

Forum

Unanticipated Harm to Patients: Deciding When to Disclose Outcomes

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Health care organizations are now engaged in numerous activities to address the widespread safety problems detailed in the Institute of Medicine's report *To Err Is Human: Building a Safer Health System*.¹ However, even before the report was released, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was preparing patient safety standards.

The JCAHO patient safety standards require that "patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."^{2(RI-10)} The intent of this standard requires that, at a minimum, information is provided about the following:

- Outcomes of care that the patient (or family) must be knowledgeable about in order to participate in current and future decisions affecting the patient's care.
- Unanticipated outcomes of care that relate to sentinel events considered reviewable by the Joint Commission (that is, events that result in an unexpected death or serious injury or pose a risk thereof). The responsible licensed independent practitioner or his or her designee informs the patient (and, when appropriate, the patient's family) about these outcomes of care.^{2(RI-11)}

It is worth noting that the JCAHO standard does not directly address error. Serious, unanticipated outcomes may or may not be the consequence of error. Those that are clearly caused by error pose legal and psychological difficulties for practitioners but are fairly easy to analyze from an ethical perspective. Perhaps the most common and difficult situations for health care practitioners and the institutions in which they practice are those instances in which the patient has suffered an unanticipated adverse outcome and it is not clear whether medical error was involved.

Article-at-a-Glance

Background: Patient safety standards of the Joint Commission on Accreditation of Healthcare Organizations require that "patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."

What Outcomes Should Trigger Disclosure: Given that all medical treatments have an array of possible outcomes, how do we confidently say that an outcome is unanticipated? It is proposed that an adverse outcome meet one of two criteria to be considered unanticipated: (1) It would not be included in a reasonable informed consent process for treatment of the patient's condition(s) and/or would not be expected during the usual course of treatment; and (2) it may have been caused by human or systemic error—that is, it is not immediately possible to clearly and decisively rule out error. This definition requires less judgment because it represents an extension of the existing norms of communication that are expressed through the process of informed consent. The norms of the informed consent process require that the patient be given all pertinent information needed to participate in future treatment decision making.

Conclusions and Recommendations for Organizational Policies: Institutional policies and procedures should provide a clear approach to the identification, reporting, and discussion of unanticipated adverse outcomes, whether or not they are associated with error, as well as guidance and an educational program to help physicians, staff, and students disclose unanticipated adverse events and error in the most appropriate manner.

The patient safety standards demand an appropriate response from those organizations seeking JCAHO accreditation. However, it is important that we see the enormous opportunity that lies beyond fulfilling accreditation requirements. We are in an era in which trust between physician and patient needs to be strengthened. We often hear of a “malpractice crisis” in which patients are overly aggressive in seeking compensation through litigation. If the medical profession can restore the confidence of patients, this crisis may be ameliorated. Restoration of confidence is likely to require greater physician and institutional responsibility for forthright disclosure and treatment of injury.

Effective organizational responses to disclosure of medical harm, particularly where error may be involved, require an understanding of the ethical issues, the legal and cultural barriers to disclosure, and the practical matters concerning what outcomes should be disclosed. We address each of these issues in turn, but we are particularly interested in providing a framework for leaders of health care organizations such as hospitals to use in formulating a policy on disclosure to patients. In addition, we offer guidelines to help determine what type of outcomes should trigger implementation of formal institutional procedures to disclose outcomes to patients and/or families.

The Ethical Issues

Unanticipated adverse outcomes and medical errors are different categories of events that may be related in important ways. Disclosing adverse outcomes when error is not suspected seldom poses ethical or even practical questions. Such disclosures are routinely made. As a result, what we must provide is a justification for disclosure of the most difficult kind of unanticipated outcome—one in which the adverse outcome *may have been* due to error. Three main ethical foundations support disclosure under such circumstances:

- Medical professionalism
- Respect for persons (informed consent)
- Institutional responsibility

Medical professionalism entails fostering the trust of patients, and truth telling is essential to the creation of a trusting fiduciary relationship between patients and physicians. Honest, effective, and open communication is the foundation of the relationship between clinicians

and patients. Telling the truth is always the right thing to do. Concealing the truth is wrong.

Second, all persons have a right of self-determination. This right requires that patients be able to fully and effectively participate in decision making regarding their medical care. This participation has generally been codified in terms of the ethicolegal doctrine of informed consent. To participate effectively in their health care, most patients and/or their families need information regarding the causes of and prognoses for their conditions.

Finally, health care organizations have a duty to foster practices that maximize potential benefits to patients (beneficence) and minimize the possible harms (non-maleficence). Understanding the magnitude and types of errors provides opportunities to improve patient safety. Gathering these data requires that health care professionals report errors and near misses accurately. Although this does not argue directly for reporting errors to patients, creating an organizational culture of effective communication supports and fosters the ethical principles of truth telling and patient autonomy.

In spite of these seemingly straightforward ethical principles, unanticipated adverse occurrences due to error are frequently not discussed. For example, in a study of residents, Wu and coworkers³ observed that only 50% informed their attending physicians of errors and fewer than 25% informed the patients or the patients’ families. Similarly, Andrews and colleagues found that problems in care that are identified at rounds and at clinical meetings are rarely reported to the risk management department.⁴ A recent report of a 2002 survey of hospital risk managers indicated that the number of disclosures had increased in the previous two years, but half of the respondents still reported fewer than 5 disclosures per 10,000 annual admissions.⁵

Barriers to Disclosure

The widespread failure to disclose errors to patients is no surprise. Clinicians face significant legal, cultural, and personal barriers as they contemplate communicating such outcomes to patients and families.

Legal Liability

Fear of increased exposure to legal liability is arguably the largest barrier to full disclosure of error.⁵

However, there is considerable disagreement regarding the impact of open, honest disclosure on legal claims and financial settlements. Thurman argues that the weight of evidence supports the view that honest disclosure reduces liability.⁶ The Lexington Veterans Affairs Medical Center, where full disclosure has been the policy since 1987, has not experienced significant increases in financial losses.^{7,8}

On the other hand, the intensely litigious climate of some localities and the current dramatic escalation in malpractice awards raise the specter (albeit without evidence) that an ill-conceived disclosure policy could result in an escalation of malpractice actions and payments that threatens organizational viability.

Some attorneys express concern that malpractice insurers could interpret disclosure of an error as a contract violation. Malpractice contracts usually contain provisions related to physician and institutional duty to cooperate in the legal defense of a claim or lawsuit. An insurer may argue that disclosure of an error to a patient violates this provision and thereby voids the insurer's obligation to indemnify the defendants.

Given that such barriers reflect *fears* related to legal liability rather than *facts*, analysts are likely to have difficulty assigning an appropriate moral weight to these concerns. Nevertheless, it is clear that what is needed is measures that are both courageous and prudent. That is, we must not let fears of legal liability become so consuming that they prevent us from being ethical, but we must also avoid unduly contributing to liability exposure.

The Medical Culture of Blame

Traditional approaches to the handling of error focus on identifying "those responsible" and assigning blame. Punishment ranges from reprimand to loss of privileges and/or licensure. Humiliation and profound shame often overwhelm those involved in an error that results in significant patient injury. This is due, in part, to current medical education and training, which emphasizes personal accountability to the exclusion of system defects as causes of error. To make matters worse, many organizations provide little or no emotional or other support to caregivers who have been deeply affected by their involvement in serious errors. Individuals will always be exceedingly reluctant to report adverse outcomes or

near misses if they are seen simply as indicative of personal and professional failings.

The "Silent World" of Physician and Patient*

The ideal of shared decision making between physician and patient is now widespread in the United States—the era of unbridled medical paternalism is long over. The goal of physician–patient communication is to make transparent the evaluative processes of each party so as to empower patients to be active participants in their care.⁹ Nevertheless, the world of physician and patient remains one in which the flow of information is often problematic and miscommunications are common. Several studies have shown that physicians are reluctant to discuss with patients matters in which there is some uncertainty.^{10–12} By their nature, unanticipated outcomes fall into this category.

It can be reasonably concluded from the ideal of shared decision making and the obligation to keep the patient safe (nonmaleficence) that health care organizations have a duty to provide policy leadership regarding the disclosure of unanticipated outcomes, especially those involving error, and to develop an implementation strategy that includes the creation of a culture where it is safe to report adverse occurrences, regardless of their cause.

What Outcomes Should Trigger Disclosure?

Although honest disclosure may appear straightforward, in reality there is often ambiguity regarding *what is the truth* and *when* and *how* to disclose it.¹³ Multiple witnesses to a complex set of clinical events often see the truth in different ways. What may seem obvious at the outset often turns out not to be true after extensive investigation. Adverse outcomes attributed to individual practitioner error in the heat of the moment are later often found to be the result of multiple system defects. In addition, separating adverse outcomes due to the patient's medical condition from those due to error or system defect is at times challenging. Finally, the causes of some adverse events are never completely understood, even after intense analysis.

What kind of unanticipated adverse outcome should trigger a disclosure policy? All medical treatments have

* Jay Katz, in *The Silent World of Doctor and Patient* (New York: The Free Press, 1984) uses the term *silent* to reflect his position that not much is said in informed consent encounters.

an array of possible outcomes. Given this array, how do we confidently say that one or another is unanticipated?

We propose that an adverse outcome must meet one of two criteria to be considered unanticipated:

1. The outcome is one that would not be included in a reasonable informed consent process for treatment of the patient's condition(s) and/or would not be expected during the usual course of treatment

2. The outcome may have been caused by human or systemic error—that is, it is not immediately possible to clearly and decisively rule out error

Both these criteria for “unanticipated” are more inclusive than the minimum required by the JCAHO intent. Criterion 2 does not impose a restriction of “reviewable sentinel events”² but rather encompasses error-related adverse outcomes of mild to moderate severity. Also, unlike the JCAHO intent, it refers to the possibility of error.

Some may argue that patients do not need to know about mild-to-moderate-severity events (such as an overdose of a nephrotoxic agent causing a transient decrease in renal function for which no monitoring is required over and above that already planned for concomitant conditions) to participate in care decisions. However, there is no reason that physicians should be less truthful about less serious unanticipated outcomes than about more serious outcomes. Second, this definition requires less judgment because it represents an extension of the existing norms of communication that are expressed through the process of informed consent.

And, of course, the norms of the informed consent process require that the patient be given all pertinent information needed to participate in future treatment decision making, be that information “large” or “small.” We suggest that *unanticipated* be defined by the context of the physician–patient relationship. In this relationship, communication must include an informed consent process for invasive procedures; the technical competence of the health care team is assumed. As a result, an unanticipated outcome is one that is outside these norms.

A good informed consent process includes apprising the patient of the risks of the proposed treatment, the potential benefits, and possible alternative plans of care. This process should include disclosure of all the risks that a “reasonable person” might want to know. That is, a physician should elaborate the risks of fairly common

negative outcomes and probably also mention less common adverse outcomes if such outcomes are extremely devastating (for example, death). But a physician should not approach the consent process as if he or she is “Mirandizing” the patient regarding every conceivable outcome.¹⁴ Thus, simply mentioning very-low-frequency possibilities does not mean that they are anticipated. The ultimate test as to whether an event enters into the informed consent process is that it is the kind of outcome one would typically expect, given the circumstances.

Furthermore, even outcomes that are mentioned in such an informed consent process constitute *unanticipated* adverse outcomes if error cannot be ruled out. This is obvious if we consider the fact that nowhere in the informed consent process is the patient warned of the risk of such errors.^{15,16} For better or worse, error is not assumed to be an ordinary part of the treatment process. Thus, when an error is suspected (not necessarily proven), the event must be treated as unanticipated.

We believe that using the existing framework of informed consent can promote the trust between patient and physician in a way that is consistent with the evolving culture of the clinical environment. That is, the long history of the silent world of physician and patient has evolved toward greater transparency. We propose that this evolution continue. Although some have argued for the disclosure of near misses to patients, we believe that this is not required by the concept of unanticipated adverse outcomes or by the framework of informed consent. A near miss, by definition, is not related to an unanticipated adverse outcome; in fact, it is not related to the actual outcome at all and is thereby not required to be reported by the JCAHO guidelines.

Perhaps of greater import, the disclosure of near misses is not directly relevant to the informed consent process. That something harmful almost happened to a patient is not medical information that is needed for the patient to make further treatment choices. In fact, at the time it would be disclosed, it is not actually information *about* the patient and could rather divert attention from the patient's actual situation. Nevertheless, we believe that physicians and health care professionals need to report such information expeditiously to the appropriate personnel within their organizations for review and possible quality improvement interventions.

It is not clear that requiring disclosure of near misses to patients would facilitate such reporting.

As we have noted, medical culture has not traditionally been supportive of the free flow of information that involves an element of uncertainty. So there is often earnest disagreement regarding when and how to disclose adverse occurrences due to error. Many suggest that it is best to wait until all the details are known and understood. The desire to protect the patient from bad news and/or to minimize legal liability may reinforce this tendency but adds to a climate of increasing suspicion. Others argue for a change in the prevailing climate and seek early disclosure of what is known and ongoing disclosure as new fact-based conclusions are reached.^{7,17} Developing a “standard of care” regarding disclosure from this diversity of opinion is likely to require development of educational, quality improvement, and leadership programs to deal with these difficult questions.

Conclusions and Recommendations for Organizational Policies

Health care organizations have a responsibility to foster the highest moral standards in patient care. As such, they must be committed to the ethical principles of truth telling and to the furtherance of a trustful fiduciary relationship between caregivers and patients. At the same time, many organizations are now attempting to implement policies and procedures responsive to the JCAHO patient safety

standards. Given the issues as we have addressed them, we believe that patients, physicians, staff, students, and health care organizations will all benefit from institutional policies and procedures that provide the following:

1. A clear approach to the identification, reporting, and discussion of unanticipated adverse outcomes, whether or not they are associated with error. The disclosure policy at the Loyola University Health System, still in review, has incorporated the definition of *unanticipated* proposed in this article.
2. Guidance from a readily available professional(s) to assist with the what, who, when, where, and how of disclosing unanticipated adverse events.
3. An educational program that helps physicians, staff, and students disclose unanticipated adverse events and error in the most appropriate manner.
4. Mechanisms to provide psychological and professional support to physicians, staff, and students involved in the care of patients who have suffered adverse consequences, whether or not error is involved. **■**

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