Commission of Inquiry on Hormone Receptor Testing

EXAMINING DISCLOSURE OPTIONS

PROCEDURES FOR DISCLOSING ADVERSE EVENTS:

A LITERATURE REVIEW

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ACKNOWLEDGEMENTS

I would like to thank Justice Margaret A. Cameron and Timothy Caulfield for inviting me to contribute to this very important project. I am truly honoured as it is my hope that this project will be embraced and supported by communities who recognize the importance of patient safety within healthcare systems.

I would like in particular to acknowledge Lisa Rorabeck for her outstanding contributions and ongoing commitment to the research and preparation of this report. I would also like to thank Sarah Whyte, PhD(c) and Lianne Jeffs, PhD(c) for their time on editing the final draft; this was very much appreciated. Dr. Heather Beanlands and Dr. Jasna Schwind both offered editorial comments that were extremely beneficial to this report.

Finally, I would like to extend my support to the breast cancer patients and their families associated with the faulty hormone receptor testing in Newfoundland and Labrador.

EXECUTIVE SUMMARY

Introduction

This report reviews existing literature on the disclosure of adverse events within the Canadian healthcare system. Concerns about the disclosure of adverse events were raised by the public disclosure that faulty hormone receptor testing was conducted in Newfoundland and Labrador between 1997 and 2005. A Commission of Inquiry into the faulty testing was established July 3, 2007. The appointed Commissioner of the Inquiry, Justice Margaret A. Cameron, requested the preparation of this report. The ultimate purpose of the report is to assist the Commission in situating its inquiry within the larger patient safety field.

Methods

A targeted literature review on the disclosure of adverse events within the Canadian healthcare system was undertaken. Key data sources included policy documents and reports, peer reviewed research literature (accessed through scholarly healthcare databases), and media sources obtained from several relevant websites. This review of literature focused on current and developing policies and guidelines; key terms and concepts associated with patient safety; and the assumptions and frameworks that underlie current disclosure procedures and practices.

Findings

Over twenty major reports on patient safety and the disclosure of adverse events were included in this review. A number of themes emerged across these reports: the growing attention to patient safety; the high incidence of preventable adverse events within Canada; the responsibility of healthcare providers to fully disclose medical errors to their patients; methods of how to disclose including the approach of public disclosure; key stages of the disclosure process (preparation to disclose, initial disclosure and documentation); the central importance of culture change to patient safety. The literature also suggests that many improvements must be made within the Canadian healthcare system in terms of patient safety and the policies associated with disclosure. Some of the key recommendations include addressing the need for culture change to promote patient safety; providing more education on the processes and practices of disclosure within healthcare facilities; and embracing the advantages of the disclosure process for patients and healthcare professionals.

Conclusions

Disclosure procedures and practices within Canada continue to develop as many facilities are “adopting increasingly comprehensive polices supporting the open and transparent disclosure of adverse events to patients and families” (Sidorchuk, 2007, p.2). With this in mind, healthcare facilities must continue to build a foundation for disclosure and to create a culture of patient safety which balances both the system and

individual in order to prevent the reoccurrence of adverse events. The ultimate goal of disclosure is to "provide information to the patient, assist with the disclosure process, provide support, and facilitate ongoing patient care" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p.16).

DISCLOSURE EXAMPLES

A number of widely publicized adverse events have occurred within Canada's healthcare system. These examples will set the frame for this report by illustrating the importance and consequences of disclosure practices.

The case of faulty hormone receptor testing in Newfoundland and Labrador provides the example that prompted this report. This case sparked media attention around the problems of medical error, the culture of patient safety, and the procedures for disclosure within Canadian hospitals and is the focus of this inquiry. The case of the Newfoundland and Labrador hormone receptor testing is just one of the public cases of adverse events to occur within Canada recently. In 2003, Oshawa's Lakeridge Health Corporation reported that 150 patients had to be screened for Hepatitis A, B, and HIV due to "improperly sterilized equipment" used during scoping procedures (Goveia, 2003, p.7).. Sunnybrook & Women's Health Sciences Centre in Toronto also reported the use of "improperly sterilized equipment" during prostate biopsies (Goveia, 2003, p.7). In 2007, a public apology was issued by the Alberta Health officials when "a 44-year-old Edmonton mother of three died from an accidental overdose of a chemotherapy drug" (Talaga & Cribb, 2007).

In all of these examples, the adverse events have been "disclosed" not only to the individuals who are directly affected but also to the broader public through the popular media. One benefit of such public disclosure is that it often leads to improvements in patient safety practices both within the local institution where the event(s) occurred and across other institutions and healthcare systems. For example, according to the Toronto Star investigation *Coming Clean on Medical Mistakes* (2007), serious action took place within the walls of Princess Margaret Hospital in Toronto after the Alberta health officials made the disclosure of the overdose of the chemotherapy drug public. Princess Margaret "reviewed their procedures on dispensing chemo [...] to prevent the same mistake from happening" (Talaga & Cribb, 2007). Following their public apology, Lakeridge Health announced "that the hospital had implemented a new 'double-check' process, verifying proper disinfection procedures" (Goveia, 2003, p.7).

Media attention and academic research both emphasize the value of transparency when it comes to adverse events in healthcare. According to the Toronto Star's 2007 report, Dr. Steve Kraman, Professor of Medicine at the University of Kentucky and author of a study titled "Extreme Honesty May Be The Best Policy," explains that studies

have shown that people are legitimately satisfied with learning the truth about what went wrong during their hospital stay, and therefore are less likely to sue when disclosure occurs. People are ultimately receptive to being told the truth and to receiving the information being disclosed to them. The "deserved" truth becomes more valuable than money (Talaga & Cribb, 2007). Therefore, Dr. Kraman believes that disclosure benefits all in years to come, whether it is made public or limited to the individuals directly involved. Interestingly, the Toronto's Star investigation concludes that "the consensus from most in the health field is to make it *all* public" (Talaga & Cribb, 2007). Physicians and patient safety researchers Wendy Levinson and Thomas Gallagher similarly conclude that the "healthcare environment is clearly changing toward supporting physicians in effective and full disclosure" (Levinson & Gallagher, 2007, para. 10). They envision a future in which disclosure is routine, communication is transparent, and negative events are used to facilitate quality improvement.

LITERATURE REVIEW

How is Disclosure Defined?

With the growing attention to patient safety within Canada, The Royal College of Physicians and Surgeons of Canada, along with its partners, thought it was necessary to create a dictionary dedicated to patient safety. The *Canadian Patient Safety Dictionary* was published in 2003. It is a useful resource that collects key terms and information associated with patient safety, and also highlights potential problems and common misunderstandings about the terms.

Within the dictionary, "patient safety" itself is defined as "the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes" (2003, p.12). The following recommendations are presented for using the term "disclosure":

> Disclosure should "be understood as the imparting, by health-care workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an adverse outcome. (RCPSC, 2003, p. 19)

The *Canadian Disclosure Guidelines* (2008) is another report that will be a particular focus in this review. These guidelines provide a shorter list of definitions that are especially relevant to disclosure. These guidelines define disclosure more simply as "The process by which an adverse event is communicated to the patient by health care providers" (2008, p. 30). This definition is significant because it emphasizes that

disclosure is an ongoing *process* of communication rather than a singular event. The components of this process will be discussed later in this report. Table 1 presents a selection of terms from the guidelines that will be helpful for this discussion.

Table 1. Terms Related to Patient Safety

Term	Definition
Adverse event	An unexpected event in healthcare delivery that results in harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.
Informing	Providing information about adverse events and the performance of the healthcare system to the public, mainly through the media.
Close call	The event did not reach the patient because of timely intervention or good fortune. (The term is often equated to a near miss or near hit.)
Reporting	The communication of information about an adverse event or near miss by healthcare providers, through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of reoccurrence of adverse events in the future.

(Canadian Patient Safety Institute: Canadian Disclosure Guidelines, 2008, p.30)

One term that is not included as a key concept in either of these resources is "error." This is because both reports emphasize that an important distinction must be made between harm itself (the effect or potential effect on a patient) and the causes of the harm. The process of identifying the underlying causes of harm is often challenging and complex. For example, the harm could result from inherent risks of a patient's treatment, from features of the healthcare system, from the actions of individuals, or from a combination of all of these factors. The term "error" tends to muddy the distinction by implying that the actions of individuals are the primary cause of harm. The preferred term in many research and policy documents is "preventable adverse event." The term "error" is nonetheless important to the practice of disclosure. Research has shown that healthcare professionals and patients have different understandings of the term "error" which may affect their attitudes toward disclosure (Espin, 2006). "Error" is also frequently used in commentaries, both in the medical literature and the popular media.

What are the Current Standards for Disclosure in Canada?

According to Levinson and Gallagher (2007), many organizations in Canada are rapidly developing policies and procedures to support and facilitate disclosure practices (p. 3). As new patient safety policies are being created, it is important to understand the multiple levels at which they take effect. Disclosure practices are established at various levels within the Canadian healthcare system. These levels include the "macro level"

(government systems such as the provincial legislation on disclosure), "meso level" (healthcare organizations), and "micro level" (teams and individuals).

At the Macro Level: Provincial Disclosure and Legislation

A review of the Canadian provincial policies, guidelines, and legislation related to the disclosure of adverse events is provided in the Canadian Patient Safety Institute's *Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events* (2006). The existing, province-specific guidelines for "what must be disclosed" are summarized in Table 2.

Table 2. Provincial Guidelines

Province	What must be disclosed?
Alberta	"At all disclosure meetings, information shared should be factual and agreed upon through a process of consensus by the healthcare team prior to initiating the disclosure process. Information to be disclosed should only be related to the event, and not about any healthcare providers involved. Only facts related to the patient's diagnostic, treatment and care information (as defined by the Health Information Act (HIA) Section 1 (1)(k)) should be shared. This information includes: • a description of what happened; • the sequence of events; • diagnostic test results; • consequences of the harm and resulting changes to the treatment plan; and • any other relevant factual information." "Other specific elements to be included in the initial conversation are corrective actions that were and will be taken; an expression of remorse and empathy to the patient and family; an appropriate apology based upon whether the expected standard of care was met (benevolent apology) or not met (full apology); and a brief overview of the investigative process that will follow and what the patient and family can expect to learn, with timelines" (*Health Quality Council of Alberta: Disclosure of Harm to Patients and Families Provincial Framework, 2006).*
British Columbia	"FACTS: Stick to the facts during an explanation of the events. The nature of the event, the level of severity and outcomes if known. Do not speculate on any details surrounding the event or begin to attribute blame to any individual. APOLOGIZE: Empathize with the patient/family, "we are so sorry this has happened to you." However, the discussion should not involve a legal admission of liability. TAKE RESPONSIBILITY: The team should communicate ownership of the event to the patient and family. This is separate and distinct from an

	assumption of liability. The patient and family must feel confident that the team takes responsibility for determining the causes of the event, ensuring the patient's care is managed and any future complications are expressed to the patient and family. CLARIFY: If the adverse event was clearly not due to an error, or the cause is unclear, make sure the patient understands that the injury is not the result of a failure of care, but an inherent risk" (*Provincial Health Services Authority: Disclosure of Adverse Events, 2006).*
Newfound-land and Labrador	"The nature, severity and cause (if known) of the adverse event(s)/occurrence(s) (AE/O) should be presented in a straightforward and non-judgmental fashion. An expression of sympathy is often appropriate and not an admission of guilt. Speculation should be avoided and focus should be placed on what is known at the time. Answer questions and provide assurance that unanswered questions will be investigated further. Describe what, if anything can be done to correct the consequences of the AE/O. Offer a second opinion, the involvement of outside assistance, or transfer of care to another practitioner if applicable" (*Association of Healthcare Risk Management: Policy on Adverse Events/Occurrence, 2005).*
Nova Scotia	"The initial disclosure should include: • the facts of the event and its outcome, known at the time • the next steps to be taken in the care of the client • any changes to the overall plan of care • the offer of opportunities for further discussion • a designated contact person for further discussion and support • the support of other resources such as spiritual services, counselling, social work, etc. as relevant • what the organization is doing to find out how the event occurred The policy recognizes that the disclosure obligation is a continuing one, as more information becomes available" (*Nova Scotia Health: Disclosure of Adverse Events Policy, 2005).*
Saskatch-ewan	"Discussions should focus on currently known information about the facts surrounding the event. Blame should not be assigned, and speculation as to cause should not occur. Disclosure should occur as soon as possible following a triggering event, ideally within 24–48 hours. Follow-up discussions may be necessary for information discovered at a later time" (*Saskatchewan Health: Disclosure of Harm Guideline, 2005*).

(Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events: Appendix D&E, 2006, pp.38–41)

At the Meso Level: Disclosure Policies of Health Organizations

Health organizations often develop policies and procedures specific to their local context. Table 3 highlights the *adopted disclosure policies* of some health organizations as reported by the *Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events* (2006).

Table 3. Adopted Disclosure Policies of Healthcare Organizations

Healthcare Organization	Content of Disclosure
• McGill University Health Centre • Montreal, Quebec	Disclosure should be made at the earliest possible moment, as appropriate. It should include the facts of the accident; the measures taken to correct the consequences suffered and an explanation of plans to prevent such an accident from recurring. Personal opinions as to fault or responsibility are to be avoided.
• Vancouver Coastal Health and • Richmond Health Services • Vancouver and Richmond, British Columbia	Facts of an incident (i.e. not suppositions, conjecture, or conclusions). The patient should also be advised that an investigation will be undertaken, and appropriate follow up implemented
• The Ottawa Hospital Ottawa, Ontario	Disclosure discussions concerning preventable adverse events should include: • The facts of the adverse event or adverse outcome, no speculation and blame • The cause of the event, if known • Regret that the adverse event or adverse outcome occurred. • Plans for a review to identify causative factors and prevent its recurrence • Impact and consequences of the occurrence to the patient and proposed treatment plan • Offers of assistance, including support of Social Work, Spiritual Care, Patient Relations Disclosure should be made as soon as reasonably possible after the adverse event occurs.

(Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events: Appendix F, 2006, pp.42–45).

At the Micro Level: Disclosure at the Microsystem

Disclosure at the micro level is focused around the practices of healthcare professionals and healthcare teams. Disclosure cannot work at the provincial or the organizational level without support from these individuals and teams. At this level, the general recommendations for disclosure (provided at the macro and meso levels) must be adapted to the specific situation. The physician and/or the best qualified individual within the healthcare management team should disclose to the patient. A closer look into disclosure at the micro level is provided in the section "Disclosure Approaches and Procedures."

What Do We Know About Disclosure Practices?

Canadians are paying particular attention to patient safety, as reported by a Canadian adverse events study in 2004, due to the number of legal cases and media stories resulting from unfortunate adverse events within Canadian hospitals (Baker et al., 2004). Therefore, the Canadian government has begun the Canadian Patient Safety Institute, "at the cost of $50 million dollars for its creation as a start in battling preventable adverse events" (Baker et al., 2004). The sudden attention surrounding patient safety is not surprising as the statistics on medical errors illustrate a need for help. In 2004, a major study published in the Canadian Medical Association Journal found that between 9,000 and 24,000 deaths occur in Canadian hospitals every year due to preventable adverse events (Baker, et al. 2004, p.1684). Interestingly, in 2007, The Canadian Institute for Health Information (CIHI) reported improvements in the number of adverse events within hospitals between 2002 and 2005. Although improvements have been reported, Canadians still feel insecure about the quality of patient safety within hospitals. The *Health Care in Canada Survey* revealed that over 50% of adults believe that a hospital stay could potentially cause them harm as a "serious medical error" could occur (POLLARA Research, 2006). It is without a doubt that Canadians are becoming increasingly conscious of the alarming numbers surrounding adverse events within their own healthcare system. The CIHI (2007) analysis found that:

> Some adverse events are relatively rare, such as those related to blood transfusions [while] others occur more frequently. Of those examined, the most common adverse events were related to medications, infections and obstetric trauma during childbirth. Less common are adverse or fatal events due to blood transfusions and having foreign objects, such as a sponge or an instrument, left in after a procedure (CIHI, 2007, p. 4).

With the amount of preventable adverse events occurring within Canadian hospitals, the act of disclosing errors to patients and families has been widely encouraged—yet the actual practice of disclosure has been widely criticized by patients, healthcare workers, and the media. Interestingly, a status report in 2007 reveals that within the last ten years, disclosing errors has gradually become more acceptable and frequent between doctors and their patients (Levinson & Gallagher). However, studies have shown that patients and healthcare providers have not always seen eye-to-eye when it comes to disclosure. "A 2002 survey found that disclosure of errors occurred in less than one-third of cases, falling short of patient expectations" (Blendon RJ et al. 2002 as cited in Levinson & Gallagher, 2007, para. 4).

Past studies have indicated that patients want full disclosure (Espin et al. 2006; Gallagher et al. 2003). According to one of these studies conducted in 2003, physicians believe in disclosure but are very cautious and selective when explaining medical errors to their patients (Gallagher et al. 2003, p.1001). Similarly, a study by Espin et al. (2006) suggested physicians and nurses advocated for partial disclosure ("to disclose only what happened" p.1) more often than full disclosure. Thus, patients fear they are not being told the truth (Levinson & Gallagher, 2007, para. 3). However, a study conducted in 1997 by Wu et al. argues that patients receiving full disclosure of a medical error might cause unwanted resentment towards the physician, medical team and/or healthcare system, as well as cause unnecessary "anxiety" (Wu et al. 1997, p.771). The motivation and responsibility for full, open and honest disclosure of adverse events is supported by "ethical, professional and legal considerations; national and international leading practices; and current literature" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p.9). The Canadian Medical Association's *Code of Ethics* provides the following advice to physicians: "provide patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of your ability; consider first the well-being of the patient, [and] make every reasonable effort to communicate with patients in such a way that information exchanged is understood" (Canadian Medical Association: Code of Ethics).

How and Where Does Disclosure Occur?

The literature behind the processes and approaches to disclosure suggest that disclosure of adverse events involves a couple key stages. The Canadian Patient Safety Institute's *Canadian Disclosure Guidelines (2008)* outlines two stages that are necessary to ensure that a full and accurate disclosure takes place. The two main stages include:

1. Initial Disclosure:	2. Post-Analysis Disclosure
Who should disclose? When should disclosure take place? Where should disclosure take place? What should be disclosed? How should disclosure take place?	Documentation

Table 4 illustrates a literature review, based on the Canadian Patient Safety Institute's (2008) criteria of the disclosure process that should be used when planning and disclosing an adverse event to a patient.

Table 4. Recommended Components of the Disclosure Process

1. Initial Disclosure
Who should disclose?
• "Assistance by those trained in the disclosure process, with strong interpersonal skills may be helpful. The participation of others over time may be appropriate to help the patient understand his or her current and anticipated health status and needs" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p.16). • The patient and the family should hear from the physician immediately involved with the patient's care (ASHRM, 2004, p.6). • "The medical practitioner who was the most responsible physician for the health care treatment during the course of which the adverse outcome occurred, should disclose the adverse outcome to the patient" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 10). • "A medical student or resident should disclose an adverse outcome to his or her clinical teacher or supervisor. If the clinical teacher or supervisor is not the most responsible physician for the affected patient, then the clinical teacher or supervisor should ensure that the most responsible physician is informed of the adverse outcome. Upon becoming aware of the adverse outcome, the most responsible physician should disclose the adverse outcome to the patient" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 13).

When should disclosure take place?

- "The initial disclosure discussion should take place at the earliest practical opportunity and preferably within one to two days after discovery of the adverse event. Subsequent disclosure discussions should also occur in a timely fashion. When harm has occurred, the immediate and ongoing welfare of the patient is of the highest priority. However, a delay in disclosure may precipitate anxiety and feelings of abandonment in patients who suspect an adverse event has occurred" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p. 17).
- "Where harm or deterioration of condition may result unless there is immediate disclosure of the adverse outcome, the medical practitioner should disclose the adverse outcome with the according urgency, to either the patient or an authorized substitute decision maker" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 17).

Where should disclosure take place?

- "The choice of setting and location for disclosure discussions is important. The discussions should be, to the extent possible: in person; at a location and time of the patient's preference; in a private area to maintain confidentiality; and free from interruptions" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p. 17).
- "Disclosure to the patient directly should first be considered. The setting for the disclosure should afford the patient privacy. The patient should be offered the opportunity to be accompanied by a support person. The medical practitioner himself or herself may want to have a support person present" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 20).

What should be disclosed?

- "The initial disclosure discussion should include:
  - the facts of the adverse event and its outcome known at the time;
  - the steps taken and the recommended options and decisions in the care of the patient (changes to care plan as applicable);
  - an expression of sympathy or regret, a statement saying sorry as appropriate;
  - a brief overview of the investigative process that will follow, and what the patient can expect to learn from the investigation, including appropriate timelines;
  - an offer of future meetings, including key contact information;
  - an allowance of time for questions;
  - an offer or offers of practical and emotional support, such as spiritual care services, counselling, social work, and patient safety advocates, as needed; and facilitate further investigation and treatment if required" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p. 17).
- "The adverse outcome should be factually described, with care taken to explain medical terminology so that it is understandable by the patient. Speculation or conjecture should be avoided, and the practitioner may respectfully decline to respond to questions or comments from the patient which invite speculation or conjecture" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 21).
- "Options for treatment to address the adverse outcome should be raised. The patient should be told when such treatment or a second opinion may be able to be provided, or should be provided, by another practitioner" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 22).

How should disclosure take place?

- "If upon commencing disclosure, it becomes evident that the patient is unable or unwilling to continue the discussion, the medical practitioner should offer to continue or resume the discussion at another time. In some circumstances, the patient may want to have the disclosure made to an authorized substitute decision maker or in writing, and the practitioner should give due consideration to such requests." (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 23).
- "Some programs already exist which provide advice about how to disclose an adverse event. Effective communication strategies are essential for the disclosure process and various factors influence the content and direction of the communication. Some considerations and communication strategies for the initial and subsequent disclosure discussions include:
  - terminology and words that are likely to be understood by the patient;
  - active listening skills such as empathizing to help understand the patient's experiences and needs;

- open and forthright approach, conveying sincerity with body language;
- adequate time for questions;
- clarification of whether the information is understood; and
- sensitivity to cultural and language needs" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p. 18).

2. Post-Analysis Disclosure

Documentation

- "Documentation of the disclosure process should be consistent with the requirements of the provider's policies and practices of the organization for documentation of patient care and communication. Documentation should include:
  - time, place and date of disclosure discussion;
  - identities of all attendees;
  - facts presented in the discussions;
  - offers of assistance and the responses;
  - questions raised and the answers given; and
  - plans for follow-up, including key contact information for the dedicated contact person" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p. 18).
- "Details of the adverse outcome and of its disclosure to the patient should be documented in the patient's record. Where necessary for the observation or treatment of the patient, the patient's family doctor or other treating physicians should also be informed of an adverse outcome" (College of Physicians and Surgeons of Newfoundland & Labrador: Disclosure of an Adverse Outcome, 2006, para. 24).
- "Describe the event. Documentation should be factual – not an emotional catharsis for the caregiver. Only known facts of the event should be included. Opinions that a particular event caused a specific result do not belong in this record" (ASHRM, 2004, p.9)

What are the Advantages and Disadvantages Associated with Disclosure?

A study in 2007 reported that there are many potential advantages along with disadvantages behind the rationale for disclosure (Levinson & Gallagher, 2007, p.1). Healthcare providers and healthcare facilities should use full disclosure to patients when faced with an adverse event because it is especially helpful to the patient and because it is the patient's right to know. The advantages of disclosure could include the physician being "relieved to admit the mistake" as the "patient or family member may be the only person to forgive the physician" for it. This could perhaps serve as a cathartic

experience for the physician and/or medical team, and encourage the practice of full disclosure in the future (Wu et al. 1997, pp.771–772). Table 6 summarizes some of the key advantages for disclosure from the perspective of patients, healthcare professionals, and healthcare organizations.

Table 5. Disclosure Advantages

Patient	• Full disclosure could positively benefit the patient as he/she would be able to receive "timely and appropriate treatment" (Wu et al. 1997, p. 771). • "Disclosure of a medical mistake may also prevent the patient from worrying needlessly about the etiology of the medical problem" (Wu et al. 1997, p.771). • It improves the quality of treatment patients receive as "it allows patients to be more active participants in their health care and encourages organizations to practise more safety" (Stewart, 2002, p.188). • "Acknowledgement of fallibility brings uncertainties into the open, reduces the possibility for misunderstandings and encourages the patient to take greater responsibility for his or her own care" (Wu et al. 1997, p. 771).
Physician	• "The Physician may be relieved to admit the mistake. In the case of a serious mistake the patient or family member may be the only person to forgive the physician for making the mistake" (Wu et al. 1997, pp.771–772). • Physicians can view their colleagues' disclosures of adverse events as learning experiences, as well as their own (Wu et al. 1997, p.772). • The physician can maintain an "honest patient-doctor relationship" and continue to "strengthen it" (Wu et al. 1997, p.772).
Risk Management	• "Historically, healthcare organizations have been reluctant to admit mistakes because of potential legal liability. Admitting mistakes and taking corrective and compensatory action may reduce the likelihood of a lawsuit and, if a lawsuit is lost, may reduce the punitive damage award. Financial consequences involve admitting mistakes and incurring the associated compensatory costs or not admitting mistakes and incurring associated compensatory and punitive damages for the mistakes that are discovered later… Managers in healthcare organizations frequently are reluctant to admit mistakes, especially in patient care, because they perceive that they have a duty to protect the organization from legal liability. Such action, however, has not only legal consequences but also financial and

	ethical consequences that, in the long run, may not serve the best interests of the organization" (Nowicki, 1998, para. 1 & 3).

In terms of the process of disclosure, there is another approach to revealing the mistakes of an adverse outcome, which not only includes the immediate parties involved but the public as well. When healthcare facilities decide to reveal adverse events which have occurred within their walls to the public, it usually involves a massive error that has taken place. During the public disclosure, the adverse event is explained along with the accompanied steps the facility took, and will take, in order to help correct itself for the future. Although healthcare institutions have been both criticized and praised for publicly reporting their adverse events; it is still ultimately up to the discretion of the healthcare facility to publicly disclose or not. Therefore, a "balance" between the privacy of patients and the public's right to know; which asks if healthcare professionals can "honour their duty to patients and the organization when public disclosure of medical errors is involved?" needs to be established (Stewart, 2002, p.187). To answer this question, a further look into the advantages and disadvantages of public disclosure is needed as there is little research and literature surrounding this concept. Table 6 outlines both sides:

Table 6. Advantages and Disadvantages of Public Disclosure

Advantages	• "The safety of the public outweighs individual confidentiality. If managers take the position of greater public good, they are no longer forced to choose between duty to patients and their organizations" (Stewart, 2002, p. 189). • "It permits individuals to protect their organizations appropriately while protecting patients from harm. Ultimately, patients would benefit from this proposal because of improved safety and quality" (Stewart, 2002, p. 189). • "Public disclosure of medical mistakes is in the best interest of the health care system and the public [as] it does not compromise the fiduciary duties to patients or organizations" (Stewart, 2002, p.188).
Disadvantages	• Public disclosure of risk management documents could place physicians and health care organizations at risk for litigation (Stewart, 2002, p.188). • Changes may not occur immediately following public disclosure of adverse events; therefore, patient safety is not insured, leading both organization and patient to be compromised (Stewart, 2002, p.188). • There are concerns about how to manage relations with the press. It can be politically embarrassing if a family member learns for the first time of a serious reportable event involving a family member when it appears in the media"(Weissman et al. 2005, p.1360)

Both sides present powerful arguments. However, we all learn from mistakes, and therefore without taking interest in them, we would never have the opportunity to teach others not to do the same (Stewart, 2002, p.189). Publicly disclosing an adverse event can serve as a global learning experience and reminder to us all that we need to continually improve our healthcare policies and educate medical professionals. Therefore, the healthcare system needs to stay vocal.

What is Required for Disclosure to Take Place?

One point that is emphasized across all of the reviewed documents is that successful disclosure requires a strong patient safety culture. Patient safety culture is defined as "the collective values, knowledge, skill and commitment to safer patient care that is demonstrated by every member of the organization" (National Disclosure Working Group and the Canadian Patient Safety Institute, 2007, p.10). More specifically, positive safety culture within organizations is broken down into 10 dimensions as delivered in a presentation by the Agency for Healthcare Research and Quality (AHRQ, 2004). The 10 dimensions are listed in Table 7.

Table 7. 10 Dimensions of Patient Safety

1. Supervisor/manager expectations and actions promoting patient safety.
2. Organizational learning—continuous improvement.
3. Teamwork within units.
4. Communication openness.
5. Feedback and communication about error.
6. Non-punitive response to error.
7. Staffing.
8. Hospital management support for patient safety.
9. Teamwork across hospital units.
10. Hospital handoffs and transitions.

(AHRQ, 2004, slide 35)

In a strong patient safety culture, failures are not automatically blamed on individuals; instead, they prompt a critical review of the whole system in which the failure occurred. According to the National Disclosure Working Group together with the Canadian Patient Safety Institute in *Creating a Culture of Patient Safety* (2007):

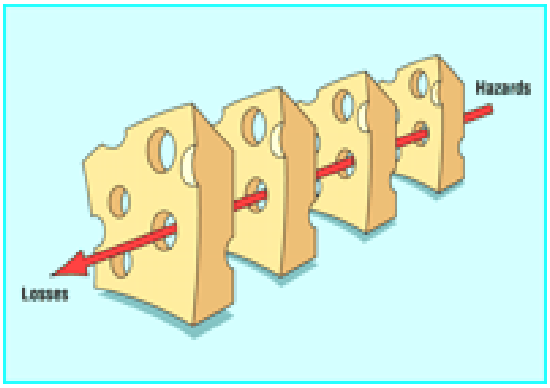
> Many health adverse events in healthcare are now recognized as system failures, where safeguards to protect patient safety were not

> in existence, or a series of safeguards that were in place failed in sequence resulting in harm to the patient. Adverse events often occur after recurrent patterns of failures, regardless of the dedication or experience of the health professionals involved. Systems theory emphasizes that focusing on the system rather than on the individual will prevent more adverse events. (2007, p. 10)

Due to this, Powell (2004) writes that there must be a "paradigm shift" away from the errors associated with patient safety. However, this "shift" is not easy when you face "fear, shame, and blame" (p.212). Therefore, Reason (2000) created "The Swiss Cheese Model of System Accidents" as an analogy for understanding the "system" versus the "individual" during adverse events. Reason's model examines how "people rely on others such as surgeons and anaesthetists [for example], and yet others depend on procedures and administrative controls," which are parts of a system (p.768). Reason (2000) further explains that:

> [A system's] function is to protect potential victims and assets from local hazards [and] they do this very effectively, but there are always weaknesses. In an ideal world each defensive layer would be intact. In reality, however, they are more like slices of Swiss cheese, having many holes—though unlike in the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one 'slice' does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity bringing hazards into damaging contact with victims (Figure 2). The holes in the defences arise for two reasons: active failures and latent conditions. Nearly all adverse events involve a combination of these two sets of factors. (Reason, 2000, p.768)

Figure 3. The Swiss Cheese Model of how defences, barriers, and safeguards may be penetrated by an accident trajectory.



(Reason, 2000, p.768)

In regards to the "individual" versus the "system," Reason says that "blaming individuals is emotionally more satisfying than targeting institutions" (pp. 769–770). Therefore, the National Disclosure Working Group together with the Canadian Patient Safety Institute concludes:

> Healthcare providers in a just culture are held professionally accountable for the quality of their work in a fair way. Blaming an individual for an adverse event is discouraged except for those rare situations in which system factors play a limited role and the individual's behaviour or judgment is shown to be unprofessional. All other occurrences are viewed in the context of identifying system contributors in order to improve safety. The adverse event is analyzed for such system contributors, and the lessons learned are used to strengthen the system, and if appropriate to support and educate the healthcare providers to help prevent like events. (2007, p.11)

According to a study conducted in 2006, there is a call "for a culture change in health care to improve patient safety. However, effective change cannot proceed without a clear understanding of perceptions and beliefs about error" (Espin et al. 2006, p.12). Similar to Reason's beliefs and theories, "the dominant refrain by the ensuing patient safety movement has been the call for a culture change: to move health care from a blame-and-shame response to error toward a high reliability response that confronts, reports, and learns from error. To meet the demand for change we must understand both professional and patient perceptions and beliefs about errors" (Espin, et al. 2006, p.13).

DISCUSSION

The existing literature on the approaches and procedures of disclosure indicates that great strides have taken place within the Canadian healthcare system, but further education and action is still needed to improve and create a consistent and mandatory disclosure system for the treatment of adverse events across Canada. The literature reviewed suggests that there are many advantages to the disclosure process such as allowing the patient to receive necessary and "timely treatment," allowing the patient to be more vocal in his or her treatment, and allowing for healthcare institutions to recognize their mistakes and make quality improvements for the future (Wu et al. 1997, p. 771). These advantages outweigh the disadvantages. Therefore, healthcare officials and workers should not fear the processes of disclosure as the culture of blame is shifting away from attacking the individual. Instead, people are recognizing that the healthcare system is not perfect; patients' safety and their right to information need safeguarding. The *Canadian Disclosure Guidelines* (2008) addressed many important points to ensure facts are learned and "further discussions occur to ensure full and complete disclosure" (Sidorchuk, 2007, p.2). The literature based on the disclosure process further reveals that disclosure:

> Should be delivered by providers trained in disclosure, capable of effectively managing not only their own emotional responses, but also attendant to the needs of the patient/family as well as the healthcare providers involved in the event. These conversations are some of difficult conversations that people can be involved in throughout the course of their lifetimes, and support in the form of training, debriefing, peer and inter-professional support, and ongoing professional development is essential for the effective evolution of a comprehensive disclosure program throughout the organization. (Sidorchuk, 2007, p.2)

However, according to the Canadian Institute for Health Information, there are still unanswered questions in regards to "the state of patient safety and how to translate these findings into improvement initiatives" (2007, p.20). Some of the most important questions CIHI has included in their report on *Patient Safety in Canada* are:

- How is the patient changing over time? What is driving these trends?
- What does patient safety look like across the health care continuum? What are the rates and types of adverse events occurring outside of the acute inpatient hospital environment?

- What are some of the risk factors contributing to different types of adverse events? How can these be addressed? Do hospital types and hospital volumes play a factor in the rate of adverse events?
- How can we translate adverse events into learning opportunities? How is reporting and communication of adverse events changing? How can it be increased or encouraged?
- Which policies, strategies and practices are most effective in improving patient safety, and how can this knowledge be applied more broadly?

(2007, p. 20)

Addressing more of these questions is critical, as is institutional support. In order to promote disclosure, "it is essential that senior leaders in hospitals, including chief executive officers and board members, take responsibility for regularly reviewing medical errors and for creating policies related to disclosure" (Levinson & Gallagher, 2007, para. 9).

CONCLUSION

The disclosure process and its approaches are increasing within the Canadian healthcare system. Education is key to improving and developing disclosure policies and procedures. Adverse events within Canada's healthcare system are continuous reminders that human error exists, and therefore needs constant support and education in collaboration with the improvement of the system. As the *National Guidelines for the Disclosure of Adverse Events* concludes, "Disclosure is always the right thing to do" (Sidorchuk, 2007, p.2).

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