Disclosing Adverse Events to Patients

A Report by the National Ethics Committee of the Veterans Health Administration

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Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

Executive Summary

Institutional and professional policies that require the routine disclosure of adverse events to patients were first seen in the mid-1980s and are now emerging in many health care settings. However, the ethical and legal rationale for such policies is not well understood, and there are unanswered questions about how the policies should be implemented. This report examines the rationale for, and recommended approaches to, disclosing adverse events to patients, using as its example the Veterans Health Administration (VHA).

In VHA and elsewhere, the disclosure of adverse events is a controversial part of the *uncontroversial* goal of improving patient safety. This report contends that some disagreement results from the confusing use of similar terms. To address this, the report cites the VHA definition of "adverse events" and presents current VHA policy regarding their disclosure. It then explores the pros and cons of disclosing adverse events to patients in terms of utilitarian and duty-based ethics. The report addresses pertinent legal concerns and precedents, professional codes, organizational missions, and aspects of the doctor-patient relationship, and concludes that routine disclosure is ethically obligatory when any of the following conditions is met:

- The adverse event has a perceptible effect on the patient that was not discussed in advance as a known risk.
- The adverse event necessitates a change in the patient's care.
- The adverse event potentially poses a significant risk to the patient's future health, even if the likelihood of that risk is extremely small.
- The adverse event involves providing a treatment or procedure without the patient's consent.

The report offers practical suggestions about who is responsible for disclosing the adverse event to the patient or family, who else may need to be involved, optimal timing of the disclosure, appropriate physical environment, and how to approach the disclosure conversation.

Introduction

In 1999, a report by the Institute of Medicine (IoM)[1] alarmed the public with its claim that tens of thousands of injuries and deaths occur each year in U.S. hospitals as the result of medical errors. While the number of such events is still debated,[2-4] the IoM report focused national attention on the fact that *too many* people are harmed rather than healed while undergoing medical care. In response, health care institutions, government agencies, accrediting bodies, professional societies, researchers, and others have mounted major activities around the twin goals of improving patient safety and managing adverse events.

The Veterans Health Administration (VHA), an acknowledged leader in the patient safety movement, has initiated national programs and policies to reduce the incidence of adverse events that occur in the delivery of health care and to mitigate harms caused by the adverse events that do occur. Many of these approaches are applicable or instructive beyond VHA. A key element of VHA's patient safety program[5] is its emphasis on acknowledging, analyzing and learning from adverse events in order to improve future care. In particular, VHA national policy requires not only that adverse events be monitored and examined, but also that all adverse events that result in injury be promptly disclosed to patients or their families.

Current VHA policy, however, leaves important questions about the process of disclosing adverse events unanswered. For example, 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? This report by VHA's National Ethics Committee attempts to answer these questions with practical guidance for health care professionals and institutions.

Definition of Terms

One of the difficulties in discussions of adverse events is the lack of clear definitions. Although "adverse event" is often used interchangeably with other terms such as "medical error," "sentinel event," and "unanticipated outcome," there are some important differences.

All of these terms describe unexpected and undesirable circumstances associated with the provision of health care. The terms differ, however, in the degree to which they imply causality or blame, and 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, while "adverse event" applies to processes as well as outcomes of care.

In this report, 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 VHA facility. Adverse Events may result from acts of commission or omission (e.g., 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.[5]

VHA policy distinguishes adverse events from "close calls" (situations that could have resulted in an adverse event but did not, either by chance or through timely intervention) and from "intentionally unsafe acts" (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).

Adverse events are understood in VHA to range in severity from minor (no potential injury to the patient, no increase in length of stay or level of care) to catastrophic (death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition). The cause of an adverse event is typically multifactorial. Contributing factors may include miscommunication, inadequate training, unclear policies, faulty procedures, equipment malfunction, and other systems problems.

VHA's definition of adverse events is intentionally broad because VHA policymakers want to encourage identification and analysis of all events "that may be candidates for a Root Cause Analysis."[5] However, in this report, we are most concerned with the subset of adverse events that are potentially preventable (i.e., events that should not have occurred), for it is these events that health care practitioners hesitate to discuss 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 (e.g., one that occurred as a result of the inexorable progression of a disease or because of a patient's informed choice about treatment) needs to be discussed, not "disclosed."

Note also that although this report often cites data and discussions specifically relevant to the disclosure of adverse events by physicians, in general, the recommendations offered here apply to other clinicians as well.

Reluctance to Disclose

Institutional policies requiring that adverse events be disclosed to patients have been in existence for at least fifteen years. In 1987, the Lexington VA Medical Center in Kentucky developed and implemented one of the first such policies.[6] Over the next few years, similar policies were adopted by a few other hospitals.[7] VHA's policy requiring disclosure to patients was first implemented on a national scale in 1995.[8] But in some places, policies like these are still considered a new, even radical, idea; they hold clinicians and institutions to what may be perceived as a standard of "extreme honesty."[9]

In many health care settings today, 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.[10] 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.[11] A study of house officers found that they seldom disclosed adverse events, especially if they believed the institution would be judgmental.[12]

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.[13] 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. This section presents two ethical arguments that are commonly used in health care discussions, as well as arguments derived from professional standards and organizational values.

Utilitarian Ethics

Utilitarian ethics places the highest value on actions that produce the greatest balance of benefit over harm for all persons affected by the action.[14] While 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, at least, minimize the harm. Disclosure may also reduce a patient's anxiety about what already occurred, including suspicion of a possible cover-up, and provide reassurance about future care.[15] It has been suggested that what patients do not know *but suspect* may cause more harm than disclosing the truth.[16-18] In addition, patients who are fully informed are more likely to cooperate with treatment. The case is frequently made that disclosing adverse events to patients or family members could *itself* cause harm. The view that "bad news" may produce serious emotional or physical distress in patients has endured for centuries. Referred to as the "therapeutic exception" or "therapeutic privilege," this belief is still sometimes invoked as a justification for withholding important information from the patient. While 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.[19]

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"[20] and whose prime directive is to "do no harm." In addition, many physicians and other clinicians believe that admitting fallibility or fault, especially to patients, undermines their ability to project the confidence and authority they need to do their work.[21] Silence, partial disclosure, or distorting 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. Physicians and other clinicians who make mistakes suffer significant emotional distress, regardless of whether they disclose or discuss their error with patients or colleagues.[22-25]

While 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.[23, 26-27] Also, in one study, house officers who disclosed mistakes said that disclosure helped them learn from errors and improve their practice.[12]

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 open discussion of adverse events.[28] In such a climate, nondisclosure may seem not only easier but also socially desirable. This is especially likely in settings where policies regarding disclosure are either not established or not clear, where support or incentives for openness about adverse events are absent, where disciplinary action is expected, where competition among clinicians is keen, and where job security is lacking.[29]

In fact, an organization that demonstrates institutional support for 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. Institutional support for acknowledging and learning from things that go wrong 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 disclose adverse events. Three main sources serve as the

foundations of the professional duty of "truth telling." [30] First, respect for patient autonomy requires that patients be provided with information that they need to make health care decisions. Second, 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. Finally, 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]

Societal and professional attitudes regarding disclosure of information to patients have evolved over time. Recognition of patient autonomy has gradually led to significant changes in practice.[30, 33] Physicians routinely used to withhold bad news from patients, such as news of a terminal diagnosis, because they thought the information would result in harm. Now, however, patients and clinicians alike generally expect full disclosure of medical information, good and bad.[34] At the same time, disclosure of adverse events is rapidly gaining in practice.

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 major physician organizations, including the American Medical Association (AMA)[35] and the American College of Physicians,[36] specifically require physicians to fully disclose errors contributing to an undesirable health care outcome. The AMA code states:

> Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. [35]

Similarly, the American College of Physicians' 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]

The American Nurses Association also supports disclosure of adverse events:

> …when errors do occur, nurses are expected to follow institutional guidelines in reporting errors committed or observed to the appropriate supervisory personnel and for assuring responsible disclosure of errors to patients. Under no circumstances should the nurse participate in, or condone through silence, either an attempt to hide an error or a punitive response that serves only to fix blame rather than correct the conditions that led to the error.[37]

Other professional codes, while they may not specifically address disclosure of adverse events, contain general requirements for honesty and integrity.[38] For example, the American College of Health Care Executives 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]

In addition, as of July 2001 the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) began requiring acute care hospitals to have policies ensuring that "[p]atients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."[40] JCAHO standards have significant influence in the health care industry and may be expected to provide a powerful impetus for disclosure policies.

Organizational Mission and Values

Some health care organizations have adopted explicit mission statements or statements of corporate values that help to 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. For example, VHA's "core values"—trust, respect, commitment, compassion, and excellence[41]—contributed to the decision by VHA policymakers to require the disclosure of adverse events to patients who are harmed.

All health care institutions have a responsibility to the communities they serve, and those with enrolled populations or with affiliations to religious institutions or to special segments of the population may have additional responsibilities to their constituencies. For VHA, the fact that many veterans have risked their lives for their country, and may not have other options for obtaining health care, adds special importance to the organization's obligation to those it serves.

Legal Support for Disclosure

Among the most common reasons for not disclosing adverse events are fears of liability, criminal prosecution, or professional sanctions. While 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 fact, attorneys and legal commentators are increasingly among the strongest proponents of disclosure.[42-44]

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. Both clinicians and health care institutions 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, and self-doubt.[11,45-46] Furthermore, clinicians who experience malpractice suits are more likely to consider retiring from practice.[46]

Despite these reasons for not disclosing, some attorneys are beginning to support disclosure. Plaintiffs' attorneys may favor disclosure because physicians may be liable for *failing to disclose* adverse events.[47] In a landmark New York case, *Simcuski v. Saeli*,[48] a patient successfully sued his surgeon for failing to admit an error that might have been mitigated by prompt treatment, but instead resulted in permanent disability. This precedent-setting case held for the patient who, without proving negligence, was able to recover damages for fraud. Unlike negligence, fraud exposes the physician or other clinician to potential liability for punitive damages that can increase the size of an award and are often excluded from coverage by liability insurance policies.[49] Defense attorneys may also favor disclosure, because disclosing adverse events to patients can reduce total liability payments resulting from lawsuits. Since implementing its policy of disclosing all adverse events that result in harm, the Lexington VA Medical Center has experienced reduced liability payments.[6] In addition, studies of how patients decide whether to file malpractice claims have found that patients are less likely to sue physicians who communicate with them honestly and effectively.[50-52]

Some clinicians may fear not only civil liability but criminal prosecution as well.[42] In several states, physicians have been prosecuted for clinical mistakes, and, in at least New York and California, been convicted.[53] 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 of the nurses were ultimately acquitted, but only after a painful and lengthy legal process.[54]

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.[55]

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. This section offers practical recommendations for implementing this policy.

What Adverse Events Warrant Disclosure?

VHA Patient Safety policy specifically requires disclosure "to patients who have been injured by Adverse Events."[5] In some cases an injury to the patient may be self-evident, as with what JCAHO calls "sentinel events": "unanticipated death[s] 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."

In the view of the National Ethics Committee, disclosure of adverse events to patients should not be limited to cases in which the injury is obvious or severe. Rather, the Committee believes that from an ethical perspective respect for patients requires disclosure in all of the situations described below.

1. **Disclosure is called for whenever an adverse event has a perceptible effect on the patient that was not discussed in advance as a known risk:**

   - <u>Whether the effect is perceptible only to the clinician, to the patient or family, or is obvious to all</u>. For example, a patient develops seriously abnormal liver function tests as a complication of a medication or procedure. Such an adverse event should be disclosed, even if the patient experiences no overt symptoms.
   - <u>Even if the effect is not actually harmful.</u> For example, the wrong side or wrong body part is shaved in preparation for surgery, but the mistake is discovered before surgery is performed. Although one could argue no real harm was done, disclosure is nonetheless required.
   - <u>Whether the effect is physical, psychological, or both.</u> For example, a patient who receives a double dose of pain medication may feel inexplicably "fuzzy-headed." The adverse event must be disclosed even if there was no discernible physical effect.
   - <u>Whether the effect is actual or anticipated.</u> For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output), disclosure is required because a perceptible effect is expected to occur.

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 (i.e., 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 (e.g., increased incidence of cancer) requires disclosure.

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, while under anesthesia, undergoes an additional unanticipated procedure, the adverse event should be disclosed regardless of whether the patient experiences any ill effects.

As a general rule, disclosure to patients of adverse events that do not fall in the above categories is optional and at the discretion of the clinicians involved. Cases should be considered individually and in relation to the specific circumstances.

Disclosure of "close calls" 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. For example, a nurse sets a patient up for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, abruptly stops the transfusion just before the blood enters the patient's vein. The patient surely deserves an explanation, if not a formal disclosure as described below.

Who Should Disclose?

Who should disclose an adverse event depends on the specific circumstances, especially the nature, likelihood, and severity of injury; the potential for remedy; the need for further treatment; and the 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. JCAHO standards require that the "responsible licensed independent practitioner or his or her designee clearly explain the outcome of any treatments or procedures."[40] 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 multi-step process. The first step is the "clinical disclosure," when one or more members of the clinical team provides preliminary information to the extent it is known, expresses concern for the patient's welfare, and reassures the patient and family that steps are being take to investigate the situation, remedy any injury, and prevent further harm. The next step, if applicable, is the "institutional disclosure," when 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 VA Medical Center, a multi-step process has been used since 1987.[6] Under the Lexington 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, 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. House officers and other clinicians in training provide much of the clinical care in academically affiliated medical centers, including those in VHA. 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 time to collect preliminary information and plan the best way to disclose. Organizations that adopt a multi-step approach to the disclosure process should encourage clinicians to undertake clinical disclosures promptly, and 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 prior to disclosure increases the chance that patients will think information is being deliberately withheld. Institutions should establish general timeframes 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 the disclosure must be. For serious adverse events, both the clinical and institutional disclosures should follow accepted methods for "breaking bad news."[24, 56-58]

First, disclosure should occur in a proper setting. The location should be a quiet, private place suitable for discussion; adequate time should be set aside, with no 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.[59] 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. These arguments derive from utilitarian and duty-based ethical theories, professional standards, organizational mission and values statements, and legal considerations. Based on these arguments, the National Ethics Committee endorses a policy that calls for routinely disclosing adverse events to patients—and considers disclosure mandatory when certain criteria are met.

Current national VHA policy requires disclosure to patients or families of all adverse events that result in injury. This report provides support and justification for that policy, as well as guidance

about which adverse events should be disclosed, by whom, when, and how. This report's recommendations are consistent with (and do not change) current VHA policy on disclosure of adverse events.

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