

## REVIEW ARTICLE

## CURRENT CONCEPTS

# Disclosing Harmful Medical Errors to Patients

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**S**TUDIES FROM MORE THAN SIX COUNTRIES<sup>1-7</sup> REPORT A HIGH PREVALENCE of harmful medical errors. Most providers and patients realize that health care services are potentially hazardous and that errors sometimes occur despite the best efforts of people and institutions.<sup>8</sup> Patients expect to be informed promptly when they are injured by care, especially care that has gone wrong.<sup>9</sup> However, a divide between these expectations and actual clinical practice is increasingly evident.<sup>8-12</sup>

Regulators, hospitals, accreditation organizations, and legislators in the United States and other countries are moving to bridge the gap by developing standards, programs, and laws that encourage transparent communication with patients after harmful errors have been made. In the United States, the National Quality Forum (NQF), an organization that develops standards for health care delivery through a process of developing a consensus among stakeholders and experts, recently added standards for disclosure of unanticipated outcomes to its list of safe practices.<sup>13</sup> Several institutions report that the implementation of aggressive disclosure policies has reduced their exposure to malpractice litigation.<sup>14,15</sup> A few states have mandated the disclosure of certain events to patients, and many states have adopted laws that protect apologies for unanticipated outcomes from being used in litigation as evidence of fault on the part of the provider.<sup>16,17</sup> Australia<sup>18</sup> and the United Kingdom<sup>19</sup> have launched ambitious disclosure programs.

Although the push for transparency originated outside the medical profession, there appears to be increasing receptivity to the concept within the profession.<sup>20</sup> Historically, physicians have been conflicted about disclosure. They have wanted to be open with patients but have been fearful of litigation, embarrassed, or unsure of effective disclosure strategies. A professional ethos of discretion or even coverup after harmful errors predominated,<sup>21</sup> but there is emerging evidence of greater openness to disclosure. In a recent survey in Canada and the United States, physicians generally endorsed the importance of disclosing harmful errors to patients.<sup>22</sup> External pressures for disclosure, coupled with some thawing of reluctance within the medical profession, have created an environment that is ripe for change.

## DISCLOSURE STANDARDS

Until recently, virtually no guidance was available to health care professionals regarding how or when to disclose errors; professional societies merely identified disclosure as an ethical obligation.<sup>23-25</sup> In 2001, the Joint Commission on Accreditation of Healthcare Organizations, now called the Joint Commission, issued the first nationwide disclosure standard.<sup>26</sup> This standard requires that patients be informed

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about all outcomes of care, including “unanticipated outcomes.” It was a modest start. The standard did not specify the content of disclosure, nor did it mandate that patients be told when unanticipated outcomes were due to error, partly out of concern that the standard not force admissions of liability.<sup>27</sup> Nonetheless, the Joint Commission’s move was groundbreaking; it heralded a shift from mere endorsement of the importance of disclosure to a requirement with teeth because it was linked to the accreditation status of hospitals.

Health care organizations have responded to the Joint Commission’s standard in varying ways. A 2002 survey of institutional risk managers showed that 36% of institutions had established disclosure policies<sup>28</sup>; by 2005, this fraction had apparently increased to 69%.<sup>29</sup> These policies range from simple restatements of the Joint Commission’s standard to quite detailed disclosure procedures.<sup>30,31</sup> There is little systematic evidence available regarding the impact of these new policies on the practice of disclosure.

Interest in disclosure is also growing outside the United States. In 2003, Australia launched its “Open Disclosure Standard,” which is currently being tested in pilot programs across the country.<sup>18</sup> A similar disclosure initiative, “Being Open,” was promulgated in the United Kingdom; it was accompanied by an ambitious educational campaign.<sup>19</sup> Both programs strongly encourage transparent communication with patients after unanticipated outcomes, and they supply some impressive tools for helping clinicians achieve this goal. However, neither program addresses how disclosure should proceed in circumstances in which the unanticipated outcome was caused by error, other than generally stressing the importance of not admitting liability. Compliance with these standards is not currently mandatory in either country, and to our knowledge, outcomes data have not yet been published.

Last year, disclosure efforts in the United States took important steps forward. In March 2006, the Full Disclosure Working Group of the Harvard Hospitals released a consensus statement emphasizing the importance of disclosing, taking responsibility, apologizing, and discussing the prevention of recurrences.<sup>30</sup> In November 2006, the NQF endorsed a new safe-practice guideline on the disclosure of serious unanticipated outcomes to patients.<sup>13</sup> NQF safe practices are evidence-based practices that, according to

expert opinion and consensus among major quality-of-care organizations such as the Joint Commission, the Institute for Healthcare Improvement, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services, represent essential dimensions of high-quality health care.

The new safe practice is poised to advance disclosure in important ways (Table 1). First, it frames the disclosure of unanticipated outcomes to patients as a core component of high-quality health care. Traditionally, communication with patients about unanticipated outcomes has been handled by risk managers who sought to minimize malpractice claims and often operated independently of the institution’s quality and safety leaders. By presenting disclosure as a patient-safety challenge rather than a risk-management problem, the safe practice emphasizes that effective disclosure is a component of broad system improvement. It also encourages hospitals to integrate their risk-management, patient-safety, and quality programs.

Second, the safe practice recognizes that disclosures are uniquely challenging conversations and calls for appropriate staff preparation. Few clinicians have had training in disclosure, and even for those who have, disclosure conversations occur infrequently enough to make support necessary at the critical moment. The safe practice describes a support system that provides training for health care workers and coaching just before a disclosure. Third, the safe practice outlines the basic content of the disclosure discussion, which includes an expression of regret for unanticipated outcomes and an apology if error played a causal role. Fourth, it encourages the application of performance-improvement tools to the disclosure process, beginning with the tracking of disclosure outcomes.

The potency of the safe-practice guidelines, like that of the Joint Commission’s standard, stems from the presence of an underlying enforcement mechanism. The 29 large health care purchasing coalitions in the Leapfrog Group use the NQF safe practices as standards in their pay-for-performance programs.<sup>32</sup> In addition, more than 1300 hospitals representing more than half of the nation’s hospital beds currently submit information regarding their compliance with these safe practices to the Leapfrog Group, which then publishes the information on the Internet. Thus,

performance scores for disclosure will soon be publicized alongside hospital-specific scores related to each of the other safe practices.<sup>33</sup> This combination of direct financial incentives and visibility to consumers has the potential to catalyze the development of relatively sophisticated disclosure programs.

Skeptics may question whether the NQF's endorsement of disclosure will promote substantive change. Compliance with the safe practices is voluntary, and the submitted data are not externally validated. Moreover, many health care organizations do not participate in NQF or Leapfrog programs. Nonetheless, the NQF standard represents a sensible step forward, given the limited data on effective disclosure strategies. In particular, its link to the pay-for-performance movement may prove to be strategically important.

#### LEGAL DEVELOPMENTS

A flurry of laws concerning disclosure have been proposed or enacted at the state and federal levels. Most prominent nationally was the proposed National Medical Error Disclosure and Compensation (MEDiC) Act of 2005, introduced by Senators Hillary Rodham Clinton (D-NY) and Barack Obama (D-IL).<sup>34</sup> The bill was innovative in casting patient safety and the ills of the medical liability system as twin problems and then proposing enhancement of the disclosure processes as a reform with the potential to address both.<sup>15</sup> The bill emphasized open disclosure of medical errors to patients, apology and early compensation, and a comprehensive analysis of the events. Congress did not pass the MEDiC Act, but its introduction indicates the rising profile of this issue, and similar legislation is likely to appear.

State governments have pursued a greater range and volume of disclosure-related legislation. Seven states — Nevada, Florida, New Jersey, Pennsylvania, Oregon, Vermont, and California — have mandated that institutions disclose serious unanticipated outcomes to patients. Pennsylvania's 2002 law was the first and arguably stands as the sternest.<sup>35</sup> It requires hospitals to notify patients in writing within 7 days after a "serious event." To counteract concerns about litigation exposure, the law includes a provision prohibiting the use of such communications as evidence of liability for the disclosed event. Interest in adopting this type of legal protection has been wide-

**Table 1. Key Elements of the Safe Practice for Disclosing Unanticipated Outcomes to Patients.\***

#### Content to be disclosed to the patient

Provide facts about the event

Presence of error or system failure, if known

Results of event analysis to support informed decision making by the patient

Express regret for unanticipated outcome

Give formal apology if unanticipated outcome caused by error or system failure

#### Institutional requirements

Integrate disclosure, patient-safety, and risk-management activities

Establish disclosure support system

Provide background disclosure education

Ensure that disclosure coaching is available at all times

Provide emotional support for health care workers, administrators, patients, and families

Use performance-improvement tools to track and enhance disclosure

\* Data are from the National Quality Forum.

spread and is not limited to states with disclosure mandates. At least 34 states have adopted "apology laws" that protect specific information conveyed in disclosures, most commonly apologies or other expressions of regret.

There are good reasons to be skeptical about the suitability of disclosure practices for regulatory oversight. With respect to disclosure mandates, enforcement is a formidable challenge. Without comprehensive adverse-event reporting systems and the substantial resources needed to audit charts and contact patients, it is extremely difficult for regulators to monitor the occurrence of disclosures, much less their quality. To our knowledge, none of the states that have enacted mandates have attempted serious enforcement, and only Pennsylvania actually specifies the sanctions for noncompliance.

The content of disclosures is an especially elusive target for regulation. Recent research suggests that a key barrier to disclosure is the uncertainty of health care workers regarding how much information to share with patients after adverse events.<sup>36</sup> Disclosures are complex and subtle discussions and should be tailored to the nature of the event, the clinical context, and the patient-provider relationship; as such, they are not amenable to "cookbook" rules specifying what information to disclose.

In addition, there are holes in the protections that many apology laws provide. Approximately two thirds of the state apology laws protect only

the expression of regret, not accompanying information related to causality (“our care caused your injury”) or fault (“this should not have happened”). In addition, plaintiffs’ attorneys, who must sift through dozens of prospective claims in choosing which ones to pursue, will prize information gained from disclosures, whether or not they are permitted to use that information as evidence in subsequent litigation. Thus, although apology laws are useful policy endorsements of disclosure, they will probably have little influence on disclosure behavior.

The potential for top-down regulation to have a meaningful effect on disclosure conversations is limited. The most successful disclosure initiatives are likely to be those that emerge locally, are driven by an institutional leadership and a workforce committed to transparency, and focus on providing health care workers with the skills needed to conduct these difficult conversations well.

There is considerable speculation and debate about the impact of disclosure on litigation. Patient-safety experts and proponents of disclosure tout its litigation-reducing potential and point to several success stories (which we review below) as well as research linking poor communication with patients’ decisions to sue.<sup>37-39</sup> The actual effect is not known and will not be evident for years. Overall, disclosure probably will not have the chilling effect on litigation that some advocates have claimed. Although disclosure may quell some patients’ interest in litigating, it will ignite interest in others, particularly those who would never have known of their injury in the absence of the disclosure. The net impact of disclosure on the size and cost of litigation ultimately depends on the balance between these two effects.<sup>40</sup>

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#### PROMINENT DISCLOSURE PROGRAMS

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Although many organizations are experimenting with disclosure initiatives, relatively little is known about their effectiveness. In 1999, the Veterans Affairs Hospital in Lexington, Kentucky, issued the first published report of the effect of an open-disclosure program. There were no dramatic changes in the volume of claims or the size of payouts after the hospital adopted the program.<sup>14</sup> Recently, the University of Michigan Health System reported that the cost and frequency of litigation decreased substantially in the 5 years after

the implementation of an open-disclosure program, with annual litigation expenses reduced from \$3 million to \$1 million and the number of claims decreasing by more than 50%.<sup>15</sup> These two initiatives clearly spotlight institutions with a serious commitment to transparency. The data are provocative but difficult to interpret because they rely largely on historical comparison groups and do not attempt to control for other factors that influence litigation rates and outcomes over time. In addition, the generalizability of the results at a single Veterans Affairs hospital and a single academic institution is questionable.

The best-known private-sector disclosure program is the “3Rs” program at COPIC, a liability insurer directed by physicians in Colorado. COPIC insures approximately 6000 physicians and is the largest insurer in Colorado. In 2000, the company developed a program designed to facilitate transparent communication about injuries and expedite compensation in selected circumstances.<sup>41</sup> The program’s key features and outcomes are listed in Table 2.

The 3Rs program links interventions to improve communication with a mechanism that provides patients with up to \$30,000 in compensation for out-of-pocket health care expenses and “loss of time.” The program is “no-fault” in that it does not tie compensation to evidence of fault on the provider’s part. The payments are not made in response to written demands, and patients do not waive their rights to sue, so 3Rs payments are not considered reportable to the National Practitioner Data Bank.

The 3Rs program has handled more than 3000 events; approximately one quarter of the patients involved received payments averaging \$5,400 each. Seven cases in which patients were paid proceeded to litigation. Two cases resulted in additional tort payments. Sixteen 3Rs cases that closed without payments were subsequently litigated; six of the patients secured tort compensation (Lembitz A: personal communication). Although the range of cases handled by the COPIC program is limited, the outcomes suggest that these events can be resolved less adversarially than they might be by means of traditional litigation. In addition, the low average payment per incident reinforces the view that maximum compensation is frequently not the main objective for patients in the wake of medical injury.<sup>42</sup>

Whether COPIC’s outcomes can be general-



ized is also not known. Colorado has enacted broad tort reform that provides a fertile environment for the 3Rs program. COPIC has long fostered a strong culture of patient-safety awareness and early incident reporting among its insured physicians; this culture also may have influenced the program's outcomes. The 3Rs program requires close relationships among COPIC, the Colorado Board of Medical Examiners, and the Colorado Insurance Commissioner; these connections may be difficult to establish elsewhere. Whether initiatives like those in the 3Rs program are feasible outside of Colorado will soon become evident as other insurers such as Medical Mutual in Maryland and West Virginia Mutual Insurance Company embark on similar programs.

#### FUTURE DEVELOPMENTS

Disclosure programs and practices are in their infancy. The fast pace at which they have developed over the past 5 years appears to be set to continue and perhaps even accelerate during the next 5 years. There will be ongoing experimentation with disclosure by health care delivery organizations and some malpractice insurers. This work will yield useful information about the impact of various disclosure approaches on key outcomes such as patient satisfaction and the rates and cost of litigation. Insights gained by institutions that use standard quality-improvement techniques to track, test, and refine their disclosure strategies will be especially valuable. Disclosure activities continue apace outside the United States. Canada's recently formed Canadian Patient Safety Institute, for example, is set to release new national disclosure guidelines, and some Canadian provinces have adopted legislation concerning apology and disclosure.<sup>43</sup>

To many practicing clinicians, the concept of disclosing harmful errors to patients will remain novel and raise concerns. Research is needed to better understand patients' preferences in relation to specific components of the disclosure discussion.<sup>19</sup> Sophisticated investigations involving multicenter controlled trials of training interventions are planned, but the results are several years away. Similarly, evidence of the medical and legal implications of disclosure will remain an open question for the foreseeable future. Although it may be disconcerting to individual practitioners, the absence of such an evidence base will proba-

**Table 2. Key Elements of COPIC's 3Rs Program.**

#### Key features

- Disclosure linked to no-fault compensation for patient's out-of-pocket expenses (up to \$30,000)
- Disclosure training for physicians
- Exclusion criteria: death, clear negligence, attorney involvement, complaint to state board, written demand for payment
- Disclosure coaching for physician and case management for patient provided by 3Rs administrators
- Payments not reportable to National Practitioner Data Bank

#### Key outcomes (January 2000–October 2006)

- 2853 Colorado physicians enrolled
- 3200 events handled in program
- 25% of patients received payments; average, \$5,400 per case
- Seven paid cases subsequently litigated, two of which resulted in tort compensation
- 16 unpaid cases subsequently litigated, 6 of which resulted in tort compensation

bly not halt the widespread implementation of disclosure policies and procedures. The momentum for change is now too great for any stakeholder group to brush aside demands for transparency.

As organizations gain experience with disclosure, the challenges of conducting these conversations and the need for provider education will be increasingly apparent.<sup>44</sup> Eventually, most organizations will probably provide introductory disclosure training for their health care workers and more intensive skills training with the use of techniques such as simulation for clinicians who are likely to be on the frontlines of the disclosure process. Many organizations will also train risk managers or medical directors to be coaches who provide guidance at the time that disclosure is warranted. Other organizations, troubled by the difficulty of disclosures and the risks associated with conducting them poorly, will move the involved clinicians to the periphery and will rely on rapid-response teams to conduct disclosures. It remains to be seen whether the benefits of the use of disclosure "pinch hitters" will outweigh the potential harm to the clinician-patient relationship.

Additional national organizations and specialty societies may follow the NQF's lead and disseminate disclosure standards. Key uncertainties about disclosure practice include the effect of disclosure on patient satisfaction and claiming behavior and the role of apology and acceptance of

responsibility in disclosure. Until research helps to resolve these uncertainties, most disclosure standards will remain advisory and general in nature. This paucity of evidence is also likely to prevent the Joint Commission from issuing more detailed disclosure standards and tying their fulfillment to accreditation. Although additional legislative activity is likely, most of it will be geared toward providing incentives for disclosure or penalizing failures to disclose, and the regulatory impact will be modest. In the short term, voluntary standards coupled with pay-for-performance-type incentives represent the best hope for making substantive improvements in disclosure. Reactions to the NQF's new disclosure standard — in terms of payers' interest in it as a performance measure and how willing they are to use it in commercial decisions — will provide an early field test of this approach.

A transformation in how the medical profession communicates with patients about harmful medical errors has begun. Within a decade, full and frank disclosure of these events to patients is likely to be the norm rather than the exception. Making disclosure of harmful errors to patients an expectation in medicine and giving providers the tools to turn this principle into practice may prove to be critical steps in restoring the public's trust in the honesty and integrity of the health care system.

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