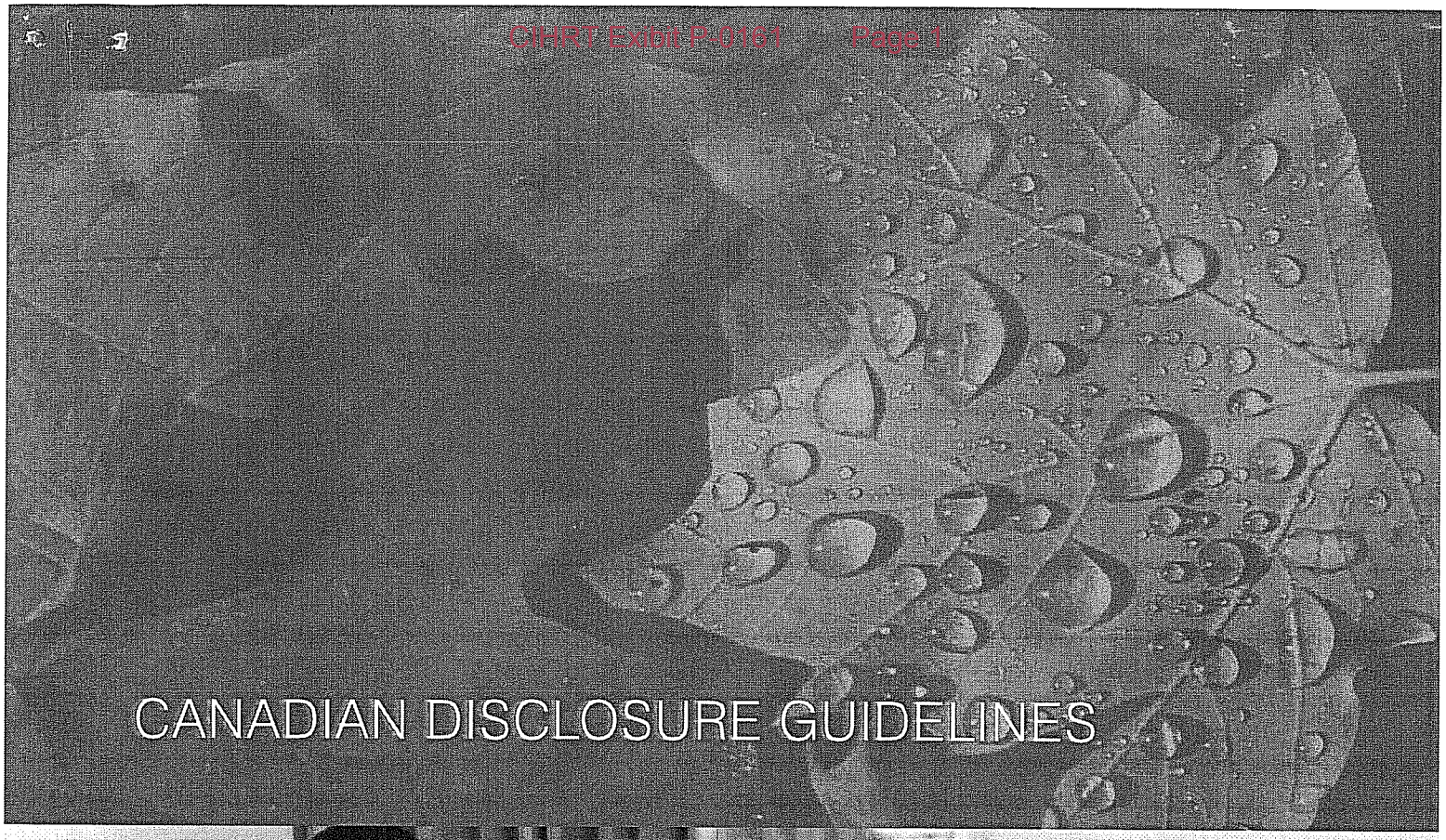

CANADIAN DISCLOSURE GUIDELINES

Canadian
Patient
Safety
Institute

Institut
canadien
pour la sécurité
des patients

cpsi-icsp

The Canadian Patient Safety Institute would like to acknowledge funding support from Health Canada. The views expressed here do not necessarily represent the views of Health Canada.

ISBN 0-9739270-1-1

The Patient's Perspective on Disclosing Adverse Events

PATIENTS FOR PATIENT SAFETY CANADA*

The principles of openness and transparency are becoming increasingly important to the Canadian public. This is especially evident in healthcare and as it relates to information that enables us to make the right choices about our health, and care and treatment we receive. Applying these principles to one of healthcare's most important goals, patient safety, is especially timely and relevant.

Patients and families are supportive of open and transparent disclosure of harm, as it expands our knowledge of our own health and strengthens the relationships that we have with our healthcare providers. We acknowledge the need to be a part of the disclosure process when harm may have occurred. As patients and families who have experienced harm, most often in the absence of disclosure, we offer our voice and perspectives in support of Canadian guidelines for the disclosure of harm.

We agree that disclosure is a process of open communication and information sharing, and that it includes a review of all of the facts when an adverse event is thought to have occurred. We support an understanding that disclosure be viewed as a process rather than a single conversation. We acknowledge that respect, compassion, honesty, and patience will be needed in this process as time will be required to gather all of the necessary facts and information.

We support the need that patients and families receive an apology for what has happened, and where it is applicable, that apologies are provided for adverse events that are known to have contributed to the harm of the patient. We know that these situations are very stressful for both the patient and family, and the healthcare providers involved. It is important that support is provided to all involved.

We also acknowledge that disclosure is needed for healing. It is necessary to re-establish trust between patients and families and their healthcare providers. It is needed to re-establish confidence in the organization where the care was provided.

Finally, disclosure is needed for learning so that improvements to patient safety can be made. We believe the accountability for disclosure, learning and improvements rests at the most senior levels in an organization. We believe disclosure is the responsibility of all healthcare providers and the right of every patient.

** Patients for Patient Safety Canada is a national network of patient safety champions who are advocating for improvements in patient safety at the local, provincial, national, and international levels in conjunction with the World Health Organization's World Alliance for Patient Safety.*

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The members of the Disclosure Working Group and the CPSI acknowledge and appreciate the key contributions of the following individuals: Anne Matlow, Gayle A. Langford, Gerald Robertson and Patients for Patient Safety Canada. In addition, the staff and CEO of the Health Quality Council of Alberta are acknowledged for their leadership in developing the *Disclosure of Harm to Patients and Families: provincial framework* (2006) and sharing their work with the Disclosure Working Group.

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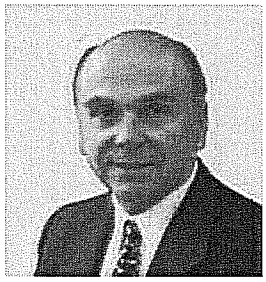
Foreword



Message from Philip Hassen

Chief Executive Officer, Canadian Patient Safety Institute

There is growing recognition of the complexity of our healthcare system, as well as the human fallibility of those professionals who work within it.[1] The 2004 "Canadian Adverse Events Study" identified adverse events arising from the delivery of healthcare services as a significant problem in Canadian hospitals.[2] A focus on patient safety is now emerging in Canada in an effort to learn from and take coordinated action to reduce preventable patient harm and death. Early in the mandate of the Canadian Patient Safety Institute (CPSI), five advisory committees were established to provide feedback and input into strategic initiatives in key areas of patient safety. The Legal and Regulatory Affairs Advisory Committee[i] was established under this framework in the fall of 2005. Their first recommendation was that CPSI provide leadership and support for the development of Canadian disclosure guidelines.

CPSI has been pleased to provide secretariat and funding support to the Disclosure Working Group[ii] chaired by Mr. Brent Windwick. The Working Group's tireless efforts to develop the guidelines are gratefully appreciated as the product of their work is an important tool for supporting open and transparent communication about harm, including the disclosure of adverse events in Canada. Our patients deserve no less.

[i] See list of Legal and Regulatory Advisory committee members at www.patientsafetyinstitute.ca under advisory committees

[ii] See list of Working Group members and participating organizations on Page 4

Message from Brent Windwick

Disclosure Working Group Chair

At the request of the Canadian Patient Safety Institute, and with the support as well as the involvement of participating organizations, a Working Group[ii] was formed in the spring of 2006 to develop Canadian disclosure guidelines. The objectives of the guidelines are to:

1. Facilitate patient/healthcare provider communications that respect and address the needs of patients and strengthen relationships.
2. Promote a clear and consistent approach to disclosure.
3. Promote interdisciplinary teamwork.
4. Support learning from adverse events.

The guidelines build on various patient safety initiatives currently underway across Canada and are directed at healthcare providers, healthcare organizations, health ministries, health professional regulatory and/or other public bodies. Through these guidelines, the Working Group hopes to support and encourage these bodies to develop and/or enhance disclosure policies and practices. The latter should incorporate the core elements found in this document, but in a way that adapts this discussion to their respective needs.

A national and international environmental scan and extensive literature review were completed to inform the development of the guidelines including the professional and legal aspects of disclosure in Canada. The results are available on the CPSI website at www.patientsafetyinstitute.ca and a list of the recommended reading on disclosure is included in Appendix A.

The approach taken in developing these guidelines was to integrate ideas and concepts from the Disclosure Working Group discussions, expert presentations and stakeholder consultations. Additionally, a number of local, provincial/territorial, national and international best practices were reviewed and synthesized.[iii] A list of the health system stakeholders that have endorsed the guidelines is included in Appendix B.

[iii] *For further information on national and international leading practices see Appendix A.*

Introduction

Achieving a culture of patient safety requires open, honest and effective communication between healthcare providers and their patients. Patients[iv] are entitled to information about themselves and about their medical condition or illness, including the risks inherent in healthcare delivery. Autonomy, the patient's right to control what happens to his or her body, is the cornerstone of the informed consent discussion. At times this will mean that information will be provided about possible unexpected and undesired results. Experience tells us that when harm[v] occurs in healthcare delivery, unique challenges in communication may arise. The purpose of these guidelines is to support and guide healthcare providers in these communications, and to encourage organizations to develop policies and processes to effectively support the communications between patients and providers, in these difficult circumstances.

The guidelines emphasize the importance of a clear and consistent approach to disclosure regardless of the variance in definitions across Canada related to harm and adverse events; patients have a right to be informed about all aspects of their care. While the guidelines focus on the disclosure of adverse events,[vi] they emphasize that all harm must be communicated to patients, irrespective of the reason for the harm.

In healthcare, the use of the term *disclosure* in communications with patients should not in any way imply blame for or fault of the healthcare provider.

Patients may suffer harm as a result of an underlying medical condition or as a result of an adverse event. For purposes of clarity, some examples are a patient:

- Who develops brain metastases from underlying primary lung cancer experiences harm as a result of the underlying medical condition.
- Without a known allergy suffers an allergic reaction (an inherent risk of the treatment) from a properly prescribed medication suffers harm as the result of an adverse event.
- Who has a loss of hearing because the wrong dose of medication was prescribed or administered suffers harm also as the result of an adverse event.

Harm may be recognized by healthcare providers and/or the patient before the reason can be established.

Harm: An outcome that negatively affects a patient's health and/or quality of life.[v]

Disclosure: The process by which an adverse event is communicated to the patient by healthcare providers.

Adverse event: An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.

[iv] The term 'patient' is intended to encompass everyone who receives health services across the continuum of care.
[v] A full glossary of terms is included in Appendix C.
[vi] The use of the term "adverse event" in this document differs from the definition of "adverse event" in the Canadian Patient Safety Dictionary. The latter is a surveillance definition used retrospectively and considers the disability (e.g. prolonged hospital stay) resulting from the event whereas in these guidelines adverse event is defined in real time.

The following equally important guiding principles underpin the development and use of the guidelines.

Patient-centered healthcare: An environment of patient-centered healthcare fosters open, honest and ongoing communication between healthcare providers and patients. Healthcare services should be respectful, supportive and take into consideration the patient's expectations and needs at all times.

Patient autonomy: Patients have the right to know what has happened to them in order to facilitate their active involvement and decision-making in their ongoing healthcare.

Healthcare that is safe: Patients should have access to safe healthcare services of the highest possible quality. Lessons learned from adverse events should be used to improve the practices, processes and systems of healthcare delivery.

Leadership support: Leaders and decision makers in the healthcare environment must be visible champions of disclosure as part of patient-centered healthcare.

Disclosure is the right thing to do: "Individuals involved at all levels of decision-making around disclosure must ask themselves what they would expect in a similar situation."[3]

Honesty and transparency: When an adverse event occurs, the patient should be told what happened. Disclosure acknowledges and informs the patient, which is critical in maintaining the patient's trust and confidence in the healthcare system.

Use of the Term "Patient"

The term "patient" is used throughout the guidelines. It is recognized that often the patient's family or Substitute Decision Maker (SDM)[vii] may be included in the disclosure process. Therefore, the term "patient" throughout the guidelines includes family members or SDM where applicable. The inclusion of individuals other than the patient is subject to confidentiality requirements and to the provisions of applicable provincial or territorial legislation, which differ across Canada. It is important to be familiar with and adhere to applicable privacy and SDM legislation in each provincial or territorial jurisdiction.

Application of the Guidelines

The guidelines are intended to encourage and support healthcare providers, interdisciplinary teams, organizations and regulators in developing and implementing disclosure policies, practices and training methods. The recommended elements of a disclosure policy are provided in Appendix D. The term "healthcare providers" includes those who provide or manage patient care and are working in healthcare facilities, in independent practice and/or in the community.

The guidelines are not intended to dictate the policies or practices of healthcare organizations or providers, or to describe every consideration that may be relevant to disclosure. Variation in policies and practices are to be expected and encouraged to facilitate adaptation to local circumstances.

[vii] *Substitute Decision Maker (SDM): A person, other than the patient, who is legally authorized to make a decision on behalf of the patient. The authority may be granted by the patient via a legal document (e.g. an advance directive), legislation (e.g. the Mental Health Act) or courts (e.g. court appointed guardians).*

The guidelines are also not intended to define or serve as a legal or professional standard of care, or to replace advice about provincial variations in legislation and legal rules across Canada, including those related to health information privacy, apology and substitute decision making. Disclosure policies should be developed with legal advice from counsel familiar with applicable legislation.

Importance of Disclosure

Current literature, national and international leading practices, and ethical, professional and legal considerations all support open and honest disclosure of adverse events.

Patient Perspective

An emerging body of literature describes the patient's perspective about disclosure and the importance of being told whenever harm occurs. Patients want to know:

- The facts about what happened.
- The steps that were and will be taken to minimize the harm.
- That the healthcare provider regrets what happened.
- What will be done to prevent similar events in the future. [4, 5, 6, 7, 8, 9]

Patients may lose trust, or become anxious or fearful when they sense that information is being withheld. This loss of trust can negatively affect the therapeutic relationship. Patients may be more understanding of adverse events when there has been open disclosure.[10,11,12] Disclosing an adverse event to the patient shows respect, involves the patient in the clinical decision-making process, and facilitates future safe and appropriate clinical care.

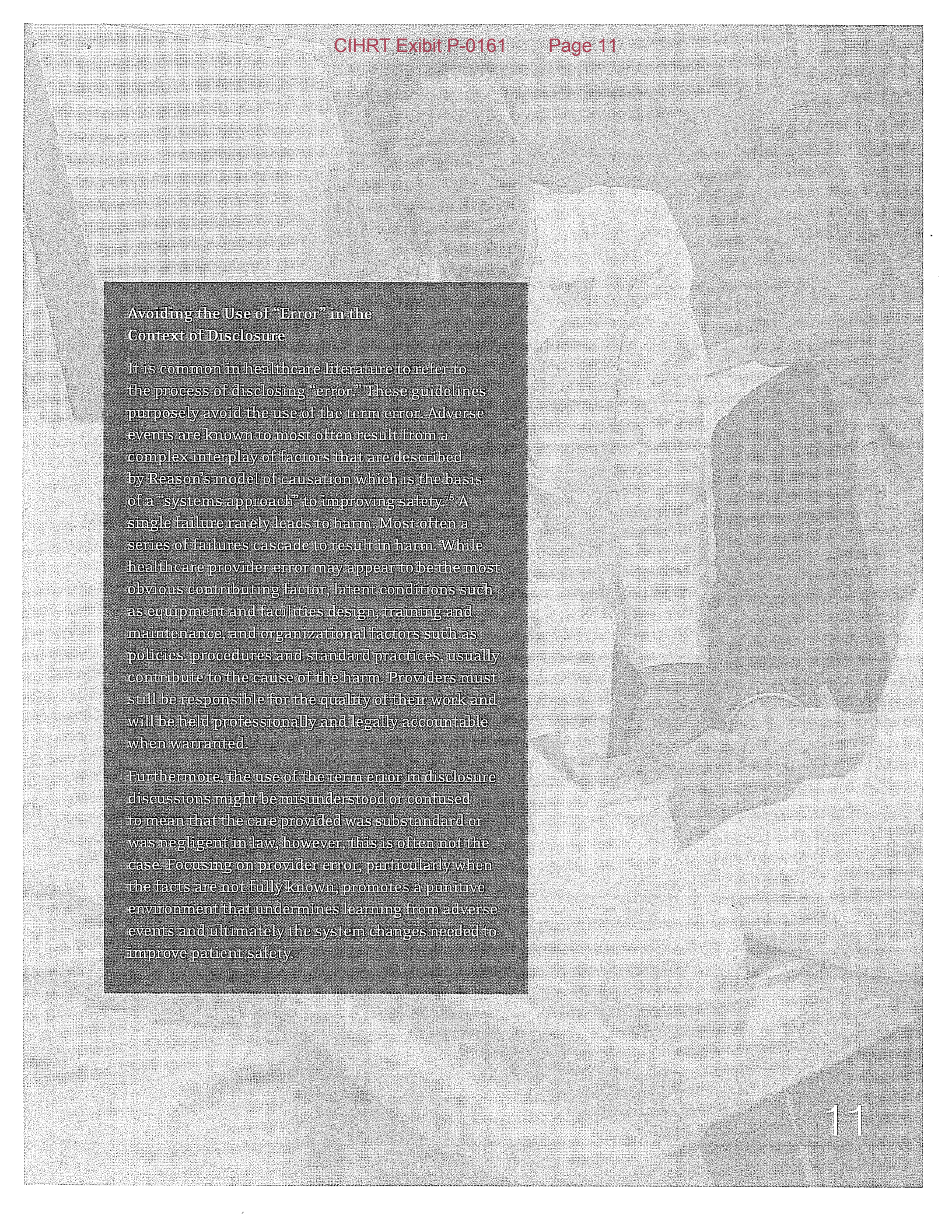
Patients also may be more likely to initiate legal action when they believe that facts are withheld. Although patients may litigate for a number of reasons, effective communication and appropriate provision of care after an adverse event are key factors influencing a patient's decision about whether to initiate legal action.[12, 13, 14, 15]

Ethical and Professional Perspective

Healthcare providers have ethical and professional obligations to be open and honest when communicating with patients. Most professional codes of conduct specifically require disclosure. Patients have a right to relevant information about all aspects of their care and healthcare providers have a corresponding obligation to provide that information to patients without being asked and to answer their questions.

Healthcare Organization Perspective

The Canadian Council on Health Services Accreditation (CCHSA) supports healthcare organizations in examining and improving the quality of care and service they provide to their patients. The CCHSA includes in its program a focus on the disclosure of adverse events. It specifies that organizations must implement a formal and transparent policy and process of disclosure of adverse events to patients, which includes support mechanisms for patients, family and care or service providers.[16, 17]



Avoiding the Use of "Error" in the Context of Disclosure

It is common in healthcare literature to refer to the process of disclosing "error." These guidelines purposely avoid the use of the term error. Adverse events are known to most often result from a complex interplay of factors that are described by Reason's model of causation which is the basis of a "systems approach" to improving safety.[15] A single failure rarely leads to harm. Most often a series of failures cascade to result in harm. While healthcare provider error may appear to be the most obvious contributing factor, latent conditions such as equipment and facilities design, training and maintenance, and organizational factors such as policies, procedures and standard practices, usually contribute to the cause of the harm. Providers must still be responsible for the quality of their work and will be held professionally and legally accountable when warranted.

Furthermore, the use of the term error in disclosure discussions might be misunderstood or confused to mean that the care provided was substandard or was negligent in law, however, this is often not the case. Focusing on provider error, particularly when the facts are not fully known, promotes a punitive environment that undermines learning from adverse events and ultimately the system changes needed to improve patient safety.

Building the Foundation for Disclosure

Creating a Culture of Patient Safety

The patient safety culture of an organization is the collective values, knowledge, skills and commitment to safer patient care that is demonstrated by every member of the organization. Within a culture of patient safety, there is respect for the patient's right to receive information about their health care. Irrespective of the cause, the involved healthcare providers and/or organizational representatives should communicate with the patient about all harm.

An important element in establishing an organizational culture of patient safety includes the creation of an environment in which adverse events are openly identified and reported. Reporting is a different process from disclosure and refers to the communication by healthcare providers of information about an adverse event (or close call) through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of reoccurrence.

Many adverse events in healthcare are now recognized as system failures, where safeguards to protect patient safety were not in place, or a series of safeguards that were in place failed in sequence, which resulted in harm to the patient. Adverse events often occur after recurrent patterns of failures, regardless of the dedication or experience of the healthcare providers involved. Systems theory emphasizes that focusing on the system rather than on the individual will prevent more adverse events.[18,19]

A "just culture" is a key element of a broader patient safety culture that seeks to reconcile professional accountability and the need to create a safe environment in which to report

System failure: A fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.[viii]

adverse events.[20] Healthcare providers in a just culture are fully aware of the expectations of the organization and are held professionally accountable for the quality of their work in a fair way. Adverse events are viewed in the context of identifying system contributors in order to improve safety. The adverse event is analyzed for such system contributors, and the lessons learned are used to strengthen the system and, if appropriate, to support and educate the healthcare providers to help prevent similar events.

Patient Support

Patients should be supported emotionally and practically when they experience harm; such as when they are impacted by an adverse event. Healthcare providers and organizations can and should provide a supportive environment to patients by:

- Providing timely access to further health care, including clinical investigations, treatments and transfers.
- Designating a knowledgeable staff member, preferably one with whom the patient is familiar and comfortable, to provide practical and emotional support.
- Facilitating emotional support, as determined by the patient, from family, friends, spiritual representatives, etc.
- Assisting patients to access professional support when needed such as social workers or counselors, and community services such as homecare aid or support groups.

[viii] *A full glossary of terms is included in Appendix C*

Healthcare Provider Support and Education

Emerging research indicates that healthcare providers receive very little support after an adverse event occurs.[5] Feelings of sadness, failure to heal and overwhelming guilt can erode the healthcare provider's self-esteem and drain them emotionally and physically.[13] Disclosure and apology are believed to assist healthcare providers to heal and preserve relationships with their patients.[21] Emotional and practical support should be made available to healthcare providers involved in adverse events and/or in disclosure discussions. A variety of strategies may be used that are supportive, discourage speculation and/or attribution of blame, and assist the healthcare provider to access organizational and professional support such as counseling. When healthcare providers are given opportunities to share their experiences, it can help reduce feelings of isolation and facilitate a culture of safety.[3]

There is often uncertainty about what to say to patients following an adverse event. It is recommended that healthcare providers receive education and training in how to effectively participate in a disclosure discussion, and that this training be ongoing to maintain these skills. Empathetic communication is a skill that needs to be developed and practiced.

Specific guidance and instruction on how to effectively communicate and respond to unintended patient outcomes and adverse events should be integrated into the undergraduate and graduate curricula for all healthcare providers. Educational strategies should include disclosure training for senior healthcare providers so that they may be role models for trainees. Opportunities should be presented for trainees to be involved in the disclosure process when appropriate. Effective training promotes open and effective communication that will become more widely practiced, and will, in turn, support and sustain a culture of safety.

The Disclosure Process

When developing and implementing a disclosure policy or process it should be understood that each patient and adverse event is unique. The disclosure process requires flexibility to ensure it is effective and meets the information needs of each individual patient.

Following any harm including an adverse event, the first priority should be to attend to the care of the patient and deal with any emergencies and immediate concerns to prevent or mitigate harm. Depending on the nature of the event, an immediate safety risk may also exist for patients. The safety risk should be addressed and reduced if possible.

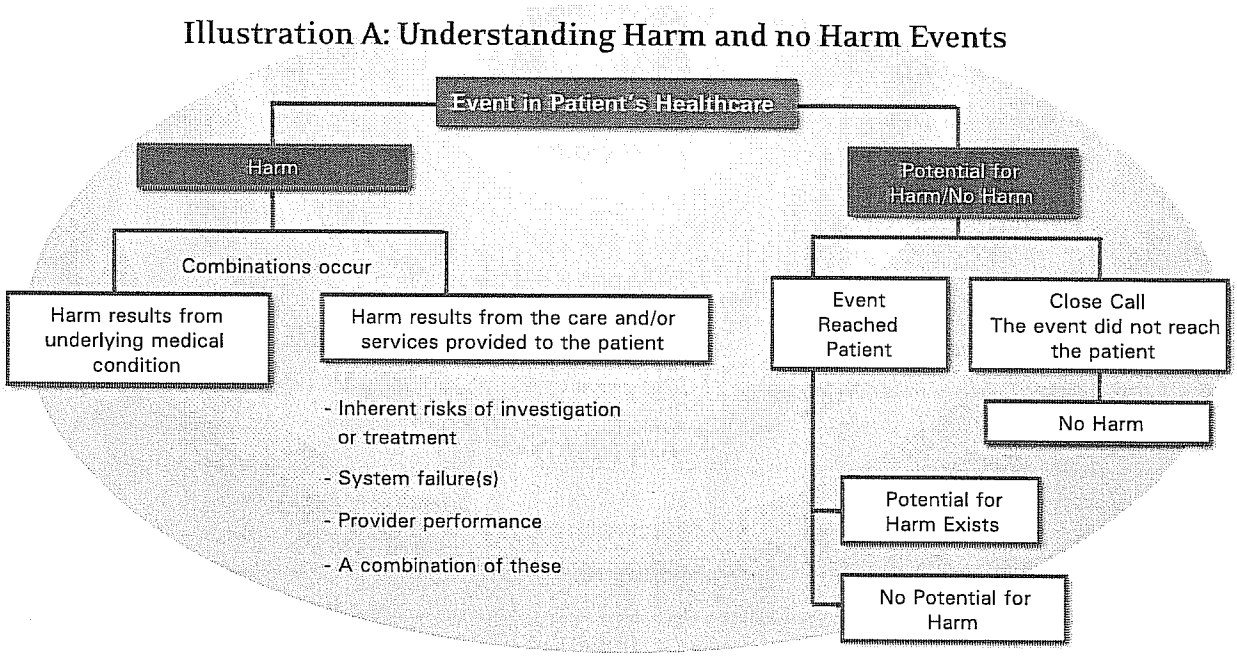
Adverse event: An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.

Understanding harm

Illustration A provides a framework for understanding harm and no harm events.

Almost all investigations or treatments unfortunately may result in harm. Prior to investigation, it may be difficult to discern if the harm is a result of the patient's natural progression of the underlying medical condition, the risk inherent in the patient's investigation or treatment (risks known to be associated with the provision of health care services would be commonly discussed in an informed consent discussion prior to an investigation or treatment to ensure that such risks are appreciated and agreed to by the patient), system failure(s), provider performance or a combination of any or all of these. Gaining clarity as to what happened, as well as how and why it happened is very important for the understanding of both patients and providers.

Illustration A: Understanding Harm and no Harm Events

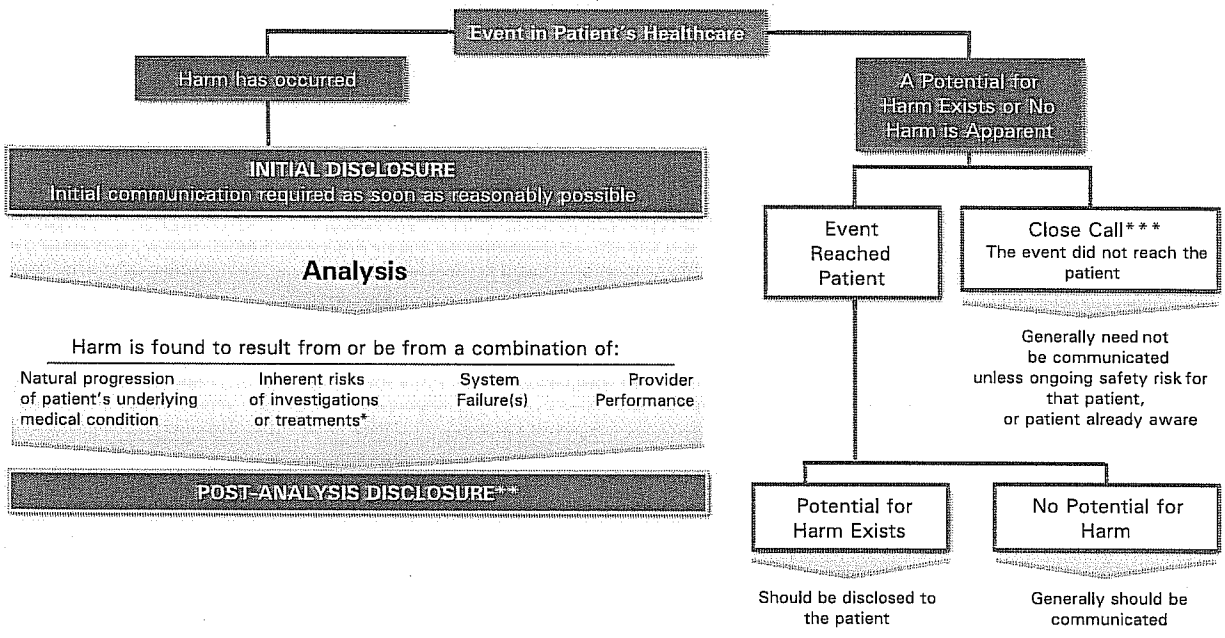


A. Threshold for disclosure

Whenever a patient suffers harm, whatever the reason, the healthcare provider or organization has an obligation to communicate to the patient about that harm and, if applicable, the event that led to the harm. *Illustration B* provides an overview of the requirements for disclosure for different types of harm and certain no harm events.

Harm that has resulted from the inherent risks of an investigation or treatment should always be communicated to the patient. Such harm should not prematurely be attributed to simply "a complication" of the investigation or procedure. Events should be appropriately examined to understand all of the contributors involved. An analysis may indicate a combination of reasons actually resulted in the harm.

Illustration B: Determining the Type of Event and the Requirements for Disclosure



* Refers to harm known to be associated with the investigation or treatment

** Management in consultation with providers to determine what furt her information is to be disclosed.

*** It is strongly encouraged that close calls be reported to healthcare organizations

Stages of disclosure

Disclosure is most often a dialogue over time. It is helpful to think of disclosure as generally occurring in two broad stages, recognizing that it is an ongoing process in which multiple "disclosure conversations" may occur over time. This is therefore a conceptual model, and must be adapted to each individual situation. Each stage may consist of one to several discussions depending on the patient's condition, understanding of events and questions that arise. Refer to Illustration B to assist in understanding these stages.

The first stage, initial disclosure, is the initial discussion with the patient that should occur as soon as reasonably possible after an event. This discussion is principally the obligation of the providers, although organizational leadership/management may provide advice or assistance as required. This discussion will often focus on the medical condition as it now exists, and the inherent risks of any further investigations or treatments.

Even if an adverse event is recognized, it is seldom that all the contributors to the event are clearly known initially. The facts that are known are communicated during the initial disclosure. If appropriate, a commitment is made to learn more about what contributed to the event. Important other elements to this discussion include:

- An expression of regret for what happened.
- The avoidance of blame and speculation.
- The provision of emotional and practical support for the patient.

It is important to note that, depending on the circumstances, initial disclosure may represent a discussion or a series of discussions. Much of the advice for providers about communicating with patients in these guidelines is focused on this first stage of disclosure.

The second stage of disclosure is called *post-analysis disclosure*. An analysis may have identified additional facts, and the reasons for the event are usually better understood at this stage. Preliminary discussions that have already occurred in initial disclosure should be continued. Leadership/management may likely have a greater role at this stage, and the providers involved should be updated about the results of the analysis and encouraged to continue to participate in the discussions.

Leadership/management, in consultation with providers, must determine what information will be disclosed. They must consider not only the information needs of the patient, but also any restrictions or requirements on information exchange that might arise from the application of national or provincial legislation, regulations or local institutional/hospital bylaws and policies. The advice of legal counsel may be required.

It is at this stage that patients may learn of improvements made to prevent similar events, if such improvements are possible. In addition, a further expression of regret is important that may include an apology with acknowledgement of responsibility for what has happened as appropriate.

[ix] *Certain information gathered in quality committees or performance reviews may be legally protected or prohibited from disclosure. These protections need to be considered when developing local policy in a given jurisdiction.*

Providing communication support

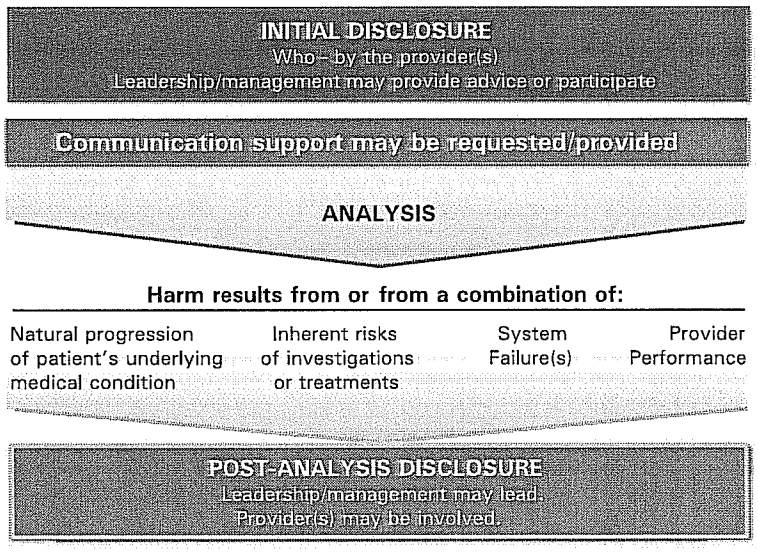
Support by an organization for initial disclosure may include the provision of advice to the providers on how to best communicate to improve the patient's care and understanding of what has happened about an adverse event. The provision of such communication support will vary, depending on the kind of event, the communication abilities, and the comfort level and emotional stress of the healthcare providers involved.

Healthcare providers and organizations may develop disclosure policies that recognize different levels of harm and incorporate varying levels of administrative response and communication with the patient.[ix] The steps in the disclosure process must be flexible to try to meet the clinical and information needs of patients and provide support to healthcare providers. Organizations should support the patient-provider relationship by implementing an organized and practical disclosure process for adverse events. Harm resulting from system failure or provider performance is likely to require communication support to better improve patient care and understanding.

Illustration C outlines the role of leadership/management and the provision of communication support to healthcare providers.

Initial disclosure is generally led by the providers involved. However, depending on the setting, the nature and severity of the harm, individuals in leadership/management positions may provide advice or want to participate. In later meetings, during the post-analysis disclosure, those in senior leadership/management positions may take on the lead role in communication with the patient. Providers would, as appropriate, be encouraged to continue to participate and should be kept informed of the communications. Refer to Who should participate in disclosure discussions for more information.

Illustration C: The Role of Leadership/Management and the Provision of Communication Support to Providers



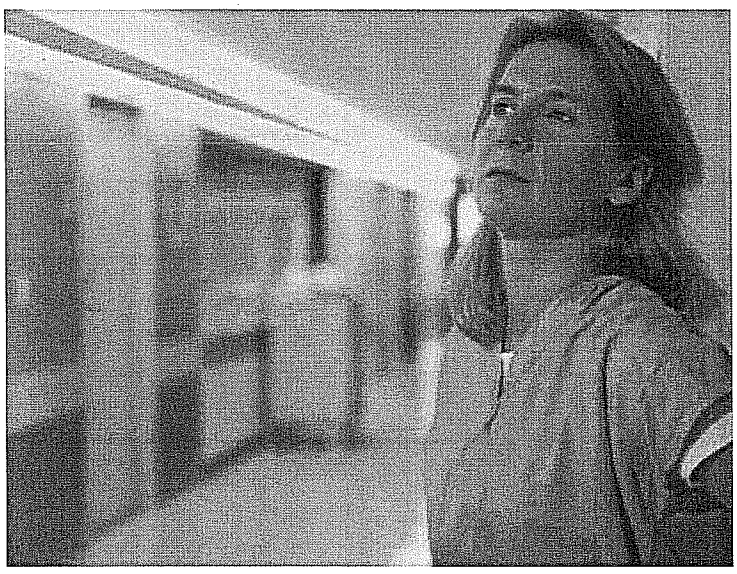
Close calls, events with the potential to harm and no harm events

Close calls, events that did not harm but could potentially result in harm in the future, and events that reached the patient but did not cause harm all require special consideration. Illustration A outlines a framework to understand these events. Illustration B provides an overview of the requirements for disclosure in such circumstances depending on the nature of the event.

In deciding whether to communicate to the patient regarding a close call, providers should consider whether an ongoing safety issue exists for the patient or whether the patient is aware of the event. One example of a close call would be if a patient narrowly avoids being given a medication intended for someone else with a similar or identical name. Although the medication is not given (i.e., that is it does not reach the patient) it would be prudent to discuss this kind of close call to ensure the patient is aware of any ongoing safety risk related to the potential name mix-up and may also watch for this risk in the future. In addition, if a patient is aware of a close call, an explanation may alleviate concerns and maintain trust.[x] Where an event reached the patient but does not result in harm, healthcare providers and organizations should consider whether a reasonable person would want to know about the event under the given circumstances.

Close Call: The event did not reach the patient because of timely intervention or good fortune.

The need to disclose when there is no immediate harm but the potential for harm exists is influenced by the future likelihood of severe consequences, the severity of possible consequences and the potential to prevent, identify or mitigate future harm through clinical testing or treatment. When uncertain about whether harm has occurred, it is recommended that disclosure take place; however, further consultation may be required before proceeding. Consider consulting with an ethics committee or another similar body of experts for advice about the clinical risk of future harm and the need to disclose.



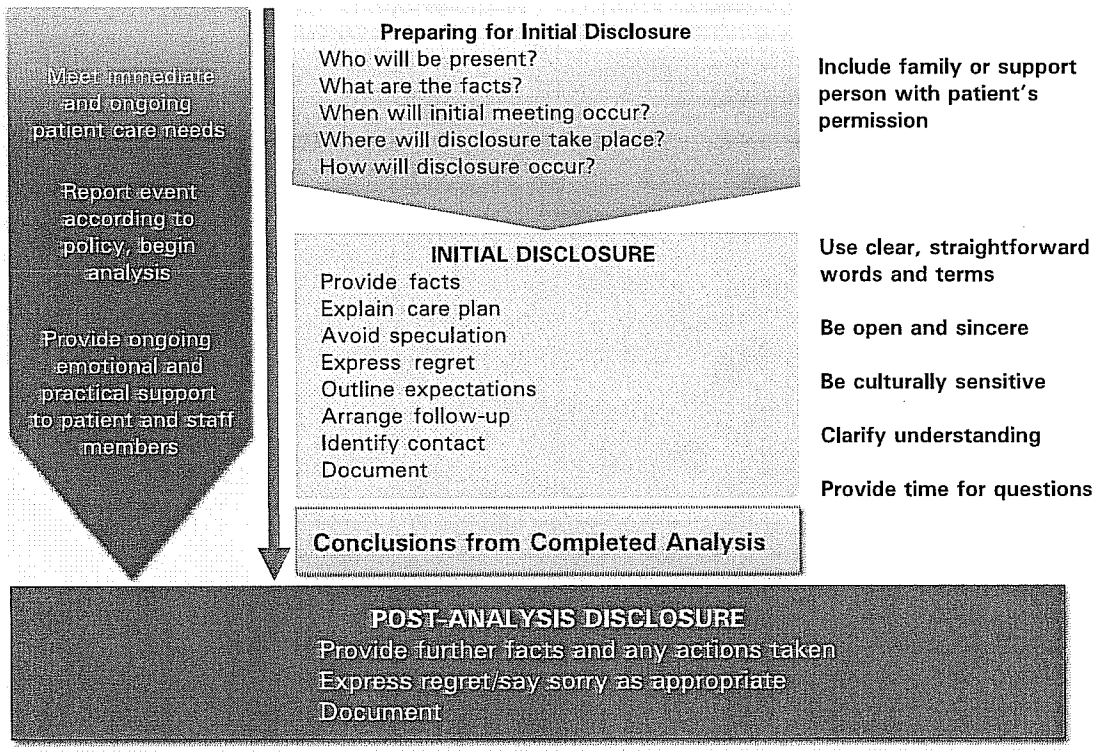
[x] It is also strongly encouraged that close calls be reported to organizations so that safety improvements can be made to reduce the likelihood of a similar adverse event in the future

Illustration D demonstrates how disclosure is an ongoing process that begins when harm is identified and continues through to subsequent discussions depending on the nature of the event.

Preparing for initial disclosure

After ensuring the patient's care needs have been met, the individuals who will participate in the disclosure should be identified and plan how they will proceed. The planning discussion helps to ensure that all relevant facts known at the time are collected and understood.[3] Everyone should agree on how, when and where the disclosure will happen. It is important to anticipate the response and emotional reaction of the patient and the healthcare providers involved in the event. Ultimately, the goal is to facilitate a supportive and effective disclosure discussion. A checklist for healthcare providers use for disclosure process is provided in Appendix E.

Illustration D: The Disclosure Process



B. Who should participate in disclosure discussions

The choice of who will be part of the initial disclosure is influenced by the setting, type of adverse event and local policy. Assistance by those who are trained in the disclosure process and have strong interpersonal skills should be encouraged. Depending on the setting, the nature and severity of the harm, others in leadership/management or the same healthcare discipline most involved in the event may provide advice or wish to participate. During later meetings, and particularly in post-analysis disclosure, leadership/management may take on the lead role. Providers would, as appropriate, be offered to continue to participate. The participation of other types of health professionals over time may be appropriate to help the patient understand his or her current and anticipated health status and needs, for example, a dentist, physical therapist, nurse practitioner or physician. In private practice or the community setting, there may only be one or two healthcare providers involved in the disclosure.

The decision about who should lead should take into consideration:

- Which healthcare provider is most knowledgeable about what has occurred.
- Which healthcare provider has an existing relationship with the patient and family.
- Who is able to explain the future care plan.[15]
- What, if any, patient preferences.

If disclosing on behalf of other healthcare providers, delegates should explain in a sensitive and blame-free manner why the provider involved is not speaking with them directly. Provider students are encouraged to be present if the patient agrees to this and the team believes that it is appropriate.

The goal of all healthcare providers in attendance is to provide information to the patient, assist with disclosure, provide support and facilitate ongoing patient care. It is recommended that the total number of individuals present be limited to three or four, a balance is needed to ensure that the number of providers do not overwhelm the patient. In all circumstances, the patient should have the option of having a support person(s) at these meetings and the organization should ensure there is an offer of other support such as spiritual care or social assistance.

C. When disclosure should take place

The initial disclosure discussion should take place at the earliest practical opportunity and preferably within one to two days after discovery of the adverse event. Subsequent disclosure meetings should also occur in a timely fashion. When harm has occurred, the immediate and ongoing welfare of the patient is of the highest priority. However, a delay in communication may precipitate anxiety and feelings of abandonment in patients who suspect an adverse event has occurred.

D. Where: Setting and location

The choice of setting and location for meetings is important. Meetings should be, to the extent possible:

- In person.
- At a location and time of the patient's preference.
- In a private area to maintain confidentiality.
- In a space that is free from interruptions.

E. What to disclose

In the initial disclosure, the information to be communicated should include:

- The facts of the harm and/or event known at the time.
- The steps taken and the recommended options and decisions in the ongoing care of the patient (e.g. changes to care plan as applicable).
- An expression of sympathy or regret.
- A brief overview of the investigative process that will follow, including appropriate timelines and what the patient can expect to learn from the analysis.[3]
- An offer of future meetings, including key contact information.[3]
- Time for questions and the answers given.[3]
- An offer or offers of practical and emotional support, such as spiritual care services, counseling, social work, and patient safety advocates, as needed.
- The plan for further investigation and treatment if required.

When conducting an investigation, such as a Root Cause Analysis (RCA),[xi] in a legally protected quality of care or similar committee, it is important to be aware of the legislation in each province or territory that will impact information exchange. Providers and patients should be made aware that there are explicit limitations to discussing some of the investigative information, such as opinions and speculations shared, as defined in legislation within each of the provinces or territories quality of care protections.[xii]

Healthcare providers need to be prepared to have ongoing discussions with patients, as required. Disclosure should be seen as a dialogue over time. Further discussions will depend on the patient's condition, understanding of events and questions that may arise. A patient needs to know his or her providers are working to try to improve the clinical situation and to provide information in a timely manner to meet the patient's needs.

Subsequent and post-analysis disclosure discussions with the patient and those support people that the patient chooses to have present should include:

- Continued practical and emotional support as required.
- Reinforcement or correction of information provided in previous meetings.
- Further factual information as it becomes available.
- If applicable, and when all the facts are established, a further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate.
- Actions taken as a result of internal analysis that have resulted in system improvements.

It is essential during any disclosure discussion that speculation, opinion or attribution of blame does not occur.

[xi] A full glossary of terms is included in Appendix C

[xii] Legislation protecting quality assurance information limits disclosure in certain circumstances.

Other practical considerations

The style of disclosure must be appropriate to the kind of adverse event that has occurred. On one end of the spectrum, "openness and honesty might require only a 10-second acknowledgement of a minor problem and a simple apology. At the other end, it could involve a series of meetings over several months; in serious cases disclosure and ongoing support might literally have life-long implications for some patients."[22]

F. How to disclose

Effective communication strategies are essential and various factors influence the content and direction of the communication. Some considerations and communication strategies for disclosure include:

- Using terminology and words likely to be understood by the patient.
- Using active listening skills such as empathizing[3] to help understand the patient's experiences and needs.
- Adopting an open, forthright and sincere approach, and conveying this also with body language.
- Providing adequate time for questions.
- Clarifying whether the information is understood.
- Being sensitive to cultural and language needs.[xiii]

G. What should be documented

Documentation should be consistent with all legal and regulatory requirements for documentation of patient care and communication. Documentation should include:

- Time, place and date of the meetings.
- Identities of all attendees.[4]
- Facts presented.
- Offers of assistance and the responses.[3]
- Questions raised and the answers given.[3]
- Plans for follow-up, including key contact information for an appointed contact person.[3]

[xiii] *See Section on Particular Circumstances*

Apology: An expression of sympathy or regret, a statement that one is sorry.

H. Expression of regret

When patients feel they have received a sincere statement saying sorry, they feel respected, cared for, validated and their trust is often restored.[23]

An early expression of regret that communicates genuine concern and sympathy for a patient's physical and emotional well-being is valuable and essential. In initial disclosure discussions the healthcare provider should express regret for what happened, as a general rule as soon as the patient has been told what has happened. The exact words will depend on the nature of the event, the nature of the harm, and the relationship between the healthcare provider and the patient. Sincere statements such as "I am sorry you had such a difficult experience" or "I was sorry to learn of all the pain that you and your family have experienced" reflect a caring nature. Such expressions are often helpful emotionally for both the patient and healthcare provider.

Subsequent expressions of regret, as more is learned about the event that caused harm to a patient, are also important. Whatever the factors that contributed to the harm, there is nothing lost and much to be gained by reinforcing genuine concern and sympathy for the patient's situation. At the post-analysis stage, a suitable expression of regret will vary depending on what additional facts have been established. A repetition of concern for the well being and circumstances of the patient will always continue to be appropriate. Where it is clear that a healthcare provider or organization is responsible for the adverse event, it would be appropriate to acknowledge that responsibility and provide an apology.

In principle, apology as part of disclosure of an adverse event (for example related to a system failure or provider performance) is consistent with patient-centered care, honesty and transparency, and intuitively is the right thing to do. In practice, apology as part of disclosure is complex because of the ambiguity of commonly used apology language. There is a belief that apology implies blame for providers, which is often inconsistent with a just patient safety culture. There is also a widely expressed concern that an apology could be taken as a confession or admission of legal responsibility, exposing healthcare providers, organizations and others (e.g., professional colleagues, defense organizations and liability insurers) to potentially unwarranted risk. While there is little evidence to date that Courts have taken apology in this way,[15] if this perception persists it can discourage participation in and support for disclosure.

An apology to patients by healthcare providers or organizations should not be taken as an admission of legal responsibility. In some provinces, legislation expressly prevents apologies from being taken as an admission of legal responsibility. In any event, using words such as "negligence," "fault," or "failing to meet the standard of care," should be avoided. These words express or imply legal determinations that are complex and are not appropriate as part of disclosure.

Particular Circumstances

The following section highlights some important situations that may affect the approach to disclosure. Each circumstance should be addressed on a case-by-case basis and some may require consultation with legal counsel.

Paediatric

Generally, the child's ability to make treatment decisions will determine who may be included in disclosure discussions without the child's specific consent. In most circumstances, the paediatric patient with the cognitive ability and emotional maturity to understand the information provided should be included.

Capacity issues

If a patient has limited capacity to understand and deal with the event, then disclosure should accommodate the patient's particular circumstances. The determination of incapacity must be decided on a case-by-case basis. Who should accompany such patients will generally depend upon provincial or territorial legislation. It may not always be appropriate to disclose all information to a patient with capacity issues.[xiv] If there is concern about the patient's ability to understand the meaning of the information, consultation with other healthcare providers and, at times, legal counsel, may be required.

[xiv] It could include legal incapacity or inability to participate for other reasons (e.g. heavily sedated).

Communication issues

If a patient has difficulty communicating, due to visual, hearing or other impairment, appropriate supports may be needed to ensure effective communication. Supports may include interpreters, other care providers, family or friends of the patient. Their role is to assist the patient during the disclosure process, focusing on ensuring that the patient's views are considered and discussed.[9]

Language and/or cultural diversity

There should be sensitivity to both the patient's language needs and cultural background. Underlying principles and beliefs regarding health matters need to be considered, and advice should be sought to ensure that disclosure is conducted in the most culturally sensitive way. It may be necessary to include translation and advocacy services when planning disclosure. Prior to involving others in the disclosure process, the privacy rights of the patient must be considered.

Research settings

In the course of a clinical trial, adverse events may occur. They may or may not be related to the treatment being studied. The obligation to disclose to the patient remains. There are likely further obligations to report the occurrence of the adverse event to the sponsor of the trial and usually to the research ethics board that approved the study.

Multi-patient disclosure

In some situations there may be a need to disclose to more than one patient about the same adverse event. Privacy and confidentiality remain important. The disclosure discussion should be with only one patient at a time and in person if possible. If disclosure cannot be in person, it should be done by registered mail and/or telephone with opportunities for follow-up made available.[3,24,25] In addition, disclosure should be timed, if possible, to occur with all patients involved at approximately the same time and, if possible, prior to any informing process, especially media coverage, being considered.

Multi-jurisdictional disclosure

It is not uncommon for patients to receive health care at more than one hospital, clinic, health region, and province or territory. The discovery of an adverse event may be in a different jurisdiction than where the adverse event happened. The importance of privacy and confidentiality must be considered based on the circumstances. If possible, the healthcare provider or organization involved in the actual adverse event should lead the disclosure process and ideally representatives from both jurisdictions should collaborate in the process.[3,24,25] Effective communication between the jurisdictions, including consultation and discussion of the facts is important during this process. These issues should be addressed on a case-by-case basis and usually require consultation with legal counsel and/or other experts in privacy law.

APPENDIX A: Recommended Reading on Disclosure[1]

Legal Considerations in Disclosure

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Canadian Resources

Provincial Frameworks/Policies

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Other Canadian Articles and Resources

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8. Ontario Hospital Association, Council of Academic Hospitals of Ontario. *Patient safety in Ontario: an overview of patient safety policies in select Ontario academic hospitals, part 1: disclosure.* 2005.
9. Wallace, G. How to apologize when disclosing adverse events to patients *CMPA Information Sheet.* 2006; September.

International Frameworks/Policies

1. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: a national standard for open communication in public and private hospitals, following an adverse event in health care.* Standards Australia; 2003. Retrieved January 3, 2008 from: *http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/3D5F114646CEF93DCA2571D5000BFEB7/$File/OpenDisclosure_web.pdf.*
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3. National Patient Safety Agency. *Being open: communicating patient safety incidents with patients and their carers.* National Patient Safety Agency; 2005. Retrieved January 3, 2008 from: *http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=5592.*

Other Relevant Articles and Research

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16. Wojcieszak, D., Banja, J., Houk, C. (2006). The Sorry Works! Coalition: making the case for full disclosure. *Joint Commission Journal on Quality & Patient Safety*. 2006; 32 (6): 344-350.

APPENDIX B:
Health System Stakeholder Endorsement

The participating organizations listed on pg.4 will be invited to endorse the Canadian Disclosure Guidelines and will be listed when endorsement has been received.

APPENDIX C:
Glossary of Terms

Adverse Event: An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.

Apology: An expression of sympathy or regret, a statement that one is sorry.

Close Call: The event did not reach the patient because of timely intervention or good fortune. (The term is often equated to a near miss or near hit.)

Disclosure: The process by which an adverse event is communicated to the patient by healthcare providers.

- **Initial Disclosure:** The initial communications with the patient as soon as reasonably possible after an adverse event.
- **Post-analysis Disclosure:** Subsequent communications with a patient about known facts related to the reasons for the harm after an appropriate analysis of the adverse event.

Event: A significant occurrence or happening.[26]

Harm: An outcome that negatively affects the patient's health and/or quality of life.[27]

Informing: Providing information about adverse events and the performance of the healthcare system to the public, mainly through the media.[28]

Patient safety: The reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices, shown to lead to optimal patient outcomes.[29]

Reporting: The communication of information about an adverse event or close call by healthcare providers, through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of reoccurrence of adverse events in the future.

Root Cause Analysis (RCA): An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, identification of risk reduction strategies, and development of action plans along with measurement strategies, to evaluate the effectiveness of the plans.[30]

Substitute Decision Maker (SDM): A person, other than the patient, who is legally authorized to make a decision on behalf of the patient. The authority may be granted by the patient himself or herself, by a legal document such as an advance directive, by legislation (e.g. the Mental Health Act) or by the courts (e.g. court appointed guardians).

System failure: A fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.[31]

APPENDIX D:
Recommended Elements of a Disclosure Policy

1. **Policy Statement/Objectives:** A positively worded statement that sets out what the policy is, when it applies, and what it is intended to do.[32]
2. **Definitions of Key Terms:** In the policy, particular to your region or organization.
3. **Provision for Patient Support:** List supports and resources.
4. **Provision for Healthcare Provider Support and Education:** List supports and resources.
5. **The Disclosure Process:** Outlined with the necessary steps.
    a. Threshold for Disclosure: A brief statement that information about all harm must be communicated and a statement of what warrants disclosure and a definition of the levels of severity/harm as applicable to an organization
    b. Preparing to disclose.
    c. Who should disclose and the participants involved.
    d. When should disclosure take place.
    e. Where should disclosure take place: Setting and location; give examples of private, comfortable and interruption-free areas.
    f. What should be disclosed: The facts and applicable legal requirements and limitations.
    g. How should disclosure be conducted: Initial and post-analysis disclosure that includes expressing regret and/or saying sorry as appropriate.
    h. What should be documented.
6. **Provision for Particular Circumstances:** General and applicable to your organization.

APPENDIX E:
Checklist for Disclosure Process

- ❑ The immediate patient care needs are met.
- ❑ Ensure patient, staff and other patients are protected from immediate harm.

DISCLOSURE PROCESS PLAN

- ❑ Gather existing facts.
- ❑ Establish who will be present and who will lead the discussion.
- ❑ Set when the initial disclosure will occur.
- ❑ Formulate what will be said and how effective disclosure will be accomplished.
- ❑ Locate a private area to hold disclosure meeting, free of interruptions.
- ❑ Be aware of your emotions and seek support if necessary.
- ❑ Anticipate patient's emotions and ensure support is available including who the patient chooses to be part of the discussion such as family, friends or spiritual representatives.
- ❑ Contact your organization's support services for disclosure if uncertain on how to proceed.

INITIAL DISCLOSURE

- ❑ Introduce the participants to the patient, functions and reasons for attending the meeting.
- ❑ Use language and terminology that is appropriate for the patient.
- ❑ Describe the facts of the adverse event and its outcome known at the time.
- ❑ Describe the steps that were and will be taken in the care of the patient (changes to care plan as applicable).
- ❑ Avoid speculation or blame.
- ❑ Express regret.
- ❑ Inform the patient of the process for analysis of the event and what the patient can expect to learn from the analysis, with appropriate timelines.
- ❑ Provide time for questions and clarify whether the information is understood.
- ❑ Be sensitive to cultural and language needs.
- ❑ Offer to arrange subsequent meetings along with sharing key contact information.
- ❑ Offer practical and emotional support such as spiritual care services, counseling and social work, as needed.
- ❑ Facilitate further investigation and treatment if required.

SUBSEQUENT AND POST-ANALYSIS DISCLOSURE

- ❑ Continued practical and emotional support as required.
- ❑ Reinforcement or correction of information provided in previous meetings.
- ❑ Further factual information as it becomes available.
- ❑ A further expression of regret that may include an apology with acknowledgement of responsibility for what has happened as appropriate.
- ❑ Describe any actions that are taken as a result of internal analyses such as system improvements.

DOCUMENT the disclosure discussions as per organizational policies and practices and include:

- ❑ The time, place and date of disclosure.
- ❑ The names and relationships of all attendees.
- ❑ The facts presented.
- ❑ Offers of assistance and the response.
- ❑ Questions raised and the answers given.
- ❑ Plans for follow-up with key contact information for the organization.

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