Disclosure of "Nonharmful" Medical Errors and Other Events

Duty to Disclose

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An estimated 98 000 patients die in the United States each year because of medical errors. One million or more total medical errors are estimated to occur annually, which is far greater than the actual number of reported "harmful" mistakes. Although it is generally agreed that harmful errors must be disclosed to patients, when the error is deemed to have not resulted in a harmful event, physicians are less inclined to disclose it. Little has been written about the handling of near misses or "nonharmful" errors, and the issues related to disclosure of such events have rarely been discussed in medicine, although they are routinely addressed within the aviation industry. Herein, we elucidate the arguments for reporting nonharmful medical errors to patients and to reporting systems. A definition of what constitutes harm is explored, as well as the ethical issues underpinning disclosure of nonharmful errors. In addition, systematic institutional implications of reporting nonharmful errors are highlighted. Full disclosure of nonharmful errors is advocated, and recommendations on how to discuss errors with patients are provided. An argument that full error disclosure may improve future patient care is also outlined.

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Inevitably, physicians and other contributors to the medical system will commit errors. Errors and other system failures may have serious consequences for a patient's health and quality of life. It has been estimated that as many as 98 000 patients die in the United States each year because of medical errors.[1,2] This figure may underestimate the scope of the problem because an estimated 50% to 96% of errors go unreported,[2,3] and it is possible that more than 1 million preventable errors occur annually.[4]

A medical error can be defined "as the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (ie, error of planning)."[4(p45)] Perhaps a more clinically useful definition of medical error is "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 negative consequences."[5(p770)] Using this definition, a medical error can be either active (ie, a commission) or passive (ie, an omission). Similarly, a medical error can lead to harm or no harm. Harms can range from minimal to permanent injury or death. In contrast, a near miss (or close call) is a recovery from potential harm before the consequences of a medical error reach the patient because of checking for such events or by fate alone (**Table 1**).

It is generally agreed that harmful errors must be disclosed to patients, although it is unclear what the true frequency is for disclosing these adverse events.[6,7] When minimally harmful events or near misses occur, research indicates that physicians are less inclined to disclose it.[3,6] Physicians may justify nondisclosure because they likely do not be-

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lieve that the patient was seriously harmed.[3] The objective of this article is to elucidate the arguments for increased reporting of events that might be considered minimally harmful or near-miss mistakes to patients and to hospital reporting systems. We also investigate if such actions may, in turn, improve future patient care.[1-3,8-10]

MEDICAL ERRORS: WHAT AND WHO DEFINES HARM? HOW DOES ONE DEFINE PROCEDURE-RELATED ERRORS?

Among physicians, definitions of medical error do not necessarily distinguish between harmful and nonharmful mistakes. Rather, *error* is defined as a failure in the process of delivering medical care, without considering the outcome. However, in practice physicians may judge the importance of an error based on whether it causes harm to the patient. What constitutes harm may be further complicated by the complexity associated with care involving advanced medical procedures. Medical procedures often involve numerous decision processes and actions and will by their nature be associated with problems or errors that require correction. Examples might include a broken stitch, a vascular stent that is not optimally placed, or a positive surgical margin when resecting a cancer. The determination as to whether such events constitute errors or expected potential complications remains unclear.

A physician's decision to disclose may be based on the perception whether an event actually constitutes an error and the degree of harm incurred. Physicians are often poor at predicting future medical outcomes. At the time a potential error occurs, a surgeon is often not in the position to say unequivocally whether the event will result in a subsequent adverse clinical event or whether there will be long-term significant harm. Accurate classification of the event may require a period to elapse. At the time of the medical event, the surgeon only knows that a potential problem has occurred but cannot definitively define its consequences. The physician is also often the only person with knowledge of the potential mistake. As such, the physician who is responsible for the potential medical mistake may also be the one asked to define whether an error has occurred. By defining an error as "harmless," physicians may justify avoiding disclosure.[11] Disclosure of medical events as errors may lead to professional consequences, such as loss of respect by colleagues or even litigation. By not acknowledging and disclosing a minimal or nonharmful event, the physician may be able to avoid these negative professional outcomes. This conflict of interest may bias how medical errors are classified.

When defining error and harm, one needs to consider the patient perspective, which may differ from that of the surgeon. Simply because a medical event may not cause physiological harm does not necessarily mean the patient would agree that it does not warrant disclosure. To the patient, nonclinical events like long wait times or physician poor communication skills may be considered medical errors.[6] Patients are more inclined to define harm in terms of discomfort and psychological harm, as well as family- and economic-related consequences.[12]

Table 1. Definitions of Different Types of Medical Incidents

Definition
Near Miss
Unsafe conditions.
The event did not reach the individual because of chance alone.
The event did not reach the individual because of active recovery by caregivers.
Nonharmful Event
The event reached the individual but did not cause harm, or an error of omission, such as a missed medication dose, reached the patient.
The event reached the individual, and additional monitoring was required to prevent harm.
Harmful Event
The individual experienced temporary harm and required treatment or intervention.
The individual experienced temporary harm and required initial or prolonged hospitalization.
The individual experienced permanent harm.
The individual experienced harm and required intervention necessary to sustain life.
Death
The individual died.

The perception or suspicion of an error on the part of the patient, even without any physiological consequences, can erode patient trust, engender patient anxiety, and erode the patient-surgeon relationship.[5,12-14]

ETHICS OF DISCLOSURE: INFORMING THE PATIENT

There is almost universal agreement in Western countries that errors resulting in serious harm must be disclosed to the patient.[7] Large physician organizations, such as the American Medical Association in their general *Code of Medical Ethics*,[15] state that physicians need to inform patients about medical errors so that patients can understand the error and participate in informed decision making about subsequent management of their health care. Opinion 8.12 of the *Code of Medical Ethics of the American Medical Association* states that "physicians should at all times deal honestly and openly with patients."[15(p102)] Similar to the preoperative informed consent process in which patients are made aware of the benefits and risks of the operative procedure, surgeons are responsible for informing patients when a medical error occurs.[16] However, admitting mistakes can be difficult and can force physicians to confront their own perceptions of inadequacy, fallibility, and guilt.[5] It can be easier to avoid acknowledging mistakes, especially when the event or potential error has a perceived minimal or no-harm effect. However, there are several reasons why minimal and even no-harm errors should be disclosed to the patient.

In Western societies, individual autonomy and self-determination are seen to have an inherent self-worth and intrinsic value. Self-determination and the ability of the individual to make autonomous decisions about his or her health care have particularly critical roles in medical decision making.[17] When deciding whether to disclose a nonharmful medical event or error, patient autonomy must be considered. If a physician chooses not

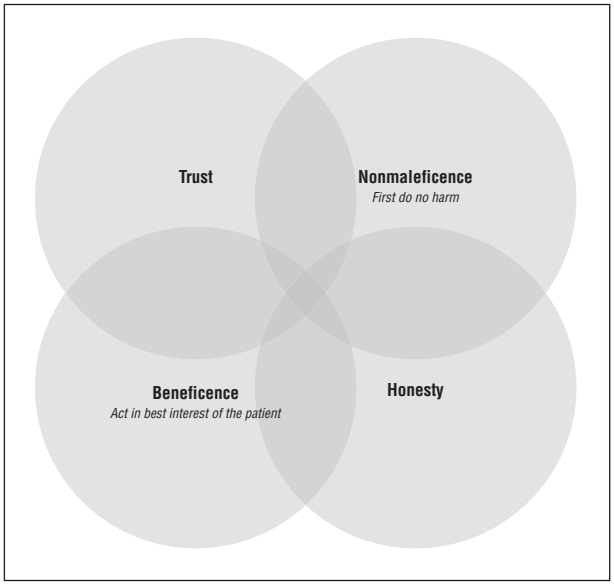

Figure. The patient-surgeon relationship has an intrinsic fiduciary nature. Fiduciary relationships are characterized by a foundation of honesty and trust and by the ethical responsibility to uphold the principles of nonmaleficence (doing no harm) and beneficence (acting in the welfare of the patient).

to disclose certain events or errors because of their perceived nonharmful nature, the physician first must presuppose what a patient may or may not want to know. However, research shows that most patients want to be made aware of virtually all events and potential mistakes and believe that full disclosure may in fact improve the patient-physician relationship.[5,7,13,18-21] Patients understand that medical events and mistakes can occur, but they want to be informed and involved when an error takes place.[5] Instead of being passive recipients of care from a physician who paternalistically decides it is in their best interest not to be informed, most patients want to participate in decision making.[22-24] However, full disclosure of events to patients can create more questions and uncertainty for patients, especially those less versed in health care. As such, patient education has a critical role in the disclosure process.

The patient-surgeon relationship has an intrinsic fiduciary nature that is based on confidence and trust.[25] In a fiduciary relationship, one party (the patient) is in part dependent on the other party's (the physician's) privileged position in the relationship. The essence of the relationship is based on mutual respect and honesty; surgeons have an ethical responsibility to uphold the principles of nonmaleficence (doing no harm) and beneficence (acting in the welfare of the patient) (**Figure**).[5,17,22] Surgeons are charged with disclosing all information that can facilitate patient participation in the fiduciary relationship. In this manner, the physician acknowledges patient autonomy, allowing the patient to partner in his or her own care.[5] This can only be accomplished when physicians are forthright about all medical issues, including when an error occurs. When a physician fails to disclose a potential medical error, even a minimal or no-harm error, the foundation of the fiduciary relationship is undermined. Physicians may inappropriately withhold information based on well-intentioned, but misplaced, assumptions about what a patient may or may not want to know. By not disclosing, the surgeon shifts the focus of the relationship away from being patient centered. The decision to not disclose a harmless event places emphasis on physician decision making rather than inviting patient-surgeon conversation and deliberation. Other pillars of the patient-physician fiduciary relationship are the principles of nonmaleficence and beneficence. A decision not to disclose an error because of self-interest is at odds with these principles.[25] Rather, when an error occurs, the physician must work to abrogate the harm induced by such a mistake. By disclosing and discussing near-miss or nonharmful errors, the surgeon can take ownership of the incident and work constructively to minimize any resulting subjective harm. Perhaps as important, the surgeon can use the experience to inform systematic processes and institutional policies so that similar potential harmful errors do not occur in the future.

META-IMPLICATIONS OF REPORTING EVENTS, NONHARMFUL ERRORS, AND NEAR MISSES: SHOULD SUCH EVENTS BE REPORTED AND TO WHOM?

The transparent reporting of nonharmful errors not only has important implications for the patient-physician relationship but also has benefits for the medical system as a whole. The reporting of medical errors, including nonharmful near misses, may provide information necessary to prevent future harmful mistakes.[1-3,9,22] Although certain events may be unavoidable because of the complexities of medical care, many nonharmful medical errors are potentially avoidable. Understanding the root cause of such errors can help avoid similar future errors that could eventually cause injury. As Patel and Cohen have pointed out, "Through investigation of the emergence of and recovery from error, one can identify new approaches for error management."[26(p456)]

The airline industry has long recognized the importance of reporting near misses as a means for discovering systematic problems and preventing fatal accidents. Because few aviation accidents occur per year,[27] near-miss reporting produces a wealth of data that would not exist based on accidents alone.[2] Aviation's confidential nonpunitive system of reporting near misses is often cited as an example for the health care industry.[2,28] Near-miss reporting can augment the current harm-only reporting system to provide a broader understanding of medical errors. Some states already track surgeon-related outcomes. In Pennsylvania, summary cardiac outcomes are publicly available on any surgeon in the state. Overall mortality rates in Pennsylvania since 1996, when data were first collected, have decreased by 50%.[29] Most states require only errors that result in harm or death to be reported to an outside organization, such as The Joint Commission.[30] A million or more total medical errors are estimated to occur annually, which is far greater than the actual number of reported harmful mistakes.[9] Data and details about most near misses are often not recorded. In turn, the opportunity to learn from a near miss to prevent a future event is largely lost. Disclosure of all medi-

cal errors, harmful and nonharmful, would provide the opportunity to better understand the root causes of errors and ethically be in line with the goal of improving health care in general. These considerations are perhaps even more important in an era of shorter work hours and the need for full disclosure of all events to ensure accurate handoffs between physicians.

Although the reporting of all medical mistakes may provide an opportunity to prevent future errors, the logistics of such a system are daunting. Most experts agree that a confidential, anonymous, and nonpunitive reporting system for events and near misses with reporter feedback would be best, with the goal being to use these data in aggregate. For such a reporting system to work, it would need to evaluate physicians on their performance yet avoid the "blame and shame" associated with making medical mistakes. Physicians would need to perceive themselves safe and be assured that they would not experience repercussions.[1,9,22,31,32] By encouraging confidential and anonymous disclosure of all events and errors (including nonharmful mistakes) to the institution and to regulatory authorities, near misses could be proactively analyzed and potentially prospectively corrected.[1]

DISCLOSURE OF MEDICAL ERRORS: IS THERE A DOWNSIDE?

One argument for not disclosing all medical errors revolves around the notion that it would erode the public's trust in medical institutions.[25] In disclosing all medical errors, patients may become disillusioned with physicians in general and lose trust in the medical profession. However, research findings suggest that patients actually have increased trust in the medical system when they believe that physicians are not withholding information from them.[6,14]

Disclosure of medical errors may be associated with an increased risk of patient litigation of events that otherwise would not have been recognized by the patient and caused no "real" harm. Some patients do not pursue litigation because they were unaware a medical mistake occurred.[33] However, other research has shown that patients are not more likely to sue when an error is disclosed, especially if the disclosure is immediate, the physician offers an apology, he or she informs the patient that steps are being taken to ensure the mistake will not happen again, and an immediate settlement or compensation is offered to cover any additional costs (eg, another surgical procedure, additional medication, or an extra stay in the hospital).[19,22,25] Data accrued based on the policy of the Department of Veterans Affairs to mandate disclosure of all unanticipated adverse outcomes have been credited for saving hundreds of thousands of dollars.[17,34] In contrast, patients have been shown to be more likely to sue if they perceive that the physician is being dishonest or is delaying disclosure.[11,20] Therefore, from this point of view, immediate disclosure of all medical errors seems the best approach. Additional data suggest that, even if a patient pursues litigation for a fully disclosed error that truly induces no harm, the suit is usually not sustainable.[25]

Table 2. Recommendations on Disclosing Medical Errors

Disclose the error in a timely manner. Do not wait to see if the patient or family member discovers the error.
Do not use ambiguous language to mislead the patient. Be clear and concise using terms that the patient and the family can understand.
Explain potential outcomes, including if the medical team does not foresee any long-term consequences.
Invite questions from the patient or family members.
Apologize for the error, and explain that the error will be reported to the medical institution.

RECOMMENDATIONS ON HOW TO DISCLOSE EVENTS AND NONHARMFUL MEDICAL ERRORS

Most patients today want to understand and participate in their health care decisions.[13,21] To accomplish this, physicians need to disclose both harmful and nonharmful events to patients. An example of a current open disclosure guideline comes from the Veterans Health Administration (VHA). The policy of the VHA states that all "VHA facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future."[35(p1)] This policy requires that health care staff must disclose all factual information from the patient's medical record. Any event that occurs must be fully documented and disclosed to the patient in a timely manner.

Although disclosure is important, the manner in which an error is discussed with the patient is also critical (**Table 2**). Disclosure should begin with the consent process, when the risks and benefits associated with a major medical procedure are discussed. Disclosure as part of the informed consent process should prepare the patient and significant others to understand and respond to subsequent events if they arise.[36] Physicians should avoid ambiguous language, as well as the temptation to have the patient believe that the error was unpreventable or an expected outcome.[7,11,20] Physicians need to explain the circumstances of the error in nontechnical, clear, honest, and understandable language. The surgeon should probe the patient's or family's understanding of the error by providing time for questions and discussion. Before disclosing information about an error, the physician should gather all the facts, review the details of the event, and be prepared to provide a realistic assessment of potential future harm.

In the course of the conversation, the surgeon should discuss what the details of the error are, why and how it occurred, what was done to repair or correct the error, and what is the expected potential outcome related to the error. In many cases, the outcome of the error will be uncertain and may range from no harm to potentially serious clinical consequences. The physician should acknowledge this ambiguity and detail how the potential consequences of the error will be followed up. The patient and family should be reassured that the medical team is cognizant of the situation and will be monitoring for

any potential sequela of the error. Most important, the surgeon should also apologize for the error and invite questions from the patient or family. In addition, the physician should note that the error has been reported to the appropriate institutional resources and that efforts will be taken to prevent recurrence in the future. In this way, the patient is informed that the institution takes the error seriously and is working to prevent any future errors. In doing this, the physician respects the patient's right to know and participate in his or her health care, and the physician places the error into the large institutional context of protecting the patient.

CONCLUSIONS

Surgeons can find themselves in a position of having to define the magnitude of an error, its potential consequences, and whether to disclose the error to the patient. Even errors that result in no physiological harm may still induce pain, psychological harm, and anxiety for the patient. The ultimate consequences of apparent minimal-harm errors are often unknown until a certain amount of time has elapsed. Therefore, immediate disclosure of all medical errors seems the best approach. Full disclosure of minimal-harm or near-miss errors strengthens the patient-surgeon relationship, cultivates an open atmosphere of dialogue, and facilitates patient participation in medical decision making.

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