



## **Commission of Inquiry on Hormone Receptor Testing**

**DISCLOSING UNANTICIPATED OUTCOMES TO PATIENTS:  
INTERNATIONAL TRENDS AND NORMS**

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## Introduction

In countries around the world there is a growing expectation that patients will be fully informed about unanticipated outcomes in their care, especially those unanticipated outcomes that were due to medical errors.(T. H. Gallagher, Studdert, & Levinson, 2007) However, it is also increasingly apparent that, at present, the practice of disclosure falls far short of meeting this expectation. Multiple studies in several countries suggest that as few as one-third of patients are told about harmful errors in their care.(Blendon et al., 2002; T. H. Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003; Schoen et al., 2005; The Kaiser Family Foundation/Agency for Healthcare Research & Quality/Harvard School of Public Health) These failed disclosures represent a fundamental breach in the provision of patient-centered care, impairing patients' decision making, their trust, and satisfaction.(Mazor et al., 2006) Defective disclosures may also make it more likely that patients will file a medical malpractice claim.(A. Kachalia, Shojania, Hofer, Piotrowski, & Saint, 2003) Finally, breakdowns in transparency generally are considered important impediments to improving the quality of healthcare and reducing harmful errors.(T. H. Gallagher, Denham C, Leape L, Amori G, Levinson W, 2007)

Surveying recent disclosure developments around the world reveals a wide range of activities and programs being undertaken to promote more effective disclosure of unanticipated outcomes to patients. Such programs are being implemented in a variety of healthcare environments, ranging from the United States, where the medical malpractice system is thought to be "in crisis" and healthcare is delivered in a

fragmented system when many lack health insurance, to the United Kingdom and Canada, where medical malpractice concerns are somewhat less problematic and healthcare is available to all citizens, to New Zealand, where a nearly no-fault medical malpractice system exists. Yet despite these different healthcare delivery and malpractice environments, the disclosure programs emerging in these countries are much more similar than different. Furthermore, almost no systematic data exists regarding the outcomes of these disclosure programs. Nonetheless, reviewing how disclosure practices are evolving in these different countries can help identify important emerging trends and suggest directions for future developments.

### United States

The United States is a useful starting point when considering international norms and developments in disclosure, as the factors that encourage and inhibit disclosure in the United States are also present to a greater or lesser degree in other countries. The absence of a powerful centralized governmental health authority in the U.S. allows considerable innovation in disclosure efforts, particularly at the level of individual institutions. However, the malpractice climate in the United States, a frequently cited barrier to disclosure, is as challenging as it is in any industrialized country around the world.(Studdert, Mello, & Brennan, 2004) Thus, there is good reason to believe that disclosure programs that have taken root in the United States could serve as successful models for other countries to consider.

The need to disclose unanticipated outcomes to patients has long been recognized as an ethical imperative by professional organizations and ethicists. In 2001, the United States Joint Commission, the body responsible for accrediting hospitals and healthcare organizations, added disclosure to its list of hospital accreditation requirements. (The Joint Commission, 2007) The requirement itself was deceptively simple, requiring that “patients be informed about all outcomes of care, including unanticipated outcomes.” U.S. hospitals took up this Joint Commission standard in a variety of ways, some adopting policies that merely mirrored the Joint Commission statement, and others adopting very detailed disclosure policies and procedures. (T. Gallagher et al., 2006; Lamb, Studdert, Bohmer, Berwick, & Brennan, 2003)

The evolution of disclosure practices in the United States continued to occur at mostly the institutional level until 2006, when the Harvard Full Disclosure Working Group issued its report, “When Things Go Wrong.” (The Full Disclosure Working Group, 2006) This report was noteworthy in providing a considerably more detailed set of guidance regarding when and how to disclose unanticipated outcomes to patients. Particularly significant was the policy’s emphasis on accepting responsibility for unanticipated outcomes, as well as the importance of offering a full apology.

Shortly thereafter, the National Quality Forum (NQF), a U.S. organization that articulates consensus standards for high quality healthcare, added disclosure of unanticipated outcomes to its list of thirty “safe practices.” (T. H. Gallagher, Denham C, Leape L, Amori G, Levinson W, 2007; National Quality Forum: Safe Practices for Better

Healthcare", 2007) This safe practice helped advance disclosure in a number of ways. The Joint Commission standard made no mention of whether patients needed to be informed if an unanticipated outcome was preventable, i.e. whether it was due to a medical error. The NQF safe practice, however, emphasized the importance of informing patients of "the facts" regarding the outcome including its preventability. Also innovative was the safe practice's recognition of the challenges of disclosure and its call for hospitals and healthcare organizations to develop "disclosure support systems," including disclosure education for healthcare workers, the availability of around the clock disclosure coaches, and emotional support for affected patients, their families, and healthcare professionals. The safe practice also recognized the importance of informing patients about plans to prevent recurrences "in sufficient detail to support informed decision-making." Finally, the safe practice called on institutions to begin studying the outcomes of the disclosure process and to use performance improvement tools as a means of tracking and improving disclosure outcomes.

The NQF safe practices are important not only because they represent consensus standards, but also because they are used in public reporting and pay-for-performance programs. Thus, consumers can currently visit the Leapfrog group's web site and see hospital specific scores on each of the thirty safe practices for the over 1,300 hospitals that voluntarily report this data.(Leapfrog Group, 2007) This public reporting of institution-specific disclosure practices is a unique strategy for encouraging institutions to improve their disclosure performance.

In addition to these national policies and consensus statements, important disclosure programs have been developing at the local level in the U.S. In 1999, the Veterans Affairs (VA) Hospital in Lexington Kentucky published a paper describing their new policy of full disclosure of harmful errors to patients and its impact on their malpractice claims experience.(Kraman & Hamm, 1999) The Lexington VA program was notable not only for its endorsement of full disclosure, but also for explicitly assisting patients in seeking compensation for their injuries. The Lexington VA's claims experience did not appear dramatically different compared with similar VA hospitals despite implementation of this open disclosure policy. More recently, the University of Michigan reported that its program of open disclosure and early offers of compensation had significantly reduced its malpractice expenses and shortened the time to resolution of malpractice claims.(Clinton & Obama, 2006)

Another well-known U.S. disclosure effort is the "3Rs" program that was developed at COPIC, a large Colorado malpractice insurance company.(*COPIC Insurance Company. COPIC's 3R's program: a success story*, 2005) The 3Rs program, as with the University of Michigan program, integrates disclosure with early offers of compensation.(T. H. Gallagher, Studdert, & Levinson, 2007) However, there are important differences between the Michigan and COPIC programs. While the University of Michigan program handles all events regardless of their severity or whether negligence was involved, the COPIC 3Rs program excludes events if they involve patient death, the patient has retained an attorney, the patient has made a written demand for payment, the patient has filed a formal complaint with the Board of Medical

Examiners, or if the events were due to gross negligence. The 3Rs program is a no-fault program, meaning that no effort is undertaken to determine whether the unanticipated outcome was due to a medical error. COPIC encourages physicians to disclose all unanticipated outcomes to patients. In addition, for those events that meet the 3Rs criteria, patients can receive payments for out-of-pocket expenses and lost time up to \$30,000.

To date, the program has handled over 3,000 events in the 3Rs program. Two-thirds of these events have been closed with no payment to the patient. Of those events where payment was made, the average payment was only \$5,000. No 3Rs event has proceeded to a formal jury trial. For this selected group of events, COPIC's approach of open disclosure and early offers of compensation appears to be a way to resolve these events less adversarially and more effectively than could be accomplished through the traditional torts system.

Important developments have also been taking place at the level of U.S. state legislatures. (Cohen, 2000; Sparkman, 2005; Wei, 2007) Physicians' and healthcare institutions' fear that disclosure might precipitate litigation is often cited as an important barrier to disclosure. In response, thirty-six U.S. states have adopted "apology" laws that provide varying degrees of legal protection for these statements. At a minimum, all of these laws protect "an expression of regret" from being used in court as an admission of liability. Six U.S. states also protect "an explanation" of the event. Four states provide protection for the entire disclosure and apology, including an admission of

liability. Because many of these laws only provide limited legal protection, it is unclear whether they will have a significant impact on physicians' or healthcare institutions' fear of disclosure triggering a lawsuit.

In addition to these apology laws, eight U.S. states have adopted legislation requiring disclosure. The disclosure burden is generally placed on the healthcare institution rather than on the individual healthcare workers. Of these states, Pennsylvania and Oregon require that the disclosure be made in writing. The content of what needs to be disclosed is not specified in any of these laws, and it is unclear whether and how states intend to enforce these disclosure mandates.

There is very little systematic evidence regarding the impact of these disclosure programs in the U.S., other than the anecdotal evidence cited above. In particular, there is no prospective evidence regarding the effectiveness of any specific disclosure strategy.(T.H. Gallagher & Lucas, 2005) This has hampered efforts to issue disclosure guidelines that are truly evidence-based. Furthermore, while many U.S. physicians continue to cite the malpractice environment as a major impediment to disclosure, recent research suggests that the external malpractice environment may have less influence on physicians' disclosure decisions than previously thought. For example, one study compared the disclosure attitudes and experiences of physicians in the U.S. and in Canada, a country where physicians are significantly less likely to be sued and pay much lower malpractice insurance premiums than in the U.S.(Baker et al., 2004; Coyte, Dewees, & Trebilcock, 1991; Picard & Robertson, 1996) The U.S. and Canadian

physicians' disclosure attitudes and experiences were much more similar than different in this study, suggesting that these attitudes may be more firmly rooted in the culture of medicine than in the external environment itself.(T. H. Gallagher et al., 2006) This suggests that making substantive changes in disclosure practices will involve large-scale culture change within the healthcare profession, a process which will occur over a long time period and require considerable energy and resources.

### Australia

Australia has also taken a leadership role internationally in the development and dissemination of disclosure standards. In 2003, the Open Disclosure Standard was published and endorsed by the Australian Health Minister's conference.(Australian Council for Safety and Quality in Health Care, 2003; Grace & Queau, 2002) The goal of the standard was to encourage more open and effective communication with patients following adverse events. The standard calls for patients to be informed of the known facts about the event, consequences of the event, the steps being taken to manage the event and prevent recurrences, and to receive an expression of regret. Parts of this information are typically conveyed in an initial conversation with the patient, while the remainder is discussed with the patient in a follow up discussion after an analysis is completed. The standard encourages that the initial conversation be led by the most senior healthcare professional responsible for the clinical care of the patient, though it also allows for a "substitute person" who is well trained in disclosure to conduct the conversation.

This standard divides events into “low level” and “high level” events based on their severity, and calls for more robust disclosure processes for the higher level events. Low level events involve adverse events where there is no permanent injury or increased level of care required, whereas high level events involve those with death or major permanent loss of function, the need for surgical intervention, those transferred to a higher level of care, or a major change in clinical management. This standard was accompanied by an impressive package of educational material and workshops throughout the country.

The Open Disclosure Standard sought to strike a balance between promoting transparency while recognizing the potential medico-legal impact of this policy. The Open Disclosure Standard emphasizes the importance of not admitting liability to the patient. While the Open Disclosure Standard encourages “an expression of regret”, it does not sanction a full apology; in fact, the word “apology” does not appear anywhere in the standard.

After the standard was endorsed in 2003, individual states within Australia were responsible for drafting local policies that were consistent with the standard and the specific state laws. (State government of Victoria, 2007) Over time, areas of tension between state laws and elements of the open disclosure process have become apparent. For example, in New South Whales the results of root cause analysis information is considered legally protected, complicating disclosure to the patient after the root cause analysis process has started. In addition, around the same time that the

Open Disclosure Standard was being disseminated, a highly publicized scholarly paper suggested that the disclosure process might generate more malpractice claims, not fewer. (Studdert, Mello, Gawande, Brennan, & Wang, 2007) Using malpractice claims data and computer modeling, the authors concluded that open disclosure was more likely to prompt a patient to sue than it was to prevent a patient from suing. The paper heightened concern amongst some Australian hospitals about unanticipated consequences of the open disclosure process.(Koh & Alcock, 2007; Madden & Cockburn, 2007; Wakefield, Jorm, & Ryan, 2007)

Across the country of Australia, an extensive pilot project has been underway to evaluate the initial implementation of the Open Disclosure Standard. Formal reports from this pilot are not yet available but will be published soon. Informal conversations with the authors of these reports suggest that the initial implementation of this standard has been a qualified success. As was found in research amongst U.S. physicians, support among healthcare workers in Australia for the open disclosure process was widespread but many unanswered questions about implementation remain. For example, while the standard calls for disclosure conversations to be led primarily by the patient's clinician, in practice many of the initial and follow up disclosure conversations are led by healthcare workers and administrators trained in the Open Disclosure process but who have not cared for the patient. Relying on disclosure "experts" to conduct these delicate conversations makes sense in many respects. Few clinicians have had disclosure training, and even for those who have, disclosure conversations are relatively infrequent events for any individual clinician. Nonetheless, patients may

prefer to have the event disclosed directly by their clinician.(T. H. Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003; Mazor et al., 2004) In addition, balancing the time needed to conduct a thorough investigation of the event with the patient's desire to receive information promptly proved a challenge in many cases.

### The United Kingdom

Australia's publication of its Open Disclosure Standard was influential in the United Kingdom's development of its disclosure policy. In 2003 the Department of Health published the document *Making Amends*, which reported results from interviews with 400 people who had been harmed as a result of their healthcare treatment.(National Patient Safety Agency, 2003) A prominent finding from this report was that patients valued an apology, as well as an investigation and emotional support, after a harmful healthcare event.

In 2006 the National Patient Safety Agency published its safer practice notice introducing their Being Open policy.("National Patient Safety Agency: (UK): Safer practice notice: Being open when patients are harmed. 2005") The Being Open policy emphasizes the importance of being open when patients are harmed by their healthcare. In contrast to Australia's Open Disclosure project, the Being Open policy puts an apology at the centerpiece of the disclosure process. The policy notes "patients and/or their carers should receive an apology after the patient safety incident has occurred and staff should feel able to apologize on the spot. Saying sorry is not an

admission of liability and it is the right thing to do. The patients have a right to expect openness in their healthcare.”

The safer practice notice requires that all National Health Service organizations providing patient care in England and Wales should:

- 1) Develop a local policy, based on the NPSA’s Being Open policy but adapted to suit local requirements, by June 2006.
- 2) Raise awareness of local policy among healthcare staff and provide them with the appropriate information and support.

As in Australia, a wide-ranging set of educational materials has been developed to accompany the Being Open policy. Being Open training workshops are available for interested organizations, the most extensive of which includes opportunities to practice disclosure skills with actors. No published information is yet available about the local implementation of the Being Open policy.

### Canada

Canada was the most recent country to issue major guidelines on disclosure, with the Canadian Patient Safety Institute releasing its Canadian Disclosure Guidelines in 2008.(Canadian Patient Safety Institute, 2008) The guidelines incorporate many of the key features from other countries. Most notable, however, is the guideline’s reflection of the ongoing tension between open disclosure and acknowledgement of error. The guidelines emphasize the importance of open and transparent communication with

patients following adverse events. However, the guidelines are explicit about the recommendation to avoid the use of “error” in the context of disclosure.

*“These guidelines purposely avoid the use of the term ‘error’. Adverse events are known to most often result from a complex interplay of factors...a single failure rarely leads to harm. Most often, a series of failures cascade to result in harm. While healthcare provider error may appear to be the most obvious distributing factor, latent conditions...usually contribute to the cause of the harm. Providers must still be responsible for the quality of their work and will be held professionally and legally responsible when warranted. Furthermore, the use of the term ‘error’ in disclosure discussions might be misunderstood or confused to mean that the care provided was substandard or was negligence in law, however, this is often not the case.”*

However, the guidelines note, “if applicable, and when all the facts are established, a further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate” can be included in the disclosure statement. The guidelines acknowledge the complexity of walking this fine line between expression of regret and full apology.

*“In principal, apology as part of disclosure of an adverse event is consistent with patient-centered care, honesty and transparency, and intuitively is the right thing to do. In practice, apology as part of disclosure is complex because of the ambiguity of commonly used apology language. There is a belief that apology*

*implies blame from providers, which is often inconsistent with a just patient safety culture.”*

Clearly, considerable work remains in Canada and countries around the world regarding how to balance these competing requirements for open and honest disclosure with the medical legal realities in these countries.

### New Zealand

New Zealand is of interest when surveying the international disclosure landscape primarily because it highlights the disconnect between the malpractice climate and the development of disclosure programs. As with all of the Nordic countries, New Zealand has moved away from negligence-based strategies for compensating patients who have been harmed by their medical care. (A. B. Kachalia, Mello, Brennan, & Studdert, 2008)

The Accident Compensation Corporation (ACC) was established in 1974 to administer a new program for compensating individuals who were injured as a result of their employment. Though not intended initially to address injuries due to medical care, in 1992 legislation was passed to clarify that the ACC did apply to two types of medical injuries: “medical errors” and “medical mishaps.” In 2005, the eligibility criteria were relaxed, such that any injury that is causally related to the process of health care is eligible for compensation, with the exception of injuries that are a “necessary part of treatment” or an “ordinary consequence of treatment.” However, this nearly no-fault approach to compensation is coupled with an active system whereby patients can file complaints about their healthcare providers, as well as a vigorous disciplinary system

for healthcare providers.(M. Bismark, Dauer, Paterson, & Studdert, 2006; M. Bismark & Dauer, 2006; M. Bismark & Paterson, 2006; M. M. Bismark, 2006; M. M. Bismark, Brennan, Davis, & Studdert, 2006)

Despite what in many ways would be considered a favorable litigation climate for providers, and despite their geographic proximity to Australia, New Zealand's disclosure programs are less far along than in other countries. There is clearly a strong expectation that New Zealand healthcare workers will communicate openly with patients about unanticipated outcomes. For example, the New Zealand Code of Health and Disability Services Consumers' Rights includes the patients' right to open disclosure.(Health & Disability Commissioner, 1994) In March of 2007 the Health and Disability Commissioner issued guidance on Open Disclosure, and articulated basic guidelines for the open disclosure process.(Health & Disability Commissioner, 1994) Educational materials are being developed but have not yet been released. The Health and Disability Commissioner's Strategic Plan includes the target that all District Health Boards will have open disclosure policies in place by 2010.

### Looking forward

The experiences with developing and implementing disclosure programs across these different countries share important common threads and highlight areas for future growth:

- 1) Support for the concept of open disclosure is high, but implementation is uneven.

Developing thoughtful disclosure policies and educational programs is an

important first step towards closing the gap between expectations that unanticipated outcomes will be disclosed to patients and current practice. Yet the challenges with implementing these ideals highlights how difficult it will be to change the entrenched culture of healthcare related to disclosure. The key barrier does not appear to be healthcare workers' commitment to disclosure, but rather important unanswered questions about the most effective disclosure strategies.(T. H. Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003; T. H. Gallagher et al., 2006) For example, who should disclose the event-the patients' caregivers or a team of disclosure experts? What is the appropriate balance between timely disclosure and allowing for a full investigation of an event to occur? What is the relative importance of a full apology vs. an expression of regret in the disclosure process?

- 2) Little is known about how the disclosure process is currently taking place. Even in those countries that have made major investments in developing and disseminating disclosure training programs, little quantitative information is available about how disclosures are currently taking place, or about patients' or healthcare workers' assessment of the quality of actual disclosures. Developing and implementing systematic strategies for measuring the effectiveness of disclosures in real time will be essential for applying performance improvement tools to the disclosure process.(T. H. Gallagher, Denham C, Leape L, Amori G, Levinson W, 2007) Even less is known about the relative contribution of disclosure vs. compensation to the overall resolution of these events.

- 3) The malpractice environment is an obstacle to open disclosure, but not the most important obstacle. Fear of litigation is clearly a barrier to disclosure. However, there is no clear relationship between the malpractice environment in a given country and its progress towards implementing open disclosure. Many of the most advanced disclosure programs have taken place at individual U.S. institutions committed to transparency, some of whom are located in states that provide little to no legal protection for apologies or disclosures.
- 4) Some of the legal barriers to disclosure are erected from within healthcare itself, rather than imposed by the external malpractice climate. Patients clearly want to know why an unanticipated outcome happened and how recurrences will be prevented. (T. H. Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003; Hobgood, Peck, Gilbert, Chappell, & Zou, 2002; Mazor et al., 2004, 2005) Yet in some countries, laws meant to protect event analyses from legal discovery conflict with the ability to provide patients with this information.

Important progress has been made towards creating a healthcare culture where patients can expect to be informed openly, promptly, and compassionately when they are injured by their healthcare. Yet the journey towards transparency with patients following these events is still in its early stages. Developing tools to measure how the disclosure process is currently taking place, using this information to identify effective disclosure strategies, and then training healthcare workers to implement these evidence-based disclosure techniques consistently are critical next steps towards meeting patients' justifiable expectations for open disclosure.

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