## Patient and Family Involvement

# Disclosing Adverse Events to Patients

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In the wake of the Institute of Medicine's 1999 report on medical errors,[1] health care organizations, government agencies, accrediting bodies, professional societies, researchers, and others have mounted major activities to improve patient safety and manage adverse events.

The Veterans Health Administration (VHA) is an acknowledged leader in the patient safety movement, and many of its approaches are applicable or instructive beyond VHA. A key element of VHA's patient safety program[2] is its emphasis on acknowledging, analyzing, and learning from adverse events in order to improve future care. In particular, VHA national policy requires that adverse events be promptly disclosed to patients or their families. Yet important questions remain about the process of disclosing adverse events: What is the ethical and legal rationale behind disclosure? What qualifies as an adverse event that needs to be disclosed? What information should be included in the disclosure? Who should disclose this information and when? These questions were addressed by VHA's National Ethics Committee in 2003. This article reports the practical guidance the committee developed for health care professionals and organizations.

## Definition of Terms

Although an "adverse event" is often used interchangeably with other terms such as "medical error," "sentinel event," and "unanticipated outcome," there are some important differences. All these terms describe unexpected and undesirable circumstances associated with

## Article-at-a-Glance

**Background:** The rationale for, and recommended approaches to, disclosing adverse events to patients are examined on the basis of the experience of the Veterans Health Administration (VHA). The VHA's National Ethics Committee endorses a general policy requiring the routine disclosure of adverse events to patients and offers practical recommendations for implementation.

**Practical Approaches to Disclosing Adverse Events:** Disclosure is required when the adverse event (1) has a perceptible effect on the patient that was not discussed in advance as a known risk; (2) necessitates a change in the patient's care; (3) potentially poses an important risk to the patient's future health, even if that risk is extremely small; (4) involves providing a treatment or procedure without the patient's consent. From an ethical perspective, disclosure is required and should not be limited to cases in which the injury is obvious or severe. Disclosure of near misses is also discretionary but is advisable at times. In general, disclosure by a clinician involved in the patient's care is appropriate.

**Conclusion:** Although a variety of psychological and cultural factors may make clinicians and organizations reluctant to disclose adverse events to patients, the arguments favoring routine disclosure are compelling. Organizations should develop clear policies supporting disclosure and should create supportive environments that enable clinicians to meet their ethical obligations to disclose adverse events to patients and families.

the provision of health care. The terms differ, however, in the degree to which they imply causality or blame, and as to whether they focus on the outcomes or the processes of care. For example, "medical error" implies that there was a mistake in the provision of care, whereas "adverse event" implies only that something bad happened, not that anyone did anything wrong. Similarly, "unanticipated outcome" focuses on the end result, and "adverse event" applies to processes as well as outcomes of care.

We use the term "adverse events" as defined in VHA policy:

> Adverse events . . . are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other [health care] facility. Adverse events may result from acts of commission or omission (for example, administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment). Some examples of more common adverse events include patient falls, adverse drug events, procedural errors and/or complications, completed suicides, parasuicidal behaviors (attempts, gestures, and/or threats), and missing patient events.[2 (p. 2)]

VHA policy distinguishes adverse events from close calls or near misses—situations that could have resulted in an adverse event but did not, either by chance or through timely intervention—from intentionally unsafe acts, that is, events that result from a criminal act, a purposefully unsafe act, an act related to alcohol or substance abuse by an impaired provider, or events involving alleged or suspected patient abuse of any kind.

VHA's definition of adverse events is intentionally broad to encourage identification and analysis of all events "that may be candidates for a root cause analysis."[2 (p. 2)] For the purposes of this article, we are most concerned with the subset of adverse events that are potentially preventable (that is, events that should not have occurred) because health care practitioners hesitate to discuss these events openly. The word *disclosure* suggests revealing or exposing something that is otherwise concealed or secret. In general, an adverse event that could not have been prevented (for example, one that occurred as a result of the inexorable progression of a disease or caused by a patient's informed choice about treatment) needs to be discussed, not disclosed. Unpreventable adverse events are often tragic, but because they are beyond health care providers' control, there is typically nothing to conceal.

Although we often cite data and discussions specifically relevant to the disclosure of adverse events by physicians, in general, the recommendations offered in this article apply to other clinicians as well.

## Reluctance to Disclose

Organizational policies requiring that adverse events be disclosed to patients have been in existence for at least 15 years.[3–5] However, in some places, such policies are still considered a new, or even a radical, idea; they hold clinicians and organizations to what may be perceived as a standard of extreme honesty.[6]

Many clinicians remain skeptical about policies requiring disclosure of adverse events. Moreover, some clinicians may fail to disclose adverse events to patients even though they believe that disclosure is the right thing to do.[7,8] For example, in a study of clinicians' responses to a hypothetical case in which a drug error led to a patient's death, one third of the clinicians said they would disclose only incomplete or inaccurate information to the patient's family.[9] A study of house officers found that they seldom disclosed adverse events, especially if they believed the institution would be judgmental.[10]

Reluctance to disclose arises from a variety of psychological and cultural factors as well as both legitimate and unfounded concerns about legal and financial risks.[8,11] On the other hand, ethical and legal considerations argue strongly in favor of disclosure.

## Ethical Arguments Favoring Disclosure

The ethical reasons why clinicians and organizations should disclose adverse events to patients are compelling. Two ethical arguments—Utilitarian and Duty-Based Ethics—commonly cited are briefly described, as are arguments derived from professional standards and organizational values.

### Utilitarian Ethics

Utilitarian ethics place the highest value on actions that produce the greatest balance of benefit over harm

for all persons affected by the action.[12] Although there are no definitive studies of the effects of disclosing adverse events, anecdotal evidence suggests that disclosure of adverse events is beneficial to patients, clinicians, and organizations.

For patients harmed by an adverse event associated with health care, timely disclosure makes it possible to initiate remedial care and, thereby, to restore health or minimize the harm.[13] Disclosure may also reduce a patient's anxiety about what occurred, decrease suspicion of a possible cover-up, and provide reassurance about future care.[13,14] What patients do not know but suspect might cause more harm than disclosing the truth.[15–17]

It is frequently argued that disclosing adverse events to patients or family members could cause harm. The view that bad news may produce serious emotional or physical distress in patients has endured for centuries. Referred to as therapeutic exception or therapeutic privilege, this concept is still sometimes invoked as a justification for withholding important information from the patient. Although withholding information from patients may be appropriate in certain exceptional cases, this rationale is now generally recognized as inherently paternalistic and inappropriate when used as justification to avoid discussing difficult or embarrassing information.[18]

No one likes to admit responsibility for an error or to face a person they may have harmed. Perhaps no group of professionals likes this less than physicians, whose profession "values perfection"[19(p. 74)] and whose prime directive is to do no harm. In addition, physicians can face serious consequences if they disclose an adverse event, particularly one that involves a medical error, including "loss of referrals, hospital admitting privileges, preferred provider status, credentials, and even licensure."[13 (p.775)] Many physicians and other clinicians also believe that admitting fallibility or fault, especially to patients, undermines their ability to project the confidence and authority they need to do their work.[20] Silence, partial disclosure, or distorted information is the path of least resistance and is easier than disclosing an error to patients or family members, accepting one's fallibility, implicating colleagues, or incriminating oneself. However, physicians and other clinicians who make mistakes suffer significant emotional distress, regardless of whether they disclose or discuss their error with patients or colleagues.[21–25]

Although the occurrence of adverse events, especially those involving error, takes an emotional toll on physicians and other health care professionals, disclosure of adverse events can actually benefit them. Disclosure has been found to help lift the emotional burden that physicians carry after causing or contributing to an adverse event.[22,26,27] Also, in one study, house officers who disclosed mistakes said that disclosure helped them learn from errors and improve their practice.[10]

Within some groups of professionals and some health care institutions, the culture instills a "code of silence" that places a greater value on protecting members of the group than on openly discussing adverse events.[28] In such a climate, nondisclosure may not only seem easier but also socially desirable. This is especially likely when the following conditions apply:

- Policies regarding disclosure are either not established or not clear
- Support or incentives for openness about adverse events are absent
- Disciplinary action is expected
- Competition among clinicians is keen
- Job security is lacking[29]

In fact, an organization that institutionally supports truthfulness and transparency by encouraging disclosure of adverse events to patients may help reduce the likelihood that similar events will occur in the future and thereby improve the overall quality of patient care. Although the interests of organizations and individual practitioners may at times diverge, institutional support for acknowledging and learning from adverse events can make a positive contribution to the overall culture of safety within an organization.

## Duty-based Ethics

A duty-based ethical framework holds that health care professionals have a duty to be truthful to their patients and, by extension, a duty to honestly disclose adverse events.[13] Three main sources serve as the foundations of the professional duty of "truth telling."[30 (p.284)]

***Respecting Patient Autonomy.*** Respect for patient autonomy requires that patients be provided with information that they need to make health care decisions.

***Maintaining a Promise.*** Truth telling is part of an implicit promise professionals make to patients to act in

the patient's best interest. When patients seek care they entrust their health and their most intimate information to their physicians; in turn, physicians have both the privilege and the duty to act in patients' best interests.

***Ensuring Patient Trust.*** Truth telling is essential to assuring that patients trust their physicians.[31] The therapeutic relationship relies on trust and is threatened by deception or concealment of information.[32]

It was physicians' routine practice to withhold bad news from patients, such as news of a terminal diagnosis, in the belief that such information would result in harm.[30,33] Now, however, patients and clinicians alike generally expect full disclosure of medical information—good and bad—including adverse events.[8,34]

### Professional Standards

Professional ethics standards—the defined norms or expectations for the conduct of the members of a profession—also support disclosing adverse events to patients. Codes of ethics of the American Medical Association (AMA),[35] the American College of Physicians (ACP),[36] and the American Nurses Association (ANA)[37] specifically require full disclosure of errors contributing to an undesirable health care outcome. For example, the ACP's *Ethics Manual* states:

> In addition, physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior but failure to disclose them may.[36]

Other professional codes, even if not specifically addressing disclosure of adverse events, contain general requirements for honesty and integrity.[38] The American College of Healthcare Executives (ACHE), for example, calls on health care executives to "be truthful in all forms of professional and organizational communication and avoid disseminating information that is false, misleading, or deceptive."[39]

### Organizational Mission and Values

Some health care organizations have adopted explicit mission statements or statements of corporate values that help define the ethical obligations of the individuals within that organization. Policies calling for the disclosure of adverse events can be a reflection of such organizational values. Moreover, the Joint Commission on the Accreditation of Healthcare Organizations has recognized the responsibility of all health care organizations to support disclosure. In July 2002* the Joint Commission began requiring acute care hospitals to have policies ensuring that "patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes"[40(p.RI-12)] (Standard RI.2.90). Furthermore, the Joint Commission requires "that the responsible licensed independent practitioner or his or her designee informs the patient (and when appropriate, his or her family) about those unanticipated outcomes of care, treatment, and services"[40(p.RI-12)] (Standard RI.2.90, EP 3). The Joint Commission standards have significant influence in the health care industry and may be expected to provide a powerful impetus for disclosure policies.

## Legal Support for Disclosure

Among the most common reasons for not disclosing medical errors are fears of liability, criminal prosecution, or professional sanctions. Even though these fears are understandable, there are countervailing legal reasons for disclosure. Legal and regulatory systems often encourage and, under certain circumstances, may even mandate disclosure of adverse events. In addition, attorneys and legal commentators are increasingly among the strongest proponents of disclosure.[41–43]

Fear of civil lawsuits and liability is cited by numerous sources as the single most significant reason why people are reluctant to disclose adverse events. Clinicians and health care organizations fear litigation costs, higher malpractice premiums, and loss of patients. For individual clinicians, the risk of legal action is also associated with a significant emotional burden. Studies show that threatened or actual malpractice suits lead to psychological trauma, job strain, shame, self-doubt,[9,44] and even early retirement.[45]

Despite these reasons for not disclosing, some attorneys are beginning to support disclosure. Plaintiffs' attorneys may favor disclosure because physicians may

* In the June 2002 issue of *Joint Commission Perspectives®*, the Joint Commission announced the new language and requirements for standard RI.2.90 (labeled as RI.1.2.2) in the article titled "Two Intent Statements Revised for Hospitals."

be liable for failing to disclose adverse events.[46] In a landmark New York case, *Simcuski v. Saeli*,[47] a patient successfully sued his surgeon for fraud for failing to admit an error that might have been mitigated by prompt treatment but instead resulted in permanent disability. Fraud can invalidate liability insurance coverage and can expose the physician or other clinician to potential punitive damages that can increase the size of an award.[48] Defense attorneys may also favor disclosure because disclosing adverse events to patients can reduce total liability payments resulting from lawsuits. Since 1987, when it implemented its policy of disclosing all adverse events that result in harm, the Lexington Veterans Administration Medical Center (VAMC) has experienced reduced liability payments.[3]

Some clinicians may fear not only civil liability but also criminal prosecution.[41] In several states, physicians have been prosecuted for clinical mistakes and have been convicted in at least New York and California.[49] In the well-known "Denver Nurses Trial," three nurses were indicted on charges of criminally negligent homicide for administering an overdose of penicillin that led to the death of a newborn. All the nurses were ultimately acquitted but only after a painful and lengthy legal process.[50]

Finally, at least one jurisdiction now requires that adverse events be disclosed to patients. The Pennsylvania Medical Care Availability and Reduction of Error Act, enacted in March 2002, mandates written disclosure of serious events to patients.[51]

## Practical Approaches to Disclosing Adverse Events

Given these compelling ethical and legal arguments, the National Ethics Committee endorses a general policy requiring the routine disclosure of adverse events to patients and offers practical recommendations for implementation.

### Which Adverse Events Warrant Disclosure?

VHA's national patient safety policy specifically requires disclosure "to patients who have been injured by adverse events."[2(p. 12)] In some cases an injury to the patient may be self-evident, as with what the Joint Commission calls sentinel events (unanticipated deaths or major permanent loss of function not related to the natural course of the patient's illness or underlying condition).[40] In other cases, however, whether a patient has been injured by an adverse event may not be so clear. Moreover, patients, clinicians, and third parties may have different perspectives on what it means to be injured.

The National Ethics Committee of the VHA believes that, from an ethical perspective, disclosure is required and should not be limited to cases in which the injury is obvious or severe. The committee believes respect for patients requires disclosure in all the situations described in Table 1 (page 10). As a general rule, disclosure to patients of adverse events that do not fall in those categories of situations is optional and at the discretion of the clinicians involved. Cases should be considered individually and in relation to the specific circumstances. Disclosure of near misses is also discretionary but is advisable at times, such as when the patient or family becomes aware that something out of the ordinary has occurred. Patients deserve an explanation, if not a formal disclosure as described below.

### Who Should Disclose?

Who should disclose an adverse event depends on the following:

- Specific circumstances, especially the nature, likelihood, and severity of injury
- Potential for remedy
- Need for further treatment
- Degree of risk for legal liability

The nature of the relationship between the patient and the clinician or team providing care may also influence who is most appropriate for making the disclosure.

In general, disclosure by a clinician involved in the patient's care is appropriate. The Joint Commission standards require that the "responsible licensed independent practitioner or his or her designee clearly explain the outcome of any treatments or procedures"[40(p.RI-12)] (Standard RI.2.90, EP 3). However, in cases resulting in serious injury or death or those involving potential legal liability, disclosure by a clinician alone may not be sufficient. In such cases, disclosure of adverse events may be best managed as a multistep process. The first step is clinical disclosure, where one or more members of the clinical team (1) provide preliminary information to the extent it is known, (2) express concern for the patient's

**Table 1. Veterans Health Administration National Ethics Committee: Recommendations for Situations Requiring Disclosure of Adverse Events**

1. **Disclosure Is Called for Whenever an Adverse Event Has a Known Effect on the Patient that Was Not Discussed in Advance as a Known Risk.** The following possibilities apply to this situation:
   - Whether the effect is perceptible only to the clinician, to the patient or family, or is obvious to all. For example, a patient who develops seriously abnormal liver function tests as a complication of a medication or procedure, even if he or she experiences no overt symptoms.
   - Even if the effect is not actually harmful. For example, the wrong side or wrong body part is shaved in preparation for surgery, but the mistake is discovered before surgery is performed and no real harm is done.
   - Whether the effect is physical, psychological, or both. For example, a patient who receives a double dose of pain medication may feel inexplicably "fuzzy-headed," even if there is no discernible physical effect.
   - Whether the effect is actual or anticipated. For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output).
2. **Disclosure Is Called for Any Time an Adverse Event Necessitates a Change in the Patient's Care.** An extreme example is an improperly performed surgical procedure that necessitates further (that is, corrective) surgery. A less extreme example is a medication error that necessitates close observation, extra blood tests, or follow-up visits that would otherwise not be required.
3. **Disclosure Is Called for When the Adverse Event Potentially Poses a Significant Risk to the Patient's Future Health even if the Likelihood of that Risk Is Extremely Small.** For example, accidental exposure of a patient to a toxin associated with a rare but recognized serious long-term effect (for instance, increased incidence of cancer).
4. **Disclosure Is Called for Whenever the Adverse Event Involves Providing a Treatment or Procedure Without the Patient's Consent.** Patients have a fundamental right to be informed about what is done to them and why. For example, if a patient undergoes an additional unanticipated procedure while under anesthesia, disclosure is required regardless of whether the patient experiences any ill effects.

welfare, and (3) reassure the patient and family that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. The next step, if applicable, is institutional disclosure, where patients and/or family members are invited to meet with institutional leaders and risk management personnel (with or without members of the clinical team). An apology is made and discussions about compensation are initiated, when appropriate, advising the patient and family about procedures available to request compensation.

For example, at the Lexington VAMC, a multistep process has been used since 1987.[3] Under the Lexington VAMC policy, an adverse event with potential legal liability triggers both a clinical disclosure and an institutional disclosure by the chief of staff and members of the Patient Safety Committee. The institutional disclosure usually involves facility attorneys as well as those who are present to discuss options for compensation. Although clinicians are encouraged to participate, their attendance is not mandatory. During this phase of the disclosure process, patients are given additional information about the adverse event, its causes, and what has been or will be done to minimize harm to the patient.

Disclosure of adverse events involving house officers deserves special consideration and planning. As future clinicians, they must acquire the skills necessary to effectively disclose adverse events. Facilities and residency programs should provide their trainees with specific guidance and instruction on how to identify and respond to adverse events, and faculty should act as role models for disclosure.

## When Should Disclosure Occur?

Optimal timing of disclosure varies with the specific circumstances of the case. If a patient needs urgent treatment to minimize injuries resulting from an adverse event, clinical disclosure must occur quickly. If immediate corrective action is not required, disclosure may be delayed but only long enough to give staff members enough time to collect preliminary information and plan the best way to disclose. Organizations that adopt a multistep approach to the disclosure process should encourage clinicians

to undertake clinical disclosures promptly and to use that first step to let patients know that the adverse event is being investigated. For patients who are aware of or suspect an adverse event, more time before disclosure increases the chance that patients will think information is being deliberately withheld. Institutions should establish general time frames for completing the various steps in the disclosure process.

### How Should Adverse Events Be Disclosed?

As a general rule, the more serious the adverse event, the more formal and carefully planned disclosure must be. For serious adverse events, both the clinical and institutional disclosures should follow accepted methods for breaking bad news.[23, 52–54]

First, disclosure should occur in a quiet, private place suitable for discussion and adequate time should be set aside, without interruptions. Social workers, chaplains, or other staff may be present to help the patient and family cope with the news and to offer ongoing support if needed. Second, the explanation of what happened should be thorough. It should include the nature of the adverse event, the decisions that led up to it, its likely consequences, and what corrective actions can and will be taken. During the clinical disclosure phase, clinicians should be careful not to speculate about causes of the event unless these are clear. Third, if the event is known to be the result of substandard care (this may not be known until after a careful analysis), an explicit apology should be made. Expressions of regret and answers to the patient's or family's questions should follow.[55] The individuals making the disclosure should not behave defensively, and they should be prepared for emotional, even angry responses.

## Conclusion

Although a variety of psychological and cultural factors may make clinicians and organizations reluctant to disclose adverse events to patients, the arguments favoring routine disclosure are compelling. Arguments from utilitarian and duty-based ethical theories, professional standards, organizational missions and values statements, and legal considerations together call for routinely disclosing adverse events to patients-and considers disclosure mandatory when certain criteria are met. Organizations should develop clear policies supporting disclosure and should create supportive environments that enable clinicians to meet their ethical obligations to disclose adverse events to patients and families. J

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