

Disclosing Unanticipated Outcomes to Patients: The Art and Practice

Thomas H. Gallagher, MD,* Charles R. Denham, MD,† Lucian L. Leape, MD,‡
Geri Amori, PhD,§ and Wendy Levinson, MD||

Abstract: Open disclosure of unanticipated outcomes to patients is a key component of patient-centered care and is increasingly mandated by hospital accreditation requirements and some state laws. Yet, transparent communication with patients about unanticipated outcomes appears to be the exception rather than the rule. We describe why the current approach to disclosure is broken and review a new Safe Practice that the National Quality Forum has adopted to enhance the disclosure of unanticipated outcomes to patients. This Safe Practice emphasizes that disclosure and transparency are core components of organizations' patient safety programs. We describe what events are covered by the Safe Practice and articulate the essential steps in the disclosure process. The Safe Practice encourages organizations to create a disclosure and improvement support system, which includes supplying emotional support for caregivers and administrators following serious unanticipated outcomes, providing health care workers with disclosure education and skill building, establishing a process for ready access to adjust-in-time disclosure coaching, and developing processes for measuring and improving disclosure. We then use the "4A's" frameworks of awareness, accountability, ability, and action to delineate what key players should understand and do to begin closing the disclosure performance gap, and list of practical steps that organizations can take to implement this Safe Practice.

Key Words: disclosure outcomes, communication, patient safety

(*J Patient Saf* 2007;3:158–165)

Open communication about unanticipated outcomes is critical to saving lives and preventing undue suffering of patients.^{1,2} Open communication requires providing critical information in a timely manner to the affected patient and family and to appropriate individuals within the health care organization who can prevent future events.^{3,4} Patients need this information to understand their health situation and to make important decisions regarding their future care. Health care organizations need this information to identify hidden

systems failures, perform careful analyses of causes, and develop strategies to prevent recurrences.

Despite these needs, available evidence suggests that open communication of unanticipated outcomes occurs infrequently.³ Within health care organizations, critical information often does not reach key stakeholders, particularly members of senior management and trustees who have the power to move organizations toward greater transparency.⁵ The disclosure of unanticipated outcomes to patients is even more problematic.^{6–10} Full disclosure to patients poses special challenges for caregivers and institutions and thus constitutes an important barometer of an institution's values and commitment to quality, transparency, and patient-centered care.

In this article, we describe the current breakdown in disclosing unanticipated outcomes to patients and describe a new Safe Practice proposed by the National Quality Forum (NQF) to enhance disclosure.¹¹

The Current Approach to Disclosure and Why It Is Broken

Ethicists and professional organizations have long recommended that unanticipated outcomes be disclosed to patients, emphasizing patients' right to be informed about important events in their care. Disclosure is being increasingly required.^{12–16} The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now requires that patients be informed about all outcomes of care, including unanticipated outcomes.¹⁷ Some states have also adopted disclosure requirements.¹⁸ At the federal level, in 2005, Senators Clinton and Obama introduced legislation requiring that harmful errors be disclosed to patients.¹⁹ Yet, research shows that patients are infrequently told about unanticipated outcomes and harmful errors in their care or are given incomplete information.^{6,7,9,20–28}

There are multiple reasons why disclosure is not happening, ranging from the external environment to the individual health care worker.

External Disclosure Context

Although standardization of the external requirements for disclosure is an important first step, existing standards provide little guidance regarding the practice of disclosure. For example, current standards do not address how much information should be disclosed or whether to apologize. As a result, health care institutions and caregivers are uncertain exactly how disclosure should take place.

This uncertainty about the best approach to disclosure is especially troubling in light of the litigious health care

From the *Department of Medicine, University of Washington School of Medicine, Seattle, Washington; †Texas Medical Institute of Technology, Austin, Texas; ‡Harvard School of Public Health, Boston, Massachusetts; §The Risk Management and Patient Safety Institute, Lansing, Michigan; and ||Department of Medicine, University of Toronto, Ontario, Canada. Supported by the Agency for Healthcare Research and Quality (grant nos. 1K08HS01401201, U18HS1665801) and the Greenwall Foundation Faculty Scholars Program.

Correspondence: Thomas H. Gallagher, MD, University of Washington School of Medicine, 4311-11th Ave NE, Suite 230, Seattle, WA 98105-4608 (e-mail: thomasg@u.washington.edu).

Copyright © 2007 by Lippincott Williams & Wilkins

environment. The American Medical Association reports that 22 states are “in crisis” regarding affordable medical malpractice insurance.²⁹ Many states are adopting laws that protect some apologies from being an admission of liability.^{30,31} However, because most of these apology laws provide only limited protection, they may not reduce institutions’ and caregivers’ concerns that disclosure will lead to lawsuits.

Institutional Environments

Although publicly espousing transparency, many health care organizations worry that disclosing unanticipated outcomes may lead to litigation and bad publicity.³² As a result, institutional disclosure policies are often vague. They may send caregivers mixed messages, such as requiring personnel to disclose unanticipated events to patients but not admit liability. Many institutions have also been reluctant to provide caregivers with disclosure education, fearing that such training could stimulate disclosure in problematic ways. These institutional concerns are compounded by the inertia that accompanies any attempts at broad cultural change such as increasing transparency.⁵

Institutional Trustees, Senior Leadership

Individuals in leadership positions with the power to move institutions toward greater transparency are often unaware of the problems with disclosure, both across health care and at their own institution. One reason is that middle/upper managers may not be informing them about the full spectrum of unanticipated outcomes at their institution. Trustees hear about celebrated catastrophes such as wrong site surgeries, but may not know about other serious but less widely discussed unanticipated outcomes. In addition, institutional leaders frequently receive very conservative advice from internal and external legal counsel about how these events should be handled. This advice from their attorneys is primarily concerned with financial risk to the institution rather than what is best for patients and may not reflect accumulating evidence about the beneficial effects of disclosure, both therapeutic and financial.^{1,18}

Health Care Professionals

The attitudes and experiences of individual health care professionals can inhibit transparency. Although caregivers are generally committed to being truthful, they are also extremely unsure whether and how to disclose unanticipated outcomes to patients.^{27,33–35} They naturally fear the negative and punitive consequences of disclosure, including lawsuits, shame and embarrassment, and disciplinary actions. Furthermore, few caregivers have had disclosure training, so even those who wish to disclose are uncertain how to conduct these challenging conversations.

Does Disclosure Matter? Is Disclosure Really a Patient Safety Issue?

Some may consider disclosure to be only a service recovery and risk management issue. Yet, the impact of disclosure is much more wide ranging, including the following.

Disclosure as Patient-Centered Care

Patients unanimously want unanticipated outcomes disclosed to them, especially when it was due to a medical error. Multiple studies have shown that patients wish to be informed about what happened, the implications of the event for their care, why the event happened, and how recurrences will be prevented.^{7,22,24,36–42} Patients care deeply that lessons have been learned from the event and that recurrences are less likely. When there has been an error or systems failure, patients also desire an apology, as recognition of the seriousness of the event and its emotional impact on them. Meeting patients’ preferences for disclosure is fundamentally aligned with the Institute of Medicine’s vision of patient-centered care.³ Effective disclosure enhances patient-centered outcomes, including the patient’s medical decision making, trust, and satisfaction. Inadequate disclosure clearly angers patients and contributes to malpractice suits.^{37,40,43–48}

Disclosure as a Core Patient Safety Activity

In many institutions, disclosure decisions are made by risk managers operating in “silos” disconnected from those working on patient safety and quality. As a result, information gleaned from risk managers’ conversations about these events with caregivers may not be shared with the patient safety programs or communicated up the institutional chains of command. By recognizing disclosure as a key dimension of a transparent health care culture, institutions will stimulate improved communication and also promote greater reporting of unanticipated outcomes by caregivers to risk managers and patient safety programs. As previously unreported unanticipated outcomes are shared with patient safety experts, process improvements can be implemented to prevent recurrences and save lives. Sharing this information with senior executives and trustees will also create greater awareness of patient safety breakdowns among those who can commit the resources required to implement solutions.

Disclosure as Reflecting Institutional Values

Transparency should be a core institutional value. When senior leaders and trustees publicly commit to transparency, clearly delineate accountability for transparency, and commit the necessary resources to enhance transparency, it has important repercussions throughout the organization and on the public’s perception of the integrity of health care.

The Business Case for Disclosure

Many health care leaders worry that full disclosure will damage their institutions’ bottom line. Yet, accumulating information suggests the opposite—that full disclosure reduces malpractice costs.^{19,49,50} Furthermore, as pay-for-performance initiatives continue their rapid development, the business case for transparency becomes even more compelling.^{51,52}

Safe Practice on Disclosure

The NQF Safe Practices for Better Healthcare—2006 Safe Practice no. 4 states: “Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, family should receive

timely and transparent clear communication concerning what is known about the event.”

Thus, a disclosure practice is recommended for hospitals to provide open and clear communication with patients and families regarding serious unanticipated outcomes, supported by systems that foster transparency and performance improvement to reduce preventable harm. This Safe Practice explicitly links disclosure to an organization’s broader patient safety programs and emphasizes transparency as a core component of patient safety. The Safe Practice also articulates a process for disclosure and describes an institutional disclosure support system that includes disclosure policies, education, coaching, and emotional support for caregivers.

What Events Are Covered?

Those events that require disclosure under this Safe Practice are a subset of all unanticipated outcomes termed “serious unanticipated outcomes.” The definition of serious unanticipated outcomes was designed to harmonize similar definitions of serious events from various organizations, including the JCAHO and NQF. At a minimum, the serious unanticipated outcomes addressed by this practice include (a) *sentinel events* as defined by the JCAHO (any unexpected occurrence involving death or serious physical or psychological injury or risk thereof; serious injuries specifically include a loss of limb or function); (b) *serious reportable events* as defined by the NQF (one that results in death or the loss of a body part, disability, or loss of bodily function lasting more than 7 days or still present at the time of discharge from an inpatient health care facility or, when referring to other than an adverse event, an event that the occurrence of which is not trivial); (c) any other unanticipated outcomes involving harm requiring substantial additional care (such as diagnostic tests, therapeutic interventions, or increased length of stay) or causing loss of limb or function lasting 7 days or longer. Disclosure is appropriate for less serious events as well.

Organizational Elements

The governance and administrative leadership’s commitment and engagement are essential to the success of this Safe Practice. Trustees and administrative leadership can use the “4A” framework of awareness, accountability, ability, and action to educate themselves and their institutions about the nature of their disclosure performance gaps; they can then establish clear accountability for implementation, invest resources, and develop effective disclosure procedures.⁵ Essential elements of this Safe Practice include applying continuous quality improvement techniques such that information gleaned from disclosure is systematically used for performance and quality improvement. Annual reviews and updates of disclosure policies and processes should also take place to measure and ensure that current best practices are being used. In addition, the physician staff must be actively engaged to successfully develop and implement the disclosure process. Trustees and administrative leaders should consider implementing a policy for credentialing caregivers that requires both adherence to this disclosure practice as well as participation in a broader disclosure support system.

To implement this Safe Practice, organizations should develop a formal process for disclosing serious unanticipated outcomes to patients and ensuring that information about these events is reported both internally to patient safety programs and externally as required. Information reported by caregivers about these events to the institution then drives formal event analyses and planning for prevention, the results of which are shared with the patient. Thus, disclosure is a bidirectional process in which caregivers share information about events both with the institution and with patients.^{53,54}

Key Steps in the Disclosure Process

Following a serious unanticipated outcome, the patient should be informed about “the facts” of the event. This includes an explicit statement of what happened and the implications of the event for the patient’s future health, as well as why the event happened and its preventability to the extent known. In addition, the patient should be told of the commitment to investigate the incident and to report back regarding what is found about the event’s causes. The results of the event analysis should be provided to the organization’s patient safety leaders, including those in governance positions, so that systems changes can be made, if possible, to prevent recurrence. The patient can then be informed of the results of the event analysis and the changes made to prevent recurrences in sufficient detail to support informed decision making. Providing this information helps meet patients’ expressed preferences following unanticipated outcomes and emphasizes the value that patients place on the learning that comes from these events.^{7,38,39}

Skillful disclosure includes understanding not only *what* information to share with the patient but also *how* to share it.⁵⁵ Empathic communication techniques are essential for effective disclosure.⁵⁶ Serious unanticipated outcomes create significant emotional distress for patients. Patients are typically deeply disappointed that they were harmed by the care they were hoping would help them and anxious about future errors. Empathic communication involves caregivers recognizing and understanding each patient’s distress and communicating this understanding back to the patient. As part of empathic communication, an expression of regret that the outcome was not as expected is appropriate for all unanticipated outcomes. Patients and their families may also need support from someone other than their caregivers, such as a psychologist or patient’s advocate.

The Safe Practice envisions an initial conversation with the patient and/or their family within 24 hours of the event’s recognition. While patients should be notified promptly about these events, the information provided to them must be accurate. The content of this initial conversation will oftentimes be relatively limited, namely, that an event has occurred, what has been done to mitigate the event, and that the event will be carefully analyzed and the results later shared with the patient or family. Disclosure generally involves multiple conversations with the patient, which allows caregivers to provide information as it becomes available, gives the patient time to ask questions, and helps maintain the patient-provider relationship. Not infrequently, the caregiver’s initial thoughts

about the event and its preventability change substantially after careful analysis.

Many health care institutions are experimenting with who should lead disclosures. To preserve the patient-provider relationship, we believe that such conversations should be led

by the patient’s responsible licensed independent practitioner. When the patient’s provider is poorly suited or unwilling to lead the disclosure, a senior administrator should assume this role. Including other involved caregivers in the disclosure can also help in the explanation of what happened to the patient.

TABLE 1. What Key Players Should Understand and Do to Enhance Disclosure

Key Players	What They Need to Understand (Awareness)	What They Need to Do (Accountability, Ability, Action)
Everyone	<ul style="list-style-type: none"> • There is a disclosure gap across health care • There is a disclosure gap at their institution • There are disclosure barriers • There are consequences of the disclosure gap <ul style="list-style-type: none"> ◦ Patients develop lower trust and satisfaction ◦ Transparency provides a key to patient safety ◦ There is a business case for closing the gap 	<ul style="list-style-type: none"> • Participate in the process of developing and implementing Disclosure Safe Practice appropriate to their role/discipline
CEOs/trustees	<ul style="list-style-type: none"> • Trustees/CEOs are critical to closing disclosure gap • Success of Disclosure Safe Practice depends on integrating risk management and patient safety systems • Reports they currently receive on patient safety and disclosure may only be the tip of the iceberg 	<ul style="list-style-type: none"> • Enhance awareness <ul style="list-style-type: none"> ◦ Promote education ◦ Incorporate disclosure into their strategic plans • Establish accountability <ul style="list-style-type: none"> ◦ Remove institutional barriers to disclosure and transparency ◦ Make leadership and key staff accountable for disclosure ◦ Ensure serious unanticipated outcomes are reviewed with the board • Develop ability <ul style="list-style-type: none"> ◦ Invest in disclosure education and skill building ◦ Invest in disclosure support and improvement system • Promote action <ul style="list-style-type: none"> ◦ Attack inertia ◦ Demand transparency and integrity ◦ Ensure disclosure measures and targets are created
Department heads/medical directors	<ul style="list-style-type: none"> • Disclosure is a team activity • Collaboration is necessary between physician and nonphysician departments 	<ul style="list-style-type: none"> • Enhance awareness <ul style="list-style-type: none"> ◦ Promote education ◦ Incorporate disclosure into strategic plans • Establish accountability <ul style="list-style-type: none"> ◦ Remove institutional barriers to disclosure and transparency ◦ Make leadership and key staff accountable for disclosure • Develop disclosure coaching skills • Incorporate consideration of disclosure into morbidity and mortality conferences
Risk managers	<ul style="list-style-type: none"> • Disclosure may require conflict-resolution skills; conflicts are likely among caregivers regarding the nature of event, whether and how to disclose 	<ul style="list-style-type: none"> • Promote integration with quality improvement/patient safety program • Develop disclosure coaching skills
Malpractice insurers	<ul style="list-style-type: none"> • There is a positive impact of disclosure on fiscal outcomes (the “business case”) 	<ul style="list-style-type: none"> • Support disclosure process • Consider establishing early offer program
Patient safety experts	<ul style="list-style-type: none"> • Disclosure is a patient safety, not service recovery issue 	<ul style="list-style-type: none"> • Collaborate more closely with risk managers • Provide event analysis information to those leading disclosure
Physicians	<ul style="list-style-type: none"> • Disclosure is crucial to maintaining the patient’s trust • Disclosure requires help from coaches and safety experts • Disclosure can impact outcomes, especially litigation 	<ul style="list-style-type: none"> • Receive background training • Access the relevant support resources before disclosure
Nonphysician caregivers	<ul style="list-style-type: none"> • There is an important role of nonphysician caregivers in disclosure • Strategies for effective team communication must be developed 	<ul style="list-style-type: none"> • Receive background training • Access the relevant support resources before disclosure

An administrative leader's presence for the disclosure can demonstrate the institution's commitment to transparency and highlight the changes being made to prevent recurrences.

Apology plays a critical role in the disclosure process.⁵⁷⁻⁵⁹

An early expression of regret that the patient experienced harm is appropriate for all serious unanticipated outcomes. However, when investigation reveals that the event was clearly caused by unambiguous errors or system failures, the patient's responsible provider should make a full apology, which requires taking responsibility for the failure, showing remorse, and making some restitution.⁶⁰ In some cases, an apology is also indicated from an administrative leader.

Disclosure and Improvement Support System

It is essential for patients, caregivers, and health care organizations that disclosure of serious unanticipated outcomes be done well. Thus, to promote elimination of the current disclosure performance gap, the Safe Practice includes a disclosure and improvement support system with the following 3 main elements:

1. *Emotional support for caregivers and administrators.* Serious unanticipated outcomes upset not only patients and their families but also the involved caregivers and administrators, distress that can last for weeks and months.^{26,35,61-65} At present, caregivers' and administrators' needs for emotional support following serious unanticipated outcomes go largely unmet.⁶⁶ Some caregivers may hesitate to seek support following errors because of the misconception that this would be a sign of weakness. Institutions have also failed to create adequate support programs and to address caregivers' concerns about the confidentiality of such programs. Failing to support the emotions of caregivers and administrators following serious unanticipated outcomes not only impairs the disclosure of these events to patients, but can also inhibit the caregivers' abilities to provide safe care. This may lead to employee burnout and staff turnover. Thus, developing effective support mechanisms for those involved in serious unanticipated outcomes is paramount.
2. *Education/skill building.* Few caregivers have had training in disclosing unanticipated outcomes to patients. Thus, institutions should invest in educational programs to teach caregivers how to conduct these difficult conversations. An institution-wide disclosure education effort can heighten awareness of the disclosure performance gap and emphasize the organizations' commitment to transparency and integrity. Those caregivers most likely to be involved in disclosure should also have the opportunity to practice these skills using innovative educational techniques, such as standardized patients.²⁰
3. *Coaching.* Although background education on the disclosure practice for caregivers and administrators is essential to the success of such a program, education alone is not likely to be sufficient. Because serious unanticipated outcomes are relatively infrequent events for any given caregiver, significant time will likely have elapsed between disclosure training and the event itself. Thus, just-in-time coaching is a core component of this Safe

Practice.⁶⁷ Disclosure coaches can help the health care team discuss the event in a blame-free way and decide how to disclose the serious unanticipated outcome to the patient. This disclosure planning process will include rehearsing the

TABLE 2. Implementing the Safe Practice: Practical Next Steps

Step 1—Initiate planning	
• Leadership uses 4A framework to initiate a strategic planning process for disclosure ³⁰	◦ Highlight the importance of interdisciplinary representation in strategic planning
• Initiate processes to create relevant policies	◦ Specify content, process of disclosure
	◦ Tie the disclosure policy to credentialing for physicians and other caregivers
• Formally link disclosure and patient safety activities	◦ Ensure that analysis of all serious unanticipated outcomes includes consideration of disclosure
	◦ Create mechanisms so that information reported by caregivers to risk management is shared with the patient safety program
	◦ Develop approaches for regularly sharing information about serious unanticipated outcomes and their disclosure with leadership, including CEOs and trustees
Step 2—Create disclosure and improvement support system	
• Identify and train disclosure coaches	◦ Key skills include understanding the disclosure process, facilitating team discussion of serious unanticipated outcomes and resolving conflicts, leading the team through mock disclosure and anticipating questions, and supporting upset emotions of caregivers
	◦ Provide for availability of disclosure coaches at all times (24/7/365)
• Develop formal strategies for supporting caregivers and administrators following unexpected events	
• Prepare for education/training of caregivers	
Step 3—Provide disclosure education	
• Make general education available across the institution to create awareness of disclosure gap	
• Provide, minimally, 2-h background education for caregivers who are likely to be involved in disclosures	◦ The goal is not to educate to mastery. Workers need understanding of basic disclosure concepts, ability to practice disclosure, and awareness of how to access disclosure support resources
Step 4—Develop process for measuring and improving disclosure	
• Apply performance improvement tools to the disclosure process	
• Develop disclosure performance measures	◦ Outcome measures: evidence of disclosure and performance improvement in traditional patient safety areas such as death, disability, adverse drug events, delayed/missed diagnoses, and other preventable harms, also operational and financial measures related to disclosure, such as events that become malpractice claims, and the costs they generate
	◦ Process measures: percent of staff trained in disclosure, frequency of events requiring disclosure for which Disclosure Safe Practice was followed and satisfaction of the staff with disclosure training
	◦ Structure measures: verification that disclosure coaches are available at all times (24/7/365), pertinent policies exist and are available, a process is in place to screen unanticipated outcomes for consideration of disclosure, and mechanisms are in place to track whether and how disclosure occurs. Also, the presence of an internal disclosure reporting structure to senior administrative management and governance board leaders is an important measure
	◦ Patient-centered measures: patient trust in integrity and transparency of the institution, and satisfaction with disclosure among patients who experienced serious unanticipated outcomes

disclosure and anticipating questions. The disclosure coach also supports the caregivers' emotional needs, helping them focus on the affected patients. Institutions should ensure that disclosure coaches are available around-the-clock. At many institutions, medical directors, patient safety officers, and risk managers can serve as disclosure coaches. At smaller institutions, a suitably trained hospital administrator could also be a disclosure coach.

Implementing the Safe Practice

Implementing this Safe Practice will require that institutions undertake a broad strategic planning process and create a detailed action plan. Table 1 uses the "4A" framework (awareness, accountability, ability, and action)³⁰ to identify the key players in the disclosure process, critical dimensions of awareness for these groups, and the general domains of action for which each group will be primarily responsible. Disclosure education should be customized for each group. For example, those charged with implementing disclosure policies and procedures, such as medical directors and risk managers, should be especially aware of the interprofessional dimensions of disclosure and ensure that all involved caregivers have the opportunity to participate in discussions about disclosures. Those most likely to lead disclosures, such as physicians, must be particularly aware of the institutional resources available to assist with disclosure, such as just-in-time disclosure coaches.

Table 2 describes practical steps that institutions might follow in implementing the Safe Practice. These steps include developing the appropriate policies, linking disclosure and patient safety activities, creating a disclosure and improvement support system, and providing disclosure education. In addition, institutions should approach disclosure as they would any other performance improvement effort and develop and track disclosure performance measures addressing outcomes, process, structure, and patient-centered domains. Potential candidate measures are provided in Table 2, step 4. These measures are early in their development and will be refined over time. Rather than waiting for perfect measures, institutions should commit to tracking the disclosure process using those measures best suited to their local environment.

Implementation Example

Case: A diabetic patient is admitted to the hospital. The admitting physician handwrites an order for the patient to receive "10 U" of insulin. The "U" in your order looks like a zero. On the following morning, the patient is given 100 units of insulin, 10 times the patient's normal dose, and is later found unresponsive with a blood sugar level of 35mg/dl. The patient is resuscitated and transferred to the intensive care unit. You expect the patient to make a full recovery.

Careful root cause analysis reveals system breakdowns in the doctor's insulin order writing (use of dangerous abbreviation), order entry, pharmacy processing of the order, and medication administration. The team reconvenes to discuss the results of the analysis and plan for a follow-up communication with the patient. The attending physician and nurse manager return to the patient's room.

"Mr. Smith, we have completed our analysis of the episode in which your blood sugar dropped and you lost consciousness. We found that we made a number of mistakes. Several of our systems failed. I wrote the order for insulin using an abbreviation "U," which I shouldn't have done. It was interpreted by the pharmacist and nurse as a 0. So, instead of getting 10 units, you got 100. The pharmacist should have rejected my order as improper because of the absence of the word "units," but he filled it. The nurse assumed that the pharmacist and I had made sure it was correct, even though it was a high dose. She was working to get you taken care of promptly. Finally, we should have a system that involves you in your care as well. I suspect that if you had been asked, or even knew, about the dose being 100 units, you would have said, 'That's a lot more than I have ever taken before.'"

"So we had a number of failures, and we are so relieved that you were not seriously injured by these mistakes. But, we want to make sure that it doesn't happen again to someone else, so we are making some changes. First of all, we are going to enforce the no-abbreviation rule in prescribing. From now on, the pharmacists will refuse to fill orders that have abbreviations. We are revamping the staffing plans for the unit to make sure that our nurses are not overworked. And we are doing something else that we think you will approve of. We are developing a program of patient participation in which we will specifically make sure every patient (who is well enough) gets a list so they know all their medications and the doses and can check them when given. We will begin to ask patients to ask us about each medication they get, so we and they know it is the right medicine and the right dose."

New Horizons

The practice of disclosing unanticipated outcomes to patients is early in its development, and a variety of progressive organizations are experimenting with innovative approaches. Some institutions, especially large academic institutions and veterans' hospitals, have adopted policies that require disclosing a broader range of unanticipated outcomes. Included in some of these broader disclosure policies are explicit efforts to accept responsibility for unanticipated outcomes and errors, which is highly valued by many patients. Preliminary and anecdotal reports suggest that these programs for broad disclosure and acceptance of responsibility following unanticipated outcomes can be implemented without significant adverse consequences and oftentimes have beneficial effects on the litigation experiences of the involved institutions.⁵⁰ For example, the University of Michigan has reported that, in the 5 years since implementing their full disclosure program, annual litigation costs, average time to resolution of claims, and number of claims and lawsuits have been cut in half.¹⁹

In addition, some institutions and malpractice insurers are experimenting with programs that make early financial offers to cover the financial needs of patients who have experienced unanticipated outcomes. For example, COPIC, a large Colorado malpractice insurer, provides its member physicians with training and support in error disclosure. In addition, COPIC actively assists patients

who have experienced an unanticipated adverse outcome, including compensation for economic losses. Since December 2001, 1900 qualifying incidents have led to approximately 500 patient reimbursements. Of these 1900 cases that qualified for the 3R program, 11 have become lawsuits, none of which proceeded to jury trial. The average cost of cases handled through the program is significantly less than cases in which a malpractice claim is filed.^{49,68}

SUMMARY

The movement toward full transparency in health care is accelerating rapidly. Not only is open disclosure of serious unanticipated outcomes to patients, including apology if there has been an error or system failure, the right thing to do, but it also has enormous potential to enhance patient-centered outcomes. It may well decrease the likelihood and negative outcomes of lawsuits. Not least, it could greatly improve the well-being of caregivers involved in these events and, ultimately, the quality of care for the patients.

REFERENCES

- Gallagher TH, Levinson W. Disclosing harmful medical errors to patients: a time for professional action. *Arch Intern Med*. 2005;165(16):1819–1824.
- Massachusetts Coalition for the Prevention of Medical Errors. *When Things Go Wrong: Responding to Adverse Events*. Available at: <http://www.macoalition.org>. Accessed July 13, 2007.
- Institute of Medicine (US). *Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
- Kohn LT, Corrigan J, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.
- Denham C. Patients safety practices: Leaders can turn barriers into accelerators. *J Patient Saf*. 2005;1(1):41–55.
- Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. *N Engl J Med*. 2002;347(24):1933–1940.
- Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289(8):1001–1007.
- Lehmann LS, Puopolo AL, Shaykevich S, et al. Iatrogenic events resulting in intensive care admission: frequency, cause, and disclosure to patients and institutions. *Am J Med*. 2005;118(4):409–413.
- Schoen C, Osborn R, Huynh PT, et al. Taking the pulse of health care systems: experiences of patients with health problems in six countries. *Health Aff (Millwood)*. [published online ahead of print November 28, 2005]. doi 10377/hlthoff.w5.509. Accessed June 2, 2006.
- Weissman JS, Annas CL, Epstein AM, et al. Error reporting and disclosure systems: views from hospital leaders. *JAMA*. 2005;293(11):1359–1366.
- Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med*. 2007;356:2713–2719.
- Ethics manual. Fifth edition. American College of Physicians. *Ann Intern Med*. 2005;142:560–582.
- AHA Management Advisory. *Ethical Conduct for Health Care Institutions*. Chicago, IL: American Hospital Association; 1992.
- Downing L, Potter RL. Heartland Regional Medical Center makes a "fitting response" to medical mistakes. *Bioethics Forum*. 2001;17(2):12–18.
- Smith ML, Forster HP. Morally managing medical mistakes. *Camb Q Health Ethics*. 2000;9(1):38–53.
- 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(12):770–775.
- The Joint Commission. *Hospital Accreditation Standards*. Oakbrook Terrace, IL; 2007.
- Comden S, Rosenthal J. *Statewide Patient Safety Coalitions: A Status Report*. Washington, DC: National Academy for State Health Policy; 2002.
- Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *N Engl J Med*. 2006;354(21):2205–2208.
- Chan DK, Gallagher TH, Reznick R, et al. How surgeons disclose medical errors to patients: a study using standardized patients. *Surgery*. 2005;138:851–858.
- Epsin S, Levinson W, Regehr G, et al. Error or "act of God?": a study of patients' and operating room team members' perceptions of error definition, reporting, and disclosure. *Surgery*. 2006;139(1):6–14.
- Hingorani M, Wong T, Vafidis G. Patients' and doctors' attitudes to amount of information given after unintended injury during treatment: cross sectional, questionnaire survey. *BMJ*. 1999;318(7184):640–641.
- Sweet MP, Bernat JL. A study of the ethical duty of physicians to disclose errors. *J Clin Ethics*. 1997;8(4):341–348.
- Vincent CA, Pincus T, Scurr JH. Patients' experience of surgical accidents. *Qual Health Care*. 1993;2(2):77–82.
- Vincent JL. Information in the ICU: are we being honest with our patients? The results of a European questionnaire. *Intensive Care Med*. 1998;24(12):1251–1256.
- Wu AW, Folkman S, McPhee SJ, et al. Do house officers learn from their mistakes? *JAMA*. 1991;265(16):2089–2094.
- Gallagher TH, Garbutt JM, Waterman AD, et al. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. *Arch Intern Med*. 2006;166(15):1585–1593.
- Gallagher TH, Waterman AD, Garbutt JM, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Arch Intern Med*. 2006;166(15):1605–1611.
- American Medical Association. *AMA (Policy) Medical Liability Crisis Map*. Chicago, IL; Available at: <http://www.ama-assn.org/ama/roindex/category/11871.html>. Accessed July 17, 2007.
- Cohen JR. Apology and organizations: exploring an example from medical practice. *Fordham Urban Law J*. 2000;27(5):1447–1482.
- Sparkman CAG. Legislating apology in the context of medical mistakes. *AORN J*. 2005;82(2):263–272.
- Flynn E, Jackson JA, Lindgren K, et al. *Shining the Light on Errors: How Open Should We Be?* Oak Brook, IL: University HealthSystem Consortium; 2002.
- Boyte WR. Casey's legacy. *Health Aff (Millwood)*. 2001;20(2):250–254.
- Calman NS. No one needs to know. *Health Aff (Millwood)*. 2001;20(2):243–249.
- Christensen JF, Levinson W, Dunn PM. The heart of darkness: the impact of perceived mistakes on physicians. *J Gen Intern Med*. 1992;7(4):424–431.
- Hobgood C, Peck CR, Gilbert B, et al. Medical errors—what and when: what do patients want to know? *Acad Emerg Med*. 2002;9(11):1156–1161.
- Mazor KM, Reed GW, Yood RA, et al. Disclosure of medical errors: what factors influence how patients respond? *J Gen Intern Med*. 2006;21(7):704–710.
- Mazor KM, Simon SR, Gurwitz JH. Communicating with patients about medical errors: a review of the literature. *Arch Intern Med*. 2004;164:1690–1697.
- Mazor KM, Simon SR, Yood RA, et al. Health plan members' views about disclosure of medical errors. *Ann Intern Med*. 2004;140(6):409–418.
- Witman AB, Park DM, Hardin SB. How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting. *Arch Intern Med*. 1996;156(22):2565–2569.
- Gallagher TH, Lucas MH. Should we disclose harmful medical errors to patients? If so, how? *J Clin Outcomes Manag*. 2005;12(5):253–259.
- Hobgood C, Tamayo-Sarver JH, Elms A, et al. Parental preferences for error disclosure, reporting, and legal action after medical error in the care of their children. *Pediatrics*. 2005;116(6):1276–1286.
- Kao AC, Green DC, Davis NA, et al. Patients' trust in their physicians: effects of choice, continuity, and payment method. *J Gen Intern Med*. 1998;13(10):681–686.
- May ML, Stengel DB. Who sues their doctors? How patients handle medical grievances. *Law Soc Rev*. 1990;24(1):105–120.

45. Popp P. How will disclosure affect future litigation? *ASHRM J*. 2003;(Winter):5–14.
46. Robbennolt JK. Apologies and legal settlement: an empirical examination. *Mich Law Rev*. 2003;102:460–516.
47. Shapiro RS, Simpson DE, Lawrence SL, et al. A survey of sued and nonsued physicians and suing patients. *Arch Intern Med*. 1989; 149(10):2190–2196.
48. Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*. 1994; 343(8913):1609–1613.
49. COPIC. COPIC's 3R Program. Available at: http://www.callcopic.com/publications/3rs/vol_3_issue_1_jun_2006.pdf. Accessed September 11, 2006.
50. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131(12):963–967.
51. Denham C. Can pay-for-performance requirements help define hospital safety programs? *J Patient Safety*. 2005;1(2):114–117.
52. Petersen LA, Woodard LD, Urech T, et al. Does pay-for-performance improve the quality of health care? *Ann Intern Med*. 2006;145(4): 265–272.
53. Liang BA. A system of medical error disclosure. *Qual Saf Health Care*. 2002;11(1):64–68.
54. Liang BA. Error disclosure for quality improvement: authenticating a team of patients and providers to promote patient safety. In: Sharpe VA, ed. *Accountability: Patient Safety and Policy Reform*. Washington, DC: Georgetown University Press; 2004:59–82.
55. Amori G. *Pearls on Disclosure of Adverse Events. Risk Management Pearls*. Chicago, IL: American Society for Healthcare Risk Management; 2006.
56. Quill T, Arnold R, Platt FM. “I wish things were different”: expressing wishes in response to loss, futility, and unrealistic hopes. *Ann Intern Med*. 2001;135:551–555.
57. Berlinger N. *After Harm: Medical Error and the Ethics of Forgiveness*. Baltimore, MD: The Johns Hopkins University Press; 2005.
58. Lazare A. *On Apology*. Oxford: Oxford University Press; 2004.
59. Taft L. On bended knee (with fingers crossed). *DePaul Law Rev*. 2005;55:601–616.
60. Lazare A. Apology in medical practice: an emerging clinical skill. *JAMA*. 2006;296(11):1401–1404.
61. Bosk CL. *Forgive and Remember: Managing Medical Failure*, 2nd ed. Chicago, IL: University of Chicago Press; 2003.
62. Gawande A. *Complications: A Surgeon's Notes on an Imperfect Science*, 1st ed. New York, NY: Metropolitan Books; 2002.
63. Goldberg RM, Kuhn G, Andrew LB, et al. Coping with medical mistakes and errors in judgment. *Ann Emerg Med*. 2002;39(3):287–292.
64. Hilfiker D. Facing our mistakes. *N Engl J Med*. 1984;310(2): 118–122.
65. Newman MC. The emotional impact of mistakes on family physicians. *Arch Fam Med*. 1996;5(2):71–75.
66. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA*. 2006;296(9):1071–1078.
67. Mink OG, Owen KQ, Mink BP. *Developing High-Performance People: The Art of Coaching*. Reading, MA: Addison-Wesley; 1993.
68. Gallagher TH, Quinn R. *What to do With the Unanticipated Outcome: Does Apologizing Make a Difference? How Does Early Resolution Impact Settlement Outcome? Medical Liability and Health Care Law Seminar*. Phoenix, AZ: Defense Research Institute; 2006.



TMIT

3011 North IH-35
Austin, TX 78722
(512) 473-2370

April 30, 2007

Dear Healthcare Leader:

We are delighted to announce that the Journal of Patient Safety has graciously given us permission to distribute copies of recently published articles to you in the interest of helping you adopt the *National Quality Forum Safe Practices for Better Healthcare – 2006 Update*.

The Journal of Patient Safety is dedicated to presenting research advances and field applications in every area of patient safety and we give our highest recommendation for them as a valuable resource toward patient safety from hospital bedside to boardroom. It is in the fulfillment of this mission that they make the gift of these articles to you in your pursuit of your quality journey.

The home page of the Journal of Patient Safety can be accessed at the following link:
<http://www.journalpatientsafety.com> and subscription information can be directly accessed online at:
<http://www.lww.com/product/?1549-8417>.

We want to acknowledge you and your institution for your current efforts in patient safety. We hope you enjoy this article and find it useful in your future work.

Sincerely,

Charles R. Denham, M.D.
Chairman
TMIT