Transparency, Apology and Disclosure of Adverse Outcomes

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Medical errors gained widespread attention with the release of the Institute of Medicine’s “To Err Is Human” in November of 1999. This release reported that as many as 98,000 people die each year from inpatient medical errors. Putting this into perspective, deaths from medical errors surpassed deaths from breast cancer, motor vehicle accidents, and AIDS. Furthermore, medication errors account for more deaths annually than workplace injuries [1,2]. With these alarming facts, few studies attracted more attention than this one; 51% of Americans surveyed stated that they “closely followed” this report, and the concerned public reaction was not surprising [3].

As a result, medical errors became a common topic of conversation, and attention to medical errors became a necessity for health care organizations and providers. Language such as root cause analysis, disclosure, safer health care, risk management, quality assurance, adverse events, and nonpunitive reporting began to appear in the medical and lay press.

This article addresses the communication of adverse outcomes to patients (disclosure) through transparency and apology. The concept of saying “I’m sorry” to patients is relatively new and one that still generates mixed emotions and opinions.

First, practitioners must appreciate that, although to patients many if not all adverse outcomes equate to a medical error, adverse or unanticipated outcomes can occur without an associated error. The Bayer Institute for Healthcare Communication clearly recognizes the various causes of unanticipated outcomes in its disclosure workshop. According to them, unanticipated outcomes can arise from unreasonable or uncorrected patient expectations,
biologic variability, or low probability risk in side effects. None of these constitutes an error [4].

Error, as defined by Stedman’s Medical Dictionary, is “a defect in structure or function. A mistaken decision” [5]. Therefore, one can see how patients can equate unanticipated outcomes with errors. Communication/disclosure of these outcomes is extremely important in correcting this disconnect in understanding between provider and patient. Wu and colleagues [6] define medical error as “a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences.”

Errors are common in medicine. Fortunately, most errors do not result in significant harm [6]. Unanticipated outcomes are not necessarily the result of medical error. Common causes of medical errors leading to unanticipated outcomes include limited knowledge, insufficient experience, fatigue, and carelessness [7]. Unanticipated outcomes not associated with medical error are caused by unrealistic, uncorrected expectations; biological variability; and low-probability, low-risk side effects. Those that are associated with medical error are caused by limited knowledge, inadequate experience, carelessness, and fatigue or faulty medical judgment.

Adverse outcomes are really a result of deficiencies in medical judgment rather than medical knowledge [7]. For example, interpretation of the history and physical examination will prompt the ordering of tests or consults. This clinical interpretation is subject to four common sources of error: (1) wrong synthesis (lack of knowledge about a disease), (2) premature closure, (3) inadequate synthesis (conclusion not supported by data), and (4) omission (key diagnostic information not obtained) [7].

Although these sources of error may not seem inherently vital to disclose, patients affected by adverse events from medical errors are very concerned about what will be done to prevent a similar occurrence. Understanding of the underlying factors contributing to the error will prevent others from being harmed. Also, little attention has been directed to the emotional impact of medical errors on the practitioner, which may contribute to the disclosure being handled in a dysfunctional fashion [8]. Wu [9] coined the term second victim to underscore how harm from error is not only traumatic to the patient but also emotionally devastating to the provider involved with the care.

Before 2001, there was no general acknowledgment of the frequency of adverse outcomes in the medical profession or the need for health care providers to be trained in disclosure. In 2001, The Joint Commission and Accreditation for Healthcare Organization (JCAHO) sought to make disclosure of unanticipated medical outcomes a requirement [10]. Research supports that lack of disclosure can be an alienating factor in the physician–patient relationship [11]. Predating both the JCAHO recommendation and the IOM’s report, a study in 1996 by Witman and colleagues [11] showed that 98% of patients wanted to be informed of even a minor error,
and the more severe the occurrence, the more desired the information. Another study showed that 92% of patients but only 60% of physicians believed that patients should always be informed of complications [12]. This disconnect in the case of an adverse outcome can be misinterpreted by patients and their families as a lack of care or concern.

In the event of an adverse outcome, patients have clearly voiced their needs and wants, which are: (1) to know the truth about the event and occurrence, (2) for health care organizations to accept responsibility, (3) an apology in recognizing patient trauma, and (4) an apology from the health care practitioner. Monetary reimbursement was not one of the top desires. The need for monetary compensation is exceeded by the patient’s desire for human interaction and communication [13]. Not only is the provision or lack of communication a key factor in malpractice litigation, but the lack of physician communication with disclosure of adverse events is disparaging to patients.

However, many health care providers and organizations have been reluctant to provide full disclosure for fear of increased litigation. Although this fear is undoubtedly real, whether reporting medical errors actually leads to a dramatic increase in malpractice claims is still unclear. Determining the impact of disclosure on litigation is difficult because data are reported in an aggregate fashion and not individually [14].

The tort law governs medical malpractice with damages awarded to injured plaintiffs allegedly to provide compensation to those who have been injured and to deter future wrongdoing [15]. In the follow-up of the Harvard Medical Practice study, Brennan and colleagues [15] showed that malpractice suits correlate poorly with the actual occurrence of injuries resulting from negligence. Most patients injured through medical negligence do not seek litigation [16].

Although a perceived barrier to disclosure is the fear of increased litigation; poor communication is actually a greater risk for litigation. Improved communication can minimize malpractice suits and decrease perceived adverse events. Poor interprofessional communication is a key contributor to adverse events. Poor patient–provider communication, even without an adverse event, may leave patients with a perception of a medical error. These miscommunications, even when no adverse event occurred, also led to obvious patient dissatisfaction and the threat of litigation [17,18]. Communication is the key to preventing dissatisfaction, preventing perceived medical error/adverse outcomes, and dealing with adverse outcomes. Although disclosure may be therapeutic for a physician, emotional distress involved with medical errors/adverse outcomes may cause physicians to experience shame and disgrace. Physicians have minimal, if any, experience in disclosure during residency or fellowship training. For many physicians, their first disclosure conversation occurs after residency and often without guidance [8].

Opinions on the value of disclosure range from commitment to full disclosure to complete skepticism. Even to risk managers the value of full
disclosure is unclear. A survey in 2000 mailed to more than 3300 risk managers asking them to evaluate five hypothetical scenarios of medical error and provide disclosure recommendations showed a lack of key consensus on full disclosure of all the known facts. The respondents agreed with the philosophical principle of disclosure, but many believed full disclosure was necessary only if the error clearly caused patient harm. In the five scenarios, respondents believed that full disclosure was appropriate 14% to 66% of the time. The risk managers consistently cited three most common barriers to disclosure: (1) fear of litigation and negative publicity, (2) lack of communication skills and education on how to conduct a disclosure, and (3) physician concerns over disclosure [19].

In 2002, Pennsylvania became the first state to require hospitals to notify patients in writing of a serious event within 7 days of its occurrence [20]. As defined by law, a serious event is “an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated outcome requiring the delivery of additional health care services to the patient” [21]. Nevada and Florida followed Pennsylvania’s lead in requiring hospitals to notify patients. These states require that patients be informed in person after a serious event/injury [22,23]. In addition, JCAHO standards mandate that a disclosure conversation occur and that health care providers become skillful in these conversations. Witman and colleagues [11] showed that patients are less likely to seek litigation if physicians honestly and directly disclose events, rather than patients learning of their occurrence later through other means. The benefit of full disclosure is evidenced by the experience of the Lexington Kentucky VA Hospital. After implementation of a hospital-wide policy for full disclosure, an overall reduction in malpractice payouts occurred, although the frequency of claims increased [24]. Despite these studies supporting the benefit of full disclosure, physicians and health care providers remain fearful of disclosing errors and offering apologies.

Changing the paradigm is important. Techniques include development of performance standards, nonpunitive error-reporting systems, and safety systems within health care organizations [25]. Training physicians in disclosure is a fundamental and necessary step toward this change. Like any other procedure, communication in the form of disclosure can be learned. Training physicians in disclosure conversations and developing and implementing hospital policies for a full and timely disclosure of adverse events are essential to changing this paradigm. As stated by Potylycki and colleagues [26], “This first step requires health care administrators to create and adapt a culture that accepts the imperfection of human performance and solicits the assistance of team members in the development of safeguards in error prevention.” Lehigh Valley Hospital and Health Network, an academic community hospital in eastern Pennsylvania, has adopted a “just” culture. This network acknowledged that a culture of punishment is counterproductive to patient safety and embraced an initiative entitled Primum Non Nocere
(first do no harm). This new culture emphasized a systems approach and specific projects for improving care and reducing medical errors. It became clear that a major barrier to the reporting of medical errors by the staff was the fear of retaliation. The hospital developed a task force that showed that a nonpunitive approach to reporting patient safety issues, particularly those of medication errors, improved staff reporting of medical errors and thereby improved patient safety [26].

Staff must receive appropriate training in error reporting in conjunction with a nonpunitive system to establish a successful risk management program. Furthermore, educational activities for training or teaching of disclosure techniques must involve aspects of the three learning styles: (1) reading, (2) watching, and (3) doing. Disclosure training must include teaching of disclosure principles, active participation in training scenarios, and practice opportunities before having to perform the disclosure “live” in a stressful situation [27].

To frame the process of a timely and accurate disclosure, understanding and remembering who, what, when, where, and how is helpful.

**Who**

As specified by JCAHO standard on disclosure, attending physicians or their designee should lead the discussion. Every effort should be made by the physician to provide the disclosure and not delegate, which might be perceived by the patient as avoidance or abandonment. However, if the physician cannot be present, it is preferable for a senior member of the health care team to lead the discussion. The circumstances of the adverse event will often dictate what other members of the health care team must also be present (eg, nursing, administration, ethics, residents, students, risk management, patient advocate) [28].

**What**

Some uncertainty or disagreement may exist within the health care team; only factual information must be communicated to the patient. Speculation about the events resulting in harm can lead to misinformation and confusion for patients. The natural tendency to speculate in trying to explain the events must be avoided. All individuals involved in disclosure must understand that it is an ongoing process, and not just one conversation, and that all facts may not be known at the initial discussion. Patients must be reassured that as additional, reliable information is obtained, they will be notified promptly [28].

**When**

Even if all details of the incident are not known, disclosure must be timely. Slow and ineffective disclosure of the adverse events increases
negative perceptions by patients [29]. Disclosure should occur as soon as reasonably possible, while emphasizing to patients that it is an ongoing process of communication. Sharing what is known about the event when it is known helps prevent patients and families from speculating or making inquiries when answers are not known. Providing a timely disclosure can be challenging, particularly when all facts are not known. A balance must be struck between timeliness and accuracy of disclosure. Patients should be informed about what additional reviews will occur and when they can anticipate additional communication [28].

Where

Disclosure should occur in a quiet and confidential setting; one which will be most comfortable to the patient.

How

Patient dignity must always be respected. Disclosure conversations should include empathy for and acknowledgment of what patients and their families have experienced [28]. Although a disclosure conversation does not imply fault or liability, patients deserve empathy, which may include the expression of “I’m sorry.” A lack of consensus exists about the concept of apology, and “I’m sorry” is even more intensely debated.

Patients desire an apology for medical errors. If they do not receive an apology, they may perceive the physician as cold and impersonal. Physicians are often reluctant to apologize because they feel it is an admission of guilt and have a fear of increased litigation [30]. The most common concerns cited by physicians for lack of full disclosure and apology can be characterized by the following quote, “apologies for medical errors are used against you in the court … making an apology is an open invitation for a suit” [31]. Resolving this dilemma and disconnect is critical in maintaining the physician–patient relationship after a medical error.

In February 2005, a group of doctors, insurers, lawyers, and patient advocates launched the Sorry Works Coalition (www.sorryworks.net) on the premise that upfront apologies and possible compensation for medical errors could reduce anger of patients and families and reduce lawsuits [32]. Furthermore, in July 2001, the University of Michigan Health System adopted a new policy for handling malpractice claims. The policy was based on three principles: (1) provide quick and fair compensation when reasonable medical care caused injury, (2) defend staff and institution vigorously when case was reasonable and/or when no cause of patient injury was present, and (3) learn from mistakes and experiences of patients. After the first year, they reported a savings of $2.2 million, and the savings continued over subsequent years. The principled approach of full disclosure and apology
when indicated was linked to quality improvement, peer review processes, and a major patient safety/patient communication effort [33]. Despite this favorable experience, much discourse continues on the benefit of apologies in the event of medical errors. Even within the legal profession no consensus has been reached on the value and possible ramifications of an apology. Although some attorneys equate physicians saying “I’m sorry” to jumping out of one’s car after an accident and saying “I’m sorry, the accident is all my fault,” others argue that it is not an admission of guilt [34].

Is the apology an admission of guilt or an expression of sympathy or remorse? The answer may vary depending on circumstances. For example, an inadvertent bowel injury during surgery requires full disclosure and, perhaps instead of an apology, a statement expressing regret that the injury occurred.

Currently, several states are considering so-called “apology laws,” which would prohibit a physician’s apology from being used in litigation. Colorado, Florida, Kansas, and New York have established statutes for legal reporting requirements, and Pennsylvania, South Carolina, and Washington have established regulations as a legal reporting system. Statutes provide a stronger legal basis for reporting system requirements, because enacting a statute is clearly within the scope of a state legislature’s authority as long as it does not infringe on the state or federal constitutional rights of the affected parties, whereas regulations are subject to challenge based on the grounds that they may exceed the agency’s rule-making authority. Therefore, statues were established to overcome these challenges [34]. Furthermore, when polled, jurors respond favorably to physician apologies and tend to be sympathetic to the physician [35]. For now, lawyers advise physicians to look carefully at the circumstances surrounding the medical event or outcome and thoroughly consider the decision before making an apology [35]. Finally, although disclosure and apology are often used together when addressing medical events or errors, the difference between them is important to understand. Many believe total disclosure is an ethical imperative, essential for healing, and the right thing to do [36]. An apology is an expression of remorse acknowledging responsibility for an event. An apology may accompany a disclosure, but the two are not synonymous. An unsuccessful high-risk surgery may involve a disclosure but not an apology [37,38].

Apology, unlike disclosure, is not an ethical right, but rather a therapeutic necessity that shows humanity, fallibility, and remorse. A true apology with responsibility and remorse may make amends and help patients with forgiveness and psychologic healing, however, the apology must be sincere with sympathy, empathy and remorse. Otherwise, the apology may be more detrimental than no apology at all [36].

Therefore, the key to an apology is its structure and content. Lazure [37] describes the four parts of an apology as follows: (1) acknowledgment of the offense, (2) explanation for committing the offense, (3) expression of remorse, shame, or humility, and (4) reparation for the offense. When performed
properly with remorse and sincerity, an apology can help restore patients’
dignity and reassure them that the physician cares about their well-being.

Although apology can be a very positive tool in the healing process and for fostering the physician–patient relationship, many physicians are still resistant for reasons beyond litigation. In contrast to patients benefiting from an apology through restored dignity and self-image, physicians may fear the loss of self-image and an admission of being too emotional and weak. An apology may be viewed by some physicians as an unnecessary demonstration of vulnerability and exposure of emotions. However, an apology may help physicians heal through diminishing their sense of guilt or shame about the medical event [37].

Although apologies can have a profound beneficial effect on patients and providers, they can fail from lack of sincerity, causing patients to perceive the insincerity as an insult and be offended. When deciding to offer an apology, providers must be cognizant of not only the substance but also the tone; the apology must be direct, specific, and avoid vagueness, such as “I’m sorry for whatever happened.” The event should be specifically acknowledged [37].

Summary

Full disclosure of medical errors and unanticipated outcomes or events has received much attention since the release of the Institute of Medicine’s “To Err Is Human.” Patients and their families want and expect to be informed truthfully, sincerely, and in a timely fashion about these occurrences. Physicians, the health care team, and the health care institution can foster better patient relationships and trust through disclosure and, when appropriate, an apology.

Healthcare providers should receive education, training, and practice in disclosure, and health care institutes should establish nonpunitive policies of medical error reporting and implement full disclosure policies. Full disclosure and, in the case of a medical error, an apology have been shown to decrease malpractice exposure, strengthen the physician–patient relationship, foster improved trust, and promote emotional healing for patients and providers.

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