Disclosing Unexpected Outcomes and Medical Error

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Health-care professionals have a responsibility to communicate honestly and empathetically with patients and families when there has been a disappointing outcome in care. They need to understand how all parties think about, feel, and react to the situation. It is too easy for health-care providers and patients and their families to feel that their interests are no longer aligned and to have expectations go unmet.

Based on the authors' clinical experience, this article outlines a suggested educational approach for organizations interested in developing their clinicians' skills in the art of disclosure when an unexpected outcome or medical error occurs.

Key words: Medical errors; patient safety; health care communication; medical malpractice; risk management; patient satisfaction; health care outcomes; ethics; physician satisfaction.

The public and health-care professionals alike have been jarred by recent data regarding medical errors. The Institute of Medicine (IOM) report,[1] public media, professional journals, and dramatic examples of individual errors all raise the question: *What would my health-care provider, medical group, or institution do if I, or a family member, had been injured as a result of medical care?"* From the medical group or provider perspective, a parallel question emerges: *"What would my medical group, malpractice carrier, institution, and patients expect me to do if there was a question that my medical care had injured a patient?"* This article addresses how best to handle unexpected outcomes or injuries caused by medical care.

WHAT IS AN UNANTICIPATED ADVERSE OUTCOME?

In July 2001 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[2] added an accreditation requirement to its initiatives to improve patient safety. The JCAHO now requires that health-care providers or their designees discuss with patients and their representatives outcomes of care that differ significantly from anticipated outcomes. What are such outcomes and what do providers, patients, families, and providers think about them?

There are a number of reasons why patients may experience a medical outcome as unexpected and adverse, whether or not a deviation from the standard of care has occurred. Following are some of these reasons and the reactions that accompany them.

Unrealistic expectations. Patients may have unrealistically rosy expectations for the success of diagnostic and treatment processes. As a result, patients might consider an outcome adverse, when to the health-care provider, though disappointing, it may be well within the expected range. Something as commonplace as an infected appendix may present differently in different children—masking its presence on an initial exam, yet calling for emergency surgery 36 hours later. In these situations, patients and families may find it difficult to understand how the doctor could have been incorrect in the initial diagnosis and still practice "good medicine." Patients and families will naturally wonder if an error was made in a treatment that produces a disappointing outcome.

Health-care providers are often uncertain how much to discuss regarding each and every low-probability com-

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plication and possible side effect of procedures and medications prior to treatment. Yet patients can be very disappointed and become contentious when they experience one of these problems and feel that they have not been forewarned. They may question whether sufficient care was taken in prescribing the treatment initially.

Medical and systems errors. Patients can be injured by care that involves a medical or systems error, or "deviation from the standard of care." By this we mean acts of omission or commission that would have been judged deficient by a reasonably skilled peer at the time the error or deviation was made. Injuries resulting from errors prove particularly challenging to the integrity, courage, and humility of health-care providers and institutions.[3] They find themselves weighing their responsibility to fully explain the outcome to the patient against their desire to protect themselves against malpractice charges.[4]

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While patients have indicated a clear desire for a full explanation and apology if appropriate,[4,5] health-care providers report trying to choose their words carefully to lead the patient away from any implication that malpractice was involved. This can extend to a reluctance to be sympathetic or to apologize for any aspect of the situation for fear such behavior could be taken as an admission of fault. To patients and families, this conveys defensiveness or indifference, both of which fuel the very antagonism that the health-care provider would have hoped to diminish.

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Patients and families, motivated by the disappointing outcome to question the care process even more closely, are likely to become suspicious of explanations that appear inconsistent or inadequate, or contradict other sources of information or their own common sense. Any appearance the health-care provider is not forthcoming increases suspicion. Many health-care providers do not appreciate that they can be sued separately for fraud if the patient and/or family feel they have been intentionally deceived. Fraud charges obviate the statute of limitations upon malpractice actions and circumvent whatever caps may be in place for noneconomic damages in malpractice claims, making this approach attractive to plaintiffs' attorneys in states with caps. Malpractice carriers may not be required to defend a provider against a fraud charge. At minimum, any behavior that casts doubt on the honesty of the health-care providers will make defense in a malpractice action more difficult.

Patient expectations. What do the patient and family expect when they have experienced an unanticipated adverse outcome? They consistently report that they want timely, accurate explanations delivered by empathetic—not defensive—providers. They want providers to have demonstrated their diligence by investigating the situation carefully and recognizing and respecting the patients' and families' legitimate rights to relevant information, regardless of the health-care providers' fears of malpractice claims.[4,5] In these instances, patients and families are at risk of being injured twice: once from the medical care and again from the way the health-care provider and organization respond to them when the medical injury occurs. It is the latter injury that depositions suggest may be the hardest to forgive.[6]

It is noteworthy that when health-care providers are asked what they would want for themselves or their families if they experienced adverse outcomes, their desires and concerns are identical to those of the lay public.

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We know from studies of actual and simulated malpractice plaintiffs[6,7,8] that how the provider and organization respond to the injury has a significant impact on exacerbating or diminishing hurt feelings, mistrust, and the subsequent demand for compensation. Health-care providers and organizations need to receive the "benefit of the doubt" from patients and families about their competence, thoroughness, commitment, humanness, willingness to collaborate, and honesty. When adverse outcomes occur, patients and families watch closely to decide whether they can reinvest trust and rapport in the relationship with their health-care providers. Too often they report feeling that they instead become adversaries whose chief interests are no longer aligned.[9]

ACTIONS BEFORE, DURING, AND AFTER A DISAPOINTMENT

Achieving and maintaining the benefit of the doubt starts before treatment begins, is retested as concerns arise during care, and faces the greatest challenge when a disappointment occurs.[9,10,11] The health-care provider does best to garner the benefit of the doubt by establishing a partnership with the patient in which both are working together to understand the problem and develop a mutu-

ally agreed-upon treatment plan. Shared decision-making and informed consent require the health-care provider to elicit and respond to the patient's ideas, expectations, and concerns. For some patients this may mean expanding the conversation beyond the too-trusting *"Whatever you say, doctor."* For others, it may mean repeatedly clarifying recommendations and reasoning, thoughtfully responding to questions and alternative viewpoints, and proceeding only upon reaching mutual agreement.

Concerns that arise during care also need to be responded to with an eye toward maintaining the benefit of the doubt. Staff should never block a patient's concerns from reaching the treating provider. People will find it harder to forgive disappointing outcomes they feel occurred in part because the providers did not respond effectively when concerns were first raised. This is particularly likely if the provider emphasizes reassurance when the patient or family wants to see more thorough consideration of their concerns.

After the disappointing outcome has occurred, the benefit of the doubt will be most precarious. The patient and family will reevaluate how competently and thoroughly they believe the health-care provider handled the medical care in part by evaluating how thoroughly the provider investigates the likely reasons for the adverse outcome. This includes the timeliness and quality of the report to the patient and family. They will look for sympathy (*"I'm so sorry you have had this difficulty"),* as well as empathy *("I can understand that you'd be upset and questioning since this has gone so differently from the way we had both hoped").* Patients and families will bristle at any defensiveness *("Well, as I told you even before we did this procedure . . . ").* They will interpret slowness to respond, an unwillingness to answer questions, and unexplained inconsistencies as reasons to mistrust the health-care provider's honesty and commitment to them.

Ultimately, if patients lose confidence that they can work through this disappointment with their providers, then they are more likely to turn elsewhere. That probably means they will seek an attorney who will be more interested in the chance for compensation than in resolving the patient's hurt feelings or desire for more understanding about what exactly happened. This focus on proving negligence and the demand for sizable financial compensation can be circumvented if the health-care team addresses the issues satisfactorily right from the beginning in the relationship with patient and family.[6,7,11,12]

COMMUNICATING THE UNEXPECTED OUTCOME

Customer service literature indicates that violating three core human needs can turn customers into "terrorists"—people who become our most bitter adversaries.[13] The three core human needs are:

- personal and financial security;
- equity and fairness; and
- preserving self-esteem.

Each of these needs is threatened by adverse medical outcomes. Meeting these needs can be a useful guide to health-care providers and organizations hoping to resolve their patients' disappointments in the most satisfactory way for all involved. It helps to recognize that these are exactly the needs that would be driving the health-care provider's own behavior if in a similar situation.

When an adverse outcome occurs, the health-care provider's first responsibility is to take good clinical care of the patient. Yet providers' own emotions may distract them from taking all the actions prudent both medically and interpersonally. Feelings of shame, fear, guilt, anger, and entitlement may undermine the quickness and thoroughness of the response. Health-care providers may find themselves tempted to minimize, circumvent, justify, defend, and perhaps even rewrite the sequence of events in their heads, as well as in the charts. Any of these responses will be hard for the patient and family to forgive later.

Such behavior may increase the chances that the family will bring a malpractice claim and make the provider's defense less tenable than the clinical facts themselves might have supported. As is obvious, defense attorneys reported to us that they would much rather present testimony about the provider's empathetic, timely, and honest response to the patient and family than to have the provider's response characterized by a plaintiff's attorney as remote, defensive, and perhaps even devious in the aftermath of the adverse outcome.

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The most effective health-care provider in these challenging situations is one who can quickly appreciate the patient's and family's normal range of emotions and questions and respond empathetically and nondefensively. This provider accepts that patients and families are entitled to an accurate understanding of the outcome, its causes, and implications. The key here is *accurate.* Patients and families (as well as the ethical codes of the American Medical Association and the American College of Physicians[14,15]) believe that health-care providers and organizations have the responsibility to investigate and explain adverse outcomes even if they recognize that the provider(s) has concerns about a potential malpractice claim and, therefore, may be reluctant to be completely forthcoming. As such, the benefit of the doubt about the provider's accuracy and truthfulness may be immediately strained. Even when investigation reveals no deviation from the standard of care, that information may initially be heard with skepticism by

the patient and family struggling to understand the cause of their disappointing outcome.

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Fortunately, despite the fears of health-care providers, the vast majority of patients and families do not sue, even when they believe some error may have been involved in their injury.[4,16] In some situations, the patient and family will not be satisfied with the provider's explanation, and more steps may be needed to resolve any dispute. For example, the provider may need to propose an outside review of the care as a way to get an external standard of fairness for all parties. It is not unreasonable to question the impartiality of an internal review. A plaintiff's attorney, upon becoming involved in the situation, would quickly ask for an outside expert to review the care.

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Sometimes the provider and the patient and family will reach an impasse. Engaging a mediator or facilitator may be crucial to move the parties toward resolution. Patience and a willingness to revisit concerns with the patient and family may be required to keep managing the disappointment.

Consider that unmet needs for personal and financial security, equity, and restoration or preservation of self-esteem will drive the patient's behaviors if not responded to. For example, making adjustments in the bills related to the care may be advisable if doing so addresses the patient's feeling of equity. This step has great value in respecting the patient's need for financial security, equity, and self-esteem. How would you feel about paying the full price for a service that you were very disappointed with? Just because your investigation revealed no negligence does not mean that the patient and family will not feel entitled to some special consideration in light of their disappointing experience.

DEVIATION FROM THE STANDARD OF CARE

When the health-care provider's or organization's own investigation indicates that some deviation from the standard of care caused injury, the ethical and legal responsibility to disclose is clear. We've encountered no risk manager, legal counsel, ethicist, or health-care administrator who recommends deception in these situations. Almost all agree that getting out in front of the situation and responding proactively rather than reacting defensively is the best way to make the most constructive repair possible, even when some liability payment will likely result.[11,12,17] Near misses or errors that did not affect the patient are usually not subject to disclosure, although they are important for the organization to know about and address.[18]

How can you most constructively go about disclosing the injury and your conclusions regarding its causes? The goal remains for the provider or organization to do everything possible to try to work through the adverse outcome within the relationship with the patient and family. This involves:

- responding sensitively and empathetically;
- providing the information needed to answer questions; and
- offering to help them recover as fully as possible from the injury.

Here health-care providers face the greatest challenge. Self-reflection can help to determine the correct response. *"How would I want the situation to be handled if I were in the patient's or family member's position? How would I feel if I suspected or later learned that the health-care providers had not been forthright with me about the injury and its causes?"*

To "deny and defend" assures that you will further embitter the patient and family, and will drive up the litigation costs if a lawsuit is initiated. Until the patient and family have been influenced by a plaintiff's attorney to think of money as the only measure of a satisfying resolution, what they appear to desire most is

- an honest explanation and disclosure;
- an apology where appropriate;
- a demonstration that the health-care organization is committed to reducing the chance that another patient will be injured in similar way; and
- a willingness to assist the patient and family in recovering from the situation as much as possible.

Hospital risk managers or malpractice carriers should be informed early of a potential untoward outcome. They are in a position of responsibility here and have the broadest experience in helping the physician deal with these situations.[5,6,7,8,10,] They will want to be confident that the investigation has clearly implicated deviation from the standard of care as contributor to the injury before they are comfortable encouraging the four steps just described.

It could take a coordinated effort by a number of individuals to deliver on these four objectives. The health-care provider can describe the investigation, explain what happened during treatment, summarize recommendations for reducing the chances of similar harm to another patient, take responsibility, and make an apology. This will go a long way toward restoring the benefit of the doubt in the patient's and family's minds about the provider's commitment, thoroughness, caring, humanness, and honesty.

Coordination with others (from informal discussion to formal root-cause analysis) could be necessary to understand the full set of events that led up to the injury and to identify and implement the most effective process changes to reduce risk to others. Others who might offer valuable assistance in the recovery process are patient advocates, nursing staff, social services, risk management, quality assurance, malpractice carrier, billing department, medical group, and organizational leadership. The patient and family will look to the treating provider to help activate these other parties.

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Of course, the provider is not the only one who may be in the position of taking responsibility for an injury caused by error. Other staff and systems may make errors that lead to an injury. For example, pharmacy or nursing errors, incorrect medical records, or computer system problems could be responsible for the injury. In these instances the organization must decide if, who, what, when, where, and how a disclosure will be made to the patient.

The choice of the individual to make the disclosure depends on the significance of the incident and injury to the patient. The staff involved could disclose a pharmacy or nursing error that resulted in little harm or discomfort. As harm or significance increases, supervisory staff up to the level of the organization's vice president for nursing, medical director, or CEO might be appropriate individuals to convey to the patient and family the seriousness with which the organization takes the event. Even where the physician is not primarily involved in the error, he or she will need to be involved in explaining the medical consequences of the event to the patient and managing them as safely as possible. All parties will need to feel satisfied with how the situation is being addressed, or the patient and family are more likely to become contentious and further lose confidence, rather than feeling that their needs are being taken care of at this difficult time.

The disclosure should be made as soon after the event as possible . . .

The disclosure should be made as soon after the event as possible, since you do not want to leave the patient and family wondering for too long if you are empathic, honest, and responsive. This may mean that in the initial disclosure you have only a partial understanding of what happened and can report only the facts that you know, with a promise to answer any of the patient's other questions as you learn more. Since family members will very often be concerned about these events, you will want to get the patient's permission to include family in the disclosure conversations. You need to be ready to repeat these discussions as you learn more and as additional family weigh in with their concerns.

Asking that a family spokesperson be appointed may help make this process efficient, but the organization must appreciate that it is in recovery mode and setting arbitrary limits on how often it is willing to communicate could be seen as arrogant and inflammatory at a time when just the opposite is essential. The organization must also establish boundaries of confidentiality, as some information must be shared with staff who will be in contact with the patients and family and whose consistent response will help to rebuild trust and confidence.

IS OPENNESS THE BEST POLICY?

Providers and medical institutions, of course, worry about the potential cost of this kind of openness. We know from the experience of ordinary people and American presidents that it is a natural self-protective urge to hide shameful or damaging information. There is a conflict between the organization's right to protect discussion from discovery through the use of peer review and quality assurance structures, and its ethical and legal obligation to the patient and family to make a full disclosure, apologize, and take responsibility for addressing the problems that would lower the risk for others.[14,15]

In our discussions with attorneys, risk managers, ethicists, and administrators, we are seeing increasingly nuanced appreciation of how to resolve this apparent contradiction. The legitimate role of peer review and quality assurance is to help the organizations and individuals understand what contributed to a mishap in order to make corrections that will reduce the chance of recurrence. Whereas laws may protect these discussions from discovery, they do not diminish the patient's and family's (and legal representative's, if it goes that way) right to review the medical record, interview staff involved in the incident, and to ask outside experts to comment on the care provided.[19]

Organizations can decide not to reflexively hide behind protected venues in an effort to keep the patients and families in the dark, in a misguided effort to "deny and defend" against any accusation (however legitimate). They can instead commit themselves to giving information to patients and families that clearly explains the injury they have suffered. This is done routinely in many institutions.[17]

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Fortunately, we have evidence that suggests doing the right thing ethically may also offer some relief from this malpractice nightmare and make business sense as well. The

Lexington, Kentucky, Veterans Health Center has practiced open disclosure of medical errors since 1987. It ranks in the lowest quartile for total liability costs among its peers.[17] It reports that open disclosure

- slashes litigation costs;
- directs any payment primarily to the injured party (since patients' attorneys in these situations are not on 40 percent contingency fees, but instead often hired on an hourly basis to review settlement agreements);
- reduces bitterness and mistrust that magnify financial demands; and
- allows more rapid and complete working through of the grief associated with medical injury for all participants. We know that providers also suffer as the threat of a malpractice verdict is drawn out over time.

More and more medical centers are promoting open disclosure, and we should see what financial trends emerge over the next few years. All of this is now occurring in an environment where patient safety is receiving increased attention. If we know we are going to disclose errors that caused injury, doesn't it make sense that we will be even more motivated to address the problems that caused these errors in the first place? For example, organizations, including the National Patient Safety Foundation, have tightly linked efforts to improve patient safety with the responsibility to disclose to injured parties.

TRAINING AND LEADERSHIP SUPPORT AS KEY

Organizations are composed of individuals who want to feel their own needs for security, justice, and self-esteem are respected. This is best accomplished when the organization demonstrates a commitment to fairness and an emphasis on solving problems rather than punishing individuals. Staff should be given support to think through and respond to these complex situations. Some of the organizations we work with are providing additional training for staff members in how to assist health-care providers in potential disclosure situations.

Staff may be in conflict about where to place the balance between individual and organizational self-interest on the one hand, and their responsibility to patients and families who have been injured by medical error on the other hand. Medical groups and institutions can exert leadership in clarifying how they would want their staffs to behave and how their patients can expect to be treated when unanticipated adverse outcomes result. These situations often involve complex sets of events and interactions between systems and processes that may not at first be evident.

Most of the organizations we work with have already developed policies and procedures that require this kind of thoughtful, coordinated disclosure process. Yet, the medical staff members whom we encounter are often unaware of the policy and its rationale and as a result may reflexively feel threatened by their exposure. They deserve explanation and dialogue with leadership about these procedures, support when disclosure is called for, and training in how to respond most effectively in these often emotionally charged and complex situations.

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Leadership is needed to clarify the legitimate role of protected, self-critical analyses such as peer review, quality assurance, and root-cause analysis. These venues are *not* intended to keep patients and families from learning information to which they are ethically and legally entitled. When an adverse outcome reaches the attention of the media, the organization learns that the court of public opinion will be a very harsh judge. As a result of these developments and an increasingly consumerist attitude among patients, the public is in a much stronger position to challenge health-care provider and institutional behavior that tries to limit access to information and punish those who appear to place their interests ahead of those of patients and families.

THE BAYER INSTITUTE/KAISER PERMANENTE EDUCATIONAL INITIATIVE

The Bayer Institute for Health Care Communication and Kaiser Permanente have developed an educational program that helps health-care providers and organizations address the issues discussed here.[20] This program has had the consultation and approval of medical groups, institutions, malpractice carriers, patient advocacy groups, and defense attorneys. It has been pilot tested and is now being taught in health-care organizations around the United States. The program's objectives include the following:

- Understand the rationale for greater openness when there has been disappointment with care and possibly injury associated with medical or systems error.
- Appreciate the perceptions of the situation by others, such as patient, family, colleagues, and staff.
- Consider the full set of steps to take before, during, and after disappointing outcomes. "Train the Trainer" programs enable individuals to teach these skills in a structured workshop that provides physician CMEs and nursing CEs. We have found that there is a need for training teams of individuals who will provide assistance to clinicians on the process of disclosure. This team, too, is trained on-site and includes advanced problem-solving and communication strategies, skills practice to assist clinicians, and perspectives from key stakeholders such as legal, risk-management, medical administration, and quality assurance professionals.

CONCLUSION

Medical groups and institutions, in cooperation with their malpractice carriers, have an opportunity and responsibility to offer leadership in the area of disclosure, just as they do in promoting clinically sound and safe health-care practices in the first place. Tort reform is crucial to address the spiraling malpractice insurance costs and to reduce the shadow that fear of lawsuits is casting on so many aspects of health care. We must recognize, however, that we will not garner our customers' support for these reforms unless they believe we can be counted on to act sensitively and fairly when adverse outcomes occur. That is our challenge, as well as our opportunity, for the future. ■

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