Disclosure After Adverse Medical Outcomes: A Multidimensional Challenge

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ABSTRACT

Objective: To review established approaches to disclosure and resolution following adverse medical outcomes and highlight barriers that may hinder universal implementation of effective disclosure/resolution practices.

Methods: An overview of established approaches to disclosure and resolution of adverse medical outcomes is presented.

Results: Clinicians must be equipped to manage situations where adverse medical outcomes occur even though the care provided was reasonable, within the standard, as well as in situations where preventable problems in the care provided were likely the cause of patient harm. Established approaches that have proven useful for investigating, disclosing, and resolving situations, captured in the acronyms AIDR, ALEE, and TEAM, can assist clinicians in the disclosure and ultimate resolution of these 2 types of situations.

Conclusion: Health care organizations with a solid commitment and a reliable structure for ensuring adherence to full disclosure and fair resolution of adverse outcomes have demonstrated sustainable progress in ethically and effectively resolving situations where patients are harmed by medical care.

Keywords: safety; medical error; adverse outcomes; resolution; communication.

Much has been learned over the 20 years since the Institute of Medicine's (IOM) report *To Err Is Human*[1] was published. At the time it was published, the IOM report made it clear that only a minority of preventable patient harms were being acknowledged, investigated, and reported. In the face of adverse outcomes "dissemble, deny, and defend" was a common strategy of many clinicians, institutions, and liability carriers.[2] The health care system appeared to place a priority on protecting itself from reputational and financial harm over the rights of injured patients to be given an accurate understanding of what had happened in their care and to pursue restitution, if appropriate.[3-5]

The emerging quality improvement movement was accompanied by calls for increased patient advocacy. This included the goal of greater transparency and more timely and equitable resolutions with patients who have been harmed by problems in care. Health care systems pressed for confidentiality protections in exchange for increased focus on quality improvement.[6] Applying medical ethics of autonomy, no-maleficence, beneficence, and justice initially took a backseat, as risk management was given priority.[7] Insurance carriers have no ethical obligation, and a clear disincentive, to assure that harmed patients are fully informed and offered restitution. Some self-insured health systems, however, began experimenting with more proactive and transparent approaches to disclosure and resolution. In contrast to the often-reported fear of a liability explosion, they reported reduced claims and suits, shorter time to resolution, and reduced overall financial cost,[8-10] providing some evidence that perhaps greater openness could work after all.

But for providers and staff to allow transparency and candor to become the norm, institutions needed to create a more "just culture" for managing errors. Individual impairment or willful disregard of safe practice would need to be handled differently from the slips and lapses that more often contributed to preventable harm.[11] For example, the nurse who was inadequately oriented to the equipment on an unfamiliar unit where she was asked to work a double shift due to a staffing shortage should not be held as accountable as an employee who knowingly

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violated agreed upon safe practices, even though patient harm resulted in each situation. It became clear that patient harm was usually the result of multiple factors involving individuals, communication, procedures, systems, and equipment. Blaming and disciplining individuals at the sharp end would not reliably reduce adverse outcomes.

Since the 1999 IOM report, we have developed general agreement on best practices for investigating, disclosing, and resolving situations where patients are harmed by medical care.[12,13] This article reviews the perspectives and practices that appear necessary for effective disclosure and resolution after an adverse outcome and highlights barriers to reliably enacting them in practice.

Elements of Effective Disclosure

Effective disclosure to patients and families hinges on determining and providing an accurate understanding of what happened in the patient's care. It should be the care providers' and their institution's responsibility to determine causation and disclose it. This should not require only the most upset patients and families initiating a legal process taking 3 years or more to complete. The most consequential question must be answered, "Was the care provided reasonable?" That is, was everything done within the standard, as would have been expected by similarly trained clinicians with the information and resources available at that time? It follows that if care was reasonable, then the adverse outcome could not normally have been prevented, no correction in care processes is called for, and no financial compensation is required. If the care review reveals deficiencies in care that were linked to patient harm, then achieving a satisfying resolution would be more complex and difficult.[13] First, individuals would have to accept that they have contributed to patient harm, itself an often-contentious process and psychologically devastating realization. Then they must have this difficult conversation with patient and family, creating liability risk for themselves in the process. They must commit to correcting the problems that contributed to the harm. They must facilitate, rather than obstruct, a path to a restitution that addresses the medical, practical, and financial harms that have resulted. Given the challenges inherent to disclosure and resolution, it is no wonder that dissembling, denying, and defending was the common practice for the preceding decades.[14]

Disclosure and Resolution Pathways

I was the co-developer of an approach to disclosure and resolution which is now widely accepted and that has been taught across the United States and Canada to more than 50,000 health care providers and administrators over 18 years.[15,16] We learned that resolving adverse medical outcomes is a 4-part process (anticipate, investigate, disclose, resolve [AIDR]). Most adverse or simply disappointing outcomes occur despite reasonable care (eg, due to biological variability, the imprecision of the science and limitations and risks of the procedures). The minority of harms are associated with deficiencies in the care (ie, unreasonable care). We need to equip ourselves to manage both situations effectively. The approach we developed can be captured in 3 acronyms: AIDR, ALEE, and TEAM,

AIDR

This acronym encapsulates the overview guidance for clinicians after an adverse event or outcome, regardless of the cause.

Anticipate the thoughts and feelings of the harmed/disappointed patient and family and reach out immediately with an expression of sympathy.

Investigate sufficiently to address questions about most likely causation and do not conjecture prior to investigation. Ask for patience—"You deserve more than a guess"—and keep in regular contact to reinforce the promise that there will be a full reporting when the review is complete.

Disclose (in a planned and coordinated manner) what has been learned in the investigation.

Resolve the situation with the patient and family consistent with our ethical principles.

If our failure caused the harm (care unreasonable/breached the standard), then working toward a fair restitution and taking corrective actions are appropriate. If the care was found to have been reasonable, then compensation would not be offered and corrective action is unwarranted. The organization would defend reasonable care if a claim was still pursued.

This process involves ethical clarity, emotional intelligence, and discipline. Clinicians must first acknowledge that a disappointing outcome or event has occurred. Clinicians involved in the care, usually led by the attending

provider, then immediately reach out to the patient and family with sympathy, a plan of care to address the medical issues, and the promise to investigate and follow-up with the patient and family when the harm and its causes are more clearly determined. To disclose simply means to provide an accurate understanding (ie, the understanding determined by the investigation we conducted) of what happened, its causes, and consequences. Depending on the extent of the harm and the complexity and time needed for the investigation, a "coach" or "disclosure coordinator" who has advanced training in managing these situations is brought in to guide the process. The disclosure coach/coordinator provides a consistent and steady hand throughout the process of investigation, disclosure, and ultimately resolution with patient and family. Patients and families often move across settings during the time of the AIDR process, and it is easy to lose track of them unless someone is following the entire process until resolved.

ALEE

When the investigation of an adverse/disappointing outcome determines the care was reasonable and therefore the adverse outcome could not have been prevented, we use the ALEE pathway to guide the disclosure conversation (Step 3 in AIDR) with the patient and family:

Anticipate. What are the questions, thoughts, and feelings we would expect the patient and family will have? On this track, there is nothing to apologize for since the care was reasonable, yet expressing compassion and sympathy for the patient's experience is essential. "I/we really sympathize with how differently this has turned out than we had hoped."

Listen. Invite and listen for their questions and concerns, how they are seeing the situation, and where and what they are finding most upsetting and in need of explanation.

Empathize. There are 2 kinds of empathy required here. Cognitive empathy means showing that we understand their thinking from their perspective, separate from whether we fully agree. Emotional empathy involves demonstrating that their emotions are understandable given the situation, even if those emotions are painful for clinicians to experience. Listening in step 2 is how we learned their perspective and emotions. Now we can show accurate empathy: *I/we can understand how upsetting it is to be facing another set of procedures to treat the unfortunate complications from your last surgery.*

Explain. Even when care is reasonable, questions and perhaps suspicions are to be expected. Listening and empathizing sets us up to focus our explanations on the patient's and family's key questions with a level of thoughtfulness and transparency that conveys credibility. We should not assume, however, that they have accepted our explanation. Instead, solicit their reactions and unresolved questions as part of the disclosure discussion. It is normal for additional concerns to emerge in the days after the disclosure discussion, and we should be ready to address these concerns until resolved. In some instances, the patient and family will not be satisfied and it may be helpful to offer an independent review of the care. If the unresolved patient and family engages an attorney, that will be the first step taken anyway. Proactively offering an independent review signals confidence in your objectivity and sensitivity to the importance of fairness for the patient and family: *Your questions and concerns are completely normal in light of the disappointing experience you have had. Let me see if I/we can address those now to your satisfaction.*

TEAM

If the investigation determines that aspects of the care were unreasonable (breached the standard) and the adverse outcome/harm was related to the deficiencies in the care, then we use the TEAM pathway to disclose and resolve the situation with the patient and family

Truthful and Transparent and Teamwork. We should be offering our most accurate understanding of how the adverse outcome occurred, with sufficient depth and clarity that the patient and family can see how we reached that conclusion. In straightforward situations involving minor harm (eg, an allergic reaction to a medication that the clinician overlooked and that resulted in an urgent care center visit), a very limited investigation may clarify the situation sufficiently that the prescribing provider, accompanied by an office or staff nurse as support and witness, may be able to complete an effective disclosure in a single discussion, and simply writing off a bill or arranging to reimburse the urgent care center visit cost may satisfy the affected patient.

In more complex situations involving greater harm, a number of people must be involved to accomplish TEAM tasks: to offer an explanation, to answer questions, to make apologies, to explain changes intended to reduce the chance of harm to others in the future, and to work through any restitution that may be appropriate. Appointing a disclosure coach/coordinator/facilitator who has had extended training in the disclosure process can help guide these more complex situations. Risk management, insurance carriers, and legal counsel should be aware and advising throughout the process and participating directly in meetings with the patient and family, as appropriate. Since on the TEAM track we are admitting liability, offering a path to financial restitution may be warranted and the disclosure process may trigger reporting requirements with regulatory as well as human resource implications.

The patient and family may want to include other people on their "team" as well. Since complex disclosure meetings need to be carefully planned in advance, we should clarify who will be attending from the health care side and who the family intends to involve. We should anticipate potential requests and questions such as: Would it be OK to record this meeting? Can we ask our attorney to attend? Who are all these people and why are they in this meeting? (We should introduce all team members and clarify how their involvement is necessary to help reach the most satisfying resolution for all involved.)

Empathize. Admitting that deficient aspects in the care contributed to the harm will trigger thoughts, emotions, and expectations for the patient and family. Empathizing involves seeing the whole situation from their perspective and acknowledging their emotions as understandable. Empathizing is not the same as fully agreeing with the patient's and family's perspective, but we will not be able to effectively address concerns and expectations that we have not understood. Organizations should have supports in place for staff who are involved in these difficult situations. Nonetheless, we must prioritize the patient's and family's feelings in a disclosure meeting.

Apologize and be Accountable. This calls for both expressions of sympathy as well as a genuine apology for having caused harm by failure in some aspect of care: *We are very sorry you are going through this difficult situation. We are especially sorry to tell you that we now recognize that problems in the care we provided are the most likely cause of this harm. Would this be a good time to explain what we learned?*

Having the responsible clinicians present increases the chances of achieving the most complete resolution in a single planned and well facilitated meeting. The tasks for that meeting include: offering an explanation that reveals the problems in care that contributed to the adverse outcome, making sincere apologies, and explaining changes to reduce chance of harm to others. The disclosure coach can work with individuals to help them understand how and why their involvement can be important and to help staff members become ready to participate constructively in the disclosure meeting. When individuals appear unable or unwilling to contribute constructively, a plan is needed for how their part can be replaced (eg, a charge nurse or department chair might need to step in to explain and apologize for the care of a subordinate). Managers/administrators can explain contributory factors for what may at first appear to have been simply individual negligence. Administrators can describe the actions that the organization is taking to correct problems that contributed to the patient harm: *As nursing executive, it is my responsibility to see that all our staff have been adequately trained on the equipment we are asking them to use. We now recognize that the nurse's lack of familiarity with that equipment contributed to the harm you experienced and I am very sorry for that. It is my responsibility to get that problem corrected, and we are already taking steps to assure that.* Patients and families often have ideas for improving care processes and appreciate being invited to share these ideas as a service to future patients.

Manage until resolved. On the "care unreasonable" track, we must signal openness to helping with the patient's and family's immediate and longer-term needs, as well as their expectations about financial and other forms of restitution. Someone should be in the meeting who can describe the next steps in working towards a fair restitution and how that process will take place following the conclusion of the disclosure meeting. The close involvement of risk and claims professionals throughout the process of investigation through to the disclosure

discussion itself will assure a more satisfactory handoff to questions about around financial compensation

Psychological Barriers to Implementation of Disclosure Pathways

Many organizations and researchers agree that disclosure and resolution pathways as just described are the most ethical and effective ways for all parties to resolve these painful situations. So why isn't this approach universally practiced? In concluding this article, it may be helpful to point out some of the human dynamics that make resolution more difficult and how they might be addressed.

A key issue is the "urge to self-preservation." Health care organizations have often been accused of disclosing only what they cannot hide. We have repeatedly observed how individuals and organizations are often initially motivated to do whatever is needed to protect themselves, even when those behaviors are frankly deceptive. This is almost to be expected. By age 4 children have learned to use deception as a defensive strategy when confronted with misbehavior. Research shows that children and adults continue the strategy to escape censure or punishment and simply get better at hiding their tracks.[18] Because people want to preserve their image as ethical individuals, they have also learned to rationalize/justify this deception as necessary for self-preservation ("My dad would have killed me," "I will lose my license," "It is not fair that I take the blame when others have done the same thing and gotten away with it."). Imagining the most extreme, and therefore "unfair" consequences, helps justify the individual's use of dissembling and frank deception in order to avoid them. Clinicians and organizations may convince themselves that they are the victims entitled to protection rather than the injured patient. Patients and families often accept explanations that are less than candid, as doctors and nurses remain among the most trusted of professionals. Sufficiently understanding the complexities of the care is beyond the capability of most lay people. Successfully challenging the clinician's or institution's exculpatory explanation for an adverse outcome is very difficult, even though many clinicians believe that the tort system is stacked against them.

As a result, even the most sensible of best practices, toolkits, and trainings will not make full disclosure and fair resolution of adverse outcomes more likely without a counterweight of solid ethical commitment and a reliable structure for ensuring adherence. Sustainable progress has been demonstrated in those institutions[8,10,17] where: (1) institutional values and ethics around disclosure were elevated above self-protection, (2) efficient processes for recognizing and objectively reviewing care involving an adverse outcome were developed and followed, (3) salaried and institutionally insured staff and providers were required to participate in and accept a fair path to resolution in the context of a just culture, and (4) the institution was able to deliver on any commitments (eg, financial, corrective actions) it has made. Conversely, disclosure and resolution programs have struggled in the following situations: where values and ethics are not clarified and made primary; where the processes for reviewing adverse outcomes are slow, inconsistent, and open to political interference; where independent providers have latitude to insist on self-protective behaviors; and where liability carriers who place highest priority on avoiding financial exposure are involved.

Conclusion

The challenge of effectively disclosing and resolving adverse medical outcomes will continue to be most formidable for health care systems with independent medical staffs with separate liability carriers. Can these systems get a firm consensus on the ethics that are paramount in disclosure situations? Can they create care review systems that are efficient and objective and reach conclusions that are binding on those involved? Are they willing to provide explanations to patients and families regardless of the consequences to themselves? Can they coordinate an efficient path to financial and other forms of restitution in those situations where problems in the care contributed to the patient being harmed? And can they enforce these practices despite the self-concerns of all the involved parties? The good news is we now know how to disclose and resolve adverse medical outcomes with patients and families in a way that is fair to providers, staff, and institutions and will not break the bank. For health care organizations, implementing effective disclosure and resolution practices starts with a commitment to both build consensus for this process and consistently enforce it.

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References

1. Kohn L, Corrigan J, Donaldson M, eds. To Err Is Human: Building a Safer Health System. Washington, DC: Committee on Quality of Health Care in America, Institute of Medicine. National Academies Press; 1999.
2. Gibson R, Singh JP. Wall of Silence: The Untold Story of the Medical Mistakes That Kill and Injure Millions of Americans. Washington, DC: Lifeline Press; 2003.
3. Rathert C, Phillips W. Medical error disclosure training: evidence for values-based ethical environments. *J Bus Ethics.* 2010;97: 491-503.
4. Wu AW, Cavanaugh TA, McPhee SJ, et al. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. *J Gen Intern Med.* 1997;12:770-775.
5. Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and doctors' attitudes regarding the disclosure of medical errors. *JAMA.* 2003;289:1001-1007.
6. The Patient Safety and Quality Improvement Act of 2005 (PSQIA); Public Law 109-41, 119 Stat. 424-434, which amended the Public Health Service Act.
7. Banja J. Moral courage in medicine—disclosing medical error. *Bioethics Forum.* 2001;17:7-115
8. Boothman R, Imhoff SJ, Campbell DA. Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: Lessons learned and future directions. *Front Health Serv Manage.* 2012;28:13-27.
9. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. *Ann Intern Med.* 2010;153:213-221.
10. Mello MM, Boothman RC, McDonald T, et al. Communication and resolution programs: the challenges and lessons learned from six early adopters. *Health Affairs.* 2014;33:20-29.
11. Marx D. Patient Safety and the Just Culture: A Primer for Health Care Executives. New York, NY: Trustees of Columbia University; 2001.
12. AHRQ Communication and Optimal Resolution (CANDOR) Toolkit. Rockville, MD: Agency for Healthcare Research and Quality; May 2016.
13. O'Connell D, White MK, Platt F. Disclosing unanticipated outcomes and medical errors. *J Clin Outcomes Manag.* 2003;10: 25-29.
14. Berlinger N. After Harm: Medical Error and the Ethics of Forgiveness. Baltimore, MD: Johns Hopkins University Press; 2005.
15. O'Connell D, Reifsteck SW Disclosing unexpected outcomes and medical error. *J Med Prac Manag.* 2004;19:317-323.
16. Robson R, and Pelletier E. Giving back the pen: Disclosure, apology and early compensation discussions after harm in the healthcare setting. *Healthc Q.* 2008;11(3 Spec No.)85-90.
17. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med.* 1999;131:963-967.
18. Ding XP, Wellman HM, WangY, et al. Theory-of-mind training causes honest young children to lie. *Psychol Sci.* 2015;26: 1812-1821.