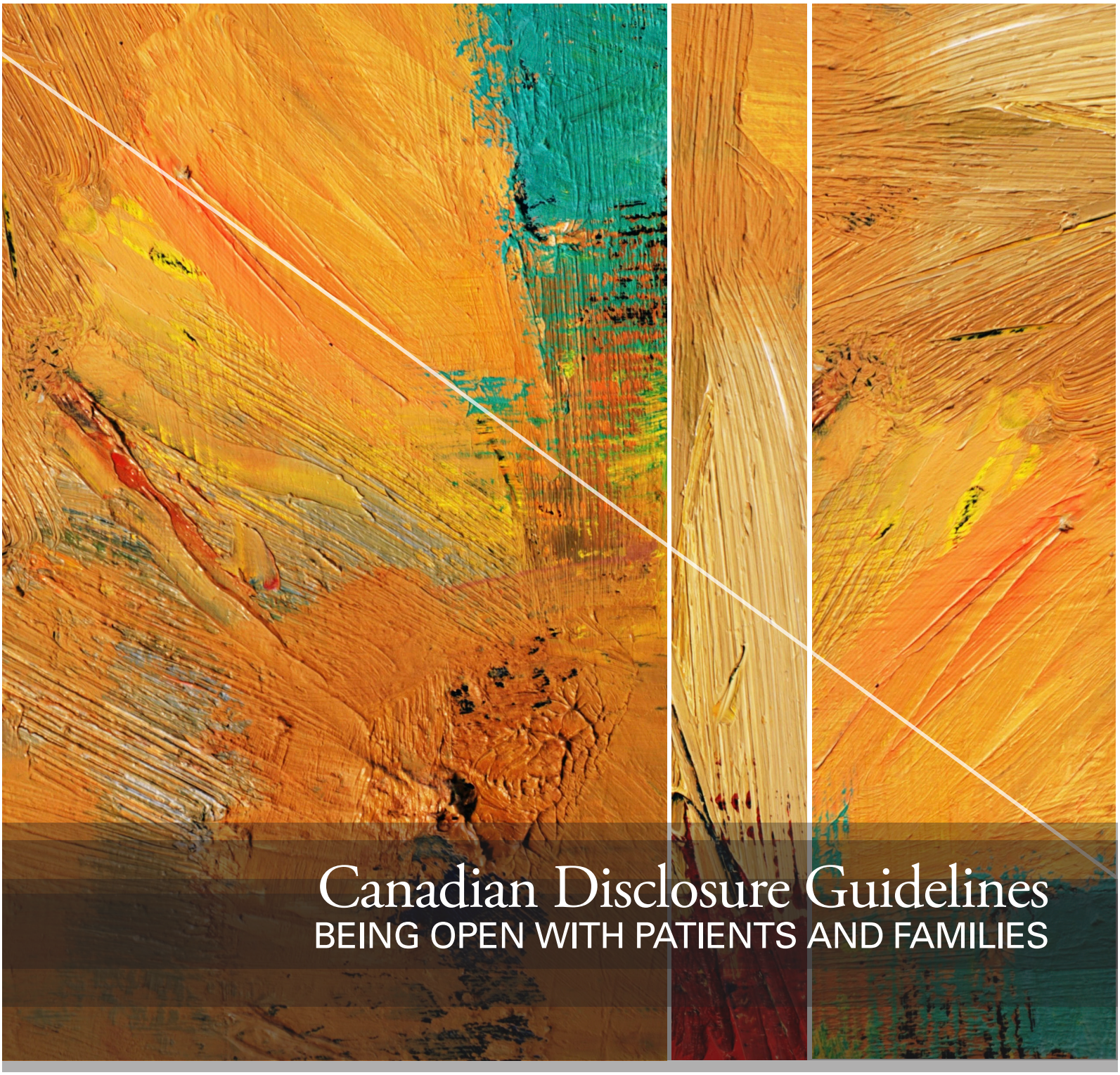

Canadian Disclosure Guidelines

BEING OPEN WITH PATIENTS AND FAMILIES

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients
Safe care…accepting no less
Soins sécuritaires…n'acceptons rien de moins

cpsi icsp

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The members of the Disclosure Working Group and the CPSI acknowledge the staff and CEO of the Health Quality Council of Alberta for their leadership in developing the *Disclosure of Harm to Patients and Families: provincial framework (2006)*, and appreciate the previous Disclosure Working Group's efforts in creating the original documents on which these revisions are based. We would also like to recognize the key contributions of the following individuals: Anne Matlow, Elaine Orrbine, Denice Klavano, Robert Devitt, Margaret Angus, Karima Bushra, Heather Loughlin and Tanya Goldberg.

A PATIENT'S PERSPECTIVE

Disclosure should be based on principles of patient safety, openness, transparency, accountability and compassion. When things go wrong, patients and families need to know what happened. We need to know what changes have been or will be made to prevent a similar event in the future. We need to hear the words "I'm sorry" from those most involved in the event and, where appropriate, we need to see and hear the organization accept responsibility for its part in the event.

When patients and families sense that information is being withheld, we lose trust, and we are more anxious, fearful and angry. We do not expect perfection, but we do expect honesty, justice and shared learning when an incident happens. We also expect to be a part of the process of finding out what happened.

Disclosing a patient safety incident with openness, honesty and compassion shows respect for the patient and family. It shows that the organization is worthy of our trust and that the needs of the patient and family are paramount.

When the loss from the harm is irreplaceable, reparation means far more than financial compensation. It means striving to understand the needs of those who have been harmed and doing everything possible to provide for those needs.

Donna Davis
Co-chair, Patients for Patient Safety Canada

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FOREWORD

MESSAGE FROM HUGH MACLEOD

Chief Executive Officer
Canadian Patient Safety Institute

With the unveiling of our new strategic plan in 2010, the Canadian Patient Safety Institute made it clear that we are "accepting no less" than safe care. We define a successful organization as one that will:

- Embrace prevention of all avoidable harm to patients as a core objective.
- Support all healthcare providers to make safety a top priority in their work.
- Nurture and support a commitment to improvement at all levels of the organization.
- Achieve long periods of incident-free care without becoming complacent or overconfident.
- Adopt leading methods to measure, monitor and report on performance.

This document, a revision of disclosure guidelines originally published in 2008, aims to help organizations achieve this success by being open and honest with patients and families about patient safety incidents. We hope these guidelines will create new conversations about disclosure, clarify how best to meet the needs of patients and families, and help align disclosure policies across Canada. Learning organizations will take the opportunity to pause and reflect each time disclosure takes place, to learn from the experience and make improvements in the system and in how they meet the needs of patients and families.

These guidelines also evoke CPSI's main guiding theme: "Ask. Listen. Talk. – Good healthcare starts with good communication." Consistent with this theme, CPSI embarked on an extensive consultation process, including two national webinars to which over 250 individuals participated and survey with 268 respondents, to ensure these guidelines are supported and embraced by healthcare organizations and providers across Canada.

CPSI has been pleased to provide secretariat and funding support to the Disclosure Working Group [i] chaired by Mr. Brent Windwick. The efforts of the original and current Working Group are gratefully appreciated, as their work greatly supports the CPSI mission "to inspire extraordinary improvement in patient safety and quality."

[i] See list of Working Group members and participating organizations on pages 2 and 3.

MESSAGE FROM BRENT WINDWICK

Working Group Chair

At the request of the Canadian Patient Safety Institute, and with the support and involvement of many participating organizations, a working group was formed in the spring of 2006 to develop the *Canadian Disclosure Guidelines*. The objectives of the *Guidelines* were 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 patient safety incidents.

Our Working Group is extremely pleased and proud of the impact and influence of the Guidelines since their publication in 2008. It is a great credit to healthcare professionals, organizations, regulators and educators across Canada that the pace of change has been so tangible. Since 2008, disclosure as a core element of patient safety culture has continued to take root across Canada through professional and organizational policies and procedures, and in health professional education. These changes have accelerated the renewal cycle for the *Guidelines*. In response to this demand, we are pleased to have participated in the development of this 2011 version of the Canadian Disclosure Guidelines.

As in 2008, our primary objective is that these guidelines will be relevant to healthcare providers, healthcare organizations, health ministries, health professional regulatory bodies and other public organizations. Through these guidelines, we hope to support and encourage individuals and organizations to develop or enhance disclosure policies and practice, incorporating the core elements we propose while adapting them to their respective needs.

The evolution of a patient-centered and safety-focused culture of healthcare has made significant progress in addressing historical barriers to meaningful disclosure and apology for patient safety incidents. The introduction of apology legislation in many Canadian provinces is one legal change that has added momentum to this evolution. The challenges remain of reconciling tensions between openly engaging with patients, providing psychological safety for individual healthcare providers, and promoting continuous learning and improvement in healthcare organizations. These challenges need to be met through regulatory and organizational policy, best professional practice and full integration of disclosure principles in undergraduate and post-graduate health professional education. We hope that these guidelines will continue to support and promote these changes.

MESSAGE FROM PATIENTS FOR PATIENT SAFETY CANADA*

Now that the patient's voice is being included in patient safety discussions, it has become very clear that patients can – in fact *need* – to provide their perspective so that the healthcare community will better understand harm from patient safety incidents and its effect on patients and families. This is particularly true in the disclosure process. The insight of the patients and families who have experienced harm and have gone through the disclosure process is invaluable.

Meeting the needs of patients and families is necessary during the disclosure process. Patients for Patient Safety Canada, a patient led organization comprised of patients and families who have experienced harm, has developed a set of disclosure principles derived directly from their experiences. These principles can be found in Appendix E.

Patients and families across Canada are supportive of open and transparent disclosure of harm, as it addresses a fundamental need when things go wrong, and strengthens the relationships that we have with our healthcare providers. 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.

Patients for Patient Safety Canada believes that disclosure is a process of open communication and information sharing, and is 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 for patients and families to receive an apology for what has happened. We know that these situations are very stressful for both the patient and family, and they need to be supported.

We also acknowledge that disclosure is often needed for healing. It is necessary to re-establish trust and confidence between patients and families and their healthcare providers.

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 (PFPSC) champions the patient voice to advance safe healthcare. Members of PFPSC share their experiences and describe how family centred care, leadership, teamwork, apology, disclosure, and a commitment to learn and change, will make safe healthcare a reality.

INTRODUCTION

INTRODUCTION

Achieving a culture of patient safety requires open, honest and effective communication between healthcare providers and their patients. Patients are entitled to information about themselves and about their medical condition or illness, including the risks inherent in healthcare delivery.

Experience tells us that when harm 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 reason for the harm.

GUIDING PRINCIPLES

The following guiding principles underpin the development and use of these 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 patient safety incidents 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[1]."

Honesty and transparency: When a harmful incident 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.

IMPORTANCE OF DISCLOSURE

Current literature, national and international leading practices, and ethical, professional and legal considerations all support open and honest disclosure of patient safety incidents, as it is important for all concerned.

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 organization and/or provider is/are sorry for what happened.
- What will be done to prevent similar events in the future.[2,3,4,5,6,7]

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 patient safety incidents when there has been open disclosure.[8,9,10] Disclosing a patient safety incident 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 a patient safety incident are key factors influencing a patient's decision about whether to initiate legal action.[10,11,12,13]

Ethical Perspective

Healthcare providers have ethical 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

Accreditation Canada supports healthcare organizations in examining and improving the quality of care and service they provide to their patients. Accreditation Canada includes in its program a Required Organizational Practice (ROP) for disclosure. It specifies that organizations must implement a formal and transparent policy and process of disclosure to patients, which includes support mechanisms for patients, family and care of service providers.[14,15]

A FEW WORDS ON WORDS

International Classification for Patient Safety

The International Classification for Patient Safety, being developed by the World Health Organization (WHO), is a framework and terminology to facilitate the sharing and learning of patient safety information globally. A purpose of the International Classification for Patient Safety framework is to harmonize language about patient safety so that providers, organizations, jurisdictions and countries may start to classify like events similarly, enabling the patient safety community to share and compare information about incidents in order to learn from each other's experiences.

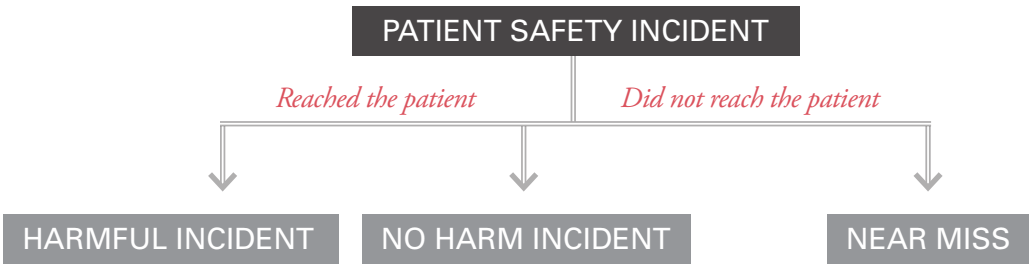
While there are 48 preferred terms and definitions in the International Classification for Patient Safety framework, there are four main terms most relevant to disclosure (for other specific definitions please see the WHO Final Technical Report[16]). These four terms will be integrated into patient safety and quality work across Canada and will greatly contribute to the clarification of and consistency of discussions. CPSI encourages the use of these preferred terms for consistency and clarity, but also recognizes that organizations have reason to continue to use other terminology.

Patient safety incident:
An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

> ***Harmful incident:***
> A patient safety incident that resulted in harm to the patient. Replaces "adverse event" and "sentinel event."
>
> ***No harm incident:***
> A patient safety incident which reached a patient but no discernable harm resulted.
>
> ***Near miss:***
> A patient safety incident that did not reach the patient. Replaces "close call."

Diagram A explains the relationship between the four terms. It is important to note that a patient safety incident may be a harmful incident but does not have to be. In other words, for a patient safety incident to have occurred, a patient does not necessarily have to be harmed; however, the **potential** for harm to a patient or patients must be present. (For a further discussion about harm, see pp. 19.)

Diagram A: RELATIONSHIP BETWEEN FOUR TERMS AS DEFINED BY INTERNATIONAL CLASSIFICATION FOR PATIENT SAFETY



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. Patient safety incidents are known to most often result from a complex interplay of factors that are described by Reason's model of causation, the basis of a "systems approach" to improving safety[17]. A single failure rarely leads to harm. Most often a series of failures cascade to result in harm. For example, while provider actions or inactions may initially appear to be the only contributing factors, it is often the case that latent conditions such as equipment and facilities design, training and maintenance, and organizational factors such as policies, procedures, clinical practices and resources are contributing factors to the harm. Even with this complex interplay, organizations and providers are still responsible and accountable for the quality of their clinical work, within their particular clinical context and setting.

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 reporting and learning from patient safety incidents and ultimately the system changes needed to improve patient safety.

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 may be included in the disclosure process. Therefore, the term "patient" throughout the guidelines includes family members or substitute decision maker where applicable, and also encompasses terms such as "client" or "resident." 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 substitute decision maker legislation in each provincial or territorial jurisdiction.

SCOPE OF THESE GUIDELINES

The guidelines are intended to encourage and support healthcare providers, interdisciplinary teams, organizations and regulatory authorities in developing and implementing disclosure policies, practices and training methods. The recommended elements of a disclosure policy are provided in *Appendix C*. 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, nor 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. CPSI recognizes that legislation related to disclosure and apology is evolving; this document is meant to help shape future improvements in legislation. We encourage readers to be informed of the current legislation relevant to their jurisdiction.

The guidelines are also not intended to define or serve as a legal or professional standard of care, nor to replace provincial or territorial 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.

Another valuable resource to consider when developing disclosure policies is input from patients and families. Only those who have experienced patient safety incidents for which disclosure is appropriate can truly understand the needs of patients in the disclosure process.

BUILDING THE FOUNDATION FOR DISCLOSURE

BUILDING THE FOUNDATION FOR DISCLOSURE

A culture where disclosure is expected and supported is a key foundation for a culture of patient safety that benefits patients, health care organizations, health care professions and health care providers.

SUPPORTING PATIENTS AND FAMILIES

A disclosure culture supports patients by:

- Supporting patients clinically;
- Respecting patients;
- Informing patients;
- Supporting patients psychologically and emotionally; and
- Supporting patients practically.

This support may take many different forms depending upon the circumstances, but some common themes will be apparent.

Supporting patients clinically includes thorough planning and providing timely access to further healthcare, including clinical investigations, treatments and transfers.

Respecting patients includes:

- being prepared for disclosure conversations,
- listening actively and striving to understand the patient's perspective, and
- designating a knowledgeable staff member, preferably one with whom the patient is familiar and comfortable, to provide practical and emotional support during the entire disclosure process.

Most importantly, healthcare providers should be sensitive to what patients need and want to hear, as described in the Patients for Patient Safety Canada Principles of Disclosure (Appendix E).

Informing patients includes keeping patients apprised of the actions taken in response to the incident and of what to expect in the future. The organization and/or provider should make patients aware of any new agreed upon facts identified in the analysis of an incident, the conclusions as to the reasons for the clinical outcome, and any steps that have been implemented to improve the provision of care for others.

Supporting patients emotionally and psychologically includes providing a supportive environment to patients by:

- Facilitating emotional support, with the patient and his/her family playing a key role in determining what this support should be (whether from family, friends, spiritual representatives, etc.)
- Helping patients access professional support when needed such as social workers or counselors, community services or support groups.

Supporting patients practically should include:

- Providing options for facilitating the disclosure process for the patient and family when it is difficult for them to travel to the organization, by using communications such as telehealth, email or videoconference (e.g. Skype™). The organization may also propose a meeting location closer to the patient/family home or suggest meeting at the patient or family residence or another location chosen in consultation with the family;
- Facilitating access to appropriate services, programs, and resources
- Facilitating access to their patient care record;
- Reimbursing reasonable expenses associated with the disclosure process by the organization(see below); and
- Being prepared to respond to patients' questions and concerns arising from patient safety incidents.

Expense reimbursement

When the harm a patient suffers is not part of the patient's underlying condition, it would be inappropriate to expect the patient or family to pay expenses to attend disclosure meetings. The patient and family may already be under physical, emotional and financial stress, and timely reimbursement by the organization for reasonable expenses will help to alleviate some of the difficulties experienced following a patient safety incident. In these difficult circumstances, the organization should also be prepared to help the patient or family access necessary health care resources.

Reimbursement relates to the disclosure process and is not intended to compensate for harm resulting from a known complication or progression of an underlying disease or injury. It is important to emphasize that expenses related to the disclosure process are solely the responsibility of the organization, and not individual providers.

Expenses incurred by the patient and family that the organization may consider for reimbursement include, but are not limited to: travel expenses, parking, meals, accommodation, child care and obtaining medical files pertinent to the incident. Every incident is different, however, and there can be no general rule about what reasonable expenses to pay. This must be determined on a case-by-case basis. Reimbursement would usually be offered at the time the disclosure meeting is being arranged; doing so respects and honours the position of the patient and family.

Reimbursement of these types of expenses reflects an understanding of the financial hardships the patient and family may be experiencing and a desire to help them through difficult times. Reimbursement is not a direct or implied acknowledgement of liability in relation to the event.

Families may ask about expenses incurred because of the event but unrelated to the disclosure process, such as those related to workers compensation programs, funeral costs, long term placement costs, continuing care expenses, or expenses/deductibles not covered in an insurance program. Organizations should anticipate these types of questions and be prepared to respond with appropriate information.

Being sensitive to the needs of the patient and family demonstrates empathy and understanding for what the patient and family are going through. It also indicates acknowledgment of the significance of the event. Willingness to reimburse costs associated with the disclosure process will help to regain trust of the patient and family and foster the positive relationship necessary for an effective and satisfying disclosure.

SUPPORTING HEALTHCARE PROVIDERS

Emerging research indicates that healthcare providers receive very little support after a patient safety incident occurs.[3] Feelings of sadness, failure to heal and overwhelming guilt can erode healthcare providers' self-esteem and drain them emotionally and physically[11]. Disclosure and apology can help them heal and preserve relationships with their patients[18].

A disclosure culture supports health care providers by:

- Providing access to emotional, psychological and practical support; and
- Providing education and training to prepare health care providers to participate in the disclosure process

Emotional and practical support should be made available to healthcare providers involved in patient safety incidents or in disclosure discussions. It is helpful to appoint someone who is accountable for supporting and following up with these providers, for helping prepare them for emotions they will experience and to be sure to close the loop and share results with all those involved in the incident. This person can follow up with the provider at regular intervals, watch to see how they are doing and facilitate getting help when they are ready. A recent study[19] suggests that providers are often not sufficiently prepared for the emotions they will experience in disclosure conversations and in particular with feelings of anger, which can undermine the entire disclosure process.

A variety of strategies may be used that are supportive, discourage speculation or attribution of blame, and help the healthcare provider access organizational and professional support such as counselling. Support may also include the provision of an appropriate leave from the workplace for healthcare providers traumatised by their involvement in a patient safety incident. Also, giving healthcare providers opportunities to share their experiences can help reduce feelings of isolation and facilitate a culture of safety.[1]

There is often uncertainty about what to say to patients following a patient safety incident and providers need to prepare fully for a disclosure meeting through practice and training. It is recommended that healthcare providers receive ongoing education, training, mentoring and coaching to enable them to effectively participate in a disclosure discussion, and understand their role in the disclosure process. Training resources could include: a training strategy and communications protocol for those who will support staff with the disclosure process; institutional policies and/or protocols identifying how to communicate with patients and their families; practice in role plays and simulation; online resources, such as the Canadian Medical Protective Association (CMPA) toolkit for disclosure[20] and; a patient safety officer to guide the process.

Educational strategies should also include disclosure training for healthcare providers so that they may be role models or mentors for trainees and students. Trainees, students and health care providers should have the opportunity to participate in simulation communication training to better prepare them for actual disclosure discussions. Trainees involved in patient safety incidents should report these to their supervisors. Supervisors should encourage their trainees to be present to observe the disclosure discussion of a harmful incident as a learning experience. Specific guidance and instruction on how to effectively communicate and respond to unintended patient outcomes and patient safety incidents should be integrated into the undergraduate and graduate curricula for all healthcare providers.

Effective education promotes open and effective communication that will become more widely practiced, and will, in turn, support and sustain a culture of safety.

SUPPORTING DISCLOSURE THROUGH A JUST CULTURE

A just culture supports a disclosure culture, and is a key building block of a patient safety culture. Health care organizations, health care professions and individual health care providers share an interest in a just culture. To be just, an organizational or professional culture must:

- Value patient-centered care, communication, and continuous learning.
- Commit to disclosure as a way of demonstrating to patients that they can trust healthcare providers and organizations to be honest and open about harmful incidents, and about delivering on organizational commitments to learn from these events to prevent them from reoccurring.
- Encourage individual healthcare providers to effectively disclose and report harmful incidents by implementing a well thought out disclosure process that includes ongoing training and support for both patients and the healthcare providers.
- Have a fair process, where analyses of harmful incidents are conducted in accordance with clearly established organizational policy and the law. Reasons for clinical outcomes and events are not prejudged, and the importance and complexity of systems and processes of care contributing to harmful incidents are recognized.
- Be supportive of individual health care providers, so that they are not held accountable for system failures over which they have little or no control.
- Acknowledge the role of system complexity as contributing causes of incidents, so that reviewers actively search for failures and opportunities for improvement.
- Expect appropriate individual health care providers' accountability for the quality of their clinical decisions, actions and behaviours. The emphasis should be on creating a safe learning environment to learn from harmful incidents, bringing about system changes to improve patient care and, if appropriate, the education of providers.
- Be focused on learning and preventing recurrence of incidents, not on punishment.

A culture of safety exists when safe care is a core value of the healthcare organization. The addition of the word "just" – a just culture of safety – reflects a fair and supportive system. Leadership sets the tone and models expected behaviour, accepting appropriate responsibility and accountability for patient safety incidents. An organization may build a just culture by focusing on patient safety as a core value and designing systems, aligning expectations and making safer choices to realize sustainable safer patient care.

THE DISCLOSURE PROCESS

THE DISCLOSURE PROCESS

When developing and implementing a disclosure policy or process it should be understood that each patient and each patient safety incident 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 that resulting from a patient safety incident, 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 other patients and sometimes even staff. The safety risk should be addressed and reduced if possible.

A WORD ON APOLOGY – SAYING SORRY

An apology is a genuine expression of being sorry for what has happened.

The words "I'm sorry" should be part of any apology. These simple words can foster increased respect and improved relationships between patients/families and the healthcare providers and organizations involved. Those making an apology should also use a personal approach, referring to themselves as "I" or "we" and ensuring they have conveyed their genuine concern and compassion.

It is well established in the literature that when patients feel they have received a sincere statement saying "sorry," they feel respected and validated, and their trust is often restored.[21, 22, 23] An early apology that communicates the genuine concern and sympathy for a patient's physical and emotional well-being is both valuable and essential. Genuine concern by providers will be appreciated by patients and families.

> "An effective apology is one of the most profound healing processes between individuals, groups, or nations. It may restore damaged relationships or even strengthen previously satisfactory relationships."[20]

At every disclosure meeting a statement of being sorry for the circumstances or the condition of the patient is important and appropriate. The exact words used by a physician, nurse, other health provider, administrator or organization representative will depend on the nature of the event, the nature of the harm, and the relationship between the provider and the patient.

An apology is not meaningful unless it is sincere; when apologizing, those apologizing should make sure they convey their sincerity both in the words they choose, as well as in their non-verbal behavior, including body language, facial expressions, gestures, and tone, pitch and pace of voice. It is important to acknowledge that this is a difficult and emotional situation for everyone involved. Patients and families appreciate compassion during these difficult conversations, as well as appropriate reassurance that the harm did not result from anything the family did or did not do.

An apology to patients by healthcare providers or organizations should not be taken as an admission of legal liability. In fact, in most provinces[ii], recent legislation expressly prevents apologies from being taken as an admission of legal liability. 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.

Apologies related to subsequent disclosures, as more is learned about the event that resulted in 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 compassion for the patient's situation. Where it is clear that a healthcare provider or organization is responsible for the harmful incident, and after a full

[ii] Provinces and territories that have apology legislation as of 2011 include: AB, BC, MB, NL, NS, NU, ON, PEI, SK

investigation and analysis of the events, it is essential to acknowledge that responsibility and provide an apology. In this situation, an apology with an acknowledgement of responsibility can restore trust, and show the patient that the organization is open and honest about harmful incidents. As with apology in initial disclosure, this acknowledgement of responsibility does not represent an acknowledgement of legal liability; liability can only be determined based on a claim of negligence, or in Quebec, on a claim of civil liability. The following quotations from recent studies on patients' and family members' views on apology and disclosure give some insight into the content and type of language that resonates with them and provides some measure of comfort to them during this disclosure process.

"The fact that other people apologized for her actions made me feel that they felt really bad that that had happened to me." [22]

"I think he did the right thing. . . he acknowledged that I'd been through a pretty terrible experience." [22]

He wasn't trying to pretend that nothing had happened. . . That made a huge difference. He was just very sincere and authentic." [22]

". . .it made me feel that I could trust my provider because, I mean she took responsibility . . . had remorse about what happened. She wasn't defensive." [22]

"I could have had counselling until the cows come home, but it would not have had the same effect as talking to those people about improving the way they transport babies." [21]

Finally, the following statement was made by a provider:

"I wasn't allowed to be a part of the disclosure process, I needed to see the family of the boy who died, I needed to say, "I'm sorry." I'll always wonder if they know how sorry I am and how it has changed my practice."
(as quoted to Patients for Patient Safety Canada)

Apology as part of disclosure is consistent with patient-centered care, honesty and transparency, and intuitively is the right thing to do.

CIRCUMSTANCES WHEN DISCLOSURE SHOULD TAKE PLACE

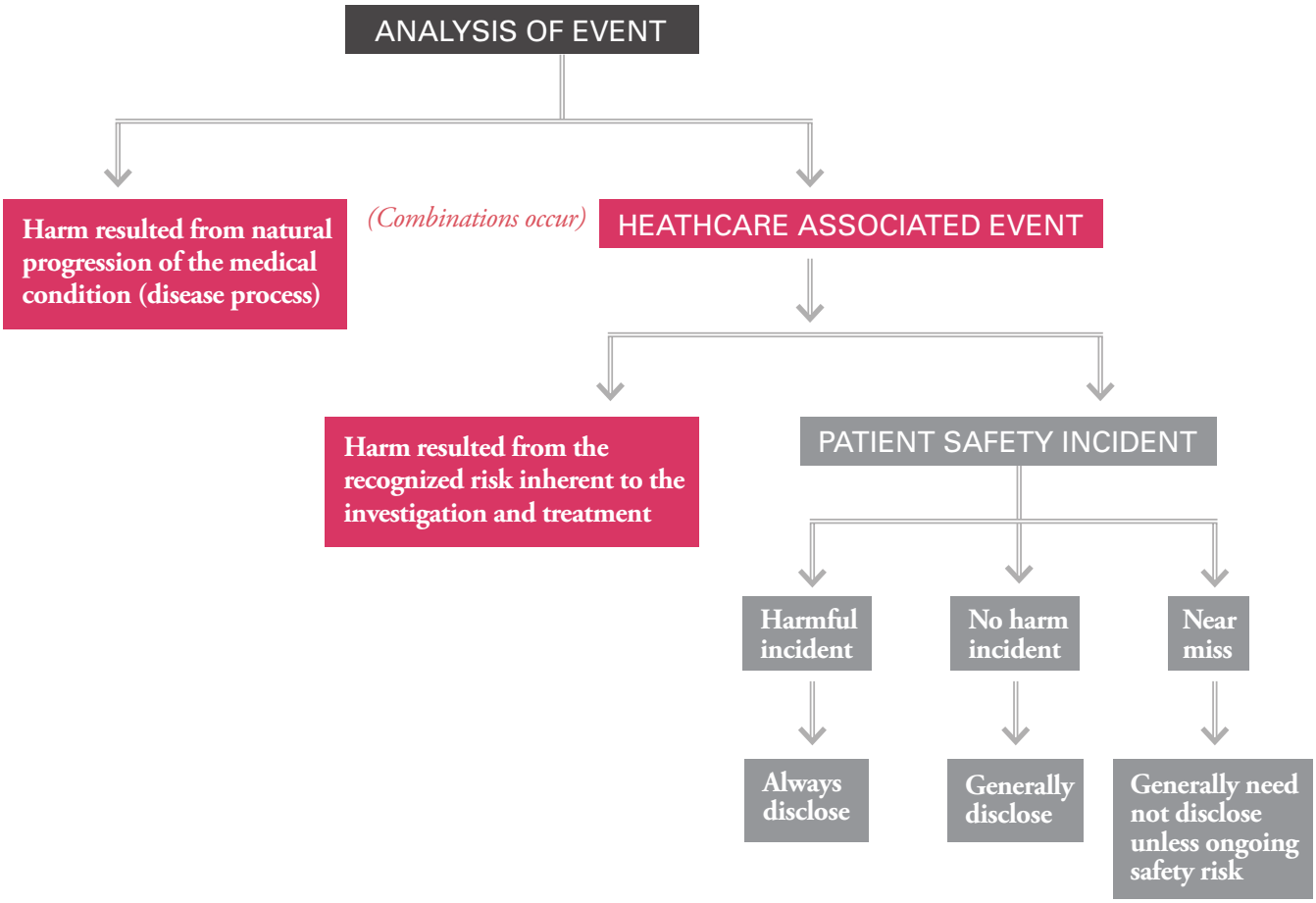
Even with the best of care and skill, almost all medical investigations or treatments unfortunately may result in harm. Prior to analysis, it may be difficult to discern if the harm is a result of the patient's natural progression of the underlying medical condition, the risk inherent in the patient's investigation or treatment, system failure(s), provider performance or a combination of any or all of these. For example, 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.
- who has a loss of hearing because the wrong dose of medication was prescribed or administered suffers harm as the result of a patient safety incident.

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. Patient and family perspective should be sought and welcomed in determining what happened.

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. *Diagram B* provides an overview of the requirements for disclosure for different types of harm and certain no harm events.

Diagram B: CIRCUMSTANCES WHEN DISCLOSURE SHOULD TAKE PLACE



Disclosure must occur if there has been any harm related to a patient safety incident, or if there is a risk of potential future harm. In the case of a near miss, disclosure is discretionary based on whether it is felt the patient would benefit from knowing, for example if there is a residual safety risk.

This diagram is also meant to demonstrate that a discussion with the patient should take place regardless of the origin of the harm. Although the term "disclosure" is used to describe the communications after a patient safety incident, any harm resulting from the disease process or healthcare should be discussed with the patient.

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. Incidents should be appropriately examined to understand all of the contributors involved. An analysis may indicate a combination of reasons actually resulted in the harm.

Healthcare associated harm:
Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.

Recognized risks inherent to investigations or treatments:
Most investigations and treatments have inherent risks (e.g., recognized complications, adverse reactions or side effects) that may occur and are independent of who is providing care.

Patient safety incident:
an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

> ***Harmful incident:*** A patient safety incident that resulted in harm to the patient. Replaces "adverse event." (Example: The wrong unit of blood was infused and patient died from a haemolytic reaction.)
> ***No harm incident:*** A patient safety incident which reached a patient but no discernable harm resulted. (Example: The wrong unit of blood was infused, but was not incompatible.)
> ***Near miss:*** A patient safety incident that did not reach the patient. Replaces "close call." (Example: A unit of blood was being connected to the wrong patient's intravenous line, but this was detected before the infusion started.)[16]

The need to disclose when there is no immediate harm but the potential for harm exists is influenced by the future likelihood of important clinical consequences, and the urgency is determined by the ability 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 clinical experts and as appropriate, an ethics committee or similar experts for advice or sometimes legal counsel, about the clinical risk of future harm and the need to disclose.

In deciding whether to communicate to the patient regarding a no-harm patient safety incident (the incident reached the patient but did not result in harm) healthcare providers should consider whether a reasonable person would want to know about the event in the circumstances.

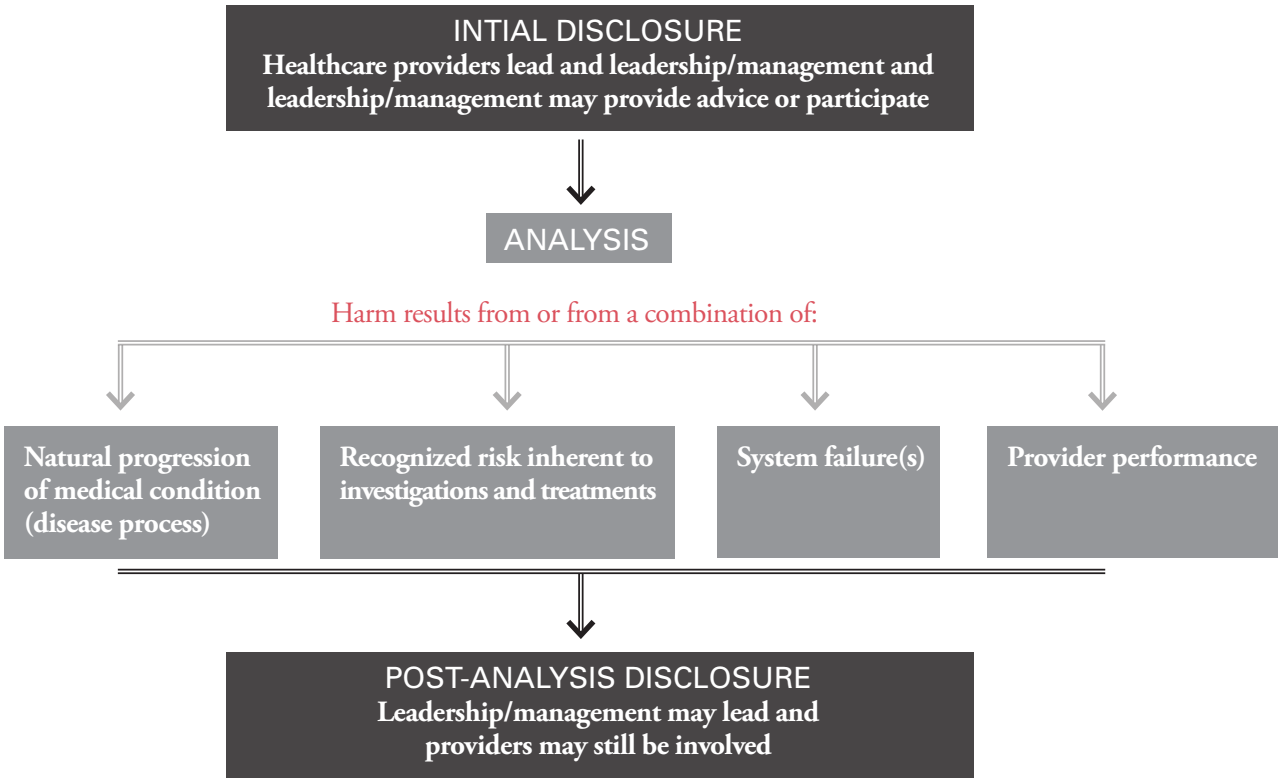
In deciding whether to communicate to the patient regarding a near miss patient safety incident (the incident did not reach the patient) where there is no harm, providers should consider whether an ongoing safety issue exists for the patient or whether the patient is aware of the event. One example would 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., does not reach the patient) it would be prudent to discuss this kind of near miss 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 near miss, an explanation may alleviate concerns and maintain trust.[iii]

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 *Diagram C* to assist in understanding these stages.

[iii] It is also strongly encouraged that near misses be reported to organizations so that safety improvements can be made to reduce the likelihood of similar harmful incidents in the future.

Diagram C: STAGES OF DISCLOSURE



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 a harmful or possible-harm patient safety incident is recognized, it is seldom that all the contributors to the event are clearly known or understood initially. Only the agreed upon 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 apology for what happened.
- The avoidance of blame and speculation.
- The provision of emotional, clinical 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 agreed upon 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/territorial legislation, regulations or local institutional/hospital bylaws and policies. The advice of legal counsel may be required to navigate the complexity of legislation.

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 apology is important, and may include an acknowledgement of responsibility for what has happened as appropriate.

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 agreed upon facts known at the time are collected and understood.[1] 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. Health care organizations should facilitate the training and maintenance of disclosure communications skills. A checklist for healthcare providers use for disclosure process is provided in Appendix D.

The initial disclosure discussion should take place at the earliest practical opportunity and preferably within one to two days after discovery of the event, or as identified by the patient and family. 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 a patient safety incident has occurred.

The Disclosure Team

The choice of who will participate in the initial disclosure is informed by patient preference, setting, type of patient safety incident, the severity of the harm and local policy.

Prior to discussing the patient safety incident with the patient, it is a good idea to meet as a team as this provides an opportunity for those involved to hear each other's perspective and to plan what will be said to the patient[24]. The healthcare providers most involved in the care of the patient should be present[25], if at all possible, considering their other clinical duties or their desire to participate. The most responsible provider, or the person most directly involved in the patient's care at the time of the incident, is usually the one to take the leadership role. However, if he or she is unable to take part in the disclosure, a delegate should be chosen. This person can be a department chair, patient safety officer, or hospital administrator, or someone with strong interpersonal skills who is knowledgeable about the disclosure process. When 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.

The decision about who should take the lead in a disclosure should take into consideration:

- What, if any, are the patient's preferences.
- Which healthcare provider is most knowledgeable about what has occurred.
- Which healthcare provider has an existing relationship with the patient and family.
- Which healthcare provider has had training in disclosure
- What, if any, are the health care providers' preferences
- Who is able to explain the prognosis and future care plan.[13]

The leader for subsequent meetings should also be chosen with the above factors in mind, since the individual who fulfills the leadership role for the initial disclosure may not necessarily lead subsequent meetings.

To facilitate communication with the patient and family, consideration should also be given to identify an individual as a contact person who can act as a liaison between the patient and the disclosure team, to ensure that the patient receives information regarding follow-up meetings and information from the investigative process. This contact person can also inform the disclosure team of questions raised by the patient and family, and potentially ongoing clinical needs. The patient should be given contact information for the assigned person, who should be easily accessible to the patient and family.

When the patient safety incident involves a variety of healthcare providers interacting with the patient, a team-based approach is beneficial to them and the patient.[5] Those most closely involved with the incident should be included in the discussions to be able to support the patient after the disclosure has occurred[13]. Indeed, the participation of the healthcare providers is beneficial to the patients, families and the healthcare providers themselves. Everyone participating in the meeting should understand and be clearly able to articulate their role and why they are present. It is also a good idea to assign an individual to coordinate follow-up meetings and to be responsible for meeting the information needs of the patient and family, and to ensure that changes or improvements identified during the analysis as being necessary are being addressed.

Consideration should be given to notifying the patient's primary healthcare provider, whether a family physician, registered nurse or nurse practitioner, or specialty physician (eg. internist, pediatrician, etc), as they may need to help manage or arrange ongoing care and follow-up for the patient.

Over time, other health professionals – such as dentists, physical therapists, nurse practitioners – may need to be consulted to help the patient understand his or her current and anticipated health status and clinical needs. Other professional caregivers within the healthcare setting, including pastoral care and social workers, may provide support for the patient, and should be involved if the patient consents.

Trainees and students who have been involved with the event or are participating in the care of the patient would also benefit from being part of the disclosure process[5, 23, 26, 27].Opportunities for trainees and students to observe modeling in the course of an actual disclosure encounter is an invaluable learning experience in how to plan and perform a disclosure meeting, and will contribute to their understanding about patient safety incidents, incident analysis, incident reporting, and other patient safety concepts.

Healthcare organizations that integrate the entire healthcare team into the disclosure process will likely improve the quality of disclosure[28]. Most importantly, members of the healthcare team need to be mindful of the patient's wishes, and respect the principle of patient/family centeredness. Patients and families should be encouraged to voice their opinions about whom they want to be present at the disclosure. In all circumstances, the patient and family should have the option of having a support person at these meetings.

The Role of Leadership/Management

Participation of leadership and administration in disclosure meetings may be appropriate and, in some instances, necessary. The more serious and complex the harm, the more likely the patient will expect leadership and administrative representatives to take part in the discussion at an appropriate time [29]. During later meetings, and particularly in post-analysis disclosure, leadership and management representatives may take on the lead role, with providers participating as appropriate or as they are emotionally able. In some instances, members of quality and safety review teams may also be involved[13].

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 a patient safety incident. 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.[iv] 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 harmful incidents. Harm resulting from system failure or provider performance is likely to require communication support to better improve patient care and understanding.

Diagram C (page 23) outlines the role of leadership/management and the provision of communication support to healthcare providers.

iv 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.

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 "The Disclosure Team" (p. 24) for more information.

Executive and board members should make a public commitment to open disclosure as part of a just culture of patient safety, and make that commitment visible (such as on the website, newsletter, or in patient education materials). Ensuring appropriate support for staff during disclosure is critical for the individuals involved, and generating support from leadership, colleagues and the institution is key during this emotionally difficult time.[30] This may include the provision of an appropriate leave from the workplace for healthcare providers traumatised by their involvement in a patient safety incident.

What to Disclose

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

- The agreed upon 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 apology
- A brief overview of the investigative process that will follow, including appropriate timelines and what the patient can expect to learn from the analysis.[1]
- An offer of future meetings, including key contact information.[1]
- Time for questions and the answers given.[1]
- 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 analysis in a legally protected quality improvement 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 certain investigative information, such as the opinions and speculations of the providers involved, as defined in legislation within each of the provinces or territories quality of care protections.[v] Newly discovered agreed upon facts that would normally be part of the medical record should be disclosed. Actual system changes or improvements implemented by the organization as a result of an analysis can be shared with the patient.

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 apology that may include an 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.

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

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 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 disclosure discussions including questions.
- Clarifying whether the information is understood.
- Being sensitive to cultural and language needs.[vi]

During the disclosure process, particular attention needs to be given to the patient and/or family's perspective of what happened in the event. This does not simply mean asking the patient or family if they have any questions. The patient may not know the questions to ask to address what concerns them the most, they may be fearful of asking "silly" questions, or they may feel too intimidated by the healthcare providers present to formulate questions. Most people can tell of their experience if given the opportunity to do so. The information they can provide is information only they know and it can change the entire course of the analysis and discussions to follow.

Remembering a recent conversation she had had with a patient about patient-centered disclosure, a healthcare provider opened a disclosure conversation by asking the patient and spouse to relate their experience in their own words, rather than asking if they had any questions. "It changed the meeting completely," she said. "The first thing the patient told us is that she hadn't felt heard when she was reporting things that turned out to be very significant. They were very grateful to be asked to tell their story before we talked about medical care specifics." *(As quoted to Patients for Patient Safety Canada)*

The style of disclosure must be appropriate to the kind of 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."[31] It is sometimes difficult for the family to sever the ties with the people who were involved in the care of their loved ones; be sensitive to this, and provide the necessary support and action that will help the family through these times. It is important to provide a support person, chosen in consultation with the patient and family, to be there for them from the beginning of the disclosure process.

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.

Documentation

At the end of a disclosure meeting, it is good practice to review key decisions and agreed upon facts so that everyone has a shared understanding of what was discussed. Brief, fact-based notes from the meeting should then be documented and shared with all those present, providing an opportunity for review by all involved before they are inserted into the medical record.[vii] This process will add further clarity to the disclosure while providing a framework for next steps and improving accountability.

[vi] See Section on Specific Circumstances

[vii] This is not intended to be a formal written disclosure; rather, these notes establish mutual understanding of what was said and decided. Also, there should be no audio or video recording of the disclosure meeting.

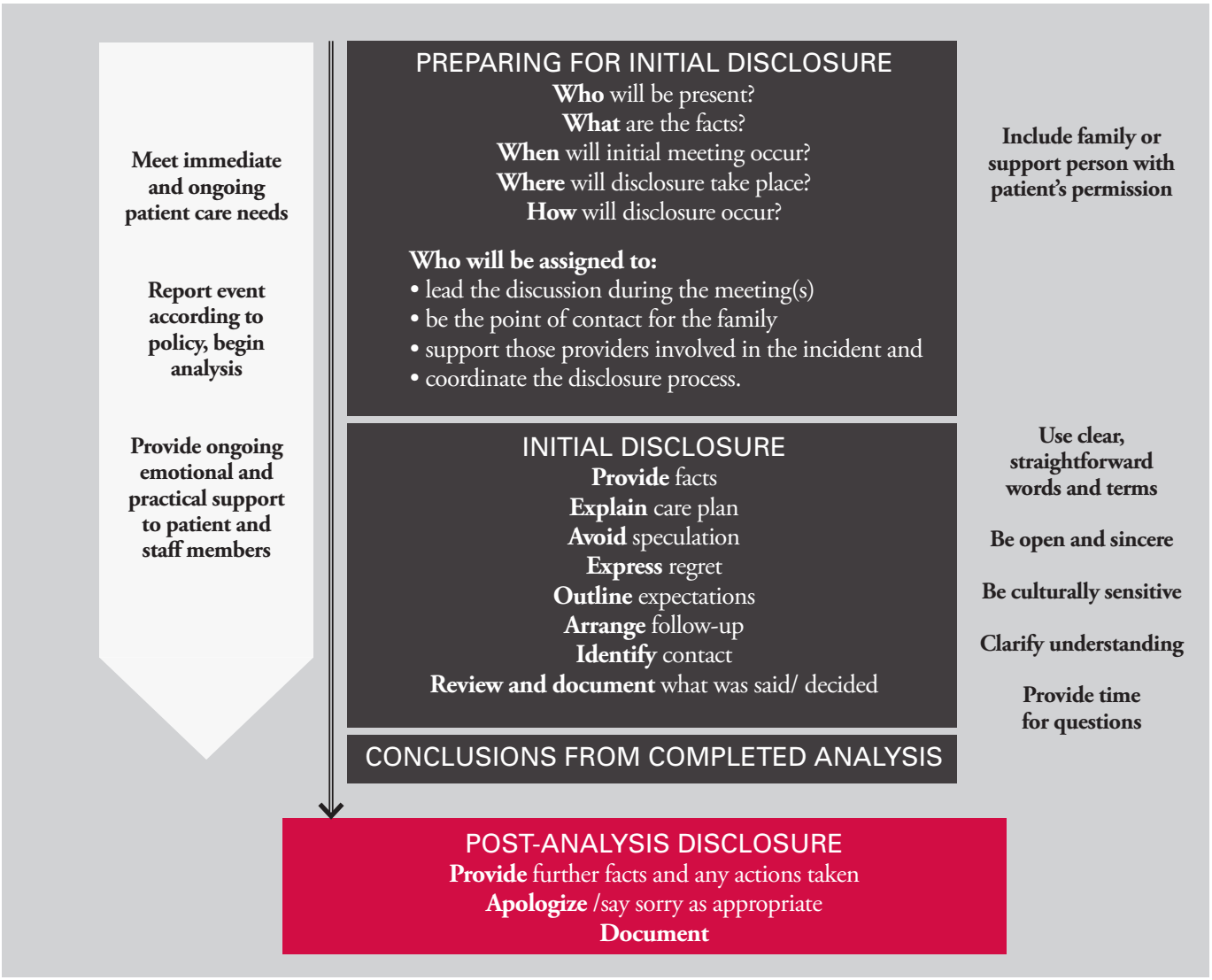
Documentation should be consistent with all legal and regulatory requirements for documentation of patient care and communication. Documentation should include:

- Time, place and date of the meetings.
- Identities of all attendees.[2]
- Facts presented.
- Offers of assistance and the responses.[1]
- Questions raised and the answers given.[1]
- Plans for follow-up, including key contact information for an appointed contact person.[1]

Summary

Diagram D is a summary of the ongoing disclosure process that begins when harm is identified and continues through to subsequent discussions depending on the nature of the event.

Diagram D: THE DISCLOSURE PROCESS



SPECIFIC CIRCUMSTANCES

SPECIFIC 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.

LARGE SCALE DISCLOSURE

Sometimes there is a need to communicate about the same patient safety incident with many patients of a single healthcare provider or organization, or patients of many healthcare providers or organizations. Although many healthcare providers and organizations have adopted policies and practices that support and guide disclosure, these policies and practices seldom address the distinctive challenges of large-scale patient safety incidents [32].

The process and content of communication about large-scale patient safety incidents can vary widely because of the enormous potential variation in the numbers of affected persons and the risk and scope of potential harm. These differences have important implications for decisions and plans about to whom, when and what to disclose. Healthcare providers and organizations should establish well thought out approaches to large-scale patient safety incident disclosure, including the following elements.

Multi-patient Disclosure

Assessing risk and identifying at-risk patient population
A very significant challenge of large-scale patient safety incident disclosure is deciding which patients, of the patients potentially exposed to a patient safety incident, are 'at risk' and require disclosure. Where the likelihood of harm is high, the need to contact all affected patients is clear. As the likelihood of harm decreases, a complex weighing of clinical probabilities and ethical obligations may be required. Ultimately, the criteria for contacting patients should be established with regard to the assessed risk.

Meeting this challenge requires access to current evidence-based risk assessment information and resources. Healthcare organizations should anticipate these challenges by having clinical, epidemiological, ethical, administrative, communications, legal and other experts, including a patient experience expert, available to consider disclosure in a structured way and decide on the requirement and potential process for a large-scale patient safety incident disclosure.

Identifying and locating at-risk patient population
Another challenge of a large-scale patient safety incident disclosure is locating patients, especially when the patient safety incident is in the distant past. Information retrieval may no longer be possible, and the contact information, if retrieved, may no longer be current. Multiple methods of identifying patients should be cross-referenced with other accessible information systems (e.g. Provincial Medical Insurance Programs) to minimize omissions, communication with patients who are not at risk, or patients who are deceased.

It is also prudent to consider whether other health care organizations need to be alerted to the possibility of similar hazards that may exist in their systems, so that they might identify and locate at-risk patients.

Communicating with and disclosing to at-risk patient population
Providing information and meeting the clinical and emotional needs of patients is paramount, and the communication plan developed by the disclosure team should reflect this requirement. Communication with patients should happen as soon as possible after the minimum amount of information required to make the communication meaningful is available. The greater the risk of harm to the patient, the more compressed this timeline should be. The best practice for initial disclosure communication with at-risk patients is that it be done concurrently. Where the scope of communication makes this impractical, communication may need to take place in sequential stages.

The best practice for initial disclosure communication with at-risk patients is that it be done in person, and the more urgent or serious the risk of harm, the stronger the case for in-person initial disclosure. However, where the risk is less urgent or less serious, or where in person initial disclosure is not practical, written communication may need to be considered.

The communications plan needs to include mechanisms for providing information to patients, and could include dedicated phone lines or a website for at-risk patients to get access to information and to ask or leave questions for response in a timely fashion by appropriate healthcare providers.

Family physicians, family practice nurses, nurse practitioners and community pharmacists can be a valuable sources of information and support to at-risk patients. There needs to be concurrent communication to the primary healthcare provider and/or written communication to the patient designed to be shared with the primary healthcare provider.

As with individual patient disclosure, initial disclosure should not identify individual clinicians or include assumptions about cause[29]. If the individual performance of healthcare providers is determined to be relevant, a clear and fair process should be used to evaluate that performance, independent of disclosure[29].

At-risk patients should be told, as early as possible in the disclosure process, what further information to expect when patient safety analysis is completed. Subsequent disclosure should be consistent with this expectation.

Supporting at-risk patients
Follow-up diagnostic testing and treatment to patients at risk from large-scale patient safety incidents should be provided promptly and with sensitivity to address or mitigate anxiety produced by the disclosure. Affected patients should be given priority over current patients when clinical and emergent priorities permit[29].

Informing public and media
It is prudent to assume that media coverage of a large-scale patient safety incident is inevitable[28]. Healthcare providers and organizations are challenged to balance competing demands of patient and healthcare provider privacy against public transparency and external demands for information (eg. media, government, regulatory).

Large-scale patient safety incident disclosure to patients must anticipate and wherever possible pre-empt media and other public releases of information that may potentially identify at-risk patients or involved healthcare providers, or compromise the analysis.

Broader publication of information, in co-operation with the media, about a patient safety incident can be a useful method of reaching at-risk patients and limit incorrect information from being released. Informing the media in a timely fashion after preliminary disclosure to the patients has begun (generally about the circumstances and the intended process) can allow disclosure to proceed without disruption or prejudice to at-risk patients or the analysis process. (see http://www.patientsafetyinstitute.ca/English/toolsResources/patientSafetyPublications/Pages/default.aspx).

Any informing of the media should be sensitive to individual patient and provider privacy concerns, and should protect the identities of patients and providers unless they have consented to this information being made public. Individual healthcare providers and patients involved need to be given advance notice of any media information release that could potentially draw attention to or identify them. The privacy of patients and healthcare providers must be respected, unless these individuals have consented to the release of their personal information.

Multi-jurisdictional Disclosure

It is not uncommon for patients to receive healthcare from many centres. The discovery of a harmful incident may be in a different jurisdiction (clinic, hospital, health region, province or territory) than where the 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 event should lead the disclosure process and ideally representatives from both jurisdictions should collaborate in the process.[1,34,35] Effective communication between the jurisdictions, including consultation and discussion of the agreed upon 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. “Jurisdiction” in this context is meant to encompass legal jurisdictions.

PAEDIATRIC PATIENTS

There are currently no formal guidelines or legislation explicitly addressing disclosure in paediatrics. Recommendations for disclosure are therefore usually extrapolated from those addressing consent to treatment; if the child is capable enough to make a decision about his/her treatments he/she is similarly capable of being told about a patient safety incident. The Canadian Paediatric Society's Position Statement on Treatment Decisions regarding infants, children and adolescents[36] can serve as a guide, where "capacity is not age- or disease-related, nor does it depend on the decision itself, but is a cognitive and emotional process of decision-making relative to the medical decision. The majority of children will not have decision-making capacity and will require a proxy to make decisions for them." In keeping with this statement, disclosure conversations in paediatrics are usually with the parents or substitute decision maker. Keep in mind, however, that although children or adolescents may find disclosure information upsetting or beyond their comprehension, many still have a keen interest in what happens to their bodies. As such, they should be given appropriate information having regard to their age, comprehension and emotional maturity, so that they may understand their situation.

Parents also want to hear about events in which their child was harmed, and need to be supported during what can be a very emotional situation. They want to know what happened to their child, the consequences of the incident, what is being done to prevent similar incidents from happening to another child, and an appropriate apology. Culture and/or ethnicity of the parent may impact parent expectations around disclosure.

Even where the child is considered intellectually capable and emotionally mature enough to make his or her own decisions[viii] the child can still be encouraged to involve the parents in the disclosure process as appropriate.

PATIENTS WITH MENTAL HEALTH ISSUES

The presence of serious mental illness is not a reason to withhold disclosure, but it may be a reason to consider the timing or to alter to whom the disclosure is initially presented.

Both the content and the timing should be determined by the healthcare team and the family or substitute decision maker, in consideration of the patient's clinical stability and safety. A careful balance must be struck between the patient's right to know, and the subsequent risk of clinical decompensation and/or harm to self or others. For the acutely mentally ill the timing of disclosure may require careful consideration and planning, including ensuring appropriate support is in place before disclosure.

The healthcare team should consult with the family and/or substitute decision maker, clinical experts, a patient safety and/or risk management expert and an ethicist regarding the serious decision to withhold content and/or timing of disclosure. This will help explore the ethical, regulatory standards of care, legal, risk and safety obligations owed to the patient, to ensure a sound decision is made. Documentation in the medical record would reflect the rationale as to why content and/or timing is being deferred until the patient's clinical status improves.

A respectful assessment of risk, along with an environment of respect, empathy and collaboration will be vital to helping people with mental illness in the disclosure process.

viii Only the Province of Quebec has established a fixed age of 14 years, below which the consent of the parent or guardian or of the court is necessary for the purposes of proposed treatment.

COMMUNICATION ISSUES

If a patient has difficulty communicating due to visual, hearing or other impairment, or if they do not fluently speak or understand the language of the disclosure, appropriate supports may be needed to ensure effective communication. Supports may include access to professionally trained interpreters or other care providers, whose role is to assist the patient during the disclosure process, focusing on ensuring that the patient's views are considered and discussed. Family and friends are also a vital support to patients and can provide valuable insight into the patient perspective. However, they are not a suitable or reliable substitute for a qualified health interpreter in the circumstances of disclosure. Access to interpretation expands knowledge and empowers both patients and healthcare providers.

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 competent way. It is necessary to include translation, interpretation (oral translation) and advocacy services when planning disclosure. Prior to involving others in the disclosure process, the privacy rights of the patient must be considered. Privacy is honoured through access to a professional interpreter, who is bound by a code of ethics and is trained to accurately interpret medical terminology and work with the healthcare team.

Use of cultural health interpretation results in strong communication and:

- increased quality of care
- greater understanding of patient conditions
- more timely and safe care
- accurate diagnosis
- appropriate referral
- informed consent
- confidentiality

RESEARCH SETTINGS

In the course of a clinical trial, harmful incidents 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 an adverse event (as harmful incidents are referred to in the research setting) to the sponsor of the trial, to appropriate data safety monitoring bodies and to the research ethics committees that approved the study.

APPENDICES

APPENDIX A – RECOMMENDED READINGS

Canadian Frameworks / Policies

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APPENDIX B – GLOSSARY

Apology
A genuine expression that one is sorry for what has happened. Includes a statement of responsibility if such is determined after analysis.

Disclosure
The process by which a patient safety incident is communicated to the patient by healthcare providers.

Event
An event is something that happens to or involves a patient (ICPS, 2009).

Harm
Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death[16].

Harmful incident
See Patient safety incident.

Healthcare associated harm
Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury[16].

Inherent risks of an investigation or treatment
Most investigations and treatments have inherent risks (e.g., recognized complications, adverse reactions or side effects) that may occur and are independent of who is providing care.

Near Miss
See Patient safety incident.

No harm incident
See Patient safety incident.

Patient safety
The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum[16].

Patient safety incident
An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient[16]. Includes:

Harmful incident: A patient safety incident that resulted in harm to the patient[16]. Replaces "adverse event" and "sentinel event."

No harm incident: A patient safety incident which reached a patient but no discernable harm resulted[16].

Near miss: A patient safety incident that did not reach the patient. Replaces "close call[16]."

Reporting
The communication of information about an patient safety incidents by healthcare providers, through appropriate channels inside or outside of healthcare organizations, for the purpose of reducing the risk of occurrence of patient safety incidents in the future.

Safety
The reduction of risk of unnecessary harm to an acceptable minimum[16].

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, Personal Directives 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[16].

APPENDIX C – 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[37].

2. **Definitions of Key Terms:** Definition of terms particular to your region or organization.

3. **Provision for Patient Support:** List of supports and resources.

4. **Provision for Healthcare Provider Support and Education:** List supports and resources.

5. **The Disclosure Process:** Outline with the necessary steps.

    a. When disclosure should take place: 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. The disclosure team: Who should disclose and the participants involved.

    c. What should be disclosed: The facts and applicable legal requirements and limitations.

    d. How should disclosure be conducted: Initial and post-analysis disclosure that includes apologizing and saying sorry as appropriate.

    e. Where should disclosure take place: Setting and location; give examples of private, comfortable and interruption-free areas.

    f. What should be documented.

6. **Provision for Particular Circumstances:** General and applicable to your organization.

APPENDIX D – 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 agreed upon facts.
- [ ] Establish who will be present at the meeting(s), and who will:
  - lead the discussion during the meeting(s)
  - be the point of contact for the family
  - support those providers involved in the incident and
  - coordinate the disclosure process.
- [ ] 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 meetings, free of interruptions.
- [ ] Be aware of your emotions and those providers involved in the process 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 agreed upon facts of the patient safety incident 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.
- [ ] Apologize using the words "I'm sorry." 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.
- [ ] Invite the patient and/or family to discuss the event from their point of view.
- [ ] Be sensitive to cultural and language needs.
- [ ] Review what was discussed and document what was said and decided, giving the patient an opportunity to read and review the documentation about the disclosure in the medical record.
- [ ] 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.
- [ ] Reimburse expenses related to the disclosure process, as appropriate.
- [ ] Facilitate further investigation and treatment if required.

SUBSEQUENT AND POST-ANALYSIS DISCLOSURE

- [ ] Continued practical and emotional support as required, for the patient, family and providers.
- [ ] Reinforcement or correction of information provided in previous meetings.
- [ ] Further factual information as it becomes available.
- [ ] A further apology which might include an 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.

APPENDIX E – PATIENTS FOR PATIENT SAFETY CANADA DISCLOSURE PRINCIPLES

When a patient safety incident occurs, patients and their families expect honesty, empathy, respect, a sincere apology, and an explanation of what happened. They also need to see that the organization accepts responsibility and is making changes and taking action to help prevent the incident from happening again.

Patients and their families need:

- To be informed about the potential for patient safety incidents
- To be informed about patient safety incidents in a timely manner
- A comprehensive and timely investigation of the facts
- The opportunity to contribute to the investigation
- Empathy, understanding, and support
- Honest, open, and transparent disclosure of the facts
- A timely, respectful, sincere apology
- Acknowledgement of accountability and responsibility
- A comprehensive investigative report that is shared with appropriate individuals and agencies
- To be kept informed about new preventive measures
- Opportunities to be part of the improvement process
- Fair and timely compensation

For more information or if you have questions about these principles, please contact us at info@patientsforpatientsafety.ca

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Diagram D: THE DISCLOSURE PROCESS

Meet immediate and ongoing patient care needs

Report event according to policy, begin analysis

Provide ongoing emotional and practical support to patient and staff members

PREPARING FOR INITIAL DISCLOSURE

Who will be present?
What are the facts?
When will initial meeting occur?
Where will disclosure take place?
How will disclosure occur?

Who will be assigned to:

- lead the discussion during the meeting(s)
- be the point of contact for the family
- support those providers involved in the incident and
- coordinate the disclosure process.

Include family or support person with patient's permission

INITIAL DISCLOSURE

Provide facts
Explain care plan
Avoid speculation
Express regret
Outline expectations
Arrange follow-up
Identify contact
Review and document what was said/decided

Use clear, straightforward words and terms

Be open and sincere

Be culturally sensitive

Clarify understanding

Provide time for questions

CONCLUSIONS FROM COMPLETED ANALYSIS

POST-ANALYSIS DISCLOSURE

Provide further facts and any actions taken
Apologize /say sorry as appropriate
Document

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

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- Locate a private area to hold disclosure meetings, free of interruptions.
- Be aware of your emotions and those providers involved in the process 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.

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- Introduce the participants to the patient, functions and reasons for attending the meeting.
- Use language and terminology that is appropriate for the patient.
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- Avoid speculation or blame.
- Apologize using the words "I'm sorry." 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.
- Invite the patient and/or family to discuss the event from their point of view.
- Be sensitive to cultural and language needs.
- Review what was discussed and document what was said and decided, giving the patient an opportunity to read and review the documentation about the disclosure in the medical record.
- 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.
- Reimburse expenses related to the disclosure process, as appropriate.
- Facilitate further investigation and treatment if required.

SUBSEQUENT AND POST-ANALYSIS DISCLOSURE

- Continued practical and emotional support as required, for the patient, family and providers.
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DOCUMENT the disclosure discussions as per organizational policies and practices and include:

- The time, place and date of disclosure.
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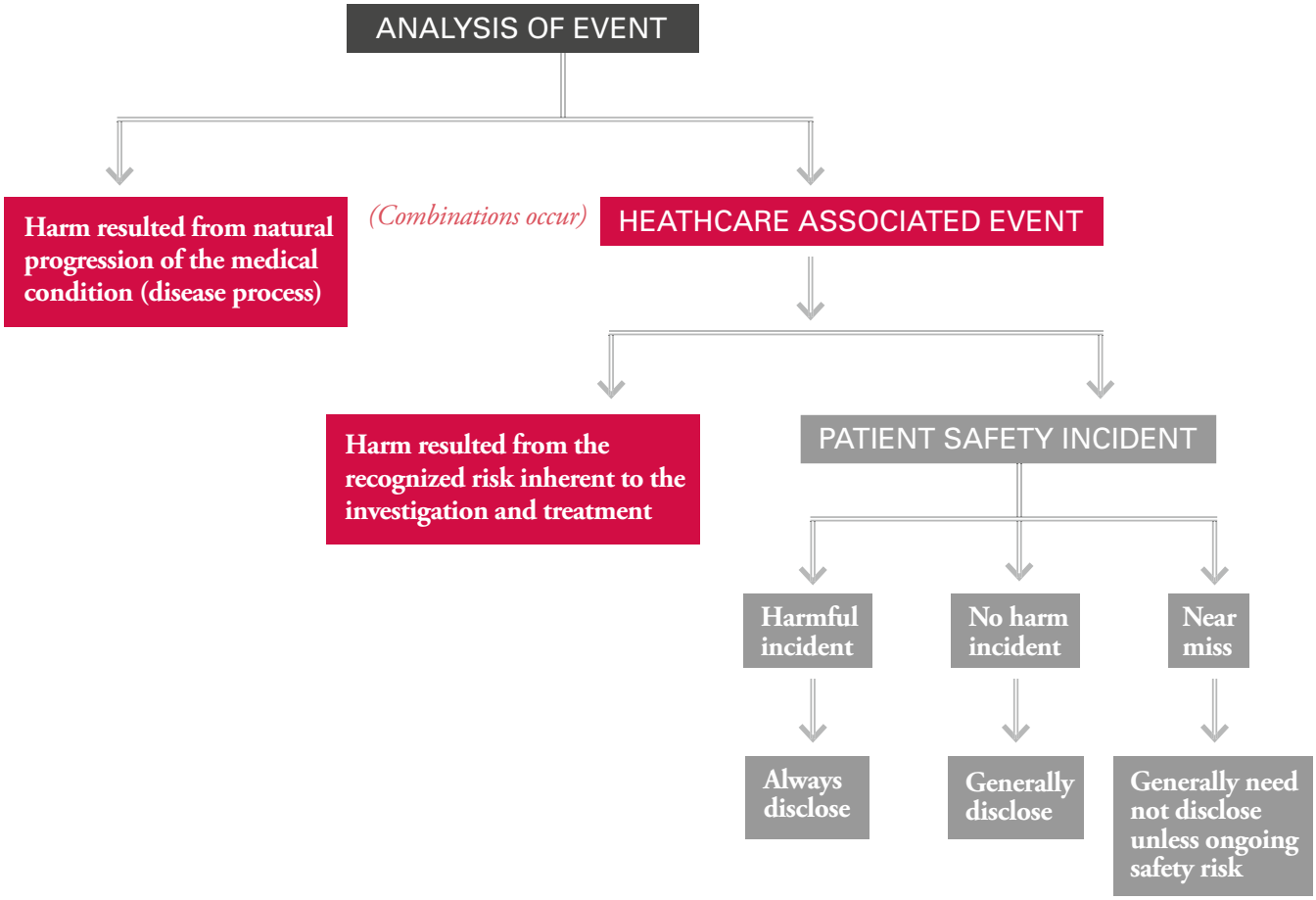
Diagram B: CIRCUMSTANCES WHEN DISCLOSURE SHOULD TAKE PLACE



Disclosure must occur if there has been any harm related to a patient safety incident, or if there is a risk of potential future harm. In the case of a near miss, disclosure is discretionary based on whether it is felt the patient would benefit from knowing, for example if there is a residual safety risk.

This diagram is also meant to demonstrate that a discussion with the patient should take place regardless of the origin of the harm. Although the term "disclosure" is used to describe the communications after a patient safety incident, any harm resulting from the disease process or healthcare should be discussed with the patient.

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. Incidents should be appropriately examined to understand all of the contributors involved. An analysis may indicate a combination of reasons actually resulted in the harm.

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