



WHITE PAPER

DISCLOSURE: MAKING THE CASE FOR A PROCESS THAT BENEFITS PATIENTS AND HEALTHCARE PROFESSIONALS

Disclosure with respect to adverse events is a key issue on the healthcare agenda. HIROC's views on Disclosure reflect its vision of partnering to create a safer healthcare system. HIROC believes the CPSI guidelines offer many excellent recommendations and reflect an optimal approach to the Disclosure of an adverse event. However, we believe areas of uncertainty and disagreement need to be considered carefully and analyzed thoroughly. HIROC is interested in working with government, healthcare professional bodies and patient advocates to arrive at a more detailed and consistent process for disclosing adverse events and their potential consequences, and an improved understanding regarding the nature of Disclosure.

The patient is at the core of healthcare, and patient safety is the driving purpose for key initiatives designed to improve the effectiveness of healthcare in Canada. Over the past five years, Disclosure with respect to adverse events has been a key issue on the healthcare agenda. Inherent in any discussion regarding Disclosure is clear acknowledgement that every person has the right to know their present health status and about events that may have an effect on their body and health.

The definition of Disclosure currently in widespread use is simple and direct: "The process by which an adverse event is communicated to the patient by healthcare providers". Despite its simplicity, the definition is comprehensive and embodies key points regarding the patient's right to know. It also reinforces that Disclosure is a process, rather than a single action.

In a healthcare setting, the Disclosure of an adverse event is taken to mean the informing of a patient when something unplanned or unexpected from a treatment point of view has occurred with potential of harm to the patient. The nature, circumstances, and likely cause of this unexpected event is explained, together with a discussion of the potential consequences.

Full Disclosure has not always been practiced in the patient-healthcare provider context. It must be appreciated that societal views on the appropriateness and obligation to disclose have changed over the years, and what is deemed proper practice today may not have been viewed as such even five years ago.

What is clear, however, is that the development of Disclosure practices and procedures has evolved to a point where an ever increasing number of healthcare organizations are adopting comprehensive policies designed to support open and transparent Disclosure of adverse events to patients.

A. Historical context for Disclosure in healthcare

Our society has shown a continuous tendency towards increased recognition of the rights of patients and the responsibilities of caregivers. Put succinctly, in the last two decades with respect to appropriate Disclosure practices, we have gone from essentially a patriarchal doctor-patient relationship to a more egalitarian partnership, with the patient expecting and demanding prompt, appropriate Disclosure and the ability to participate in decisions regarding treatment. This change was heralded by the *Pittman Estate v. Bain* legal decision of the mid-1990s, in which a physician was found liable for the consequences of a failure to adequately disclose a risk to the patient.

A status report on Disclosure in 2007 (Levinson & Gallagher) clearly shows that over the span of a decade, the act of a doctor disclosing errors to a patient has become more acceptable and frequent. Recently, Manitoba and Québec adopted and enacted right-to-know legislation requiring Disclosure of adverse events to patients. Many other jurisdictions are contemplating similar legislation to ensure patients are apprised of relevant events surrounding care. At the same time, Disclosure procedures and practices continue to proliferate in Canadian healthcare settings, as the demand for openness and transparency builds.

While, as a society, we are progressing towards a more accepted definition of appropriate standards of Disclosure, there are still significant areas of contention. The Canadian Patient Safety Institute's *National Guidelines for the Disclosure of Adverse Events* has received general acceptance as the basic framework for a national policy on Disclosure; yet several well-respected groups in healthcare still have not fully accepted these Guidelines.

As an example, the CMPA has published its own guidelines, similar to but not exactly the same as the CPSI's. CMPA makes a clear distinction on how Disclosure should be handled in each of the three main areas where harm is likely to occur during healthcare delivery; that is, as a result of risks inherent in medical investigations and treatments, as a result of failure in systems designed to safeguard patients, and as a result of poor performance by healthcare providers.

B. Disclosure & patient safety—Realizing potential benefits

HIROC believes that from a patient safety standpoint, it is in the best interest of all parties to disclose adverse events in healthcare. Communicating for the purpose of Disclosure should not imply blame or fault by the healthcare provider involved in the adverse event.

HIROC believes patient safety should be a national priority and encourages governments and healthcare organizations to support our position and be part of the movement towards open Disclosure in healthcare.

Several potential benefits can be realized by broad-based support for Disclosure; including:

- Improvements in patient safety practices in healthcare settings where adverse events have occurred, leading to reduced frequency in adverse events
- Support for the development of a more collaborative culture in healthcare, based on improved communication between patients and healthcare providers regarding treatment options, and,
- Strengthening of the option for fair compensation settlements over litigation.

There is clearly more work to be done in Canada, to realize the patient safety benefits associated with Disclosure. A literature review reveals that while there is a great deal more attention being paid to patient safety in Canada, the incidence rate of adverse events remains frustratingly high.

International studies, for example, indicate that adverse events may affect as many as 7-8% of patients admitted to acute care hospitals. The Canadian Medical Association estimates that each year between 9,000 and 24,000 deaths in Canadian hospitals are the result of adverse events. These estimates are substantiated in the definitive study of adverse incidents in Canada—*The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada* (Baker, Norton 2004).

Canadian healthcare organizations need to improve education and provide more training opportunities regarding the processes and practices of Disclosure and bring their professional staff on board. Institutional policies and guidelines also need to be put in place or re-examined and revised, if necessary.

At the same time, other areas must be addressed in order to counter some of the undesired consequences of Disclosure; including:

- The mental anguish of a patient resulting from treatment that was suboptimal, whether or not it may actually have caused harm.
- The additional costs following Disclosure, such as the necessity of laboratory tests and additional physical examinations, will increase costs in the healthcare system.
- Litigation from civil actions started as a result of Disclosure, along with the anticipated consequence of compensating patients, could reduce the amount of money available for publicly funded healthcare.
- Society as a whole suffers from a deliberate instillation of fear and concern created by media eager to sell stories, or by plaintiff counsel eager to encourage lawsuits.

HIROC is a participant in the Canadian Patient Safety Institute's continuing work on its guidelines for Disclosure, and its concentration on the development of further guidelines to assist in mass Disclosure (for those situations where a number of patients may have been adversely affected by a repeated or similar sequence of events).

HIROC's general views on Disclosure reflect our vision of partnering to create a safer healthcare system. HIROC believes the CPSI guidelines offer many excellent recommendations and reflect an optimal approach to the Disclosure of adverse events. However, we believe that areas of uncertainty and disagreement need to be considered carefully and analyzed thoroughly.

Such analysis should be done by the most qualified of individuals. HIROC recommends early consultation with medical experts, ethicists, statisticians and others to allow for an impartial assessment of the facts of the event, the actual risks and any risks inherent in Disclosure and non-disclosure alike. Their analysis also should address the best approach to take with patients, in respect to Disclosure, and also should take into consideration the perspectives of various healthcare providers as to the necessity and extent of Disclosure.

In addition, HIROC strongly advocates that the informed consent process (which is required for all medical treatment) be modified in certain cases to secure advance agreement from patients regarding what will be disclosed in the event of an adverse medical event, how Disclosure will take place, and an agreed-upon threshold below which Disclosure will not be required.

C. Disclosure & patient safety—Contentious issues

Currently, areas of contention regarding Disclosure seem to center on two specific points. The first point is the appropriate manner of Disclosure. In the literature, there are suggestions that personal contact is the preferred means in every situation requiring Disclosure, while other experts feel that the use of mass mailing and general mass media techniques are appropriate in many circumstances.

Personal contact allows for a human interaction and permits the exchange of personal information tailored to the individual circumstance. However, this can be time consuming and may be unsuitable in instances where a large number of patients need to be informed within a narrow timeframe. Different circumstances will dictate different approaches.

The second general area of contention is the lack of agreement on the appropriate risk thresholds for Disclosure of adverse events. Is the appropriate threshold one in one thousand, or one in one million, or one in one billion? Or, possibly, does any risk at all demand Disclosure? Statistician J. A. Chris Delaney found that jurisdictions report differing frequencies of adverse events that appear to be due to differences in their threshold for Disclosure.

In addition to the two main areas of contention listed above, there are several areas of outright disagreement where lively debate is taking place. Many experts feel that an error with no possibility of harm does not merit Disclosure in any situation. An error with only possible harm is held by some to mandate Disclosure; others feel that an assessment of the consequences of the possible harm must be done first, and that only those incidents which meet a certain minimum threshold require Disclosure to take place.

One of the areas currently most unsettled is that of dealing with possible errors. If there is a possibility an error has occurred, what are the requirements of the caregiver?

Some feel that the potential consequences of the error, together with an assessment of the actual risk that an error has taken place, must be fully assessed before any Disclosure would be necessary. The consequences of the Disclosure to the patient should also, according to these advocates, be taken into consideration.

If Disclosure of an uncertain event with potentially minor consequences can nonetheless result in a significant potential for mental anguish and consternation on the part of the patient, many feel that the Disclosure is frankly ill advised and should not take place. In late 2003, Sunnybrook Health Sciences Centre in Toronto disclosed that certain of its sterilization and

disinfection techniques for reusable equipment were outdated. Although no patient suffered physical injury or infection as a result of an outmoded approach, claims were advanced alleging that the Disclosure itself had resulted in mental stress and anguish.

Finally, it must be noted that the current emphasis on the right to privacy of an individual has resulted in some persons advocating that any unanticipated or incorrect Disclosure of the personal, private records of an individual are grounds for full Disclosure. Assessment of the likely consequences of Disclosure is not considered necessary by people supporting this position.

D. Current situation in Canada regarding Disclosure

While there is no standard Disclosure process in Canada, the following table presents a simplified summary of the steps that typically appear in processes currently in use in healthcare.

| DISCLOSURE PROCESS (following a decision to disclose) |
|--|
| 1. Determine who should disclose |
| 2. Determine when Disclosure should take place |
| 3. Determine where Disclosure should take place |
| 4. Determine details of what should be disclosed |
| 5. Determine how Disclosure should take place (e.g. all at once; in phases, etc) |
| 6. Conduct the Disclosure and identify follow-up steps |
| 7. Document the Disclosure and the results |

Excellent examples of model Disclosure processes abound, put in place by some of Canada's leading healthcare organizations. The Ottawa Hospital's Disclosure Tool Kit includes a book, reference sheet, checklist and effective communication techniques. The Trillium Health Centre (Mississauga ON) has implemented a protocol for the communication of unanticipated clinical care or outcome and supports it with extensive staff training.

With respect to legislation, Manitoba and Québec have both passed legislation to require that patients be informed of an adverse event that takes place during care. However, most Provinces have not enacted Disclosure legislation, relying instead on guidelines for healthcare providers and apology legislation, the intent of which is to enable contrition without the threat of liability.

Outside the scope of legislation, self-regulating groups of healthcare professionals are taking a stand in favour of Disclosure by establishing policies and guidelines. For example, the policy of the College of Physicians and Surgeons of Newfoundland & Labrador with regard to Disclosure of an adverse outcome states:

The purpose of this guideline is to affirm the College's position that patients are entitled to be informed of all aspects of their healthcare. The right to be informed includes the right of a patient to disclosure of an adverse outcome in the course of receiving healthcare. The disclosure of an adverse outcome, in accordance with this guideline, is not about attributing any fault or blame. In the view of the College, an adverse outcome will not necessarily be the result of negligence or incompetence.

E. Role of HIROC & other insurers in a Disclosure process

Institutional and malpractice insurers have a defined and an important role to play in Disclosure and in creating a culture of patient safety. One of the key underlying aspects of Disclosure is risk—the possibility that something may happen, the details of which may need to be disclosed to the wronged party. Risk is also a defining aspect of insurance. When it comes to risk, insurers traditionally play a protective and reactive role. By providing compensation when unfortunate events occur, insurers are able to mitigate the situation for the insured and the aggrieved party (claimant).

Traditionally, Disclosure has *not* been an inherent part of the insurance claim settlement process. Settlement more likely is preceded by an assignment of blame, without necessarily full Disclosure of the details surrounding the incident or situation. However, this has changed significantly over the past few years.

A context of risk management, risk prevention and, most importantly, risk sharing has created fertile ground for Disclosure to take root in the settlement process. Particularly in healthcare, a strengthened focus on building a culture of patient safety has contributed significantly to a replacement of blame with evaluation of outcomes and a striving to do the right thing, in the interest of the patient and patient safety, in general.

In short, the role of organizational and healthcare practitioner insurers is evolving from simply the settlement of claims, to contributing to risk management and patient safety in healthcare settings. In this way, the objective of insurers becomes assessing and learning from outcomes in order to manage risk to prevent an increasing number of adverse events. Disclosure must be incorporated into the claims settlement process, if ongoing improvements are desired.

While insurers have an important role to play in healthcare, insurance reciprocals in particular have a unique role to play. For the past 20 years, reciprocals have provided insurance

to public sector and professional groups. For example, Healthcare Insurance Reciprocal of Canada—HIROC—is the largest healthcare liability insurer in Canada.

Reciprocals provide subscribers with premium stability and loss reduction programs, based primarily on a pooling of insurance coverage and risk sharing across a large subscriber base, as well as through negotiation of fair settlements. As not-for-profit insurance exchanges, reciprocals also can distribute surplus capital to members.

As noted previously, there is no accepted standard process for disclosing. Yet, common elements do emerge: Promptness, factual description of the event, documentation of the event in the patient record. Also, as a result of systematic approval of Apology legislation in several provinces, there is general acknowledgment that Disclosure in itself is not an admission of fault or liability.

Despite their importance, a role for insurers is noticeably absent from current Disclosure processes. The importance of early involvement of the insurer in the Disclosure process should be recognized, and a preference for financial compensation over litigation should be specified, as noted in the following expansion of a typical process:

| DISCLOSURE PROCESS (following a decision to disclose) | |
|---|---|
| Typical Process | Proposed |
| 1. Determine who should disclose | 1. Determine who should disclose <i>(with input from insurer)</i> |
| 2. Determine when Disclosure should take place | 2. Determine when Disclosure should take place |
| 3. Determine where Disclosure should take place | 3. Determine where Disclosure should take place |
| 4. Determine details of what should be disclosed | 4. Determine details of what should be disclosed <i>(with the assistance of the insurer)</i> |
| 5. Determine how Disclosure should take place (e.g. all at once; in phases, etc.) | 5. Determine how Disclosure should take place (e.g. all at once; in phases, etc.) <i>(as well as compensation options for settlement of claims provided by the insurer)</i> |
| 6. Conduct the Disclosure & identify follow-up steps | 6. Conduct the Disclosure & implement follow-up steps |
| 7. Document the Disclosure and the results | 7. Document the Disclosure and the results <i>(with the participation of the insurer)</i> |

As noted in the table, the involvement of the insurer in Steps 1, 4, 5 and 7 would enhance the Disclosure process and could result in out-of-court settlement of claims (if any) within a more hospitable and conducive environment.

F. Summary & Recommendations

As a result of detailed review and analysis, HIROC decided several years ago that it was appropriate for it to become a major player in the ongoing development of adverse medical event Disclosure practices. HIROC's corporate vision—"partnering to create the safest healthcare system"—is much broader than that of a typical insurer, and encourages cooperation with any and all entities capable of improving healthcare.

Ahead of most, HIROC recognized that the Disclosure process offers an excellent opportunity to create improvements in the healthcare system. Because of its original and continuing commitment to proactive Risk Management, in addition to its dominant role in healthcare liability insurance, HIROC has been able to teach and to encourage the use of cutting-edge safety and process techniques among its subscribers.

Promoting patient safety is at the core of HIROC's mandate. We are working with our partner organizations to contribute to risk reduction, in general, and specifically to reduce the frequency of adverse events. We are working to establish educational programs, improve measurement and evaluation processes, and proposing changes to tort and subrogation legislation while encouraging support for processes that are designed to improve patient safety.

One of our major initiatives recognizes the need to assist our subscribers in the identification and management of risk and patient safety issues. Based on a Risk Management Assessment tool that HIROC developed in the early 1990s, we conducted a comprehensive review of 15 years of reported claims and a trends analysis of the frequency, severity and preventability of hazards. This led to the development in 2000 of a new HIROC educational tool called RMSAM™—Risk Management Self-Appraisal Modules, dealing with risk management in specific areas of the healthcare environment. New modules subsequently have been added, and RMSAM™ was recently expanded to include modules devoted to hazards and exposures frequently experienced by healthcare organizations.

As a subscriber owned, not-for-profit reciprocal, HIROC is better-suited than other insurers to advocate for the adoption of advanced Disclosure/apology techniques. Over the last dozen years, the perceived duties of Disclosure and apology have changed significantly, and HIROC has first-hand awareness that the consequences of Disclosure can sometimes be costly. HIROC's owners believe the Disclosure process should be pursued, even given the possibility for increased cost. Because HIROC is not wedded to the need to increase profits, it can afford to take a step back and assess the issue with a broader perspective, recognizing that while Disclosure may be more costly in the long run it should save expense as hospitals adjust their practices accordingly.

A concerted effort over the past several years to improve product safety is producing positive effects in the healthcare sector. HIROC believes it is in the best interest of all parties to disclose adverse events in healthcare. Communicating for the purpose of Disclosure should not imply blame or fault by the healthcare provider involved in an adverse event. HIROC encourages government and healthcare partners to do the right thing by supporting the movement towards open Disclosure, free of blame and liability, and the development of standard Disclosure processes for healthcare professionals and organizations.

In more specific terms, HIROC is continuing its relationship with CPSI, because it believes that organization is best suited and positioned to provide impartial advancement of the Disclosure discussion. HIROC also is involved in ongoing discussions with CMPA. HIROC has regular planning sessions with its legal counsel from across Canada, where the current legal

status of Disclosure is analyzed, with recommendations made to enhance and improve these definitions. Through our regular risk management seminars and educational opportunities, we circulate our views and recommendations to our subscribers, working always to create a safer healthcare system for all.

Finally, HIROC is interested in working with governmental, patient care professional bodies and patient advocates to arrive at a more detailed and consistent process for disclosing adverse events and their potential consequences, and an improved understanding regarding the nature of Disclosure.