



Background Paper for the Development of National Guidelines for the Disclosure of Adverse Events

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INTRODUCTION

When an adverse event occurs, the experience can be devastating for the patient and his or her family as well as for the healthcare professionals involved. Disclosure of adverse events will facilitate improved ongoing patient care and may help reduce the likelihood of reoccurrence in the future. However, many healthcare professionals feel uncertain about how and what to disclose to patients about adverse events. Additionally, some healthcare professionals may be wary of disclosing due to fear and uncertainty regarding possible workplace, regulatory and legal ramifications. Many professional codes of conduct direct disclosure to patients. For example, Section 14 of the CMA Code of Ethics (2004) specifies “Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient”.

Various organizations across Canada (Health Quality Council of Alberta; Saskatchewan Health; Sunnybrook and Women’s College Health Sciences Centre; Capital Health Region in Nova Scotia; etc.) have developed strong local initiatives to facilitate full disclosure across their jurisdiction. However, there is a gap in Canada at the inter-disciplinary and cross-jurisdictional policy/guideline level.

A variety of Canadian health-system stakeholders are working collaboratively on pan-Canadian guidelines for disclosure of adverse events to patients and families. This paper is intended to provide background information for the National Guidelines Working Group on disclosure for this purpose and includes a description of key references such as potential legal as well as regulatory considerations.

DISCUSSION

1. What duties to disclose are currently imposed on healthcare professionals?

a. Codes of Ethics

i. Physicians

Section 14 of the Canadian Medical Association’s *Code of Ethics* provides:

14. Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.

This provision has been adopted in most of the codes of ethics of the various provincial colleges, as summarized in [Appendix A](#). The colleges in some provinces have instituted a specific policy addressing disclosure of harm. In all cases, some obligation is placed on physicians to inform the patient of an adverse event, although the triggering event differs.

In New Brunswick, a breach of the Code of Ethics constitutes professional misconduct, and in Newfoundland and Labrador, a breach of the Code of Ethics constitutes conduct deserving of sanction. Alberta enacted legislation to provide that a contravention of a code of ethics or standards of practice constitutes unprofessional conduct (*Health Professions Act*, R.S.A. 2000, c. H-7). As the various health professions finalize their regulations under the *Act*, this legislation will apply.

ii. Nurses

Points 8 and 9 under the Value of “Safe, Competent and Ethical Care” in the Canadian Nurses Association’s (CNA) *Code of Ethics for Registered Nurses* (2002) provide:

8. Nurses must admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event.

9. Nurses must strive to prevent and minimize adverse events in collaboration with colleagues on the healthcare team, when adverse events occur, nurses should utilize opportunities to improve the system and prevent harm.

While Point 8 does not explicitly provide that nurses must admit a mistake to the *patient*, this can arguably be implied from the context, in which the obligations are owed to the patient.

The CNA's *Code of Ethics for Registered Nurses* (2002) has been adopted by most of the provincial and territorial nurse's associations, and integrated into their standards of practice (See [Appendix B](#)). In the jurisdictions where the Code has not been adopted, other provisions relating to taking responsibility for errors or the relationship of trust between a nurse and a patient suggest a similar duty.

iii. Pharmacists

The Canadian Pharmacists Association does not have a code of ethics. Each provincial association has its own code, only two of which refer specifically to disclosure of adverse events (see [Appendix C](#)). However, in the jurisdictions where there is no explicit duty, it is arguable that such an obligation can be implied from the principles relating to honesty and patient care.

b. Common Law

Physicians are under a common law legal duty to disclose error to their patients. A Common law duty is imposed by the courts as a result of its jurisdiction established through history and developed through judicial decisions. As stated by Picard and Robertson (1996, 170) "It is now well established that a doctor who makes an error in the course of treatment is under a legal duty to disclose this fact to the patient, if it is something which a reasonable person in the patient's position would want to know." This duty is an exception to the general civil rule which does not require confession; potential defendants are usually entitled to remain silent, at least until they are sued and the discovery process begins (Robertson, 2002, 357). A physician may be liable for increased damages resulting from the failure to disclose, and punitive damages may be imposed as a result of the breach (*Shobridge v. Thomas* (1999), 47 C.C.L.T. (2d) 73 (B.C.S.C.)).

Robertson (2002, 357) states that this special duty imposed on physicians arises from the doctrine of informed consent and the fiduciary relationship between a physician and a patient. "Given that patients have a legal right to be told what may go wrong with the proposed treatment, it must surely follow that they also have a right to be told what has in fact gone wrong" (Robertson, 2002, 357). The fiduciary basis is favoured in more recent cases: the fiduciary obligations stemming from the physician-patient relationship have been held to include a duty to inform the patient if something goes wrong in the course of treatment (Robertson 2002, 357).

Robertson (2002, 358) also addresses the issue of what is meant by "medical error" in the context of the common law duty to disclose. He distinguishes between "near misses" where errors are made but detected before any harm resulted, which raise prevention concerns, and those where harm actually results to the patient, which raise disclosure concerns. He continues:

"At the same time, however, this does not mean that the duty to disclose medical error arises only if the error has caused (or has the potential to cause) harm. For example, it is well-established that if a surgical error results in an operation being unsuccessful and having to be redone, the surgeon has a legal duty to disclose this to the patient. [note omitted] Ultimately, guidance on which "errors" ought to be disclosed to patients comes from the underlying principle of informed consent: if the error is something about which a reasonable person in the patient's position would want to be told, the physician has a

legal duty to disclose it. In that respect it is important to note that empirical evidence shows that the vast majority of patients want to be told if an error has occurred. [note omitted] This evidence is also consistent with the interpretation that Canadian courts have placed on the "reasonable patient" test in informed consent cases, an interpretation that views the hypothetical reasonable patient as "a fairly inquisitive being who generally wants to be extremely well informed before making a health care decision." (Robertson, 2002, 358).

Robertson (2002) notes that while the obligation to disclose is clear, there are many related issues that are unclear. First, it is unclear how much must be disclosed by a physician other than the fact that an adverse event occurred. Further, it is unclear whether other healthcare professionals and organizations are under a duty to disclose. One case suggests that nurses do not have a duty to disclose, but this conclusion has been criticized (Robertson, 2002, 361). It is arguable that other healthcare professionals who are under a duty to obtain informed consent are under a similar duty to disclose when something goes wrong in the course of treatment.

c. Legislation

[Appendix D](#) contains a table summarizing the existing legislation in Manitoba and Quebec.

i. Manitoba

The Manitoba government passed legislation in 2005, proclaimed in force November 1, 2006, amending *The Regional Health Authorities Act* and *The Manitoba Evidence Act* to require reporting and disclosure of critical incidents (*The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*, S.M. 2005, c.24).

A critical incident is defined in the *Act* as an unintended event that occurs when health services are provided to an individual and result in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health service (s. 2 (53.1)).

If a critical incident occurs, the regional health authority, health corporation or prescribed healthcare organization must ensure that appropriate steps are taken to fully inform the individual about the facts of what actually occurred, its consequences as they become known, and the actions taken and to be taken to address the consequences of the critical incident (s. 2 (53.2(2))). There is no obligation specifically placed on health professionals in this legislation to report or disclose critical incidents, the amendments simply state that they may notify the health body if they believe a critical incident has occurred (s. 2(53.4.1(1))).

The legislation also establishes requirements for reporting and investigating a critical incident. The health corporation or prescribed healthcare organization must notify the regional health authority, and in consultation with the regional health authority, establish a critical incident review committee to investigate and report respecting the critical incident. The regional health authority must notify the Minister about the critical incident. The report of the critical incident review committee must be provided to the regional health authority and the Minister. The critical incident review committee has the power to compel the production of information, including personal health information.

There are certain protections for the report prepared by the critical incident review committee. First, no person has a right of access to a record or information prepared solely for the use of a critical incident review committee, or collected, compiled or prepared by a critical incident review committee for the sole purpose of carrying out its duties. Second, a witness in a legal proceeding is not permitted to answer any question or make any statement with respect to a proceeding. However, this privilege does not apply to

the facts of what actually occurred unless those facts are also fully recorded in a record that is available to the individual affected by the critical incident.

ii. Quebec

Quebec passed amendments in 2002 to *An Act respecting health services and social services*, R.S.Q., c. S-4.2), providing that a person receiving health services is entitled to be informed, as soon as possible, of any accident having occurred during the provision of services that has actual or potential consequences for the user's state of health or welfare and of the measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring (s. 8).

“Accident” is defined in the *Act* as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person” (s. 8). An “incident” is defined as “an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances” (s. 183.2). As such, the Quebec legislation makes a distinction between accidents and incidents. Incidents do not have consequences for the state of health or welfare of a user. Only accidents must be disclosed to users.

Persons working in an institution are required, as soon as possible after becoming aware of any incident or accident, to report it to the executive director of the institution or to a person designated by the executive director (s. 233.1). The board of directors of an institution is responsible for establishing rules to be followed, on the occurrence of an accident, so that all the necessary information is disclosed to the patient, or her representative (s. 235.1). The board of directors is also responsible for establishing support measures, including the appropriate care, to be made available to the patient or her representative and measures to prevent such an accident from recurring (s. 235.1).

d. Provincial Policies or Guidelines

Recently, some provincial organizations have developed their own policies or frameworks/guidelines to assist healthcare organizations in creating or enhancing communication between the healthcare professional and the patient/family when an adverse event happens. [Appendix E](#) contains a table summarizing these policies/guidelines from Alberta, British Columbia, Newfoundland/Labrador, Nova Scotia and Saskatchewan.

i. Alberta

In August 2006, the Health Quality Council of Alberta (HQCA) released the provincial framework of *Disclosure of Harm to Patients and Families*. The framework is intended to be used by health authorities and healthcare professions in developing their policies and codes of ethics. The framework sets out a disclosure process which details the threshold for disclosure and provides guidance on what information should be disclosed, who should disclose it and how. It also discusses some unique circumstances which might arise in the context of disclosure.

ii. British Columbia

The Provincial Health Services Authority (PHSA) of British Columbia adopted the *Disclosure of Adverse Events Policy* in June, 2006. The purpose of the policy is to assist the PHSA agency inpatient areas and its healthcare providers in disclosing adverse events to patients and families.

iii. Newfoundland / Labrador

In 2005, the Newfoundland/Labrador Association of Healthcare Risk Managers (NLAHRM) produced the *Policy on Adverse Events/Occurrences with a section of the standards addressing the disclosure of adverse events to patients*. The purpose of this policy is intended as a guideline to be used in each of the health region's organizations as a template to use their own organizations policy or to use as a sample as a template for policy development. The policy also creates a standardized mechanism for identifying, reporting, investigating, trending and resolving adverse events/occurrences.

iv. Nova Scotia

Nova Scotia (2005) adopted a *Disclosure of Adverse Events Policy* in March of 2005, effective April 30, 2006. The policy requires all designated organizations providing health care in Nova Scotia that receive public funds to have a process in place to promptly inform clients of pertinent facts associated with adverse events. Organizations are responsible for establishing internal policies to meet the requirements.

v. Saskatchewan

Saskatchewan Health issued a *Disclosure of Harm Guideline* (Saskatchewan) which provides regional health authorities with guidelines concerning the disclosure of harm to patients and/or their families. The *Guideline* is not mandatory, but rather provides that it is the expectation of Saskatchewan Health that all regional health authorities will prepare and implement the use of disclosure policies based on the *Guideline*.

e. Policies Adopted by Individual Organizations

Many individual organizations have adopted policies mandating the disclosure of adverse events. Each of these policies differs slightly in terms of the event which triggers the obligation to disclose, as well as the content of disclosure. [Appendix F](#) contains a table summarizing a sampling of policies of a number of these organizations and it is not an exhaustive list.

2. What should be the extent of the duty and on whom should it be imposed?

a. What types of adverse events should trigger the duty to disclose to patients?

Clearly defining the event which triggers the duty to disclose is essential, as healthcare professionals must be aware of when they are under a duty to disclose. There are several studies which provide a good background for considering how the triggering event should be defined.

One such study is the *Open Disclosure Standard* prepared by the Australian Council for Safety and Quality in Health Care in July 2003 ("Australian Policy"). The Australian Policy states at page 5 that "There is no agreed universal definition of 'adverse event'" For the purposes of that policy, intended to promote a clear and consistent approach by hospitals in Australia, "adverse event" is defined as "an incident in which unintended harm resulted to a person receiving health care." The policy clarifies that where there may be different perspectives on whether "harm" occurred, the patient's view should govern.

In March 2006, the Harvard Hospitals released a Consensus Statement titled *When Things Go Wrong: Responding to Adverse Events* ("Harvard Statement"). The Harvard Statement recommends that health care professionals should promptly inform the patient about "any adverse event or error that reached the patient even if no harm was done. Minor errors that do not reach the patient do not need to be disclosed." (Harvard Hospitals, 2006, 12) "Adverse event" is defined as "an injury that was caused by medical

management rather than the patient's underlying disease; also sometimes called 'harm,' 'injury', or 'complication.'" (Harvard Hospitals, 2006, 4)

In Manitoba, the triggering event is a "critical incident," which is defined as an unintended event that occurs when health services are provided to an individual and result in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health service (s. 2 (53.1)). In Quebec the triggering event is an "accident," which is defined as "an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person" (s. 8).

In the Nova Scotia policy, the triggering event is an "adverse event," which is defined as "an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided." In the Saskatchewan guideline the triggering event is "harm" which is defined as any injury to the body or occurrence of a change for the worse.

The policies of the various individual organizations have varying definitions of the triggering event (see [Appendix F](#) for a summary of those policies).

One interesting issue is whether near misses should be disclosed, a near miss being an event in which harm is nearly caused to the patient, but is prevented before the harm is done. Most policies do not mandate the disclosure of near misses, but leave the decision of whether to disclose to the organization or healthcare professional. The Harvard Statement recommended that disclosure of near misses should be individualized, but "[i]f the patient is aware of the error, or if knowledge of it can help prevent a recurrence, the patient should be informed" (Harvard Hospitals, 2006, 8).

b. On whom should the duty be imposed?

Healthcare is most often provided by a team, and when an adverse event occurs, there are likely several healthcare professionals involved or aware of the adverse event. It is important to clarify which healthcare professionals are under a duty to disclose or report an adverse event for disclosure.

In the Australian Policy one person is designated as responsible for the open disclosure process in each organization (Australian Council, 2003, 6). However, the obligation to disclose is placed on the healthcare professionals involved in the patient's care, preferably the most senior professional involved (Australian Council, 2003, 19-20).

The Harvard Statement recommends that, regardless of who made the error or what system failed, the major responsibility for communication with the patient falls on the attending physician who is responsible for the patient's care (Harvard Hospitals, 2006, 8-11).

The Quebec legislation places an obligation on healthcare professionals working in an institution to notify the executive director or designated person in that organization. The Manitoba legislation does not place an explicit duty on healthcare professionals to report or disclose an adverse event; it does establish a discretion to report to the organization.

The Nova Scotia policy and the guidelines from Saskatchewan and Alberta place the obligation for developing policy on the organizations. In addition, each of the provincial guidelines and policies indicate that a team approach to disclosure is best (see [Appendix E](#) for a summary of the provincial policies/guidelines).

The policies of the various Canadian organizations tend to place reporting obligations for the purposes of disclosure on all healthcare professionals, but place the primary duty for communication on the most responsible physician. Some of the policies specify that if the adverse event mainly relates to the actions of someone other than the most responsible physician, they may be responsible for communicating with the patient (see [Appendix F](#) for a summary of those policies).

c. *What should be the content of the duty to disclose?*

i. *Information to be disclosed*

Disclosure can be limited to the bare information that the adverse event occurred, and can extend to a full expression of how it happened, or even a full apology accepting responsibility for what happened. Uncertainty about what should be disclosed can result in concerns about admissions of liability for the purposes of civil liability.

In a 2003 study reported by Gallagher et al. (2003), patients were asked about what information should be disclosed when an adverse event occurs. The patients overwhelmingly agreed they wanted to know what happened, the implications of the error for their health, why it happened, how the problem will be corrected, and how future errors will be prevented. Patients also wanted an expression of regret or an apology. This desire for an apology is rooted in western cultural expectations (Berlinger and Wu, 2005).

The Australian Policy states that the initial disclosure should include an expression of empathy and regret for the harm that has occurred, disclosure of known facts, and information on the effects of the adverse event (Australian Council, 2003, 20-1). Once the event has been investigated, further disclosure includes a summary of the factors contributing to the adverse event, and information on what has been and will be done to avoid repetition of the adverse event, and how these improvements will be monitored (Australian Council, 2003, 27).

The Harvard Statement recommends that the caregiver should acknowledge the event, express regret, and explain what happened and what is being done to mitigate the effects of the injury (Harvard Hospitals, 2006, 6-7). If an obvious error has been made, the caregiver should admit it, take responsibility for it, apologize, and express a commitment to finding out why it occurred (Harvard Hospitals, 2006, 6). Patients should be advised that an investigation will be conducted, and should be informed of the causes of the event when they have been discovered. An apology or expression of regret is an essential part of the disclosure recommended in the Harvard Statement (Harvard Hospitals, 2006, 9-10).

The Quebec legislation only refers to “necessary information”. The Manitoba legislation refers to: (i) the facts of what actually occurred with respect to the critical incident, (ii) its consequences for the individual as they become known, and (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable.

The Alberta provincial framework (HQCA, 2006) states that information to be disclosed should only be related to the event, and not any healthcare providers. Only facts related to the patient’s diagnostic, treatment and care information (as defined by the Health Information Act, s. 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.

Information that cannot be disclosed to the patient, following Alberta legislation, includes:

- information that could reasonably lead to the identification of a person who provided the health information in explicit or implicit confidence (HIA s. 11 (1)(b));
- results of an investigation relating to a health service provider (HIA s. 11 (2)(b)); and
- records of the Quality Assurance Committee, including any sub-committees conducting investigations into cases where harm has occurred.

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 appropriate timelines.

In British Columbia, the PHSA (2006) policy states the initial disclosure discussion should include the following:

- **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.

In the Newfoundland/Labrador policy (2005) the nature, severity and cause (if known) of the adverse event/occurrence 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 of discussion. 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 adverse event/occurrence. Offer a second opinion, the involvement of outside assistance, or transfer of care to another practitioner if applicable.

The Nova Scotia (2005, 4) policy outlines the type of disclosure to be made:

7.2.2 The initial disclosure discussion includes:

- 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 Saskatchewan guideline simply states that the discussion should focus on known information about the facts surrounding the event, without discussions of blame or speculations as to cause.

The various policies adopted by organizations vary widely on what should be communicated to the patient in the context of disclosure. Several policies indicate that an apology or expression of regret should be included. (For a summary of the various policies, see [Appendix F.](#))

If an expression of regret or an apology is mandated, this may raise concerns about the use of such a statement as an admission in subsequent legal proceedings. It is possible to express regret without accepting liability, but such a statement may not be satisfactory from the perspective of a patient. Legislation might be necessary to exempt such apologies from use as admissions in legal proceedings. This is discussed in more detail in the section on civil liability below.

ii. Time frame for disclosure

Where policies make provision for the timing of disclosure, they universally state that disclosure should be made as soon as possible, with regard to the health of the patient. The Harvard Statement (Harvard Hospitals, 2006) recommends a 24 hour time period, as does the Saskatchewan guideline. The Alberta provincial framework, the Newfoundland/Labrador (NLAHRM) and British Columbia (PHSA) policies state the disclosure discussion should take place as soon as reasonably possible based upon the patient's individual circumstances. At most, the HQCA (2006) recommends it should be initiated within one to two days following the discovery of harm to the patient. Most also recognize that disclosure is a continuing obligation, and certain information may not become available until a later time, and must be disclosed as it becomes available.

iii. Documentation, Reporting and Investigation

Most of the policies and provisions on disclosure of adverse events also contain requirements relating to documentation of the disclosure, reporting of the adverse event, and investigation of the causes of the adverse event. While these aspects of the disclosure obligation may be considered at a later time, the focus at present is on the disclosure to the patient.

d. Disclosure under special circumstances

Effective disclosure discussions should take into account the particular circumstances of the patient.

i. Patients in vulnerable circumstances

Vulnerability refers to a “circumstance in which a person finds himself or herself particularly susceptible to injury or harm.” These circumstances may create challenging situations for ethical and legal conduct. The source of the vulnerability of a person can be a result of (a) their possession of a particular characteristic (such as being an older patient); (b) their being in a certain place or environment (such as a prison, a refugee centre, or a place where they do not speak the language); (c) occupying a certain position with respect to others (such as being a member of a minority group, or being an asylum seeker); or (d) several or all of the above (*European Standards on Confidentiality and Privacy in Healthcare*, 2006, 16).

For example, Kapp has noted that older patients are at a disproportionately increased jeopardy when compared with younger patients in terms of incidence of errors and severity of injuries stemming from adverse drug events, inappropriate medication selection, medication discrepancies, nosocomial infections, pressure sores, delirium, and surgical complications (Kapp, 2001, 1360).

Article 8 of the *Universal Declaration on Bioethics and Human Rights* (2005), states: ‘In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.’ Patients in vulnerable situations are not always in the best position to advocate effectively for themselves and this needs to be taken into consideration when disclosing adverse events.

ii. Patients without capacity

Patients have the right to consent to or refuse treatment. A valid consent must be informed, voluntary, competent, and directed to the specific treatment. In general, capacity to consent involves an understanding of the nature and consequences of the proposed treatment, and the consequences of not receiving the treatment.

If patients are not competent, treatment decisions may be made by a substitute decision-maker. The appointment and role of a substitute decision-maker is usually governed by provincial legislation. Any disclosure discussions must take into account the competency of a patient, and any involvement of a substitute decision-maker in treatment decisions.

Healthcare decisions for minor children are made by their parents or guardians until they reach the stage when they have the capacity to make their own decisions. Elderly patients in long-term care facilities, or patients with mental health issues, may also lack the capacity to make their own healthcare decisions. In each case, the patient’s substitute decision-maker should be involved in the disclosure discussion. The substitute’s views may be sought on whether it is appropriate to include the patient in the disclosure discussion. In addition, vulnerable patients who generally have capacity may find such a discussion confusing and overwhelming, and efforts should be made to include a support person (National Patient Safety Agency, 2005).

iii. Patients with communication requirements

Communication requirements are likely to arise in a number of circumstances. For example, a blind person will not be able to read a printed pamphlet; a professional interpreter or a healthcare professional who can speak the patients’ language may be required if the patient comes from a linguistically different background to the service provider.

iv. Culturally diverse population

Barriers to communication encompass patients’ underlying principles and beliefs regarding health matters.

e. Disclosure to research participants

In Canada, there is no comprehensive legislation regulating research involving humans. Instead, requirements are found in a variety of instruments including:

- federal and provincial legislation (e.g. *Food and Drugs Act*, R.S.C 1985, c. F-27, s. 1; provincial health information legislation)
- national research policy statements (i.e. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, 2005)
- international guidelines (e.g. Health Canada, 1997)
- obligations imposed by research ethics boards (REB's) as a condition of granting approval for the research.

There is an ongoing obligation to obtain informed consent from research subjects that continues throughout their participation. For example, the *Tri-Council Policy Statement* (Canadian Institutes of Health Research, 2005) provides that research may begin only if “(1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in research.” (Article 2.1) The explanatory note to Article 2.1 states that informed consent lies at the heart of ethical research. It encompasses a process that carries through to the end of the involvement of research subjects.

The *ICH Guidance E6: Good Clinical Practice: consolidated guideline* (Health Canada 1997) specifically provides that research subjects should be informed of any new information that may affect their willingness to continue to participate in the research.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favorable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

REB's set standards for the conduct of research, and these standards vary considerably. REB's may specify what must be disclosed to research subjects (e.g. error, results of the research). However, it is not possible to ascertain their requirements for disclosure without examining the individual policies governing the conduct of the particular REB. Consideration should be given to developing guidelines that would be part of REB process.

There is a strong argument that investigators are under a common law legal duty to disclose medical error to their research subjects. As stated by Glass and Lemmons (2002, 485) “... the standard of disclosure is even more demanding for research than it is for therapy. It is the most exacting duty possible, requiring ‘full and frank disclosure’ of all risks, no matter how remote, as well as all other material information about the research. It is also clear that neither therapeutic privilege nor waiver have a place in research.”

Finally, research and treatment are often carried out at the same time. This strengthens the argument that the same standards governing disclosure to patients should apply to research subjects.

3. Other considerations

a. Therapeutic Privilege

If a physician judges that disclosure of certain information will lead to the harm or suffering of the patient, he or she is said to be free to withhold this information pursuant to therapeutic privilege. This

privilege is normally addressed in the context of informed consent, however it would seem to have application with respect to disclosure of adverse events as well.

A physician bears a heavy burden of proving the propriety of withholding the information (Downie, Caulfield and Flood, 2002, 151). While the privilege is clearly recognized to exist, its application turns on the facts of each case and the cases do not provide helpful guiding principles (Downie, Caulfield and Flood, 2002, 152). This type of privilege has been criticized, and its application in the context of disclosure of error is likely very narrow (Hebert, Levin and Robertson, 2001, 510.)

b. Legal Professional Privilege

It may be that certain communications are made and documents are created after an adverse event for the purpose of obtaining or giving legal advice on the incident or for potential use in legal proceedings. These communications are covered by litigation privilege, and need not be disclosed.

However, it is important to note that litigation privilege only covers confidential communications between a lawyer and client made for the *dominant* purpose of the client obtaining, or the lawyer giving legal advice, or for potential use in legal proceedings (Picard and Robertson, 1996, 412).

c. Legislative Privilege (Quality Assurance Provisions)

All provinces and territories in Canada have enacted legislation that protects from disclosure to third parties certain information generated as a result of particular quality assurance activities (see [Appendix G](#)).

The legislative protection varies from jurisdiction to jurisdiction. Protection is generally extended to information, documents, and opinions. In some statutes, only documents that have been prepared “exclusively” or “primarily” for the quality of care committee will receive protection.

For example, Saskatchewan’s *Evidence Act*, S.S. 2006, c.E-11.2, s.10, does not protect facts, including those newly discovered facts not found in the patient record. Protection is extended to reports, documents or records that are (i) prepared exclusively for the use of or made by a committee; or (ii) used exclusively in the course of, or arising out of, any investigation, study or program carried on by a committee.

Nova Scotia’s *Evidence Act*, R.S.N.S. 1989, c. 154 does not employ a dominant purpose or exclusivity test. Under Ontario’s *Quality of Care Information Protection Act*, S.O. 2004, c. 3, Sch. B (*QCIPA*), protection is extended to information that is collected by or prepared for a quality of care committee for the “sole or primary purpose” of assisting the committee; or relates “solely or primarily to any activity” of the quality of care committee.

Quality assurance protection is generally focused on disclosure in some type of action or legal proceeding. (For that reason, the legislative provisions dealing with quality assurance protection are generally found in the applicable evidence act) Ontario’s *QCIPA* provides much broader protection, although it too does not extend to cover the facts of what occurred (s. 2, definition of “quality of care information”). The *QCIPA* begins with a prohibition on disclosure unless certain conditions are met. The *QCIPA* even restricts disclosure to patients and/or their families, as outlined in a recent book on the Ontario legislation (Perun, Orr and Dimitriadis, 2005):

There is no provision in *QCIPA* that allows quality of care information to be disclosed to a patient, or the family of a patient, even where the patient's care was the subject of a review by a quality of care committee. Even if the committee wishes to disclose quality of care information to

the patient, it is not permitted to do so unless the disclosure falls within the scope of one of the exceptions set out above, which in most instances would not be the case.

The exceptions referred to are disclosures to management, disclosures that are necessary for the purposes of eliminating or reducing a significant risk of serious bodily harm, disclosures to another committee, and disclosures under legislation that specifically provides that it prevails over *QCIPA*.

d. Liability Protection Provider / Liability Insurance Considerations

The Canadian Medical Protective Association (CMPA) is a not-for-profit mutual defense organization provides medico-legal assistance for physicians who practice in Canada. This assistance includes legal defence and indemnification. The CMPA is independent of the liability insurers of institutions/hospitals and other health professionals. Similarly, for Registered Nurses, the Canadian Nurses Protective Society (CNPS) a non-profit society, owned and operated by nurses for nurses, offers legal liability protection related to nursing practice. Healthcare organizations in Canada and their employed healthcare providers generally have liability insurance coverage provided through provincial or regional insurance reciprocals or commercial insurers.

The 2005 CMPA Information Sheet distributed to all member physicians titled “Disclosing adverse events to patients: strengthening the doctor-patient relationship” (Beilby and Wallace, 2005) encourages physicians to disclose to patients the occurrence and nature of adverse outcomes, including those caused by adverse events, as soon as it is reasonable to do so after their occurrence. Similarly, the Canadian Nurses Protective Society (CNPS) has issued an information sheet stating that disclosure to patients is appropriate based on the patient’s right to know their own health information (Canadian Nurses Protective Society, 2005).

A detailed consideration of the potential influence of liability protection providers, or liability insurers, is beyond the scope of this paper.

e. Restrictions on Use of Records and Information in Privacy Legislation

Legislation in each of the provinces restricts the use and disclosure of health information. In Alberta, Saskatchewan, Manitoba and Ontario, there is specific health information legislation that governs collection, use and disclosure of personal health information. As well, these statutes govern a patient’s access to his or her own health information. In the other provinces, health information is governed by public and/or private sector legislation, and others continue to regulate health information in a variety of statutes dealing with various aspects of the healthcare system. (For a map setting out the privacy statutes applying in each jurisdiction, see <http://www.nymity.com/documents/PrivacyRoadmap010105.pdf>.)

To start, it is important to point out that the term “disclosure” is somewhat of a misnomer in the context of privacy legislation. In general, health information legislation, like other types of privacy legislation, begins with a distinction between “use” and “disclosure”. As long as information stays within the custody of a particular custodian or trustee (to use the terms set out in health information legislation in force in Alberta, Saskatchewan, Manitoba and Ontario) it is considered a use and not a disclosure.

“Disclosure” of harm to a patient is therefore a *use* of the health information, and not a disclosure for the purposes of privacy legislation. The team approach to discussion with patients, where information is shared with a person or committee responsible for disclosure does not change this from a use to a disclosure since it is within the same healthcare body. Generally, the information is being used to provide care and treatment to the patient. As pointed out by Robertson, *supra*, at para. 8, disclosure is part of the continuing obligation of a healthcare professional related to informed consent.

Recent decisions by Alberta's Information and Privacy Commissioner illustrate how health information legislation may affect disclosure to patients. Health information legislation contains both mandatory and discretionary exemptions to a patient's right of access to information. A recent decision has held that a custodian must refuse to disclose quality assurance records to an applicant requesting information.

4. What legal implications may arise from disclosure, and how can they be addressed?

a. Civil Liability

Healthcare professionals may be concerned about saying something during a disclosure which can be used against them in legal proceedings. An admission against interest may be used to prove a fact at trial.

The civil cases cited in Robertson (2002) make it clear that a physician is under a common law duty to disclose error, even if the disclosure may lead to civil proceedings being brought against the physician. If other healthcare professionals have a similar duty to disclose error, a similar conclusion would follow.

It is important to consider that disclosing facts relating to an adverse event does not constitute an admission of liability which can be used in court. Many adverse events occur without any actionable negligence on the part of the healthcare professional.

The Australian Policy clarifies that the duty to disclose involves stating the facts and acknowledging what occurred. In the legal considerations section, at 11, the following caution appears:

“Healthcare professionals need to be aware of the risk of making an admission of liability during the open disclosure process. In any discussion with the patient and their support person during the open disclosure process, the healthcare professional should take care not to –

- h) state or agree that they are liable for the harm caused to the patient;
- i) state or agree that another healthcare professional is liable for the harm caused to the patient; or
- j) state or agree that the healthcare organisation is liable for the harm caused to the patient.”

One study demonstrated that patients tend to prefer explanations of why the adverse event occurred, and most often desire an apology. One option, to encourage openness and honesty, is the inclusion of a legislative privilege for disclosure of error and apologies in the provincial and federal evidence acts.

British Columbia was the first province to enact an apology privilege, on May 18, 2006 (*Apology Act*, S.B.C. 2006, c. 19). Section 2 of the *Act* provides:

2(1) An apology made by or on behalf of a person in connection with any matter

- (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter,
- (b) does not constitute a confirmation of a cause of action in relation to that matter for the purposes of section 5 of the *Limitation Act*,

(c) does not, despite any wording to the contrary in any contract of insurance and despite any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available, to the person in connection with that matter, and

(d) must not be taken into account in any determination of fault or liability in connection with that matter.

(2) Despite any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any proceeding and must not be referred to or disclosed to a court in any proceeding as evidence of the fault or liability of the person in connection with that matter.

Apology is defined in s. 1:

1 In this Act:

"apology" means an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate;

Many American states have legislated an apology privilege. One of the broadest privileges exists in Colorado which provides as follows:

“In any civil action brought by an alleged victim of an unanticipated outcome of medical care[...]any and all statements, affirmations, gestures or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a healthcare provider or an employee of a healthcare provider to the alleged victim [or the victim’s relatives or representatives] which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability.” (Cohen, 2004, 21).

b. Professional Discipline

The fear of professional disciplinary proceedings is another potential obstacle to disclosure of adverse events. However, as more ethics codes mandate disclosure, healthcare professionals might be subject to disciplinary proceedings for the failure to disclose, in instances where the underlying error would not have brought about any disciplinary proceedings. For example, in New Brunswick a failure to disclose an adverse event, as required by the code of ethics, equates to professional misconduct.

The potential consequences of failing to disclose were explained by Dr. Morris VanAndel, Registrar of the B.C. College of Physicians, in a Conference on Disclosure on September 24, 2004:

“... only about one percent of complaints rise to the level of disciplinary action. Virtually all of those actions have related to conduct violations. In the past twelve years, no case has come to discipline on the grounds of medical error alone, whereas disingenuous attempts by members to minimize or conceal medical error have” (Seland, 2004, 5).

Dr. VanAndel concluded that there was no need to modify College processes to foster disclosure and reporting of error. Rather, impediments to disclosure were only perceived and the consequences of failure to disclose needed to be considered.

5. What practical implications arise if this duty is imposed, and how can they be addressed?

a. Retaliation

A further obstacle to disclosure may be the fear of retaliation. A type of “whistleblower” protection is advocated for by Outerbridge (2004). The Manitoba legislation contains a provision specifically prohibiting retaliation, in the form of dismissal, suspension, demotion, discipline, harassment, as a result of compliance with the legislation (s. 2 (53.4.1(4))(53.9)).

CONCLUSION

Recent activities by regulatory bodies, provincial governments, healthcare providers, professional associations and others have provided a foundation for the development of pan-Canadian guidelines for disclosure of adverse events to patients.

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APPENDIX A: POLICIES AND CODES OF ETHICS FOR PHYSICIANS

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------------------|-----------------------------|
| National Canadian Medical Association (CMA) | In all provinces except for Quebec, section 14 of the CMA <i>Code of Ethics</i> (2004) is embedded, under the heading of “Responsibilities to the Patient,” provides as follows: 14. Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient. | Harm, which is not a defined term. | ~ | ~ |
| Alberta | There is a duty to disclose harm, as provided in s. 14 of the CMA <i>Code of Ethics</i> (2004), as adopted by the College of Physicians and Surgeons of Alberta. | Harm, which is not a defined term. | ~ | ~ |
| British Columbia | There is a duty to disclose harm, as provided in s. 14 of the CMA <i>Code of Ethics</i> (2004), as adopted by College of Physicians & Surgeons of British Columbia in its <i>Physician Resource Manual</i> (2005). | Harm, which is not a defined term. | ~ | ~ |
| Manitoba | There is a duty to inform a patient of a deficiency in care. Section 26.2 of the <i>Code of Conduct</i> (2005) of the College of Physicians and Surgeons of Manitoba (Schedule G of By-law #1): 26.2. When you learn that a deficiency of care has occurred, you should inform the patient and make the responsible physician aware. The College of Physicians and Surgeons of Manitoba Statement No. 169 on <i>Physician Disclosure of Harm in the Course of Patient Care</i> (2002) requires that: 1. A physician must promptly inform his or her patient of any harm that has occurred in the course of that patient's medical care. 2. A physician must provide full and frank disclosure to the patient respecting the harm. | “Deficiency of care,” which is not a defined term. | ~ | ~ |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------|-----------------------------|
| New Brunswick | <p>There is a duty to disclose harm, as provided in s. 14 of the <i>CMA Code of Ethics</i> (2004). The Council of the College of Physicians and Surgeons of New Brunswick has adopted the <i>CMA Code of Ethics</i> (2004) and added commentary.</p> <p>Section 32 of Regulation #9 provides that a breach of the Code of Ethics constitutes professional misconduct for the purposes of Part II of the <i>Medical Act</i>.</p> <p>In a commentary, dated November 2002, titled "Reporting of Adverse Events," the Council of the College concluded that a specific policy regarding disclosure was unnecessary because of the Council's view that this was already an existing obligation on the part of physicians. In other words, patients remain entitled to have complete information regarding their care, including any adverse events. The Council was furthermore of the view that it is improper for such an obligation to be interfered with by other parties. It is the Council's view that early, candid, and full disclosure of adverse events to patients, and their families, will be of benefit to all concerned.</p> | Harm, which is not a defined term. | ~ | ~ |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Newfoundland/ Labrador</p> | <p>Physicians have a duty to disclose adverse outcomes. The College of Physicians and Surgeons of Newfoundland & Labrador's Policy, <i>Disclosure of an Adverse Outcome</i> provides as follows: 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. In some circumstances, it may be that more than one medical practitioner was responsible for the health care treatment, which resulted in the adverse outcome. In such circumstances, each responsible medical practitioner has an individual responsibility to ensure that disclosure is made to the patient of the adverse outcome. In such circumstances, the responsible medical practitioners should consult as to who among them will make the disclosure to the patient. The College has also adopted the CMA <i>Code of Ethics</i> (2004). Section 34 (c)(v) of <i>An Act Respecting the Practice of Medicine in the Province</i> (2005) provides that a breach of the code of ethics constitutes "conduct deserving of sanction."</p> | <p>The policy provides that "...adverse outcome means a non-trivial adverse outcome or consequence of health care treatment, which adverse outcome or consequence is not solely related to the course of the illness or condition being treated but has resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered. Adverse outcome includes a situation where the possibility of the adverse outcome may be a recognized risk of the treatment." "Adverse event" also includes an incident in the course of health care treatment which results in a recognized potential risk of a non-trivial adverse outcome or consequence at some future time.</p> | <p>The policy provides that: "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 invites speculation or conjecture. 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.... Within the foregoing context, an expression of regret for the adverse outcome may be appropriate, and should not be taken as an admission of fault or liability.</p> | <p>The policy provides that, in circumstances where questions of fault or negligence may give rise to a claim for damages or litigation, a medical practitioner may wish to first seek the advice of the medical malpractice protection provider as to how disclosure of an adverse outcome may be made without it being taken to be an admission of fault or liability.</p> |
| <p>Nova Scotia</p> | <p>There is a duty to disclose harm, as provided in s. 14 of the CMA <i>Code of Ethics</i> (2004), as adopted by the College of Physicians and Surgeons of Nova Scotia by regulation on June 3, 2005.</p> | <p>Harm, which is not a defined term.</p> | <p>~</p> | <p>~</p> |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ontario | <p>There is a duty to disclose harm. The College of Physicians and Surgeons of Ontario's <i>Disclosure of Harm</i> (2003) policy, provides that:</p> <p>When a physician becomes aware, while treating a patient, that the patient has suffered harm in the course of receiving health care, he or she should consider whether the harm does or can be reasonably expected to negatively affect the patient's health and/or quality of life. If it does, then it is the physician's obligation to inform the patient about the harm sustained.</p> | Harm is defined broadly as an unexpected or normally avoidable outcome that negatively affects the patient's health and/or quality of life, which occurs (or occurred) in the course of health care treatment and is not due directly to the patient's illness. | The focus should be on what is known about the event, a short, objective, factual non-technical summary is best. Physicians should avoid attributing blame to specific individuals or providing simple explanations as to "cause" or responsibility. A timely and empathic expression of regret and condolences may be appropriate and should not be construed or taken to be an admission of liability or fault. Discussing a plan of care that addresses the harm is of equal importance. | The policy provides that a physician may wish to contact his or her medical malpractice protection provider for advice on how to discuss with a patient issues relating to harm. |
| Prince Edward Island | There is a duty to disclose harm, as provided in s. 14 of the <i>CMA Code of Ethics</i> (2004), as adopted by the College of Physicians and Surgeons of Prince Edward Island. | Harm, which is not a defined term. | ~ | ~ |
| Quebec | Physicians have a duty to inform a patient of any incident, accident or complication which is likely to have, or which has had, a significant impact on his state of health or personal integrity. Section 56 of the <i>Code of ethics of physicians</i> (2006), provides: 56. A physician must, as soon as possible, inform his patient or the latter's legal representative of any incident, accident or complication which is likely to have or which has had a significant impact on his state of health or personal integrity. | "Incident," "accident" and "complication" are not defined. It is arguable that the definitions of "incident" and "accident" from An Act respecting health services and social services, supra, would apply. | ~ | ~ |
| Saskatchewan | There is a duty to disclose harm, as provided in s. 14 of the <i>Code of Ethics for Saskatchewan Physicians</i> (2005), as adapted from the <i>CMA Code of Ethics</i> (2004). | Harm, which is not a defined term. | ~ | ~ |

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APPENDIX B: POLICIES, STANDARDS AND CODES OF ETHICS FOR NURSES

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------|--------------------------------------|
| <p style="text-align: center;">National: Canadian Nurses Association (CNA)</p> | <p>The Canadian Nurses Association’s <i>Code of Ethics for Registered Nurses</i> (2002) provides that nurses must admit mistakes. Although it does not specify that they must admit them to the patient, this can be inferred from the context. They must also take all necessary actions to prevent or minimize harm arising from an adverse event.</p> <p>The Value of “Safe, Competent and Ethical Care” provides that:</p> <ol style="list-style-type: none"> 8. Nurses must admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event. 9. Nurses must strive to prevent and minimize adverse events in collaboration with colleagues on the health care team. When adverse events occur, nurses should utilize opportunities to improve the system and prevent harm. | <p>The terms “mistakes,” “harm” and “adverse event” are not defined.</p> | <p style="text-align: center;">~</p> | <p style="text-align: center;">~</p> |
| <p style="text-align: center;">Alberta</p> | <p>There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA’s <i>Code of Ethics for Registered Nurses</i> (2002) is integrated into the College and Association of Registered Nurses of Alberta’s <i>Nursing Practice Standards</i> (2003) under Standard #3, Ethical Practice, which states that: “The registered nurse complies with the Canadian Nurses Association (CNA) Code of Ethics for Registered Nurses (2002).”</p> | <p>The terms “mistakes,” “harm” and “adverse event” are not defined.</p> | <p style="text-align: center;">~</p> | <p style="text-align: center;">~</p> |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------|-----------------------------|
| British Columbia | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) is adopted in "Standard 4: Code of Ethics" in the College of Registered Nurses of British Columbia's <i>Professional Standards for Registered Nurses and Nurse Practitioners</i> (2005). | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |
| Manitoba | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. "Standard I: Professional Responsibility and Accountability" and "Standard V: Ethical Practice" of the College of Registered Nurses of Manitoba's <i>Standards of Practice for Registered Nurses</i> (2004) provide that nurses should practice in a manner consistent with the CNA's <i>Code of Ethics for Registered Nurses</i> (2002). | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |
| New Brunswick | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) has been adopted by the Nurses Association of New Brunswick. Their <i>Standards of Practice for Registered Nurses</i> (2005) provides under "Standard 4: Ethical Practice" that nurses must practice in accordance with the <i>Code of Ethics</i> . | ~ | ~ | ~ |
| Newfoundland/ Labrador | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) has been adopted by the Association of Registered Nurses of Newfoundland and Labrador. Their <i>Standards for Nursing Practice in Newfoundland and Labrador</i> (1995) provide under "Standard 4: Code of Ethics" that nurses must comply with the Code of Ethics of the profession. | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------|-----------------------------|
| <p align="center">North West Territories and Nunavut</p> | <p>There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The Registered Nurses Association of Northwest Territories and Nunavut has adopted the CNA's <i>Code of Ethics for Registered Nurses</i> (2002). <i>The Standards of Practice for Registered Nurses NWTRNA</i> (2002) provide that a nurse must practice in accordance with the CNA's <i>Code of Ethics</i>.</p> | <p>The terms "mistakes," "harm" and "adverse event" are not defined.</p> | <p align="center">~</p> | <p align="center">~</p> |
| <p align="center">Nova Scotia</p> | <p>There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) has been adopted by the College of Registered Nurses of Nova Scotia in their <i>Standards of Nursing Practice</i> (2004) which details under "Standard 1: Accountability" that nurses must practice in accordance with the CNA's <i>Code of Ethics for Registered Nurses</i> (2002).</p> | <p>The terms "mistakes," "harm" and "adverse event" are not defined.</p> | <p align="center">~</p> | <p align="center">~</p> |
| <p align="center">Ontario</p> | <p>The College of Nurses of Ontario's <i>Professional Standards</i> (2002) provides, under the heading of "Accountability," that a nurse demonstrates the standard by taking responsibility for errors when they occur and taking appropriate action to maintain client safety. Further, under the heading of "Ethics", nurses are directed to follow the College's <i>Ethics Practice Standard</i> (2002) which did not specifically deal with disclosure, although the obligation to disclose might be inferred from the section on "Maintaining Commitments," pursuant to which nurses are obliged to be honest.</p> | <p>"Errors," which is not defined.</p> | <p align="center">~</p> | <p align="center">~</p> |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------|-----------------------------|
| Prince Edward Island | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) has been adopted by the Association of Nurses of Prince Edward Island. The <i>Standards for Nursing Practice</i> (1999) provide under "Standard I - Code of Ethics" that nurses must practice in accordance with the CNA's <i>Code of Ethics for Registered Nurses</i> (2002). | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |
| Quebec | There is no express duty to disclose, but such a duty can be implied from ss. 11 and 28 of the <i>Code of ethics of nurses</i> (2003), which emphasize the relationship of trust between a nurse and patient: 11. A nurse shall not abuse the trust of her or his client. 28. A nurse shall seek to establish and maintain a relationship of trust with her or his client. | ~ | ~ | ~ |
| Saskatchewan | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The Saskatchewan Registered Nurses' Association <i>Standards and Core Competencies</i> (2003) provides, under "IV. Guiding Principles", that the nurse must meet the CNA <i>Code of Ethics for Registered Nurses</i> (2002). | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |
| Yukon | There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The CNA's <i>Code of Ethics for Registered Nurses</i> (2002) has been appended to the <i>Standards for Registered Nursing Practice in the Yukon</i> (2005), whose "Code of Ethics" (standard 4), provides that nurses must uphold the values contained in the CNA's <i>Code of Ethics</i> (2002). | The terms "mistakes," "harm" and "adverse event" are not defined. | ~ | ~ |

Appendix B Reference List

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APPENDIX C: POLICIES, STANDARDS AND CODES OF ETHICS FOR PHARMACISTS

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/ Qualifications? |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------|---------------------------------|
| Alberta | In the <i>Code of Ethics Bylaw</i> of the Alberta College of Pharmacists (1998) there is no express duty to disclose, but the duty may be implied from Principle I, that a pharmacist holds the health and safety of each client to be the primary consideration and Principle VI, that a pharmacist acts with honesty and integrity. | ~ | ~ | ~ |
| British Columbia | The <i>Code of Ethics</i> of the College of Pharmacists of British Columbia (1998) provides, under “Value IV. A pharmacist provides competent care to the patient and actively supports the patient’s right to receive competent and ethical health care.” that: “A pharmacist shall not participate in efforts to deceive or mislead patients about the cause of alleged harm or injury resulting from unethical or incompetent conduct.” | ~ | ~ | ~ |
| Manitoba | The Manitoba Pharmaceutical Association’s <i>Code of Ethics</i> (2001) and <i>Standards of Practice</i> (2006) does not set out an express duty to disclose, but the duty may be implied from points 1 and 2 of the Code: 1. Pharmacists shall hold the health and safety of the public to be of first consideration in the practice of the profession of pharmacy rendering to each patient the full measure of their ability as an essential health care practitioner. 2. Pharmacists shall observe the law, particularly those affecting the practice; and conduct themselves in a manner that entitles them to the respect and confidence of the public. | ~ | ~ | ~ |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------|-----------------------------|
| New Brunswick | There is no express duty to disclose, but such a duty can be inferred from Statements I and VI of the <i>Code of Ethics</i> of the New Brunswick Pharmaceutical Society (2003) which provide that the health and safety of each patient is of primary consideration and that pharmacists must preserve high professional standards and uphold the dignity and honour of the profession. | ~ | ~ | ~ |
| Newfoundland/ Labrador | There is no express duty to disclose, but such a duty can be inferred from Statements I and II of the <i>Code of Ethics</i> of the Newfoundland Pharmaceutical Association (2001) which set out the primacy of the patient's health and safety, and the importance of a professional relationship with the client and acting with honesty and integrity. | ~ | ~ | ~ |
| Nova Scotia | There is no express duty to disclose, but such a duty can be inferred from Values I and II of the <i>Code of Ethics</i> of the Nova Scotia College of Pharmacists (2003) which set out the primacy of the patient's health and safety, and the importance of a professional relationship with the patient and acting with honesty and integrity. | ~ | ~ | ~ |
| Ontario | There is no express duty to disclose, but such a duty can be inferred from Principles One and Five of the <i>Code of Ethics</i> of the Ontario College of Pharmacists (1996) which set out the ethical covenant between a pharmacist and patient, and the importance of honesty and integrity. | ~ | ~ | ~ |

| Jurisdiction | Is there a duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------------------------|-----------------------------|
| Prince Edward Island | There is no express duty to disclose, but such a duty can be inferred from Statements I and II of the <i>Code of Ethics</i> of the Prince Edward Island Pharmacy Board (2001) which set out the primacy of the patient's health and safety, and the importance of a professional relationship with the patient and acting with honesty and integrity. | ~ | ~ | ~ |
| Quebec | There is an express duty to inform a patient of error in s. 3.02.04 in the <i>Code of Ethics of Pharmacists</i> (2006). A pharmacist must inform his patient as soon as possible of any error he has made in rendering a professional service to that patient | Error, which is not defined. | ~ | ~ |
| Saskatchewan | There is no express duty to disclose, but such a duty can be inferred from sections 13.1.1 and 13.1.8 of the <i>Code of Ethics</i> (no date) of the Saskatchewan College of Pharmacists, which emphasize the importance of the health and safety of the patient and the professional integrity of the pharmacist. | ~ | ~ | ~ |

Appendix C Reference List

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APPENDIX D: EXISTING LEGISLATION

| Province | Who has the duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manitoba | The regional health authority, health corporation or prescribed health care organization. | A “critical incident,” which is defined as “an unintended event that occurs when health services are provided to an individual and result in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual’s underlying health condition or from a risk inherent in providing the health service.” | The responsible organization must ensure that appropriate steps are taken to fully inform the individual about the facts of what actually occurred, its consequences as they become known, and the actions taken and to be taken to address the consequences of the critical incident. | The legislation specifically prohibits retaliation, in the form of dismissal, suspension, demotion, discipline, harassment, as a result of compliance with the legislation. |
| Quebec | Any employee of an institution, any person practicing in a centre operated by an institution, any person undergoing training in such a centre or any person who, under a service contract, provides services to users on behalf of an institution. | An “accident,” which is defined as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person.” | “Necessary information.” | ~ |

APPENDIX E: PROVINCIAL POLICIES OR GUIDELINES

| Province | Who has the duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <p>Alberta</p> <p>Health Quality Council of Alberta:</p> <p><i>Disclosure of Harm to Patients and Families: provincial framework (2006)</i></p> | <p>This framework does not impose any duties, but suggests that the most responsible physician will be the appropriate lead for the disclosure conversations, although there may be times when it is more appropriate for other members of the health care team to take the lead.</p> <p>A team approach to disclosure ensures that all relevant individuals are present when sharing information with the patient and family. Examples of disclosure team members include: most responsible physician; member of the care team directly involved in the patient's ongoing care, organizational representative (e.g., manager for clinical area); patient care representative; patient safety team member; and/or situation managers."</p> | <p>When a patient experiences harm while receiving health care, full and complete disclosure must occur. Harm is defined as "an unexpected or normally avoidable outcome that negatively affects the patient's health and/or quality of life, which occurs, or occurred in, the course of health care treatment and is not due directly to the patient's illness"</p> <p>When an adverse event occurs and there is no apparent harm to the patient but the potential for harm remains, disclosure supports an open, transparent and trusting relationship with the patient, and enables the patient and family to proactively monitor his or her condition.</p> | <p>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:</p> <ul style="list-style-type: none"> • 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. <p>Information that cannot be disclosed to the patient, following Alberta legislation, includes:</p> <ul style="list-style-type: none"> • information that could reasonably lead to the identification of a person who provided the health information in explicit or implicit confidence (HIA s. 11 (1)(b)); • results of an investigation relating to a health service provider (HIA s. 11 (2)(b)); and • records of the Quality Assurance Committee, including any sub-committees conducting investigations into cases where harm has occurred. <p>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.</p> | <p style="text-align: center;">~</p> |

| Province | Who has the duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/Qualifications? |
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| <p>British Columbia</p> <p>Provincial Health Services Authority:</p> <p><i>Disclosure of Adverse Events (2006)</i></p> | <p>After determining disclosure should take place, the team responsible for disclosing should be determined by the appropriate health care provider and the appropriate manager. Consideration should be given to a patient's preferences not to have certain individuals present during the discussion.</p> | <p>The appropriate manager and the health care provider will immediately determine whether disclosure to the patient/substitute decision-maker and family will take place. If unsure, consultation with the Risk Management Department would be appropriate. If the incident is defined as a near miss, disclosure should be determined on a case by case basis. If a patient has knowledge of the incident, disclosure may be appropriate. The patient's best interests should be considered when deciding whether to disclose. "Adverse Event" is defined as: a bad outcome of care. An injury that was caused by health care management rather than the patient's underlying disease. Healthcare management refers to all aspects of the health care system, not just the actions or decisions of physicians or nurses.</p> | <p>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.</p> <p>APOLOGIZE. Empathize with the patient/family, "we are so sorry this has happened to you."</p> <p>However, the discussion should not involve a legal admission of liability.</p> <p>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.</p> <p>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.</p> | <p>~</p> |
| <p>Newfoundland and Labrador Association of Healthcare Risk Management :</p> <p><i>Policy on adverse events/occurrence (2005)</i></p> | <p>The responsibility to disclose usually rests with the attending physician/most responsible party. The attending physician/most responsible party and the risk manager will consider involving representatives from nursing, allied health professionals, pastoral care, social workers or staff members known to and trusted by the patient/resident/client/family.</p> <p>If the attending physician/most responsible party is unwilling or unable to disclose the occurrence, or if investigation determines that his/her involvement could exacerbate the problem, the risk manager will work with administration to identify the appropriate person to handle this responsibility.</p> | <p>Occurrences in which patients/residents/clients are harmed, including Severity Levels 3 through 6. For example: unexpected admission to intensive care, unexpected patient/resident/client death, unnecessary treatment with burdensome impact on the patient/resident/client, return to OR</p> <p>Errors that do not harm patients/residents/clients and do not have the potential to do so (insignificant or minor occurrences) do not require disclosure to the patient/resident/client.</p> | <p>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.</p> <p>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.</p> | <p>~</p> |

| Province | Who has the duty to disclose? | What type of event triggers the duty to disclose? | What must be disclosed? | Protections/ Qualifications? |
|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <p>Nova Scotia Health:</p> <p><i>Disclosure of Adverse Events Policy (2005)</i></p> | <p>Designated organizations are under an obligation to establish internal policies to provide for processes to promptly inform clients of pertinent facts associated with adverse events.</p> | <p>“Adverse event” is defined as an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided.</p> | <p>The initial disclosure should include:</p> <ul style="list-style-type: none"> • 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 <p>The policy recognizes that the disclosure obligation is a continuing one, as more information becomes available</p> | <p>~</p> |
| <p>Saskatchewan Health:</p> <p>Disclosure of Harm Guideline (2005)</p> | <p>The Guideline is not mandatory, but rather provides that it is the expectation of Saskatchewan Health that all regional health authorities will prepare and implement policies requiring disclosure of harm. The guideline encourages a team approach for discussing harm with a patient, but an individual may be more appropriate in certain circumstances. Lead for the disclosure discussion should rest with those who have the most knowledge of the events that led to the harm.</p> | <p>“Harm” which is defined as: “Any injury to the body. The occurrence of a change for the worse.”</p> | <p>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.</p> | <p>~</p> |

APPENDIX F: POLICIES ADOPTED BY ORGANIZATIONS

| Location | Who has a Duty to Disclose | What Triggers Duty | Content of Disclosure | Protections/Qualifications |
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| <p>Hamilton Health Sciences including: *McMaster University Medical Centre (MUMC) *Chedoke Hospital *McMaster Children’s Hospital *Hamilton General Hospital *Henderson General Hospital</p> <p>Issued: June 26, 2003</p> | <p>All health care professionals must report when a patient has suffered harm, but disclosure to the patient is usually made by the health care professional who has the final responsibility and accountability for the care of the patient.</p> <p>Disclosure is a co-ordinated team process, with varying levels of involvement depending on the seriousness of the occurrence.</p> | <p>Patients are to receive truthful and compassionate information about harm suffered in the course of receiving health care. This may include</p> <ul style="list-style-type: none"> • When outcome of care varies significantly from what was anticipated; • When an occurrence results in clear or potential clinical consequences; • When an occurrence does not result in clinical consequences but a reasonable person would want information about the event because it might assist them in planning future care; • When a “near miss” occurs that reaches the patient’s awareness. <p>Harm is defined as an unexpected or normally avoidable outcome that negatively affects a patient’s health or quality of life which occurs (or occurred) in the course of healthcare treatment and is not due directly to the patient’s illness.</p> | <p>Disclosure is to include</p> <ul style="list-style-type: none"> • a factual summary of the event, and how it affects the patient’s health and treatment plan. • an expression of sympathy • a statement that the matter will be investigated so that recurrences will be prevented • a promise to keep them update on that investigation <p>Disclosure is to be made as soon as practically possible after the occurrence is identified, taking into account the clinical and emotional condition of the patient and their ability to understand.</p> | <p>The policy provides that prompt and thorough reporting and disclosure will not lead to any disciplinary action by the Hospital against the involved individual(s). However, the Hospital reserves the right to appropriately address threats to patient safety when investigation reveals serious and unusual deficiencies in care, such as repeated or gross violation of hospital policy/procedure, or a reckless disregard for patient safety.</p> |
| <p>McGill University Health Centre Montreal, QB</p> | <p>In most cases, the treating physician is responsible for disclosure. Before disclosure is made, the physician involved should discuss the matter with members of the treatment team and, depending upon the seriousness of the accident, the MUHC administration. This discussion is for the purpose of establishing all relevant facts. The supporting document provides that: “Errors committed by others are not the responsibility of an observer to disclose, but should be [reported].”</p> | <p>Accidents that have actual or potential consequences for the health or welfare of a patient.</p> <p>The supporting document provides that: “Incidents where a patient has been harmed, or has the potential to be harmed by the provision of health care or where additional care must be given to rectify potential harm should be disclosed.”</p> | <p>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.</p> <p>Personal opinions as to fault or responsibility are to be avoided.</p> | <p>The supporting document provides that: “Prompt and thorough reporting of an adverse incident will not lead to any disciplinary action by the Hospital unless there are serious and unusual deficiencies in care such as repeated or gross violation of hospital policies, or reckless disregard for patient safety or illegal acts. In these cases, the hospital has the right and responsibility to address the threats to patient safety.”</p> |

| Location | Who has a Duty to Disclose | What Triggers Duty | Content of Disclosure | Protections/Qualifications |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <p>The Ottawa Hospital including: *The Ottawa Hospital, Civic Campus *The Ottawa Hospital, General Campus *Children’s Hospital of Eastern Ontario (CHEO) *Queensway-Carleton Hospital *Montfort Hospital</p> <p>Issued: October 15, 2003</p> | <p>The responsibility for disclosing an adverse event or outcome to a patient (or their surrogate) generally rests with the attending physician.</p> | <p>An “adverse outcome” which is defined as any or the following:</p> <ul style="list-style-type: none"> • development of a new temporary or permanent disability during therapy; • an unanticipated prolongation of hospitalization (where prolongation can refer to an entire admission or a readmission); or • an unanticipated death. | <p>Disclosure discussions concerning preventable adverse events should include:</p> <ul style="list-style-type: none"> • 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 <p>Disclosure should be made as soon as reasonably possible after the adverse event occurs.</p> | <p>~</p> |

| Location | Who has a Duty to Disclose | What Triggers Duty | Content of Disclosure | Protections/Qualifications |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <p>St. Michael's Hospital Toronto, ON</p> <p>October 2005</p> | <p>All healthcare professionals share the obligation, but the communication is best made by the principal caregiver, unless the adverse event was primarily associated with an hospital employee, in which case a hospital manager or designate should make the disclosure.</p> | <p>An “adverse event” which is defined as an unexpected or normally avoidable event that negatively affects, or would reasonably be expected to have the potential for negatively affecting, the patient’s health and/or quality of life, and which event occurred in the course of health care treatment and is not due directly to the natural course of the patient’s illness or underlying condition. Adverse events can include, among other things, complications or side effects of health care treatment or errors in the performance of treatment, but are not necessarily markers of substandard care.</p> | <p>Disclosure should include: (a) an explanation of what happened or what is known at the time of the meeting in a straightforward and non-judgmental fashion, including the nature, severity and cause (if known) of the Adverse Event; (b) an outline of the specific steps that will be taken to monitor and treat an Adverse Event or otherwise prevent recurrence of the Adverse Event; (c) an expression of regret, sympathy and/or an apology; and (d) an offer for follow-up contact and/or support. Communicators should avoid speculation regarding any causative or contributing factors and should focus only on the facts that are known at the time of the discussion. Communication of the Adverse Event should take place as soon as practically possible after it has been identified, taking into consideration the physical and emotional condition of the patient.</p> | <p>~</p> |
| <p>Sunnybrook & Women’s College Health Sciences Centre in Toronto (Original Policy Issued: January 2002)</p> | <p>All physicians and healthcare practitioners.</p> | <p>Adverse medical events, which are defined as “negative patient outcomes that can occur as the result of health care treatment and not due to the patient’s illness. They are often unanticipated and unexpected outcomes of healthcare that do, or have the potential to, negatively impact a patient’s health and quality of life. They include complications and side effects of treatment as well as errors in the performance of medical duties. Adverse medical events are not necessarily markers of substandard care.”</p> | <p>~</p> | <p>~</p> |

| Location | Who has a Duty to Disclose | What Triggers Duty | Content of Disclosure | Protections/Qualifications |
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| <p>Thunder Bay Regional Health Sciences Centre</p> <p>Issued: September 7, 2004</p> | <p>All health care practitioners in the hospital.</p> <p>The policy advocates a team approach in which the team discusses the adverse event and decides which health care practitioner would be most appropriate to carry out the disclosure.</p> | <ul style="list-style-type: none"> • Significant adverse medical events / critical incidents. • Any harm suffered as a result of the care provided. • Unanticipated negative outcomes. • Events that do not result in clinical consequences but a reasonable person would want information about because it might assist them in planning future care • A ‘near miss’ that reaches the patient’s awareness. <p>Adverse event is defined as an unintended, undesired, and harmful consequence of treatment occurring due to complications of treatment or due to error in treatment.</p> <p>Critical Incident is defined as any clearly preventable occurrence that led to an undesirable outcome or might have lead to an undesirable outcome if not discovered in time.</p> | <p>The person disclosing to the patient should provide a short, objective factual summary of the event, acknowledge the event with empathy, describe how the event affected the patient’s health status and treatment plan, avoid speculation, attribution of blame, indicate that there will be follow up meetings to examine the event and make appropriate changes to prevent re-occurrences.</p> <p>Disclosure should occur as soon as possible after the event.</p> <p>Timing of the disclosure may be affected by the patient’s ability to comprehend the information.</p> | <p>~</p> |
| <p>Vancouver Coastal Health including: * Vancouver General Hospital, University of BC Hospital, George Pearson Centre, GF Strong Rehabilitation Centre Richmond Health Services including: * Richmond Hospital, North Shore, Coast Garibaldi (Lion’s Gate Hospital, Squamish General Hospital, Powerll River General Hospital, St. Mary’s Hospital Sechelt, Bella Bella and Bella Coola General Hospitals)</p> | <p>Disclosure should be made by the Program Manager (or designate) and the Most Responsible Physician.</p> | <p>Incidents involving apparent or likely injury to a patient/client. For those incidents that have not caused harm, but have potential for harm, the Team should discuss with Risk Management staff the appropriateness of discussion.</p> | <p>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.</p> | |

APPENDIX G:

LEGISLATIVE PROVISIONS PROTECTING QUALITY OF CARE INFORMATION

BRITISH COLUMBIA

Evidence Act, R.S.B.C. 1996, c.124, s.51

Designation Regulation, British Columbia Regulation 363/95 as amended

ALBERTA

Alberta Evidence Act, R.S.A. 2000, c.A-18, s.9

Health Quality Council of Alberta Regulation, Alberta Regulation 130/2006, s.10

Quality Assurance Committee Regulation, Alberta Regulation 294/2003

Health Information Act, R.S.A. 2000, c.H-5, ss.35(1)(g), 35(2)-(3)

SASKATCHEWAN

Health Information Protection Act, S.S. 1999, c.H-0.021, s.27(4)(g)

Evidence Act, S.S. 2006, c.E-11.2, s.10

Regional Health Services Act, S.S. 2002, c. R-8.2, s.58

Critical Incident Regulations, R-8.2 Reg. 3

MANITOBA

Manitoba Evidence Act, R.S.M. 1987, c.E150, ss.9, 10 (C.C.S.M., c.E150)

ONTARIO

Quality of Care Information Protection Act, 2004, S.O. 2004, c.3, Sched. B

Definition of 'Quality of Care Committee' Regulation, Ontario Regulation 297/04

General Regulation, Ontario Regulation 330/04

QUEBEC

An Act Respecting Health Services and Social Services, R.C.Q., c.S-4.2, ss. 183.1, 183.3, 183.4, 190, 213, 214, 218

NEW BRUNSWICK

Evidence Act, R.S.N.B. 1973, c.E-11, s.43.3

NOVA SCOTIA

Evidence Act, R.S.N.S. 1989, c.154, ss.60, 61

NEWFOUNDLAND / LABRADOR

Evidence Act, R.S.N.L. 1990, c.E-16, s.8.1

PRINCE EDWARD ISLAND

Medical Act, R.S.P.E.I. 1998, c.M-5, s.52

NORTHWEST TERRITORIES

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15

YUKON

Evidence Act, R.S.Y. 2002, c.78, s.13

NUNAVUT

Evidence Act, R.S.N.W.T. 1988, c.E-8, ss.13, 14, 15, as duplicated for Nunavut by s.29 of the *Nunavut Act*, S.C. 1993, c.12