Disclosing Adverse Events to Patients: International Norms and Trends

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Objectives: There is a growing expectation in health systems around the world that patients will be fully informed when adverse events occur. However, current disclosure practices often fall short of this expectation.

Methods: We reviewed trends in policy and practice in 5 countries with extensive experience with adverse event disclosure: the United States, the United Kingdom, Canada, New Zealand, and Australia.

Results: We identified 5 themes that reflect key challenges to disclosure: (1) the challenge of putting policy into large-scale practice, (2) the conflict between patient safety theory and patient expectations, (3) the conflict between legal privilege for quality improvement and open disclosure, (4) the challenge of aligning open disclosure with liability compensation, and (5) the challenge of measurement related to disclosure.

Conclusions: Potential solutions include health worker education coupled with incentives to embed policy into practice, better communication about approaches beyond the punitive, legislation that allows both disclosure to patients and quality improvement protection for institutions, apology protection for providers, comprehensive disclosure programs that include patient compensation, delinking of patient compensation from regulatory scrutiny of disclosing physicians, legal and contractual requirements for disclosure, and better measurement of its occurrence and quality. A longer-term solution involves educating the public and health care workers about patient safety.

Key Words: disclosure, adverse event, malpractice, risk management, transparency

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Different terms are used worldwide to refer to the unintended harm from health care delivery. The reasons for such harm include the inherent risks of investigations and treatments (the "recognized complications"), failures related to the systems and processes of care, and issues of provider performance including errors. The commonly used term *adverse event* is often used to describe an unintended harm to the patient that is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition. An adverse event is not synonymous with medical (provider) error. The International Classification for Patient Safety, being developed by the World Health Organization, promotes the use of the term *harmful patient safety incident* to describe harm from system and provider failures. This article focuses on disclosure of harmful patient safety incidents to patients, including those caused by errors.

The disclosure of harmful patient safety incidents to those affected by them has long been recognized as an imperative by professional organizations and ethicists.[1] Policy makers, health care managers, and clinicians have been talking seriously about disclosure for more than a decade, and there is a growing expectation in many health systems around the world that patients will be fully informed when safety incidents occur.[2] However, it is apparent that current practices still fall short of this expectation. Data from several countries with well-developed disclosure policies suggest that, despite theoretical support for disclosure, as few as one-third of patients are told about harmful errors in their care.[3–9]

METHODS

The impetus for this article was an international conference that the authors conducted in London on November 19 to 20, 2009, coincident with the relaunch by the National Patient Safety Agency (NPSA) of the National Health Service (NHS) "Being Open" policy. The key goals of the conference were to review current trends in disclosure practices in the United States, the United Kingdom, Canada, New Zealand, and Australia, the countries with the most highly developed disclosure policies and programs; to identify factors slowing progress in open disclosure; and to recommend directions for future development. For the United Kingdom, there was participation by virtually all major stakeholder groups including the NHS, the NPSA, Healthcare Trusts, practicing clinicians, patients and patient advocates, medical defense societies, and patient safety researchers.

After the meeting, members of the group continued to collaborate, surveying the literature and meeting again in 2010 and 2013 to complete this article on barriers to open disclosure and potential solutions. The discussions from both large and small group sessions of the London meeting were audiotaped and transcribed verbatim, and the transcripts were reviewed by 2 of the authors (A.W.W., T.H.G.). We used nominal grouping methods to identify 5 emergent themes that represent barriers to open disclosure: (1) the challenge of putting policy into practice, (2) the conflict between patient safety theory and the reality of patient expectations, (3) the conflict between legal privilege for quality improvement and open disclosure, (4) the unexpected challenges of aligning open disclosure with appropriate liability compensation, and (5) the gap in measurement of the occurrence and quality of disclosure discussions. Examples of published reports and experience from the countries represented at the meeting illustrate the challenges and suggest possible ways forward.

RESULTS

The history of the implementation of the UK Being Open policy provides an example of the first theme.

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Theme 1—Putting Good Policy Into Practice: The Challenges of Large-Scale Implementation

Some of the challenges of implementing disclosure policies and demonstrating the desired outcomes can be illustrated by the experiences of England and Wales, where a model national policy, Being Open, was implemented in 2005. The Being Open policy states that "All NHS organizations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and to provide required support."[10] This detailed policy, embedded within the openness and learning culture that exists in the NHS, secured the support and commitment of key NHS stakeholders, including the NHS Litigation Authority, and directs its recommendations to ensure effective alignment between these major actors.

However, although the policy achieved endorsement and alignment at the highest levels of the health service, the engagement and support needed to implement Being Open were not adequately transmitted to those on the front line. Despite guidelines in place on how to create a patient safety culture, an eLearning tool, and Being Open training workshops (the most extensive of which included opportunities to practice disclosure skills with actors), uptake was slow—perhaps because insufficient numbers received the training and perhaps because of the lack of enforcement and potential sanctions for noncompliance. An evaluation 2 years after launching the policy found that 36% of physicians held unfavorable attitudes toward the policy,[11] and a report to the National Patient Safety Forum the following year, although highlighting specific successes, identified barriers to implementation at multiple levels, including fear of blame and judgment, clinicians' lack of confidence and skill in holding discussions, lack of support for staff, and the feeling that it was not safe to be open.[12]

Insufficient processes to evaluate attitudes, progress, and outcomes meant that the Department of Health was not initially aware of these issues. However, in response to the reports, in 2009, the NPSA made recommendations to address the identified barriers,[13] including publicly committing to the policy at board and senior management level, ensuring that named leaders were responsible at board and executive level, identifying senior clinical counselors to support fellow health care professionals involved in safety incidents and Being Open discussions, increasing training opportunities for staff, raising awareness among staff and patients, and strengthening support for patients through staff training in information skills and processes. In 2010, the government imposed a new contractual obligation for NHS employees "to be open and transparent in admitting mistakes."[14] Still, to date, success has been incomplete. Although nearly all NHS Trusts report being familiar with the guidance, and most report implementing for the majority of safety incidents, most of these discussions take place only 3 to 6 months after an investigation is completed.[15]

A similar contractual approach seems to have had positive effects on uptake of the Canadian Disclosure Guidelines,[16,17] published by the Canadian Patient Safety Institute in 2008 and revised in 2011. The strong support of Accreditation Canada and the Canadian Medical Protective Association (CMPA) has resulted in the guidelines being widely adopted by organizations to meet their accreditation requirements, including implementation of a formal and transparent policy and process for disclosure of harm from health care delivery, with support mechanisms for patients, family, and health care providers. Concurrently, the CMPA has worked to disseminate the guidelines to physicians effectively, including several publications on disclosure, training sessions in all of the provinces and territories, and timely advice for all physicians on the subject. Based on the Canadian Disclosure Guidelines, the CMPA booklet *Communicating With Your Patient About Harm: Disclosure of Adverse Events*[18] is used widely. It provides practical suggestions on how to meet the clinical, information, and emotional needs of patients and families that have experienced unexpected clinical outcomes. Early disclosure and ongoing discussions are suggested, including advice on who should be involved, apology, and a summary checklist of the important steps.[19] Disclosure training is increasingly taught in medical schools and residency training programs in Canada. The CMPA Good Practices Guide, published in 2012, contains relevant educational resources for trainees and teachers.[20]

However, to date, there has been no formal evaluation of the impact of the Canadian Disclosure Guidelines. Most health care institutions would likely state that they have made progress in disclosure during the last several years. As one indicator, calls to the CMPA for advice have increased.

Theme 2—The Blame Game: Balancing Patient Safety Theory With Patient Expectations

Blame and punishment of an identified "villain" are common responses to safety incidents.[4,21] In surveys, patients asked about the appropriate response to a hypothetical fatal medication error often endorse punishment. Sixty-nine percent of respondents to a large survey about medical error thought that the physician should be sued for malpractice, and 50% thought that the physician's license should be suspended.[3] Public Citizen, a watchdog group in the United States, regularly publishes rankings of state medical boards based on the number of serious disciplinary actions they take per 1000 physicians and laments that some states punish fewer physicians than others (http://www.citizen.org/hrg1949). The blame reflex is also perpetuated by the media's sensational coverage of medical "errors," which tends to emphasize the failings of individuals over underlying systems breakdowns, reinforcing the existing medical culture of trepidation around the disclosure of medical errors.

Perhaps part of the reason that many are drawn to this simplistic punitive paradigm is that it implies that the organization has taken the incident seriously and has been held accountable. People may be less aware or appreciative of alternative—and potentially more effective—responses to prevent a recurrence that focus instead around actions to improve systems. During the past decade, health care organizations have moved away from the anachronistic "blame culture" first toward a "blame-free culture" and subsequently to a more practical and necessary "fair blame culture" or "just culture" that ensures accountability in modern health services.[22] Taking further steps to establish a dialog between the public and health care workers about the nature of patient safety incidents, health care quality, and complexity could help frame incidents in terms of systems rather than solitary errors. Expanding the role for patients in quality assessment and peer review should build their confidence in systems for identifying and remediating physicians who are providing unsafe medical care[23] and better engage the public in just culture. This would likely help to reduce scapegoating, enable better quality investigations, and aid understanding—and consequently expand the repertoire of publicly satisfactory organizational responses beyond the punitive to involve more productive responses to complex incidents.

It is possible that changing terminology could help to shift the attitudes and expectations of both patients and providers toward a more sophisticated understanding of patient safety. In 2008, Canada adopted use of the terms *patient safety incident* and *harmful incident* in preference to *error*.[16,17,24] This approach reflects the reality that harm is usually not attributable to error by a single health care provider. The Canadians believe that the term

error can be misleading, implying that the care provided was substandard or negligent. Their updated terminology promotes awareness that a combination of factors usually contributes to patient safety incidents, of which individual provider error may be just one. In addition, those experienced in conducting and teaching disclosure in Canada believe that conceptualizing harm caused to patients as "error" delays conversations because of internal debate among clinicians about the reasons for harm and culpability and the flawed imperative to distill events into the one conclusive "causative error." Conceptualizing patient harm as "incidents," however, may better facilitate prompt and more open and ongoing communication with patients and their families. Moving toward terminology that is less likely to engender blame could help calibrate expectations of both patients and clinicians and facilitate more timely disclosure and helpful resolution.

It was in this spirit that the United Kingdom chose to name their harmful patient safety incident disclosure policy "Being Open."[13] The terminology implies an ongoing process of honest communication with patients both before (i.e., informed consent) and after adverse events. The Being Open terminology also implies increased communication within health care organizations. Following suit, in 2011, the Canadian Patient Safety Institute also replaced the term *disclosure* with *being open* in their materials, and the U.S. Agency for Healthcare Research and Quality has replaced *disclosure and resolution* with *communication and resolution*.[25]

Theme 3—The Confidentiality Conflict: Quality Improvement and Legal Privilege Versus Open Disclosure

Ironically, processes created to improve patient safety culture can perversely restrict open disclosure to patients. The imperative to balance quality improvement and legal privilege with effective disclosure practices is an important factor in both lack of disclosure and in delays in communicating with patients about adverse events.

A patient safety culture maximizes reporting and learning from patient safety incidents.[22,26] A prerequisite is the existence of a "safe space" that encourages providers to communicate with their institutions about incidents and enables institutions to analyze these events thoroughly without fear of being beset by legal action. There are various tactics used to achieve that safe space. Anonymity and the principle of a "blame-free" work environment have been tried.[27] However, research suggests that anonymity and no blame may obscure the connection between individuals' actions and outcomes, producing an incomplete story and supporting secrecy that inhibits the intended learning and quality improvement.[28,29]

Another more widely used method is protecting the information revealed during investigations from being used as evidence in a malpractice suit. In many countries, information gathered for a root cause analysis after an adverse event is considered legally protected and not admissible as evidence in court. Laws and regulations like these are intended to draw lessons from patient safety incidents and for objective quality improvement recommendations to be made and implemented. In the United States, when incidents are being analyzed by Patient Safety Organizations, there are penalties for sharing pertinent information with anyone outside the analysis process including the involved patient.[30]

Quality improvement protection legislation in Canada reflects the public policy objective of encouraging participation by providers. To varying degrees, legislation in each province or territory protects quality improvement information deliberations, records, and documents from being disclosed in legal proceedings. New facts discovered during the review and any measures being implemented to limit the likelihood of reoccurrence of similar events are intended to be provided to the patient.

To permit both quality improvement and timely and honest disclosure to patients, U.S. apology laws would need to be modified to allow quality improvement protections to remain intact even after disclosure to the patient. One solution would be to state explicitly in statutes that sharing information with patients that is derived from formally protected quality improvement (QI) investigations does not void that QI privilege. A second would be to remove the requirement for name reporting for incidents that are disclosed, as discussed in the next section.

Theme 4—Waiting for the Other Shoe to Drop: Linking Open Disclosure and Liability Compensation

There is concern internationally about the impact that increasing disclosure may have on litigation. This is a complex issue, with insufficient data and compelling arguments on both sides of the debate.[31] However, once disclosure has been made to a patient, even if there is no malpractice suit, the patient may have financial needs to be addressed.[32] The imperative to compensate patients for harm they have sustained from negligent patient safety incidents is a universal challenge, with considerable international diversity in approaches. This diversity reflects variables such as the presence or absence of a centralized health authority, the way in which health care is funded, and litigation laws and culture in different settings.

Lessons can be learned from New Zealand, which, along with the Nordic countries, has moved away from negligence-based strategies for compensating patients who have been harmed by their medical care.[33] The Accident Compensation Corporation (ACC), established in 1974, provides no-fault compensation for all personal injuries, including those incurred in workplaces, on the roads, at home, and during health care. Any "treatment injury" that is causally related to the process of health care is eligible for liability compensation, with the exception of injuries that are a "necessary part of treatment" or an "ordinary consequence of treatment." In exchange, medical malpractice litigation is essentially barred. Importantly, the "no-fault" approach does not equate to "no responsibility" because the ACC scheme is coupled with an active complaints resolution system as well as robust processes for addressing health, conduct, and competence concerns through health practitioner registration boards.[34–38]

A legal "duty of candor" has been recognized in New Zealand since 2002.[36] All hospitals have open disclosure policies, and health practitioners regularly support injured patients to obtain the follow-up care and compensation they need through the no-fault ACC scheme. Nevertheless, cultural barriers to openness and honesty persist—the availability of no-fault compensation removes the risk for litigation, but providers remain fearful of the potential for adverse publicity, disciplinary processes, and reputational damage after disclosure.[39] A similar duty of candor was introduced in the United Kingdom in 2013.

A tort-based legal environment may complicate the repercussions of open disclosure, but it also provides opportunities to innovate. Malpractice concerns in the United States exert a disproportionate influence on policy and practice, but most industrialized countries face similar legal climates.[40] The U.S. system is characterized by the lack of a centralized governmental health authority; devolution of regulation to individual states; complex malpractice climate; and expectations/requirements of disclosure from national regulatory bodies,[41] working groups,[42] and quality organizations[43,44] that are subject to local interpretation.[43,45] For these reasons, the United States is a useful microcosm for the development and implementation of diverse and innovative disclosure and offer programs that provide liability compensation options beyond the

courtroom, particularly at the level of individual institutions. U. S. disclosure programs such as that of the Veterans Affairs Hospital in Kentucky,[46] the University of Michigan,[47] Stanford Medical Center,[48] and COPIC insurance in Colorado[2] provide models for potential adaptation for other countries and settings. A common feature of these programs is the goal of rapid resolution and some degree of compensation or reimbursement for expenses of injured patients.

However, even these programs have encountered challenges. One key issue has been a lack of alignment between local disclosure and offer programs and the state and national bodies to which they report patient safety incidents and related awards and settlements to patients. This creates disincentives for organizations to participate in disclosure and offer programs. For example, cases of paid liability compensation are generally reported to and published by State Medical Boards and the U.S. National Practitioner Data Bank (NPDB). These findings are viewable by health care organizations and insurance companies, with the potential for reputational damage and increases in malpractice premiums.

The NPDB reporting can create problems when a physician is applying for hospital privileges and credentialing. Reporting to state boards often leads to investigation and possible action against the physician's medical licensure. The initial purpose of the NPDB was to track problem clinicians. However, it does not currently differentiate its treatment of cases of compensation arising after disclosure and offer programs from those arising from litigation. This is problematic because disclosure and offer programs are themselves intended to promote liability compensation as appropriate, and conclusions cannot be accurately drawn. More frequent compensation of patients could lead to more regulatory investigation of physicians, so grouping the 2 types of liability compensation together risks penalizing well-intentioned organizations and physicians with effective disclosure and offer systems. New and more sensitive indicators to identify providers whose skills are inadequate—and sharing this information with appropriate regulators—are needed to ensure that the public is protected.

Disclosure and offer programs cannot be successful if they trigger increased regulatory scrutiny. Because liability compensation may flow from disclosure, linked processes are needed such that adopters are not penalized. Current processes that were not designed to incentivize open disclosure may need to be modified to reduce barriers to open disclosure. One solution might be to separate cases in which providers or institutions are found culpable via litigation from cases in which a disclosure and offer program is in place.[49] It might also help if participation in disclosure and offer programs was recognized by regulators as a mitigating factor, although it would be undesirable to create the impression that apology is a replacement for accountability.

Theme 5—How Are We Doing? The Challenge of Measurement

When a harmful patient safety incident occurs, patients want to know what went wrong and why.[4,50–52] Open, timely discussions with patients and families can also be a key step toward mutual understanding, acceptance, and forgiveness.[53] Australian studies have demonstrated that disclosing only generalities to patients and avoiding open discussion about why specific clinicians acted or spoke as they did not only cause patients anger and frustration but may induce them to file complaints, take legal action, or go to the media.[7,54] Such discussions should factor in the clinical facts known at the time, the circumstances, and context of care, including the resources available.

These issues are just beginning to be recognized widely and addressed. However, a fundamental problem is that little is actually known about current disclosure practice and outcomes. There is a limited supply of measures available to evaluate the quality of disclosures. Even in countries that have made major investments in developing and disseminating disclosure training programs, there is little quantitative information available about how disclosures are currently taking place or about patients' or health care workers' assessment of the quality of actual disclosures. Developing and implementing systematic strategies for measuring and tracking the effectiveness of disclosures will be needed to apply performance improvement tools to the disclosure process. The COPIC program in the United States provides a successful example of how disclosures can be logged and tracked, but this program applies only to smaller cases without serious adverse outcomes.[2] On a larger scale, the Joint Commission already requires that health care organizations have disclosure policies. A further step would be to require organizations to track the occurrence and quality of disclosures.

As noted above, the United Kingdom, after an inquiry at Stafford Hospital, is in process to adopt a "duty of candor" requirement that makes it a legal requirement to offer explanations and apologies to patients/families to whom harm has been caused.[55] This resembles the New Zealand statutes and U.S. State apology laws in 35 states that require disclosure of unanticipated injuries

TABLE 1. Themes and Proposed Solutions

Theme	Proposed Solutions
Putting good policy into practice: the challenges of large-scale implementation	Create contractual obligation for disclosure Impose duty of candor legislation
The blame game: balancing patient safety theory with patient expectations	Replace the terms *error* with *incident* and *disclosure* with *being open* Educate the public and health care workers about the nature of patient safety incidents
The confidentiality conflict: quality improvement and legal privilege versus open disclosure	Strengthen disclosure laws to explicitly protect disclosure discussions from discovery
What next after disclosing (waiting for the other shoe to drop): linking open disclosure and compensation as appropriate	Do not punish physicians and institutions for D&O programs D&O programs with separation of litigated judgment versus D&O, recognition of D&O as a mitigating factor
The challenge of measurement: little is actually known about current disclosure practice and outcomes	Develop better measurement of disclosure occurrence and quality to ensure that the rights and needs of patients are acknowledged and met

D&O, disclosure and offer.

to patients. Hospitals are now determining how to measure that patients have been offered apologies and explanations. Common metrics need to be developed to allow monitoring and evaluation of performance, identification of best practices and opportunities for quality improvement, and accountability to regulatory bodies and the public.

Developing disclosure policies and educational programs are important first steps in closing the gap between the expectation that harmful patient safety incidents will be disclosed to patients and the current practice. However, these too need to be evaluated. Better measurements of disclosure occurrence and quality are needed to ensure that the rights and needs of patients are acknowledged and met.

DISCUSSION

Important progress has been made toward creating a health care culture in which patients can expect to be informed openly, promptly, and compassionately when they are injured by their health care. However, the journey toward actually informing patients after these events is still in its early stages. In the United Kingdom, for instance, it seems that, despite clearly stated principles and expected actions and a high level of awareness of the policy among clinicians, there has been incomplete implementation of its patient safety proposals at the front lines.[15] Examination of this and other disclosure programs in different countries reveals common threads, highlighting some key developments and areas for future development and action (Table 1).

There is a need to address unnecessary legal and policy barriers to open disclosure. More research is needed to describe the actual effects of open disclosure on claiming behavior. Common lessons can be learned from evaluating the effectiveness of open disclosure programs. Greater efforts are needed to reconcile patient safety theory with patient and public expectations. All of this information can be helpful to identifying barriers and implementing effective disclosure strategies. Strengthening and aligning patient safety culture among disciplines and organizations will be needed to consistently deliver on these expectations.

Some of the legal and disciplinary barriers to disclosure are created from within health care itself, rather than imposed by the external malpractice climate. Patients and health professionals want to have open discussions about what went wrong and why it went wrong. However, the privilege provided by confidentiality laws designed to support quality improvement can be threatened by disclosure to the patient and vice versa. Apology laws need to be modified to clarify that quality improvement protections remain intact even after disclosure to the patient. For example, laws might include disclosure and offer programs, such as those offered at the University of Michigan, the University of Illinois Chicago, and Stanford Medical Center,[33,56–58] coupled with laws making disclosures privileged and removing the requirement for name reporting for incidents that are disclosed.

Limitations

This article arose out of discussions at a conference of experts from 5 countries, supplemented by a literature review and follow-up discussions. There are inherent limitations to this methodology related to both the selection of experts and the selection of countries included in the review. Disclosure policies and programs are most highly developed in the Commonwealth countries, and some of the findings may not be generalizable to countries other than those included. It is also possible that there may be differences in the experience within regions and subcultures in the countries studied. Future investigations should consider activities in other countries and cultures around the globe.

CONCLUSIONS

A comprehensive solution could be imagined that would simultaneously address the key issues and concerns reviewed above. For example, such scheme might include (1) a national fund through which iatrogenic disability and harm can be compensated without needing to litigate (as in New Zealand/Scandinavia); (2) mandatory disclosure (duty of candor) tied to (*a*) a clear apology law that protects all aspects of the disclosure discussion and (*b*) a provision for mediation (outside the legal process) to cover cases in which disclosure fails to meet stakeholders' expectations; (3) a requirement for organizations to include interested patients in incident/outcome reporting, incident investigation, and clinical improvement initiatives (original patient, representative, or any consumer); and (4) a national, public clinician registry (as in Australia) that is protected from legal action in which information about all practicing clinicians is brought together and in which details about their certification, specialization, achievements, as well as incident disclosures and disciplinary actions can be accessed.

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