Disclosure of Harm to Patients and Families

Provincial Framework
July 2006
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Foreword

On behalf of the Health Quality Council of Alberta (HQCA) and the members of the Health Quality Network, it is a great pleasure to introduce the Alberta framework for Disclosure of Harm to Patients and Families. The framework is not meant to be prescriptive but rather is a guide for health care providers and professions for sharing information with patients and families when a patient experiences unanticipated harm during care. It also reflects a deep commitment and the concerted efforts of many individuals and diverse groups throughout the province who are striving to improve the quality and safety of our health care system.

The process in developing this framework was a thorough one. It included a review of current literature and policies and practices across Canada and around the world. It also included a detailed review of the Alberta legislative environment and extensive discussions with legal counsel and other representatives from the regional health authorities and their insurers. In addition, we consulted with representatives from two major Alberta universities and the provincial Office of the Information and Privacy Commissioner.

We consulted extensively with stakeholders through five forums scattered across the province, an online survey, presentations and discussions with key stakeholder groups such as the Canadian Medical Protective Association, Health Boards of Alberta, Alberta Medical Association and the Council of Chief Executive Officers. We also conducted focus groups with patients and family members.

The Council’s mission is to promote and improve patient safety and health service quality on a provincewide basis, primarily through the lens of the Alberta Quality Matrix for Health. One of the six key dimensions of quality in the matrix is acceptability of care. Acceptability is defined as health services that are respectful and responsive to users’ needs, preferences and expectations. Clearly, disclosure of harm falls within this dimension of quality.

In helping to create the disclosure framework, we at the Health Quality Council of Alberta were energized by the collaborative spirit and willingness to work together that we experienced with our stakeholders. Our goal as we move forward is to continue to encourage this dialogue and knowledge sharing among the health regions, health professions, health boards, government, academia and the public to make our health system better and safer for all Albertans.

John W. Cowell, MD
Chief Executive Officer
Health Quality Council of Alberta

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Introduction

This is the first edition of the framework *Disclosure of Harm to Patients and Families*, a consensus document created to provide a reliable benchmark reference for policy-makers and health care providers in the province of Alberta. Its purpose is to help guide the disclosure process for patients and families when harm occurs. The framework is written from the perspective of what a patient would want and reasonably expect to learn when he or she experiences harm while receiving health care. It also provides specific direction for health authorities based upon the current legislative environment. Future editions of the framework will be written to reflect evolving legislation and practices.

The Health Quality Council of Alberta (HQCA) is committed to supporting health authorities and health care professions to develop and implement policies and practices, and to revise codes of ethics, using this framework as a foundation. Support will be provided through comprehensive and ongoing disclosure education programs as well as developing and disseminating communication materials for patients, families and health care providers.

When a patient is harmed in the health care system, it affects the patient, his or her family and the health care provider team. It is fair to say that while people are aware harm can occur in the health care system, they don’t expect it to happen to them. When it does happen, patients and families need to know what happened and the consequences, to receive an appropriate apology, and to be provided with information on what will be done to ensure a similar situation does not happen again.²,³

While it is widely accepted that disclosure is the right thing to do when a patient is harmed, health care provider concerns about the consequences of disclosure appear to prevent it from being done consistently and effectively.

From an ethical perspective, disclosure is the right thing to do. Open and timely disclosure can benefit patients and family members by:

- Enabling the patient to receive the appropriate treatment to mitigate complications resulting from the harm experienced;
- Enabling informed choices to be made regarding the patient’s care plan;
- Helping patients as a group to develop a greater understanding and more realistic expectations about the health care system and care they receive; and
- Promoting the development of trust within the patient-health care provider relationship.⁴,⁵,⁶,⁷

Health care providers also benefit from open and timely disclosure:

- Disclosure promotes trust in the patient-health care provider relationship through a patient's appreciation of honesty and transparency;
- Honesty and transparency reduces the likelihood a patient may launch legal action against a health care provider or organization; and
- Disclosure promotes a culture of safety where learning from adverse events and improvements to practice and the health care system are valued.⁵

In contrast, adopting an approach of non-disclosure can undermine public trust in the health care system and increase the likelihood of legal action. It can lead to the perception that the interests of health care providers are
placed over that of their patients, and it can promote a culture where learning from past experiences does not occur.8

One of the biggest fears surrounding disclosure is the potential for legal action by the patient.9 Research shows that patients are often more forgiving of disappointing health outcomes than when health care providers behave in a disappointing way afterwards.3,10 Effective disclosure processes can often reduce the impetus for the patient to go outside the health care provider relationship for resolution.

A poor communication process, or a patient’s perception that he or she has not been told all relevant information about the care and experience, often results in anger and distrust. Many times it is not the harm experienced that is a motivator for litigation. Rather it is the way the communication and situation is managed following the event.3,6

Other identified barriers to disclosure include difficulty of the health care provider to admit harm has occurred; fear of implicating others during the disclosure process; fear of disciplinary action; uncertainty about how to report harm within the organization; preference to avoid upsetting patients; concerns related to how disclosure would affect self-image; and perception of skill by colleagues. The reality of these barriers and fear of litigation may account for the differences between the patient’s desire for, and the health care provider’s reluctance to share, information.11

Adopting an open and transparent process meets the obligations of health care providers and organizations to disclose. It also promotes and supports a culture where patients get the information they want, as well as facilitating learning and improvement within the health care system to prevent similar occurrences from happening again.

In addition to adopting a process of open disclosure, other initiatives are needed to promote a high-quality, safe health care system including:

- Effective processes for reporting adverse events and potential harmful hazards;
- Investigating adverse events through root cause or similar safety analysis processes; and
- Implementing changes to prevent similar events from happening again.

This framework focuses on disclosing harm in a way that is effective, honest and transparent; empathizes with, and understands the impact on, the patient and his or her family; provides an appropriate apology; supports patients, families and health care providers; and ensures ongoing opportunities for continued dialogue are provided.
Purpose of the Framework

How health authorities and community health care providers respond to unanticipated outcomes and events causing harm affects not only the quality of patient care, but also Albertans’ confidence in the health care system. This framework provides information to health care providers throughout the province about how to engage in effective and supportive disclosure processes with patients and families.

With a provincial framework in place, Albertans will know that guidelines for disclosure of harm are understood and accepted by all health authorities and professional bodies. They will also know that critical information about harm will be disclosed in a timely and consistent manner regardless of where they live. The framework provides the necessary flexibility to enable health authorities and professions to develop and adjust their own specific policies and procedures to be consistent with the overall provincial framework.

The provincial framework seeks to ensure consistent application, delivery and communication of harm requiring disclosure. Specific objectives are to:

- Provide a framework for disclosure of harm that ensures optimal communication processes for patients and families;
- Promote a culture of openness such that effective steps can be taken to prevent future events, and to move away from an environment of individual blame;
- Remove barriers to disclosing factual information to patients and families in a way that is supportive, respectful, helpful and informative; and
- Ensure alignment with provincial legislation and professional association codes of ethics.

The process of disclosure does not stand alone. It must tie into organizational policies and guidelines for reporting events causing harm. It must also include a process for sharing information with the public, media and other health care organizations and providers that may benefit from learning about and understanding the event. These policies should be entrenched within an overarching organizational commitment to promoting a culture of health care quality and safety.

Creating a Culture of Safety

An organization’s culture is demonstrated by “how we do things around here” beliefs and attitudes. Historically, attitudes about adverse events were grounded in a culture of blame and shame, which often led to secrecy and fear of reprisal. The health care provider who was the last to “touch the patient” was often seen as the cause of resulting harm. More recently, and through considerable investigation in other high-risk industries, the overriding philosophy about causation is that adverse events occur due to a convergence of many factors. This shift in thinking has changed the focus of adverse event investigations to recognize that human error is not always the cause of the failure, and often it is systematically connected to features of the health care provider’s tools, tasks and operating environment.

In a safety-oriented environment, health care providers share their concerns about actual or potential harm, and aren’t afraid to openly discuss adverse events whether they are perceived to be the result of individual or system failure. In a culture of safety, learning from mistakes or system failure is encouraged and patients are viewed as partners in their own care. It also encourages health care providers, administrators and patients to work together to develop safe processes for patient care. Adopting a proactive approach to reporting, investigating and disclosing
adverse events that have resulted in harm, or have the potential to cause harm, builds a foundation for open discussion where blame and its consequences are no longer feared. Ideally, when health care providers no longer fear the blame and shame reprisal, reporting and disclosing harm will increase along with opportunities for learning.

Guiding Principles

Patient-centered care and delivering health care that is safe and acceptable provided the foundation for the development of this framework. The principles outlined below should be used to guide any policies, actions and decisions related to the disclosure of harm. When harm occurs, the role of health care providers and organizations becomes two-fold. Patient care intensifies and the event becomes an opportunity for learning such that other potentially harmful events are prevented.

Disclosure of Harm Is the Right Thing to Do

To know the right way to act, individuals involved at all levels of decision-making around disclosure must ask themselves what they would expect in a similar situation.

Acceptability

Health care services are respectful and responsive to user needs, preferences and expectations.

Patient Autonomy

Patients have the right to make their own decisions about health care. This is the basis for informed consent. The right to know about the care that has been provided and the outcome(s) of that care extends the process of informed consent to include disclosure of harm.

Early Acknowledgement

Patient harm must be acknowledged and a disclosure process initiated as soon as possible after ensuring the patient’s health care needs are met.

Immediate Expression of Regret

An appropriate apology should be offered for both physical and psychological harm that occurs to the patient as a consequence of care provided. An apology helps to restore patient dignity and enhances the patient-health care provider relationship.

Honesty and Transparency

Building trust within the patient-health care provider relationship requires commitment to providing the patient and family with an accurate understanding of what happened when harm occurs during the provision of care. Providing such an understanding requires deliberate actions to inform patients and family members in a transparent and honest manner.

Patient Expectations Are Honoured and Respected

Patients reasonably expect to be informed of all the facts of their care, to be treated with empathy and respect, and to be provided with emotional support in a way that meets their needs.

Quality Improvement and Risk Reduction

Disclosure of harm is an integral part of the overall patient safety and quality improvement process. Adverse events provide opportunities for learning that facilitate change to prevent similar events from happening in the future.

Support for Health Care Providers

Central to an effective disclosure process is an environment where all health care providers have the appropriate training and tools to identify, manage and report an adverse event. It is essential to provide support for health care providers participating in the disclosure process, as well as providing emotional support to help them cope when an adverse event resulting in harm occurs.
Threshold for Disclosure

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". 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. An example of this is when a patient is given the wrong dose of medication and it is anticipated there will be no harm.

Where an adverse event was narrowly avoided prior to harm occurring to the patient, disclosure is discretionary and will need to be determined on a case-by-case basis by the health care team. In certain circumstances, disclosure may be in the best interest of the patient.

There may be other times when disclosure is not appropriate including rare circumstances when a patient’s condition provides a rationale not to disclose. However, disclosure builds rapport and trust with patients and families; therefore, it is recommended that health care providers err on the side of open disclosure.

Disclosure is a process and not necessarily a one-time event. It should take place as soon as reasonably possible based upon the patient’s individual circumstances. At most, it should be initiated within one to two days following the discovery of harm to the patient. At the time of the initial disclosure meeting, it is likely not all the facts about what happened to the patient will be known. Subsequent meetings will need to take place once more information is learned and an investigation has been completed.

First and foremost, steps should be taken to ensure the health care needs of the patient and emotional support for the patient and family are addressed. Following this, the initial disclosure meeting should be planned with the patient, and if appropriate, family members. Consideration should also be given as to where disclosure meetings will occur. The setting should be private and quiet, and assurances should be taken that there will be no interruptions to the process (e.g., pagers, cell phones, etc.). The Health Boards of Alberta, Canadian Medical Protective Association, Canadian Nurses Protective Association and other respective insurers should be informed and consulted as appropriate prior to the disclosure meeting.

What to Disclose

When determining what information should be disclosed to the patient and family, it must be recognized that different amounts and types of information will be available during the initial and subsequent disclosure meetings. At all disclosure meetings, information shared should be factual and agreed upon through a process of consensus by the health care team prior to initiating the disclosure process. Opinions and statements of blame should not be made.

Information to be disclosed should only be related to the event, and not about any individuals involved. Only facts related to the patient’s diagnostic, treatment and
care information (as defined by the Health Information Act (HIA) Section 1 (1)(k)) should be shared. This information includes:

- a description of what happened;
- the sequence of events;
- diagnostic test results;
- consequences of the harm and resulting changes to the treatment plan; and
- any other relevant factual information.

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.

**Quality Assurance Committees**

Facts related to patient care will most often be recorded in the patient’s chart; however, there may be situations where additional facts are uncovered by the committee that investigates the event through root cause analysis or similar health systems safety review processes. In Alberta’s regional health authorities, these investigative committees typically fall under a broader Quality Assurance (QA) Committee as defined by section 9 of the Alberta Evidence Act (Appendix A). All facts, whether in the patient’s chart or those agreed upon through consensus by the committee investigating the event, should be disclosed to the patient and family. This is the only way that the patient and family will be provided with a true and accurate understanding of what happened during his or her care.

A clear process of how event-related facts learned during an investigation that falls under QA protection will be shared with the patient and family is required. It is critical that health authorities have clearly stated policy and terms of reference for committees conducting these investigations to ensure that only facts are shared. All other information collected during an investigation and Quality Assurance Committee records must remain confidential and protected.

The process must ensure that individuals who conduct or are responsible for the investigation and QA process are not involved in disclosure meetings with the patient and family. The lead of the investigative committee will be responsible for sharing new facts learned during an investigation with an appropriate individual or department within the health authority administration for approval. These individuals will then be responsible for determining how these facts will be shared with the patient and family.

Information voluntarily shared beyond the committee that conducts the investigation must not include committee records of opinions, speculations and confidential conversations. Only new facts that would have otherwise been on the patient’s chart, as well as actions being taken to try to prevent a similar event from happening again, should be shared. These actions will likely be based upon recommendations from the committee that has investigated the event.
Disclosure Meetings

At the initial disclosure meeting, a plan should be developed with the patient and family members to determine the process for ongoing disclosure. This plan should address who will serve as the key point of contact for the patient and family to respond to questions and who should be included in subsequent disclosure meetings. It should also include an agreed to timeline for future disclosure meetings. Due to the often difficult and sensitive nature of these meetings, patients and families may not hear or understand all the facts presented during the first disclosure meeting. Requests for repeated meetings may be common.

Who Should Disclose

There may be times during the disclosure process when individuals involved in the conversation with the patient and family will change depending upon the information being shared and the needs of the patient and family. When determining who should lead the disclosure meeting, consider who is best able to share with the patient and family what happened and the consequences of the harm that has occurred; who has an ongoing relationship with the patient; and who is able to discuss changes to the treatment plan. It is also important to consider having someone present to provide support to help the patient and family recover from the harm that has occurred. Often 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.

A team approach to disclosure ensures that all relevant individuals are present when sharing information with the patient and family. Generally no more than two or three individuals should be involved in the disclosure process. Team members should be based upon the nature of the event, the relationship between the patient and family with the health care team members, and the skills of those involved in effectively disclosing the harm. 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.

It is also important to think about how to involve providers who were directly involved with the patient at the time of the adverse event resulting in harm. In a disclosure process, it is often these providers that patients and families want to hear from and indeed expect. When these health care providers do not participate, this may lead a patient and his or her family to believe information is being withheld or that the provider is “hiding” behind the protection of legislation. Health care providers involved in an event resulting in harm do have the opportunity to talk directly with the patient. Such involvement gives the health care provider an opportunity to share the devastation that he or she will likely have experienced with the patient and family.

Not all health care providers involved in the patient’s care will participate in the disclosure process, so it is important that they are informed as to when disclosure will occur and when it has occurred. Briefing the health care team members enables them to be aware of what information was shared (as per documentation in the patient’s chart) to ensure consistency and sensitivity for the patient and family.
To Whom Should Disclosure Be Made?

Disclosure should be made to the patient and/or family member(s), except where contrary to the expressed request of the patient (HIA, s. 35). Other considerations as to whom disclosure should be made include the patient’s ability to understand the situation; the nature of the information being provided; determination of who was involved in the informed consent process; and the availability of emotional support immediately following disclosure.

Disclosure should occur with family or another person with whom the individual is believed to have a close relationship. Organizations may want to obtain the consent of the patient, in situations where they are able, to identify family members or other individuals the patient would like to be involved in the ongoing disclosure process, particularly for disclosure meetings that may occur in the long term.

Documentation

Once communication with a patient and/or family has occurred, the health care provider who led the discussion should document an objective reflection of what occurred during the disclosure meeting. The documentation of the initial disclosure meeting, as well as subsequent meetings that occur while the patient is still receiving care, should be recorded in the progress notes or similar part of the patient’s chart. Documentation contributes to the briefing process that should take place with the health care team to ensure awareness of the information that was provided to the patient and family.

Details of the disclosure meeting that should be documented include:

• Who was present at the disclosure meeting and who was invited;
• Date and time of the meeting;
• Known facts that were presented;
• Offers of support and responses from the patient and/or family;
• Questions raised by the patient and family and the responses provided;
• Changes to the care plan discussed; and
• Plans agreed to for the ongoing disclosure process including key contact information for the organization.

Disclosure meetings can be a difficult time for patients and family members and further meetings may be needed to respond to additional questions. Providing the patient and family with a copy of the documentation of the meeting may promote the openness and transparency of the disclosure process.

The Disclosure Conversation

The Health Quality Council of Alberta, as part of its commitment to education and training for disclosure, has been working with known experts in the field of disclosure from the U.S. Institute for Healthcare Communication. Disclosure meetings are difficult not only for the patient and family, but also for the individual(s) disclosing the harm. Central to the disclosure process is the need for effective communication skills whereby those involved can approach the situation with empathy and sensitivity while at the same time providing information in a clear and concise manner. Involvement in a disclosure process may occur infrequently providing limited opportunities to “practice” disclosure skills. This increases the importance of training and education programs.

The disclosure conversation should be approached with the same principles as when breaking any bad news to a patient. Specific elements of the initial conversation should include:
• An explicit, jargon-free statement that harm occurred;
• A factual description of what is known about the nature of the event resulting in harm;
• Resulting consequences of the harm (including both short- and long-term effects);
• 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);
• A brief overview of the investigative process that will follow and what the patient and family can expect to learn, with appropriate timelines;
• An offer for future meetings along with information on who will be their key contact for such requests; and
• Allowance of time for clarification and questions by the patient and family.7,22

One of the most critical elements of the disclosure conversation is the apology. An apology demonstrates compassion and that the health care system and provider care about the patient and harm that occurred. The nature of the apology will be dependent upon whether or not there was a deviation from the expected standard of care. A further apology may be made in subsequent disclosure meetings as more information is learned.

How to Disclose

The process for how to disclose is based upon the approach taught by the Institute for Healthcare Communication. Adverse events resulting in harm can occur with no deviation from the standard of care or with a deviation from the standard of care. While it often takes a full investigation to determine if the standard was met, unless it is absolutely clear, most initial disclosure conversations should start with the premise that the standard of care was met in the patient’s care. If, following an investigation, it becomes apparent that the standard of care was not met, the disclosure process will change with the organization and health care provider taking responsibility for the harm that has occurred.

Prior to any disclosure conversation, members of the disclosure team will need to agree upon what information will be shared at the meeting. There may be situations where team members may want to consider using role play to prepare.

When the standard of care has been met, there are four steps to follow in a disclosure conversation.20

1. Anticipate:

   Start with an expression of sympathy and an apology. The apology should take the form of a benevolent expression of regret.

   “I am so sorry that you and your family are having such a difficult experience.”

2. Listen:

   To understand the patient’s and family’s concerns.
3. **Empathize:**

Use active listening techniques and normalize their thoughts and feelings without defensiveness.

“It sounds as though this is... very difficult for you to hear.”

4. **Apologize** for the situation:

“I am so sorry you have had this experience.”

5. **Explain:**

Make an offer to explain what happened to the patient and family.

“Would it help if I were to explain what happened?”

It may be immediately clear that the harm that occurred is the result of a deviation from the expected standard of care. Other times it may require an investigation to reach such a conclusion. A T.E.A.M. approach is recommended when it is determined that the standard of care was not met. The process outlined below may begin at the initial disclosure conversation or at a subsequent disclosure meeting following an investigation.

1. **Truth, transparency and teamwork.** Begin with a truthful and transparent statement of the facts outlining what happened.

2. **Empathize** with the experience of the patient and family.

“I can imagine this is making you feel very...”

3. **Apologize** and take accountability to try to prevent similar situations from happening again. This will include taking responsibility for what happened. Responsibility should not be confused with blame. Responsibility within a systems approach is a commitment to be open and transparent and to improve practices to try to prevent similar events from happening again.

“I am so sorry that I...”

4. **Management of all aspects including patient care,** emotional support for all those involved and ongoing communication and help in recovery from the harm (e.g., medical, practical, financial, etc.).

Effective communication techniques for disclosure are key to the success of the disclosure process. Several techniques should be used in a disclosure meeting including the use of simple language and avoiding medical or technical terms the patient might not understand. Speaking slowly and providing enough information for the patient and family to understand what is happening without overwhelming them is also important. Other considerations include: being sensitive to body language (sit down and hold the hand of the patient and/or family member); awareness of cultural differences; resist interruptions and accept moments of silence in the conversation; pause frequently to allow patients and families to digest the information and ask questions and clarify information.

**Emotional Support**

Emotional support should be offered and available to the patient and family members at both the initial disclosure meeting and in the long term. Examples of such support include the availability of a nurse or other team member who knows the patient well, social worker, counselling services, chaplain and/or support programs. Long-term support may include referrals to grief programs, support groups and/or counselling.

Health care providers commonly feel sadness, failure and guilt following a disclosure meeting. It is important that those involved in the disclosure process have the emotional support to help cope with the situation. Debriefing sessions following a disclosure meeting in the protected environment of a QA committee, offers of private counselling (usually available through Employee and Family Assistance Support Programs or the Alberta Medical Association’s Physician...
and Family Support Program) and acknowledgement of the experience by the organization are strategies that can assist these providers. Provisions should be made for both short- and long-term support.

Health care providers who were involved in the patient’s care when the harm occurred, regardless of whether or not they participated in the disclosure process, also require support. These health care providers often experience self-doubt around their ability to provide care, fear for the well-being of the patient, symptoms of depression, disappointment, self-blame, shame and fear. Opportunities for providers to share their experiences can help reduce feelings of isolation and can contribute to developing a culture of safety. Support for providers follows the same strategies used for those involved in the disclosure process and should also consider both short- and long-term support.

Unique Circumstances

Multi-Jurisdictional Disclosure

It is not uncommon for patients to be transferred between various health authorities, or from a private provider into the public system. Situations may arise where harm may not have been identified in the originating jurisdiction and is discovered by the jurisdiction where the patient is currently receiving care. In this framework, the term “multi-jurisdictional” is used to reflect the unique nature of each health care delivery entity recognizing that there are individual policies in place over the vast geographic area that encompasses Alberta.

In situations where disagreement occurs, it is anticipated that the organization discovering the harm and the entity where the event occurred will agree how, when and who will disclose to the patient and, if appropriate, the patient’s family. Where immediate disclosure is not crucial to the patient’s health or well-being, efforts should be made to contact the originating jurisdiction to inform them of the situation and the planned process for disclosure to the patient. It is further recommended that, if possible, representatives from both jurisdictions be involved in both the initial and ongoing disclosure process.

With the adoption of the provincial framework, it is anticipated that the disclosure process will be consistent across the province and disagreement between jurisdictions on how to handle disclosure in such cases will be rare. In the unlikely event that agreement among the health care providers is not possible, the Health Quality Council of Alberta (HQCA) will be available to mediate resolution of issues that have arisen. This may take the form of a confidential discussion of the circumstances, non-identifying health information and concerns involving a representative from the HQCA or the acquisition of a qualified and mutually agreed upon mediator. Only circumstances and non-identifying health information will be made available to facilitate the mediation process.

Multi-Patient Disclosure

In situations where there is potential or actual harm to more than one patient, the disclosure process undertaken should protect the privacy and confidentiality of the patients involved. Disclosure in these situations should not occur in a group setting but on a one-to-one basis with each patient involved. Steps should be taken to ensure all patients have been contacted prior to a release to the media. Patients in these situations can be contacted by telephone or registered mail or through face-to-face meetings. Opportunities for face-to-face meetings should be made available for all patients to further discuss their situation and respond to questions.
Special Considerations

Some populations, such as long-term care residents, mental health and pediatric patients, will require further consideration prior to disclosure about issues such as how to involve the patient in the disclosure process. It is also important to consider the patient’s ability to understand the situation; the nature of the information being provided; who was involved in the informed consent process; and availability of emotional support immediately following disclosure.

There are also situations where the privacy legislation governing disclosure shifts from the HIA to the Personal Information Protection Act (PIPA). This occurs when the patient’s care is covered through a source other than the Alberta Health Care Insurance Program (AHCIP). Further details around this legislative difference are explored in Appendix B.

Disclosure in the Context of an Action

It is recommended that the disclosure process be continued notwithstanding an action having been launched. However, organizations and health care providers should consult with their respective legal counsel as appropriate as there may be a need to involve legal counsel in subsequent disclosure meetings. The information being disclosed should not change simply because legal counsel is involved. Commitment to an honest and transparent disclosure process should be maintained regardless of whether or not legal action has been taken.

Communication Materials

Supporting the use and implementation of a provincial framework for disclosure of harm to patients and families requires substantial communication support. The Health Quality Council of Alberta has developed communication materials for use with patients, family members and health care providers so a consistent message will be delivered throughout the province. In addition to the materials, individual organizations will be able to develop a communication plan and materials specific to their own situation and needs (Appendix C).
Glossary of Terms

**Action**: An action includes: (i) an issue, matter, arbitration, reference, investigation or inquiry, (ii) a prosecution for an offence committee against an Act of the Legislature or in force in Alberta, or against a bylaw or regulation made under the authority of any such Act, and (iii) any other proceedings authorized or permitted to be tried, heard, had or taken by or before a court under the law of Alberta.

**Adverse event**: An unexpected and undesired incident directly associated with the care or services provided to the patient; an incident that occurs during the process of providing health care and results in patient injury or death; or an adverse outcome for a patient, including an injury or complication.

**Apology**: A compassionate and sincere expression of regret that at times involves taking responsibility for an injury, even if several systems’ failures are responsible for the harm rather than one person.

**Disclosure**: Open discussion of adverse events/incidents that results in unintended harm to a patient while receiving health care and the associated investigation and recommendations for improvement.

**Disclosure process**: A series of conversations that occur in the context of the disclosure of information about harm that has occurred. Generally there will be an initial disclosure conversation followed by numerous ongoing disclosure conversations to provide information as learning occurs and needs arise.

**Error**: The failure to complete a planned action as it was intended or when an incorrect plan is used in an attempt to achieve a given aim.

**Expression of regret**: An expression of sorrow for the harm experienced by the patient.

**Family**: Includes spouse, blood relative (next of kin), those identified as support person(s) or decision-maker designated under a Power of Attorney or other legal documents.

**Harm**: 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.

**Health care provider**: An individual or organization who provides health services.

**Health information**: Any or all of the following: diagnostic, treatment and care information; health service provider information; or registration information.

**Most responsible physician**: Physician who has the final responsibility and is accountable for the medical care for the patient.

**Non-identifying health information**: The identity of the individual who is the subject of the information cannot be readily ascertained from the information.

**Organization**: Any regional health authority or private provider that offers services related to the provision of health care to a patient.

**Patient**: An alternative for other relevant terms such as resident, client or others who received care in the formal health care system.

**Root cause analysis**: A systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.

**Standard of care**: The average degree of skill, care, and diligence exercised by members of the same profession, practicing under the same or similar circumstances.

**Unanticipated outcome**: A result that differs significantly from what was anticipated to be the result of the treatment or procedure.
References


10 O’Connell D. Disclosing Unanticipated Medical Outcomes and Medical Errors [workshop]. 2006.


16 Massachusetts Coalition for the Prevention of Medical Errors, 2006.


Alberta Legislative Context: Quality Assurance Committee

The Alberta Evidence Act\(^1\) definition of a “Quality Assurance Committee” can be broken down, for ease of interpretation, as follows:

A committee, commission, council (or other body) that has as its primary purpose the carrying out of quality assurance activities and that is properly appointed, established or designated.\(^{ii}\)

Quality Assurance Activities are defined as:

A planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of:

- the quality of health care or health services, or
- the level of skill, knowledge and competence of health service providers.

This same definition is adopted by the Health Information Act\(^{iii}\) and the Freedom of Information and Protection of Privacy Act\(^{iv}\).

The specific activities vary and the definition is of little value when attempting to determine what a Quality Assurance Committee actually does. For the purpose of this framework, we include the following as common functions of a Quality Assurance Committee:

- Identification and analysis of clinical safety hazards and adverse events;
- Conduct and coordinate all investigations into critical adverse events;
- Prepare reports for the operational arm of the organization about adverse events and make recommendations for prevention of future events; and
- Evaluate and measure system improvement in various areas including, but not limited to mortality, adverse medication event, non-critical incidents (including near miss), and infection rates.

The Quality Assurance Committee does not conduct investigations into individual staff or physician competence. Such matters should be referred to the appropriate internal and/or external body such as a provincial college that governs and regulates that professional (i.e., for physicians, the College of Physicians and Surgeons).

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\(^{i}\) RSA 2000, c. A – 18

\(^{ii}\) Appointed by the governing authority such as:
- a regional health authority;
- the Alberta Cancer Board;
- the Alberta Mental Health Board;
- the Board of an approved hospital under the Hospitals Act; or
- the operator of a nursing home.

\(^{iii}\) RSA 2000, c. F–25

\(^{iv}\) RSA 2000, c. H–5
Appendix B

Application of Privacy Legislation Where Payment for Health Care Services Is Private Pay and/or Changes from the Alberta Health Care Insurance Plan to Private Pay

The provincial framework Disclosure of Harm to Patients and Families was written from the perspective of disclosure within health care organizations and by health care providers who are paid entirely through the Alberta Health Care Insurance Program (AHCIP). There are times however, where the payment source for care changes from the AHCIP to another source even though the provider may be the same. Two examples are physiotherapists and chiropractors. There are also times when care is publicly funded but not through the AHCIP. Examples include patients who are members of the RCMP or Canadian Military and patients covered by the Workers Compensation Board. The purpose of this Appendix is to facilitate an understanding of the difference in legislation that exists for disclosure when the health care service is not paid through the AHCIP.

With the exception of pharmacists, who always remain under the umbrella of the Health Information Act (HIA), the application of the legislation is determined based upon the source of payment rather than the type of service or service provider. Where the health care service is not funded by the AHCIP, the legislation governing privacy and disclosure is the Personal Information Protection Act (PIPA). With the exception of these legislated differences, the principles and processes described in this framework apply.

Which Act Applies?

The HIA is limited to situations where individuals receive health care from providers employed or contracted by a “Custodian” or other entity listed in the HIA or its regulations. Custodians include:

- regional health care authorities and their subsidiaries;
- cancer boards;
- operators of a nursing home;
- pharmacies; and
- other government agencies.iii

As noted, regardless of the payment source pharmacists are included under the HIA. The application to other direct health care providers is determined by the source of payment for their services.iv If the health care provider receives payment from any source other than the AHCIP, the HIA does not apply and the PIPA governs.

Disclosure to the Patient under PIPA

The PIPA does not differentiate between health care information and other types of personal information. PIPA applies to the collection, use and disclosure or access to the broadly defined “Personal Information”; “information about an identifiable individual”.v Disclosure on a voluntary basis, to the individual about whom the information pertains, is not specifically referenced in the PIPA in the same manner as the HIA. Prohibitions against disclosure are limited to where:

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ii Personal Information Protection Act SA 2003, c. P-6.5  
iii See section 1(1)(f) of the HIA for complete reference to “Custodians”.  
iv HIA section 1(1)(f)(ix) and (xi)  
v PIPA section 1(k)
1. disclosure could be “reasonably expected to threaten the life or security of another individual”;
2. personal information about another person would be revealed; or
3. the information would reveal the identity of an individual who has provided an opinion about another individual in confidence.\[vi\]

There are two issues of note when considering disclosure to the patient that are not specifically referred to in the PIPA. First, there is no prohibition to disclosure or access to one’s own information where that individual could be harmed by receiving the information. Second, there is no provision for persons over the age of majority who are not competent.

It is suggested that the general principle of “First Do No Harm” should be respected when considering disclosure to an individual patient or client. It is also suggested that, where there is a concern that accessing the information by the individual to whom the personal information pertains could reasonably cause harm, disclosure/access should be avoided and advice and direction from the Office of the Information and Privacy Commissioner be sought.\[vii\]

Where an individual is over 18 but does not have the requisite decision-making capacity, the PIPA is silent. It is likely that a personal representative will be in place under other legislation. If not, it is suggested that where conflict arises over release of information the Office of the Information and Privacy Commissioner be contacted for direction.

\[vi\] PIPA section 24(3) – disclosure of information where the non-disclosable part is severed is permitted
\[vii\] See discussion of Disclosure to the Patient at page 17 of the Legal Review, which is appended to the Framework.
Quality Assurance Activities

The PIPA also refers to use and disclosure as two separate activities. Use refers to matters internal to the organization. Disclosure refers to external matters. Both use and disclosure are limited to that information which is reasonably required for the intended purpose; in essence, a need to know principle is in effect for both internal and external purposes.

Where an internal QA Committee is in place limited use of identifying information may be permitted. Where the Committee is external and allowances for disclosure are not specified in other legislation, or specifically consented to, information should again, be limited to “non-identifying”.

Disclosure of Employee Information

It is recommended that PIPA-governed organizations and individuals proceed with caution if releasing any information about an employee. The PIPA specifically sets out that an organization may disclose personal information about an employee only in the context of recruitment/employment matters.ix

Summary and Conclusion

Whatever the purpose of disclosure, it is more limited under the PIPA than the HIA because the PIPA is silent on a number of issues related to disclosure of harm: Quality Assurance Committees; significant others where the individual is over the age of majority but lacks competency; and where disclosure may cause harm to the individual to whom it pertains. Nonetheless, the general principles for disclosure are applicable.

Where other legislation is consistent with the purpose of PIPA, such as the HIA and FOIPPA, the legislation may be looked to as guiding principles only. The Office of the Information and Privacy Commissioner is also available for advice and direction.x

ix PIPA, section 15(3)  
x PIPA section 36 authorizes the Commissioner to give advice and recommendations of general application of an organization.
Appendix C

Communication Materials

Supporting the use and implementation of a provincial framework for disclosure of harm to patients and families requires substantial communication support. The Health Quality Council of Alberta has developed communication materials for use with patients, family members and health care providers so a consistent message will be delivered throughout the province. In addition to the materials, individual organizations will be able to develop a communication plan and materials specific to their own situation and needs.

Open Disclosure

Prior to initiating the disclosure conversation with a patient, refer to your organization’s policy and/or your professional code of ethics.

The initial disclosure conversation should include:

1. An appropriate apology.
2. Known and agreed upon facts.
3. Patient’s questions/concerns.
4. Consequences of harm and any side effects to look for.
5. Discussion of ongoing care.
6. What happens next (investigation of adverse event and feedback).
7. Arrangement for future meetings.
8. Contact details in case of further concerns or questions.

Effective communication techniques for disclosure:

1. Use language the patient and family will understand.
2. Speak slowly and pause frequently.
3. Listen.
4. Express empathy.
5. Be at eye level with patient and family (all).
6. Consider any cultural differences.
7. Avoid the statement: “I know how you feel...”

Wallet Card: 2” x 3”, two-sided
Checklist for Disclosure Team Discussion

**This checklist** may be useful for identifying tasks to be completed or delegated during a meeting of the disclosure team prior to speaking with the patient and his or her support person(s).

### Support Person
Information about an adverse event resulting in harm will be given to a patient's identified support person(s) in appropriate circumstances, taking into account the patient's wishes, confidentiality and privacy requirements, and the organization's internal policies. The support person(s) may be any individual the patient identifies as the nominated recipient of information about his/her care and may include family, a friend, a partner or those caring for the patient.

In cases of a dispute between family and partners or friends about who should receive information, the patient's expressed wishes are paramount.

<table>
<thead>
<tr>
<th>All relevant health care professionals involved in the adverse event have been notified/consulted.</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Establish and agree upon known facts:</td>
<td></td>
<td></td>
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<tr>
<td>• Don’t include speculation, opinion or blame</td>
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<thead>
<tr>
<th>Identify person(s) to take responsibility for the initial disclosure conversation with the patient:</th>
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<tbody>
<tr>
<td>• Known to the patient</td>
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<tr>
<td>• Familiar with the incident and care of the patient</td>
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<tr>
<td>• Good interpersonal and communication skills</td>
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<tr>
<td>• Willing to maintain a relationship with the patient</td>
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<td></td>
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<tr>
<td>• Received disclosure training</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Support person(s) (e.g., family member) for patient identified and available. Name(s):</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Relationship to patient:</td>
<td></td>
<td></td>
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</table>

<table>
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<tr>
<th>Identify and offer support for the disclosing health professional.</th>
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<tbody>
<tr>
<td>Consider appropriate timing of the initial discussion (as soon as possible following discovery of harm):</td>
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<td></td>
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<tr>
<td>• Clinical condition of the patient</td>
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<td></td>
</tr>
<tr>
<td>• Availability of key staff and support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Availability of patient's support person(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient preference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Privacy and comfort of the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Emotional and psychological state of the patient</td>
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</tbody>
</table>

Delegating communication of appropriate details to those staff that need to know (e.g., those managing the patient or who may be questioned by the patient or his/her family) to one team member.

Special considerations or support required.

Ongoing clinical care needs managed.
Available from the Health Quality Council of Alberta

Disclosure Posters

Open Disclosure

What’s it about?
- Encouraging open and effective communication with patients.
- Acknowledging that adverse events causing harm occur.
- Helping patients understand the circumstances of their care.
- Encouraging organizational cultures from blame to improvement.
- Assisting patients to recover.
- Making the health system safer.

Something not right with your patients’ care?

Don’t keep them in the dark.
- Help them get on with their life.

Have you been involved in an adverse event? Upset? Angry? Worried?

Don’t shut it in.
- Talk to the team involved with the care and your manager.
- Support is also available through your Employee and Family Assistance Program representative, the Physician and Family Support Program (AMA), and/or your professional association.

For more information on how you and your organization can access these posters, please contact the Health Quality Council of Alberta at (403) 297-8162 or visit www.hqca.ca.

Posters: 8.5” x 11”
When we visit a health professional or organization, we expect to receive the safest health care available. But sometimes things don’t work out as expected. For example, a patient may receive the wrong dose of medicine. In the health care field, we call this an adverse event. Most adverse events are minor and don’t result in harm. But when an adverse event does occur and the patient is harmed, he or she has a right to know what happened and what will be done to try to prevent it from happening again.

Every patient has the right to be treated with care, consideration and respect. We respect this right, and we’re committed to improving the quality and safety of the care we deliver. That’s why we have a disclosure policy to help patients who have been harmed during their health care treatment.

This brochure aims to inform you and your support person(s) about the disclosure process. It also tells you what to expect if harm occurs during your health care experience.

We are committed to helping you recover from any harm that may occur during your care.

For more information:

www.hqca.ca

Who should I identify as a support person?
• Someone you are comfortable with and can talk to easily.
• Someone to whom we can give personal information about you.
• Someone able to take the time, if necessary, to be with you.

Who will talk to me?
The person who talks to you about what happened will be someone who:
• Has been involved in your care and knows the facts.
• You are comfortable with and can talk to easily.
• Can contribute to action to try to stop the problem from happening again.

Open Disclosure

Information

for Patients

Brochure: 11” x 8.5”
folding to 3.68” x 8.5”,
two-sided
Partnering to achieve world-class excellence in all dimensions of quality and safety across Alberta's health system.