Disclosing Unanticipated Outcomes and Medical Errors

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Abstract

Error reporting and disclosure of unanticipated outcomes to patients are encouraged both by existing ethics codes and new policies designed to reduce medical error and create safer systems. Thoughtful disclosure helps to mitigate the emotional distress associated with unanticipated outcomes for both patient and physician and has not been shown to increase the likelihood of liability claims. Effective disclosure begins before care is delivered with informed consent and shared decision making. Steps to take following an unanticipated outcome in which there has been no deviation from standard care include achieving a balanced awareness of what needs to be done for the patient and family, maintaining quality of care, clarifying how the outcome may have occurred, and listening to the patient's concerns and responding nondefensively to questions. When an error has led to injury, the physician should be prepared to apologize and take responsibility, while steps should be taken to address the patient's financial needs.

Pt: Nurse, can you explain to me why I am not getting discharged today like we thought? And why are you guys suddenly starting to do blood draws so often?

Nurse: I think there may have been a mix-up with your medications over the weekend and they want to see that your blood is clotting normally again.

Pt: Nobody told me about any medication mix-up. What happened?

Nurse: I'm not sure. You may want to talk with your doctor when he makes rounds later.

According to the 1999 Institute of Medicine (IOM) report *To Err Is Human*, as many as 98,000 people are killed by medical errors each year in the United States [1]. In response to the IOM report, hospitals, professional bodies, state legislatures (eg, Pennsylvania), and other organizations are working to design safer systems; this includes implementing policies and procedures that require error reporting and disclosure [2,3]. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has even tied disclosure to accreditation. Implemented in July 2001, its patient safety standard states that patients and families must be informed about the outcomes of care that differ significantly from anticipated [4]. Although the JCAHO intended the standard to apply to "sentinel event"–level mishaps (ie, serious injury or death), it has the effect of raising the broader question of how we are informing patients and families of any unexpected outcomes of care.

Responsibility to disclose adverse outcomes and errors is explicitly addressed in the American Medical Association's code of ethics [5] ("The physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred") as well as the American College of Physicians' ethics manual [6], which states that physicians should disclose errors to patients "if such information significantly affects the care of the patient." However, disclosing errors can be challenging. Health care providers are fearful of lawsuits and other possible ramifications of disclosure, including professional censure, loss of colleagues' and patients' respect and confidence, and potential impacts on future practice. Furthermore, physicians are steeped in a model of intense individual responsibility and therefore are especially vulnerable to feelings of anxiety, guilt, and shame at the thought of having harmed a patient [7,8]. In this article, we describe the rationale and approach to disclosure that is the core of a training program that the Bayer Institute for Health Care Communication has developed in collaboration with Kaiser Permanente [9]. The purpose of the program is to help health care professionals respond constructively to patients and families when there has been an unanticipated outcome with or without medical error.

Benefits of Disclosure

Health care professionals tend to overpredict the likelihood that they will be sued for any mishap. Research suggests that only a small minority of patients who are injured by medical errors ever bring a claim [10,11]. Furthermore, patients who are told about errors may be more willing to negotiate fair settlements for compensable injuries. The Lexington, KY,

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Veterans Health Center has been disclosing medical errors that cause injury for more than 15 years [12]. They have paid more claims but at a lower cost per claim, and they ranked in the lowest quartile among VA centers for overall liability costs. The savings were derived from the willingness of patients and families to negotiate fair settlements and from the reduced costs of resolving these claims. Beyond potential financial benefits, there is the emotional relief for the clinician that can accompany revealing and apologizing for an injury caused by error [13,14]. Honest reporting of errors by health care professionals has been cited as a key to improving safety in health care [2,7,15]. For patients and families, thoughtful disclosure can mitigate the emotional distress and loss of trust that is compounded when an adverse outcome is accompanied by apparent professional indifference or the suspicion of deception and cover-up [16,17].

Unanticipated Outcomes versus Errors

An error refers to an act of omission or commission that would have been judged deficient by peers at the time it was made. Individuals, teams, or systems can be responsible for errors. Some errors harm patients, but most do not. An unanticipated outcome, on the other hand, includes a negative or unexpected result from a diagnostic test, treatment, or surgical intervention that may or may not be due to medical error. Biological variability often plays a role in unanticipated outcomes. For example, a disease may initially present with an unclear set of signs and symptoms, not giving sufficient hints of its presence to warrant a more comprehensive workup. When the diagnosis eventually is made, both patient and family may wonder if there was an unnecessary delay that prolonged suffering or reduced the opportunity for good treatment outcome. When treating patients, providers are sometimes uncertain how much information to give patients about potential side effects and complications due to concern over undermining the patient's optimism. In such cases, patients may be unpleasantly surprised by impacts that are not completely unexpected to health care providers. As these examples suggest, communication between physician and patient both before and after disappointing outcomes occur is key in limiting the negative effects of unanticipated outcomes.

Discussing Unanticipated Outcomes

Before Care Is Delivered

Before any treatment is begun, the clinician and patient should develop a partnership in which there is informed consent and shared decision making [18]. This helps the patient appreciate that she is sharing the risk of potential disappointments. Informed consent should include the clinician's recommendation and reasoning as well as a description of alternative approaches and the risks and benefits of each. The clinician is advised to review the most serious potential risks and the most common side effects in these discussions [19,20]. During an episode of care, the clinician must also demonstrate attentiveness and thoroughness when concerns are expressed. Patients and families who do not feel their concerns are heard will find it hard to forgive the clinician later if there is an adverse outcome that they believe could have been averted.

Mother: *(on telephone)* Brenda still has a high fever. She keeps coughing and now her stomachache has returned. I'm worried that this is not just the flu.

Dr: From what I saw in the office yesterday, the virus that we know is going around, and what you are telling me now, I still think that this is just a virus running its course. But it's important to me that you feel comfortable with any decision that we make since we cannot be absolutely certain without seeing her again. You could bring her into the urgent care center tonight and a doctor there could take a look at her or, if you would prefer, I would be glad to work her in at the office tomorrow morning. What feels most comfortable to you?

In this example, although the clinician did not share the mother's anxiety, he sensed it, acknowledged its validity, and recognized the patient and family member's legitimate role in helping to choose among options that would feel comfortable to both of them.

After an Unanticipated Outcome without Medical Error

As discussed earlier, there are a number of reasons why a patient and family may feel an outcome is unanticipated and adverse even when the standard of care has been met. Most clinicians feel capable of working through disappointments with patients and families when there is no indication of substandard care. In most of these situations, there is no threat of claim and therefore no obligation to involve risk management. Defensive sounding explanations and charting will only suggest controversy where none is indicated.

So what are steps that must be taken to respond to adverse outcomes where initial investigation suggests no deviation from the standard of care? First, recognize and correct any distortions in your thoughts and feelings that lead you away from having a balanced awareness of what needs to be done practically and emotionally for the patient and family. The clinician must recognize and address her own emotions by asking, "What thoughts and feelings am I having, and what responses are these thoughts and feelings promoting?" [21]. If the clinician suppresses recognition of the patient's disappointment, she will not respond with timeliness and understanding. If the clinician is defensive and self-absorbed, she may avoid the patient and family or argue with or blame others, stimulating controversies unnecessarily and irritating

rather than soothing hurt feelings. If the clinician is flooded with regret and self-doubt, she may take responsibility for things that were not her fault.

The second step is to take excellent clinical care of the patient. Keep the patient, family, and other staff apprised of your plans and coordinate the care effectively. More disappointment at this point will not be easily overlooked. Third, clarify how the unanticipated outcome may have occurred and be prepared to talk with the patient and family members about facts without speculation. Fourth, discuss your understanding with patient and family. Anticipate their thoughts and emotions, listen to their concerns, show empathy, and respond nondefensively to their questions [22]. Patients and families expect and deserve our sympathy and condolences when they have suffered injury and loss associated with medical care, just as they would expect from any sensitive individual who hears their story. Some states have specifically passed legislation protecting what are called "benevolent expressions of sympathy" from being admitted into legal proceedings as admissions of guilt as long as the clinician is careful to resist the urge to speculate about cause at the same time. For example, "We are all sorry that your family has been through such a difficult time" is much better than "I am sorry that I didn't have my regular nurse working that day or maybe this could have been prevented." Finally, acknowledge when information is uncertain and offer to provide more information when it is available. Expect that many of these conversations will need to be repeated as more family members learn of the adverse outcome and questions emerge.

Dr: It is natural to be very upset and disappointed when the outcome of surgery is so different from what we had hoped for. Even knowing that these complications cannot always be prevented does not make it any easier to accept them and I can completely understand that.

Pause for the patient's and family member's response. Continue to express empathy and normalize rather than defend until you sense enough rapport has been established that you can attempt to shift the conversation to an explanation and discussion of next steps.

Dr: Would it help if I went over what we experienced as the surgery progressed and how we attempted to address it?

Pressing an explanation on people who are not yet ready to hear it can sound defensive and argumentative. Getting the other person's permission to explain frames the interaction as a collaborative effort to understand what happened.

When There Has Been an Error

What must be said or done differently when an error has contributed to the unanticipated outcome? In the opening scenario, a medication error delays discharge and requires additional tests, but no long-term effects are anticipated.

Dr: *(continuing from opening dialogue)* Mr. Smith, the nurse mentioned to me that you had asked about the additional blood work and the possibility of keeping you in the hospital another day. I apologize for not getting in to see you earlier to talk with you about that myself. Last evening they called to notify me that there had been some confusion about the dosage of your anticoagulation medication. I had asked them to draw your labs again to see that your blood was clotting within the appropriate time but apparently that did not get done. All in all I think it is best and safest if we keep you in the hospital another day and check your clotting times and adjust your medications here. If everything looks good by tomorrow morning then we can plan for discharge around noon. Again, we are sorry that our mistake has led to the extra hospital day and the additional blood draws. Do you have any questions?

Is this a situation in which the patient has been "harmed" and disclosure is required? When this clinical scenario is posed in our workshops, 90% of participants say that they would feel compelled to speak with the patient as above and would want the same disclosure offered to them or a family member if they were in the patient's place. Even when the degree of harm appears minimal (at least to us), it becomes clear that some deception would be required to manage the situation without disclosure to the patient. Participants in our workshops recognize that this kind of deception would be an ethical violation, while acknowledging that deception is tempting in this age of malpractice liability fears. Workshop participants agree (and the literature suggests they are correct [13,16,17]) that it will be more difficult to reestablish trust if the patient or family is the one who learns of and raises these facts without first having been informed by the treating clinician.

When Error Has Led to Injury

Apologize and take responsibility. When an error has led to injury, the patient and family expect a sincere apology and a willingness on the part of responsible clinician(s) to accept responsibility for what went wrong [23]. A physician's failure to do so engenders bitter feelings that promote lawsuits [13,16,17,23]. This is true across industries when customers feel their right to security, justice, and self-esteem have been violated [24]. Reluctance to give a full accounting and to answer questions willingly has driven families to attorneys who they believe will help them "get to the bottom of all this."

Determine who will be involved. The type of error, the situation in which it occurred, and the degree of harm can be used

to determine who should be present in the initial and subsequent disclosure conversation. For example, who can best convey regret for the injury? Who can best describe the injury, how it occurred, and its likely impact on the patient and also give a brief description of steps that are being taken to decrease the chance of this error happening again? This can usually be done without referring to the specifics of protected analyses such as peer review, root cause, or quality assurance meeting notes. Administrative support and follow-up may be needed to resolve the situation satisfactorily for the patient and family. Having a single individual introduced as the contact person for nonclinical questions and concerns will help to reduce the family's frustration at a time when there is need to rebuild good will. The primary or attending doctor should typically take the lead in the initial disclosure conversation, introducing others who may have been invited in order to answer questions outside the clinician's area. However, clinicians should not be asked to discuss issues such as financial compensation or institution-wide quality assurance processes, nor should they be expected to be able to coordinate all the follow-up actions that effective recovery could require (eg, reporting requirements, offering social supports, or assuring that bills for related services are not sent on to the patient or family).

It is helpful beforehand to assign someone the role of facilitator for the conversation who will be responsible for helping the conversation stay constructive by promoting empathic understanding and heading off potentially nonproductive responses by the clinicians who may be facing difficult accusations. Nurses and allied health professionals also feel professional, ethical, and personal responsibility to apologize and explain themselves to patients whom they may have injured, and those individuals and/or their supervisors should be invited to be part of the disclosure discussion with patient and family. When there has been serious harm, the patient and family may feel most respected by the presence of senior leadership of the organization.

Be proactive in addressing the patient's financial needs. Some form of compensation, financial or otherwise, may be requested. Resolving such claims efficiently, sensitively, and equitably may result in the least overall expense [12,25]. At a minimum, we must quickly assure that the patient and family are protected from costs for care related to the medical error. Assisting with items such as hotel or travel costs for family and for any needed long-term follow-up treatments resulting from the error is both practically useful and psychologically compensatory for the perceived injustice of the injury. The patient and family should be offered the option of transferring care to another clinician and perhaps even to another setting. Sensitively offering these choices counteracts the feelings of powerlessness that accompany injuries from medical care. Much of the impetus to get a lawyer involved appears to emerge from the need to address this power imbalance as well as the need to be reassured that the patient will not also have to bear a financial burden as a result of the injury. Institutions and malpractice carriers are learning that they can save litigation costs and negotiate more equitable settlements (all of which go to the patient and family) if they are proactive in addressing financial needs of patients rather than waiting for a claim to be made through an attorney.

In the example below, a patient is returning to see his doctor after being treated in the emergency department over the weekend for an allergic reaction to an analgesic containing codeine.

Dr: Mr. Smith, I wanted to say how terribly sorry I am that you had that frightening allergic reaction to the pain medication that I prescribed for you.

Pt: Well, Doctor, I can tell you that was a really scary moment there. My wife and I could not figure out what the heck was happening. She wondered if it was the medication, but when it hadn't happened with the first dose we almost talked ourselves out of that.

Dr: I can imagine that was really upsetting for the two of you. I was particularly upset when I realized that the medication I prescribed contained codeine and remembered that you had told us in the past that you were terribly allergic to anything containing codeine.

Pt: I know. Every time anyone asks me if I have a medication allergy I tell them that. I have seen it stamped in orange on my chart. How could this have happened?

Dr: When I learned from the ER of your allergic reaction to the medication, it hit me that you had told us in the past that you were allergic to codeine. I went over your last visit in my mind and I remember that your chart was not available that day so of course I didn't have those reminders about your allergy right in front of me. But still it was my job to ask and for failing to do that I am truly sorry.

Pt: Well, I appreciate your apology as well as the message you left on our machine over the weekend. Anyone can make a mistake and I am willing to put that behind us.

Dr: I am grateful for your being understanding. I can promise you that I will be asking all my patients about any allergies before prescribing either in person or on the phone. I would not want that to happen to anyone else.

In this example, since the harm was not judged to be serious, the clinician appropriately initiated the initial disclosure conversation on his own. Had the patient experienced more serious harm, we would have recommended that the clinician arrange for a second person to accompany him in the discussion.

Conclusion

New requirements to disclose unanticipated outcomes to patients and families build on existing ethical obligations and ask that individual clinicians and institutions reassess how they have been handling these challenging situations. Some view this as no change at all—"Isn't this what we were always supposed to be doing?" Others view it as a great change—"You mean our prime consideration is not protecting ourselves from malpractice suits at all costs?" In their fear and self-protectiveness, many health care professionals initially underestimate the constructive impact that honesty and sensitive disclosures can have. Constructive disclosure discussions and follow-up will often determine what patients and families choose to do following unanticipated outcomes and injuries caused by medical care. Creating a partnership and sharing decisions with patients prior to treatment, empathy and forthrightness when there are adverse outcomes, a capacity to mediate disagreements, and a willingness to apologize and even initiate equitable offers of compensation for injuries involving error are all aspects of a comprehensive approach to working through adverse outcomes. Coupled with reforms to the malpractice adjudication system [26,27], we may be able to move away from the adversarial framework we fear most.

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