibility for the error and, perhaps even more important, the disclosure with the attending physician. Within teaching hospitals, the difficulty of error disclosure can be more acute because trainees are not only faced with the fear of litigation but also with the fear of losing their ability to complete training [18–20].

A recent study of residents at two large academic medical centers and medical students from seven US medical schools evaluated whether frequency of exposure to negative and positive role modeling predicted two primary outcomes: (1) attitudes regarding disclosure; and (2) nontransparent behavior in response to a harmful error [19]. The results revealed that most trainees had observed a harmful medical error and that exposure to role modeling predicted both trainees’ attitudes and behavior regarding the error disclosure. More than 75% of trainees were exposed to positive role modeling around accepting responsibility for an error, disclosing it and apologizing, and 50% were exposed to negative role modeling around colleagues being humiliated for errors or a faculty member trying to evade responsibility [19]. More frequent exposure to negative role modeling was associated with more negative attitudes regarding disclosure and an increased likelihood of nontransparent behavior in response to an error. In contrast, positive role modeling and training on how to respond to errors were associated with more positive attitudes, but did not directly protect against nontransparent behavior [19]. In another study, surgical residents reported more frequently observing a colleague being treated harshly for an error than nonsurgical residents; furthermore, surgical residents were less likely than nonsurgical residents to feel free to express concerns to other members of the team about medical errors [20, 21].

As a means of training the next generation of physicians, communication skills workshops, video debriefs, and self-paced learning tutorial sessions have been found to be very helpful. These training formats can be facilitated for any type of trainee and are often facilitated by faculty, nursing, social workers, and patients or family. All of these methods of training medical students and residents have been found to be meaningful. These

methods support the concept that timely, explicit, and empathetic disclosure of medical errors to patients and family is essential to maintaining trust and is an important part of patient-centered care [21-23].

Benefits of Disclosure to Manage the Risk: The Michigan and Ohio Experience

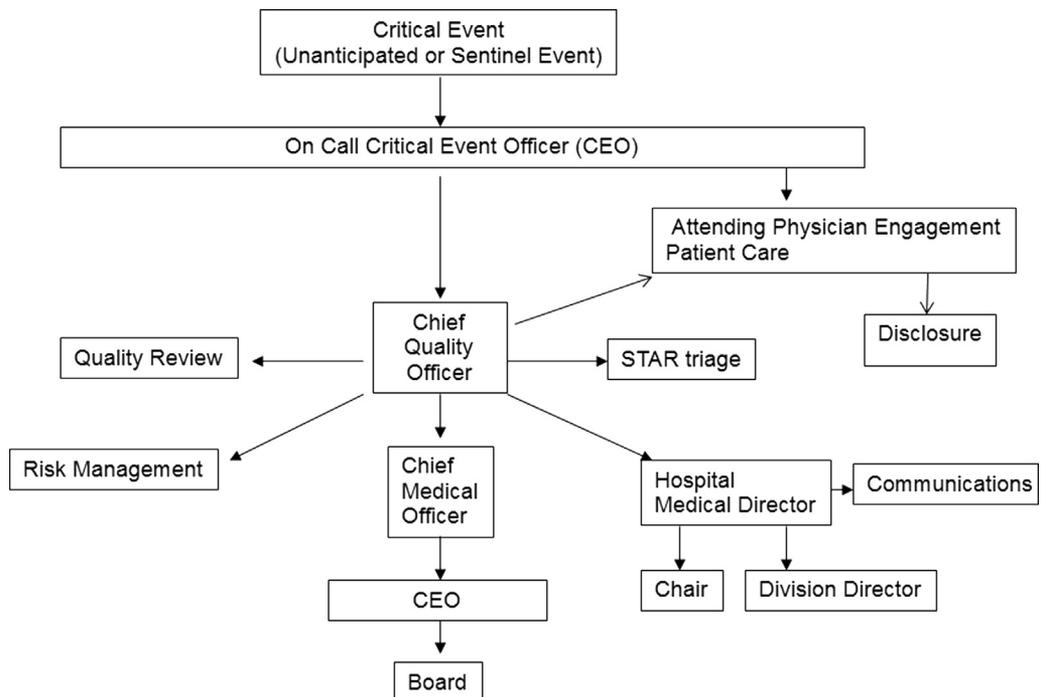
Taking a principled approach to addressing errors and a culture of openness, organizations instituting programs for active disclosure are committed to fully investigating adverse events and implementing interventions to prevent their recurrence. In mid 2001 and early 2002, the University of Michigan Health System systematically changed the way it responded to patient injuries and medical malpractice claims [24]. Michigan adopted a proactive, principle-based approach, described as an “open disclosure with offer” model, built on a commitment to honesty and transparency. Implementation was followed by steady reduction in the number of claims and various other metrics, such as elapsed time for processing claims, defense costs, and average settlement amounts. Although the model continues to evolve and improve, it has retained its core components and the culture of transparency and early disclosure and settlement [25].

Transparency in the disclosure of medical errors and a strategy of prospective risk management in dealing with errors may ultimately result in substantial reduction in medical malpractice lawsuits, lower litigation costs, and a more safety conscious environment. In what is now referred to as communication-and-resolution programs, other health systems and liability insurers have

encouraged the disclosure of adverse events, seeking of resolution proactively, and providing apology and, where appropriate, compensation. In a study of six such systems to embrace communication-and-resolution programs, including Michigan, several factors were found that contributed to the success of such programs including a strong institutional champion, investing in building and marketing the program to clinical providers, and making the results transparent [26]. A transformative culture change, particularly in the surgical arena, is required to make these programs truly integral to daily work; also, patience in and continued reassessment of the implementation process is needed to realize the long-term benefit of early disclosure and settlement.

At Ohio State University Wexner Medical Center, a culture of immediate intervention and assistance has been embodied. As detailed in Figure 1, when an unanticipated event occurs, a cascade of calls and responses occur. That starts with the critical event officer who is a senior level physician leader who immediately ensures patient and provider safety. The chief quality officer is then engaged and is integral to the critical event response and the patient and family interaction. Thereafter, the necessary senior leaders and risk management and clinical support teams are notified. Importantly, in the event of a serious and stressful event, the Stress Trauma and Resilience (STAR) program is deployed to support the providers and the staff real time to minimize the “second victim” phenomenon. The chief quality officer is ultimately responsible for facilitating the conversations with the patients or families in a timely fashion when the facts are collected and action plans are formulated for disclosure.

Fig 1. Critical event response: when an unanticipated event occurs, the critical event officer (CEO) is paged. The CEO then ensures the patient’s safety and engages the attending physician. This starts a series of notifications to facilitate the ultimate goal of disclosure and system improvement. The Stress Trauma and Resilience (STAR) program is activated to minimize the “second victim” effect.



The Ethics of Managing Risk

The American Medical Association code of ethics helps render clarity to the physician's professional obligation to disclose to patients when errors occur: "Situations occasionally occur in which a patient experiences significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred" [2].

The American College of Physicians ethics manual states that "Physicians should disclose to patients information about procedural or judgment errors made during care, as long as such information is material to the patient's well-being. Errors do not necessarily imply negligent or unethical behavior, but failure to disclose them may" [3]. These statements leave no ambiguity that physicians are obligated, and that it is their professional duty to disclose a harmful error once it has occurred or has been discovered. Furthermore, the American College of Surgeons (ACS) has strongly advocated for communicating with patients consistent with the ACS mission centered on patient safety, quality health care, and provider accountability [27]: "Adverse events should be approached with open communication and recognition that an unfortunate outcome is not synonymous with negligence. Furthermore, the ACS advocates that the compensation for injured patients, monetary or otherwise, should be fair and timely without the unnecessary delay commonly associated with the current tort process. The ACS endorses that hospitals should pursue system-level changes that assure patients of quality care and that prevent event recurrences and ultimately, negligent providers should be held accountable" [28].

Ultimately, every patient is inherently entitled to what is truly informed care in a timely fashion. In the event of a failed surgery or intervention, patients and families should not have the burden of trying to discover "what happened" or having to rely on the opinion of another clinician should they seek care elsewhere. Additionally, financial burden to the patient should be relieved. Often, the patient and family will require assistance after a serious error that prolongs the care, and they must be kept informed about the long-term care plan. The patient's needs are very real, and honest and expeditious disclosure will serve to move beyond blame to advocacy for the patient.

Many surgeons have trained—and some continue to train—in poor working conditions that include heavy workloads, inadequate supervision, and poor communication, all of which contribute to medical mistakes. Although physicians and surgeons may be ethically obligated to disclose errors, internal and external pressures make it difficult for them to rush to disclose in a timely and professional manner. Most physicians have trained in a culture that supports "shame and blame" approaches to medical errors, and surgeons not infrequently are caught up in this antiquated mindset. Shame, fears about blame, and worries about legal

liability therefore play a role in the underreporting of medical errors. In theory, however, there are many benefits to a timely and appropriate disclosure, not the least of which is managing risk. Many reports support open and honest communication in enhancing patient satisfaction and outcomes [15–19]. Improved surgeon-patient relationships and ultimately improved patient satisfaction result from open communication and honesty [24, 25]. Although good communication about adverse events may reduce litigation and malpractice payouts, data are lacking as to how and when to disclose our own or others' errors and not incur increased risk [24–26]. "Just culture" engenders an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information; at the same time, it is hoped that such an approach of appropriate medical care and disclosure can become the standard of care and caring.

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