



THE CANADIAN
MEDICAL
PROTECTIVE
ASSOCIATION

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DE PROTECTION
MÉDICALE

Communicating with your patient about harm

DISCLOSURE OF ADVERSE EVENTS

Suggestions to help CMPA members meet their patients' clinical, information and emotional needs after an adverse event



THE DISCLOSURE ROAD MAP

TAB 2

First things first: Attend to clinical care

- Address clinical needs
- Deal with emergencies
- Consider the next steps in clinical care
- Provide emotional support
- Document your care

TAB 3

Planning the initial disclosure

- What are the facts?
- Think about what you will say
- Who will be present? Who will lead?
- When will the initial meeting occur?
- Decide where to meet

TAB 4

The initial disclosure meeting

- Provide facts as known
- Express regret as appropriate
- Avoid blame and speculation
- Confirm plan for further clinical care
- Outline expectations for further information
- Arrange follow-up, identify contact process
- Document the disclosure discussions in the medical record

ANALYSIS

TAB 5

Post-analysis disclosure

- Provide further facts and information on any actions taken
- Express regret again, consider apology only if appropriate
- Document the discussions

ACKNOWLEDGEMENTS

The CMPA is grateful for the opportunity to have collaborated with the Canadian Patient Safety Institute (CPSI) and many others in the development of the Canadian Disclosure Guidelines published in 2008 (see <http://www.patientsafetyinstitute.ca>). The terminology or language used here is borrowed from those guidelines or from previous CMPA publications.

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INTRODUCTION

Definitions of the terms harm, adverse event and disclosure, a framework for understanding harm, an explanation of the different stages of disclosure and a brief synopsis about no-harm events.

► FOREWORD

Health care providers seek the best possible clinical outcomes for their patients. However, even with the best of medical care, a patient's outcome may not be what was originally desired or anticipated, and in some cases may be entirely unanticipated. Some unexpected outcomes are unfortunately related to health care delivery itself, despite the dedication, training and professionalism of the health care providers.

Patients expect to be informed about harm they have experienced, whatever the reason for it, and this information needs to be delivered in a caring manner. Effective communication with patients and the health care team can improve patient outcomes and satisfaction. Conversely, failures in communication may lead to patient harm, misunderstandings, complaints and lawsuits.

This resource provides advice on communicating with your patient if an unanticipated poor clinical outcome has occurred during care, particularly in the difficult circumstances in which health care delivery is suspected or known to have contributed to that poor outcome.

The advice in this material is based on expert opinion, knowledge of the existing medical literature and the experience of the CMPA.

Communication in these materials is meant to include communicating with a patient, or with a capable patient's permission, with family members or others, or if the patient is not capable, with a Substitute Decision Maker (SDM). An SDM is a person who is legally authorized to make decisions on behalf of the patient. This authority may be granted through a legal document such as an advance directive, by legislation, or by the courts.

WHAT IS AN ADVERSE EVENT?

Terminology is important and should be used consistently. The CMPA encourages the following definitions from the *Canadian Disclosure Guidelines*¹ be adopted in Canada:

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

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

¹ Disclosure Working Group. *Canadian Disclosure Guidelines*. Edmonton, AB: Canadian Patient Safety Institute; 2008.

WHAT IS DISCLOSURE?

Disclosure is the process by which an adverse event is communicated to the patient.

Health care providers have an ethical, professional and legal obligation to disclose adverse events.

Those knowledgeable about disclosure suggest that following an adverse event, patients want:

- An acknowledgement that something has happened;
- The facts known about what happened;
- An understanding of the recommended next steps in clinical care — what is going to happen and how the clinical situation can be improved, if this is possible;
- A genuine expression of care, concern and regret; and
- Assurance that appropriate steps, if these are possible, are being taken to prevent a similar occurrence from happening to others.

In summary, patients have clinical needs, information needs, and emotional needs after an adverse event.



In health care, the use of the term “disclosure” in communications with patients should not in any way imply blame for or fault of the health care provider.

From the Canadian Disclosure Guidelines, CPSI, 2008

IMPORTANT CMPA ADVICE: The CMPA has for many years encouraged member physicians to discuss with patients the occurrence and nature of poor clinical outcomes, including adverse events, as soon as it is reasonable to do so. However, this advice has sometimes been confused with specific CMPA guidance to limit direct communications with patients after a legal action has commenced. If a patient has initiated a legal action, all communication with the patient and his or her family should be through the legal counsel assigned by the CMPA to assist you.

If you become aware of a legal action, you must always contact the CMPA as soon as possible to ensure you receive assistance.

► UNDERSTANDING HARM

Diagram A Understanding harm

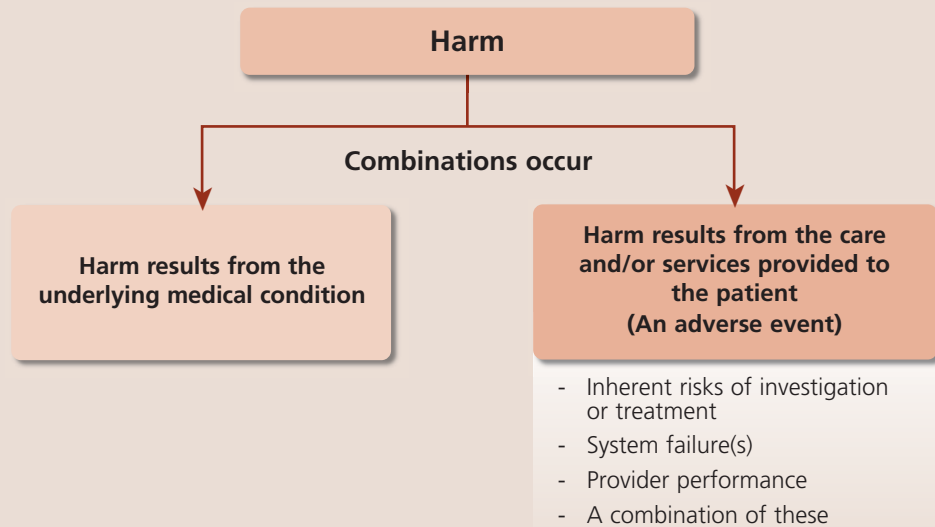


Diagram A shows the different sources of occurrences that can result in patient harm.

Harm to your patient may arise from the following two sources or from a combination of these:

The underlying medical condition: *Harm results from the disease or disorder of the patient, or is related to a natural condition. This is the most common source of harm.*

The health care delivery (adverse event): *Harm results from the care and/or services provided to the patient.*

THE UNDERLYING MEDICAL CONDITION

Prior to a full analysis, be wary of jumping to the conclusion a poor clinical outcome is the result of an adverse event. Analysis may identify the harm actually resulted from the progression of an underlying medical condition. Changes in a patient's condition most often reflect the worsening of the disease process or the natural condition.

For example, delays in diagnosis may happen because many conditions must progress to a clinical degree where the symptoms and signs suggest the diagnosis or at least indicate the need for further investigation. Delays in diagnosis are most often related to the variable progression of the pathophysiology of a disease, but sometimes system failures and/or problems in provider performance contribute to the delay.

HEALTH CARE DELIVERY

Harm from health care delivery may result from the following three sources, or a combination of these:

- The risks inherent to investigations and treatments;
- System failure(s);
- Provider performance.

RISKS INHERENT TO INVESTIGATIONS AND TREATMENTS

Most investigations and treatments have inherent risks — certain complications or side effects may occur and are independent of who is providing the care.

The inherent risks of an investigation or treatment are sometimes misunderstood as provider error. This is one reason why patient education and informed consent discussions prior to clinical interventions are so important.

Physicians understand the nature and the inevitability of these recognized complications. However, even if patients have received sufficient forewarning through the informed consent discussion, they often do not expect and may even be surprised by *the actual occurrence* of any of these. Even when the harm is determined to have resulted from a recognized risk inherent in the investigation or treatment, and even if an informed consent discussion preceded the event, most patients do not expect that the complication would actually happen. This is particularly true if the inherent risk is uncommon and the harm severe.

If an inherent risk of an investigation or treatment has occurred, the most responsible physician (MRP)² should talk to the patient about the nature and likely implications for the patient's immediate and future health, including what might be done to improve the situation.

Although all investigations and treatments have inherent risks, harm should not be prematurely attributed to being simply “a complication” of an investigation or treatment. Rather, events should be appropriately examined to understand if other contributors are involved.

The inherent risks of investigations and treatments may be reduced over time through medical research to develop improvements or different approaches.

SYSTEM FAILURES

Patient safety research and literature confirms adverse events often arise from system failures, where safeguards to protect patients did not exist or failed. Adverse events often follow a recurrent pattern of system or process failures, independent of the dedication or experience of the health care providers involved. While health professionals must still be held appropriately accountable, this shift in understanding adverse events recognizes the importance of system factors and safeguards.

² **Most responsible physician (MRP):** The physician most directly involved in the patient's care at the time of the adverse event. This may be the attending physician or a consultant. For the purposes of disclosure, MRP is not synonymous with the admitting physician in a hospital setting.

A quality improvement committee³, as part of a hospital/institution's quality improvement program, reviews unexpected clinical outcomes, adverse events and close calls, analyses these for system failures, and may provide recommendations to improve future care for all patients (See p. 28, "Quality improvement committees").

PROVIDER PERFORMANCE

Provider performance refers to any of the following concerns:

- A gap in knowledge or skills of the provider;
- A violation or departure by the provider from a known, relevant, realistic and clearly written policy;
- Poor clinical performance because of a health condition of the provider;
- Malicious patient harm — by definition this does not strictly relate to adverse events as the harm is intentional and may be criminal. Such occurrences are extremely rare.

A culture of safety reflects the knowledge, skills and commitment of all leaders, management, health care professionals and staff to the provision of the safest possible patient care. Justice is an important element of this culture; all are aware of what is expected, including the need for continuous professional development, and are held professionally accountable in a fair way.

Only a thorough and fair analysis of the adverse event can determine if it resulted from problems in provider performance and what solutions are best in the circumstances.

Although it sometimes seems obvious an adverse event is linked directly to poor performance, seldom are all of the important system or other contributing factors immediately known. Often initial perceptions are found to be incorrect after a more thorough analysis has been completed.



³ Quality improvement committees in hospitals and institutions in different provinces/territories may have different titles, for example: Quality of Care, Critical Incident Review, Risk Management committees.

► THE STAGES OF DISCLOSURE

Your approach to disclosure must be adapted to the particular situation to meet your patient’s clinical, information and emotional needs.

Most common adverse events are related to the inherent risks of investigations or treatments. Although all complications of this sort should be discussed with your patient, generally a more formal disclosure process is unlikely to be required. Most of these complications are unlikely to require much analysis.

Many other unexpected outcomes and adverse events, especially those that are serious in nature, will likely require much more discussion with your patient. These sorts of events benefit from analysis to determine the reasons for the event. It is helpful to think of the process conceptually as a dialogue occurring in stages over time:

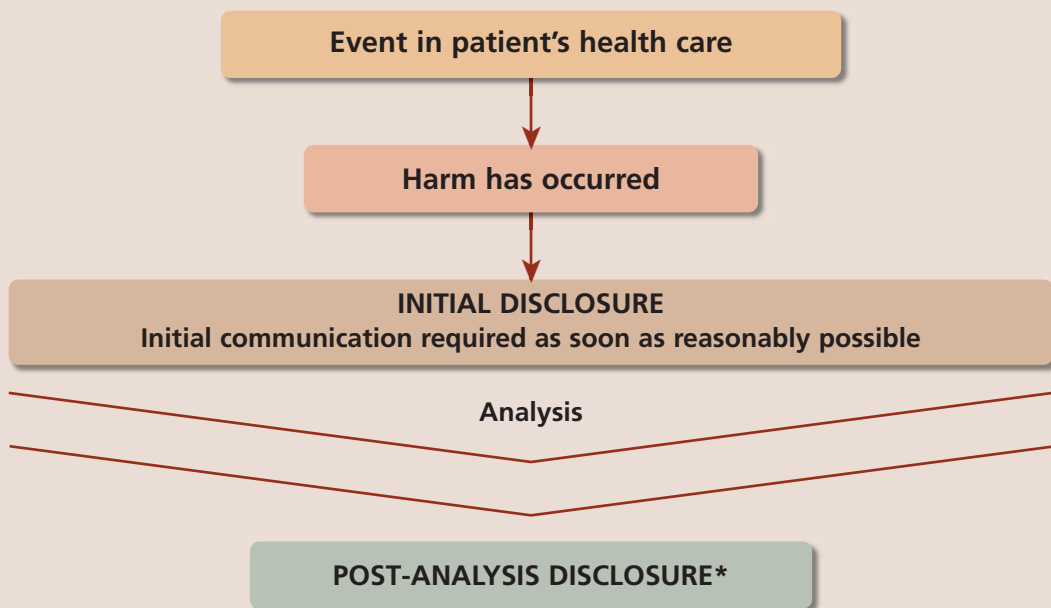


Initial disclosure: *The initial communications with the patient as soon as reasonably possible after an adverse event, focusing on the known facts and the provision of further clinical care and emotional support.*

Post-analysis disclosure: *Subsequent communications with a patient about known facts related to the harm and the reasons for the harm after an appropriate analysis of the adverse event.*

Each stage may involve a single or multiple discussions (**Diagram B**). These discussions are best accomplished in face-to-face meetings.

Diagram B The stages of disclosure



* Quality of care information and the recommendations from quality improvement committee investigations are protected by provincial/territorial laws to varying degrees. General access, even to patients, may not be permitted.

INITIAL DISCLOSURE

Initial communications with your patient should focus on facts that are known at the time: what has happened, how it will affect your patient and what might be done to fix or limit the harm. Even if an adverse event is recognized initially, how and why the event occurred will usually not be completely known at this first stage.

It is not appropriate to speculate about the reasons for the harm. Were you to speculate at this stage and find at a later date that your information was incorrect, the consequences could be significant. For example, you may cause:

- Unnecessary distress to your patient;
- Your patient to distrust all the information subsequently provided; and/or
- Your patient to lose faith in the patient-physician relationship.

ANALYZE WHAT HAPPENED

In general, after an unanticipated clinical outcome or an adverse event occurs, an appropriate and reasonable analysis should take place. The complexity of the analysis depends on the nature, severity, and frequency of what has happened, and the practicality of doing the analysis. A variety of analytic approaches exist. The purpose is to determine the reason or combination of reasons for what has happened (**Diagram C**).

An unexpected poor clinical outcome may result from an underlying medical condition or an adverse event. The reasons for an adverse event may range from the recognized and unavoidable risks inherent in an investigation or treatment, to system failures, to problems in provider performance. Combinations frequently occur.

HOSPITAL OR INSTITUTIONAL POLICIES:

Hospitals or institutions usually have a policy requiring health professionals to report the occurrence of adverse events and close calls to the administration for further analyses, establishing accountability and/or determining the need for quality improvement and risk management activities. In some provinces, this is required by law. It is important to understand what information needs to be provided, and how the information will flow out of these and other processes. You may wish to contact the CMPA for advice.

If you work in an office or clinic in the community, you and your staff will likely be responsible for analyzing what has happened, although an authority such as a coroner/medical examiner may need to be involved in the case of a death.

In a hospital/institutional practice, a mechanism of reporting an adverse event to the administration will exist.

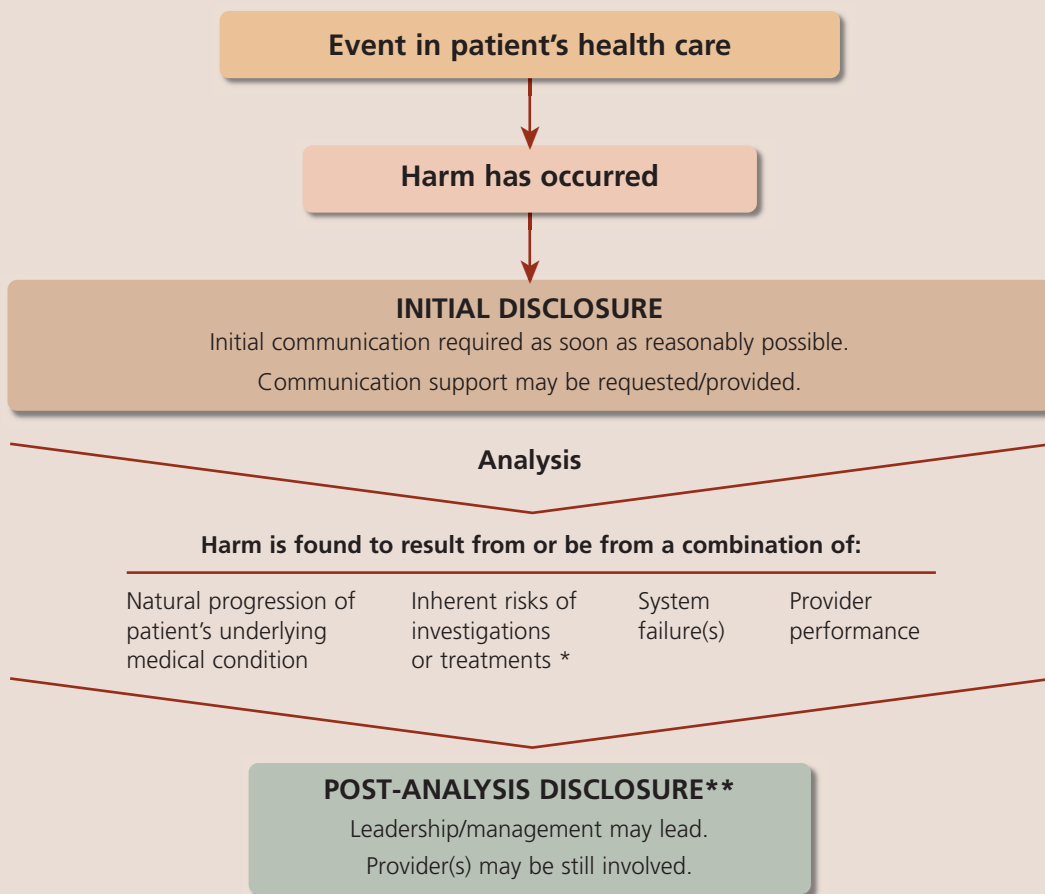
Reporting: *The communication of information about an adverse event or close call by health care providers through appropriate channels inside or outside of health care organizations for the purpose of reducing the risk of adverse events in the future.*

An important element of a culture of safety in a hospital/institution is an environment that supports the reporting of adverse events for

quality improvement purposes. Adverse events are then reviewed and analysed to determine the system contributors. The lessons learned are used to strengthen the system and, if appropriate, to support and educate health care providers to help prevent similar events in the future.

To the extent permitted by law, the reporting and review of adverse events and close calls should take place under the auspices of a properly constituted quality improvement committee so that the information generated will be legally protected from being disclosed in any subsequent proceedings. This encourages providers to participate fully in discussions, without fear that the information will be subsequently used against them.

Diagram C The stages of disclosure



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

**Quality of care information and the recommendations from quality improvement committee investigations are protected by provincial/territorial laws to varying degrees. General access, even to patients, may not be permitted.

POST-ANALYSIS DISCLOSURE

The second stage of the disclosure process is called post-analysis disclosure. An analysis may have identified additional facts and the reasons for the event may be better understood.

Leadership/management must determine which information, especially from quality improvement committees or performance reviews, should be disclosed.

THE ROLE OF LEADERSHIP/MANAGEMENT

The ethical, professional and legal obligation for disclosure rests with the providers involved in the adverse event and they should be allowed and supported to fulfill this obligation.

However, depending on the nature and severity of what has happened, the communication skills, the comfort level and stress of the providers involved and the wishes of the patient, leadership/management may wish to provide communication advice or assistance at the initial disclosure stage. Health care organizations will need practical and flexible policies related to the degree of administrative support required.

Disclosure of harm related to system failures or provider performance issues may require more support. In hospitals and institutions, leadership/management may lead at the post-analysis stage, but providers should be aware of what is being said and be given the opportunity to be directly involved if this will be beneficial to everyone (**Diagram C**).



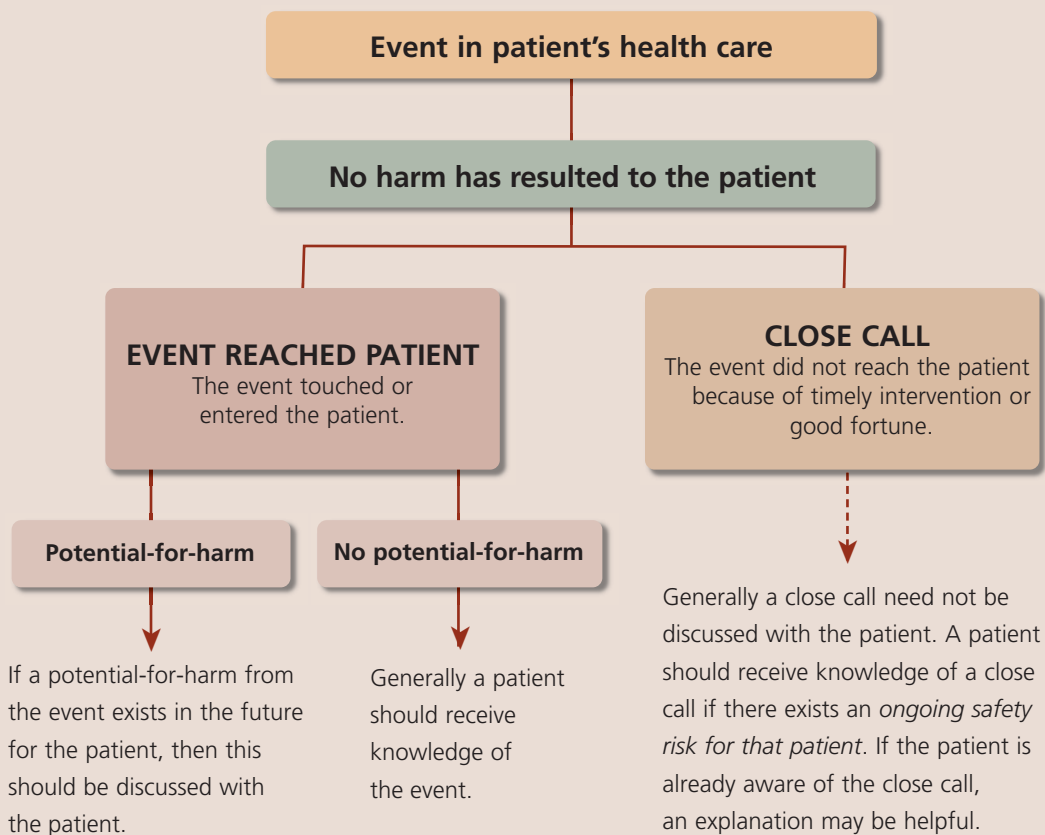
► UNDERSTANDING POTENTIAL-FOR-HARM, NO-HARM EVENTS, AND CLOSE CALLS

Sometimes unexpected occurrences related to health care delivery happen but there is no evident harm.

When an unintended event occurs but there is no immediate harm, the following three situations may apply (**Diagram D**):

- The event reached your patient (touched or entered the patient); no harm occurred at the time but a potential for harm might exist in the future;
- The event reached your patient but no harm occurred at the time and no potential for harm realistically exists in the future;
- The event did not reach your patient because of timely intervention or good fortune — this is called a “close call”(sometimes previously referred to as a near miss) — and therefore there is no possibility of harm from *this particular occurrence*.

Diagram D Discussing potential-for-harm / no-harm events with patients



The following explains what you might do in each of these situations.

THE EVENT REACHED THE PATIENT AND POTENTIAL FOR HARM EXISTS IN THE FUTURE

If a potential for harm from the event exists in the future for the patient, then generally this should be discussed with the patient. Factors to consider include the likelihood and severity of future harm. Consultation with other clinical and ethical experts, and legal counsel, may be helpful. Follow up, further clinical testing and post exposure prophylaxis treatment may be appropriate.

EXAMPLE

An example of an event that reached a patient and has potential for harm will clarify this definition.

Consider a patient exposed to medical equipment that has been inadequately sterilized. The same equipment has been used in treating other patients, some of whom are known to carry HIV infection. It is determined that a small risk of transfer of the virus from the equipment exists. The risk of infection and any future clinical options should be discussed with the patient exposed to this risk.

THE EVENT REACHED THE PATIENT BUT DID NOT RESULT IN HARM

If the event reached the patient, generally a patient should receive knowledge of the event even if it caused no harm.

EXAMPLE

An example of an event that reached a patient but caused no harm will clarify this definition.

Consider a patient with a known allergy to penicillin. The allergy is recorded on the medical chart. Despite this, you administer penicillin to the patient, yet there is no allergic reaction — in other words, the event reached the patient, but there is no harm. A discussion with the patient allows the patient to understand an allergy may not exist.



Consider using the “substitution test” — would you want to know if you were the patient?

It is not always easy to decide whether or not to make your patient aware of an event in which there is no harm. Ask yourself what facts would the patient want to know? Another approach is to use the “substitution test” — would you want to know if you were the patient or if one of your family members was the patient? Common sense must prevail.

CLOSE CALLS

Close call (sometimes previously referred to as a near miss): *An event with the potential for harm that did not reach the patient because of timely intervention or good fortune.*

As a general approach, a close call need not be disclosed to your patient, although there are certain exceptions to this. Your patient should receive knowledge of a close call if there still is an ongoing similar safety risk for that patient, or if your patient is aware of the close call and an explanation will allay concern and promote trust.

For an example of a close call that need not be disclosed, consider the same patient as in the example above who has a known allergy to penicillin.

You draw up a vial of penicillin to administer to this patient. As you approach the bedside, for whatever reason, you become aware of the potential medication problem and do not give the drug. No medication enters the patient. You need not discuss this close call with the patient.

EXAMPLE

As an example of a close call that might be communicated to a patient, consider another medication example.

It may be there are two patients on a ward with identical last names and you almost give a medication to the wrong patient. The mix-up of patient names is recognized just in time and nothing is administered to the wrong patient. In this situation, it would be sensible to alert both patients of the same name risk so that the patients themselves can also be more vigilant, contributing to their own risk management. (It would also be important to make system improvements so a similar occurrence would be less likely to happen.)

EXAMPLE

REPORTING OF POTENTIAL-FOR-HARM, NO-HARM EVENTS AND CLOSE CALL EVENTS

In hospitals/institutions, the reporting of potential-for-harm, no-harm events and close calls is encouraged to further improve the safety of patients. It may be possible to make improvements to lessen the likelihood of all types of events.

Close calls are an important opportunity to recognize weaknesses and put system safeguards in place to prevent actual adverse events from occurring in the future.

The obligation to report close calls varies across provinces. In Québec, the law requires the completion of an incident report for close calls (near misses) in government-run institutions such as hospitals. The report is kept on the patient's medical record.

In such a situation, it is prudent to alert your patient to the incident, the report and any subsequent preventative measures put in place. This will lessen the likelihood of any misunderstanding and mistrust if the patient views the medical record in the future.

FIRST THINGS FIRST: ATTEND TO CLINICAL CARE

The importance of limiting harm and providing further care to benefit your patient.

AFTER AN ADVERSE EVENT, PATIENTS HAVE CLINICAL NEEDS

The first priority after an adverse event is to take care of your patient clinically, and to reassure the patient these needs are being met.

Consider the following steps:

ASSESS AND CORRECT ANY ONGOING SAFETY ISSUES FOR YOUR PATIENT OR OTHERS

Make the environment safe. Ensure your patient, other patients and staff are protected if an immediate safety risk still exists (e.g. correct any existing biohazard or equipment problem). This may require the help of others, including the leadership/management, in your clinical setting.

TRY TO FIX OR LIMIT ANY FURTHER HARM TO YOUR PATIENT

After an adverse event, your first concern should be the clinical care of your patient. Deal with any immediate and emergent health concerns. Be there for your patient — a patient needs to know that you are fully engaged with his or her care and needs.

CONSIDER WHETHER YOU ARE THE APPROPRIATE INDIVIDUAL TO PROVIDE FURTHER CARE

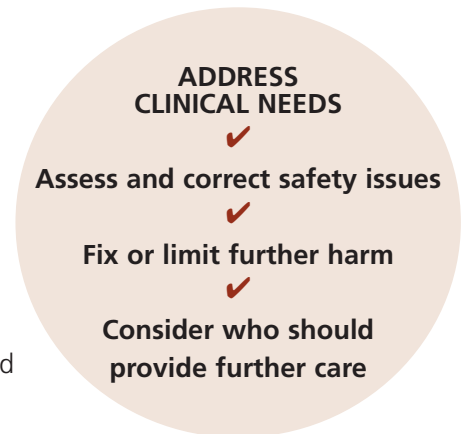
Depending on the quality and duration of your professional relationship with your patient, the nature of the clinical condition as it now exists, and the availability of other colleagues and resources, it may be better to allow others to provide further care.

Transfer the care to another physician if:

- Your patient requests or prefers it;
- Your patient's condition requires care you cannot provide; or
- You feel your own emotional state may interfere with the provision of the care now required.

Consider:

- Whether you have the necessary expertise to deliver the additional care required by your patient;
- The possible perceptions of your patient if additional complications were to occur despite your skills and best efforts; and



- Your own emotional state and degree of stress, and whether this might interfere with the provision of good care in the circumstances.

The reasons for a transfer of care should be discussed with your patient so he or she does not feel abandoned. This will help your patient appreciate that what is being done is in his or her best interests. It is also helpful to introduce the physician who will be assuming your patient's care. Facilitate the transfer by discussing the clinical details with your colleague, and completing and transferring the medical records.

Administrators and other physicians have important roles in facilitating timely access to further care, including clinical investigations, treatments, consultations and transfers. Other physicians can greatly help patients and the profession by taking on these often difficult situations.

THINK AHEAD

Anticipate the future care needs of your patient for the clinical condition as it now exists. It is helpful, where possible and when it does not add significant delay, to have the appropriate investigations, treatments, consultations and transfers tentatively arranged prior to discussing these with your patient. Discuss with your patient your recommendations on how to deal with the medical condition as it now exists, including alternate treatments and the risks and benefits of any other investigations and treatments. This is an informed consent discussion on how to move forward. Answer any questions about the proposed treatments. Your discussion might require you to alter your suggested plan.

Maintain close communications with your patient and, with the patient's consent, the family about the patient's ongoing clinical condition, the results of further investigations and how subsequent treatments are progressing.

PATIENTS HAVE EMOTIONAL NEEDS AFTER AN ADVERSE EVENT — PROVIDE EMOTIONAL SUPPORT

The occurrence of an unexpected and poor patient outcome will be stressful for your patient and his or her family.

Patients and families may experience a range of emotions after an adverse event, whatever the reasons for it. Most are concerned about what can be done to help improve the immediate situation and what the future holds. Surprise at the occurrence of an adverse event may turn into frustration, mistrust and anger. Some patients may become withdrawn. Patients may feel vulnerable and concerned about accessibility to future care. Families and even patients may feel inappropriately responsible and guilty for what has happened.

These feelings can be intensified if patients feel abandoned or perceive their health care providers lack compassion, or are evasive.

The provision of better care includes trying to meet the emotional needs of your patient and his or her family:

- Let your patients know you will be there for them. The aim is to support healing, and restore trust. Accept that some patients and families may request a transfer of care.
- Consider your patient's needs and wishes, and arrange appropriate help and comfort early. In addition to your own efforts, the care of a nurse, social worker, spiritual advisor, psychiatrist or psychologist may be helpful.
- Provide for emotional support during and after the immediate care period.

Some hospitals/institutions have developed formal support programs for patients who have experienced unanticipated outcomes of any kind, including adverse events. Important elements for the success of such programs include making health care providers aware of the program's existence and importance, having a simple process for triggering the program, and continued follow-up and support of patients after discharge.

DOCUMENTATION OF THE ADVERSE EVENT

The medical record is an important tool to document current care and to guide further clinical patient care. It is also important evidence should the clinical care be later subject to any complaint or legal action, often many months or years after the care was provided.


In a factual way, document in the progress notes:


- The clinical situation as it now exists;
- The consent discussions, options and decisions made by your patient regarding any future clinical investigations, treatments and consultations and the rationale for these; and
- Any care provided.

IF YOU FEEL THE EXISTING INFORMATION WITHIN THE MEDICAL RECORD IS INCOMPLETE

It may be necessary to add additional information to the clinical record if you feel it is not sufficiently complete or incorrect.

Add the relevant information in an "Addendum" in the progress notes to clarify for other health care providers the nature of the care given previously. An addendum should be clearly labelled as such, with the date of the entry and signed. The addendum should be factual. Avoid speculation about or second-guessing the care you previously provided. Do not use self-serving language nor blame others.


Patients need to feel they have been heard. The perception that a physician or another provider has been dismissive of their concerns, particularly if something subsequently goes wrong, is a common reason for a complaint.


IMPORTANT: After learning of an adverse outcome, never alter the existing entries in the medical record or change what has been previously written in any way.

PLANNING THE INITIAL DISCLOSURE

After an adverse event, patients have information needs. Planning how to meet these is an important step.

Your approach to disclosure must be planned to meet the patient's clinical, information and emotional needs in the specific circumstances.

Most common adverse events are related to the inherent risks of investigations or treatments. Although all complications should be discussed with your patient, a more formal and structured disclosure process is unlikely to be required. These types of adverse events require discussion with your patient.

Other unexpected outcomes and adverse events, especially those that are serious in nature or suspected to be related to system failures or provider performance, will likely require more analysis to determine what happened. For these types of events, disclosure should be seen conceptually as a dialogue that is best accomplished in stages over time. (See Tab 1, "Stages of disclosure", page 9.)

Although the advice on communications in these materials applies to all types of adverse events, this section describes how to go about planning the initial disclosure stage.

PLANNING THE INITIAL DISCLOSURE

Before speaking with your patient, determine the facts as known at this stage, decide who will be present, establish when and where the meeting will occur and how you plan to proceed. The planning discussions should involve all members of the health care team who will participate in the disclosure.

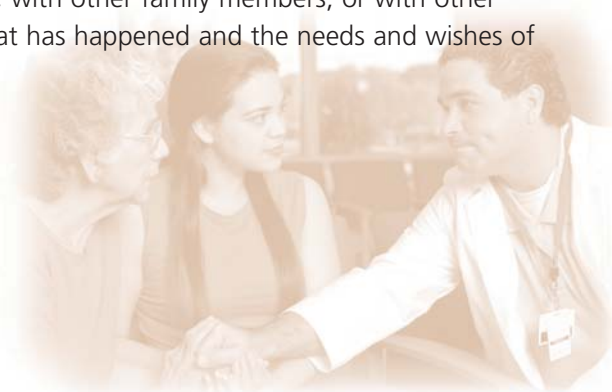
WHAT ARE THE FACTS?

Begin to gather the facts in an organized manner and review the medical record. Consult with any health care providers involved in the event to reach a common understanding of the facts.

Anticipate what you will need to gain a better understanding of what happened. For example, consider what samples, clinical materials and equipment may be helpful in future investigations.

WHO WILL BE PRESENT?

Whether you meet with your patient alone, with other family members, or with other providers in attendance will depend on what has happened and the needs and wishes of your patient and yourself.



Generally, the first initial disclosure meeting should be limited to your patient, his or her family or others your patient wants present, and the providers directly involved in the event.

Consider who should be present at initial and subsequent meetings:

Patient and family



Health care providers



Family physician



Translators



Others to support your patient

The sharing of personal health information with the family can only be done with your patient's permission. It is usually advisable to limit the number of family members present. A spokesperson can be appointed to inform the others.

Depending on the nature of the event or the anticipated reaction of your patient, you may wish to consider having other health professionals present. It may be helpful to ask a colleague who is good communicator or knowledgeable in these types of communications for advice or to accompany you.

Your patient is likely to appreciate the presence of his or her attending physician or family physician if possible, even if that physician was not directly involved, to help explain the medical consequences of what has happened and to provide an opinion on any proposed further care.

If you anticipate the transfer of your patient to a colleague, it may be helpful to have the colleague available. This will facilitate the seamless transfer of care.

If the patient or others request a lawyer to be present at any meeting, please contact the CMPA before agreeing to the meeting.

WHO WILL LEAD?

The choice of the health care provider to lead the initial disclosure discussion will depend on what has happened. The health care team should decide which team member would be most appropriate. Whoever is chosen to lead the discussion should be in a position to provide the necessary information to the patient and be able to answer any clinical questions the patient may have.

In many situations involving medical care, it is best if the discussion is led by the most responsible physician (MRP)⁴, perhaps accompanied by others involved in the care or assisted by other colleagues skilled in such communications.

Legislation or hospital bylaws may require a physician provide disclosure. In Québec, for example, it is generally recommended disclosure be done in a hospital by or after consultation with the attending physician.

If the MRP absolutely cannot be present, delegates should explain, in a sensitive and blame-free manner, why the MRP is not available to speak with the patient directly.

⁴ **Most responsible physician (MRP):** The physician most directly involved in the patient's care at the time of the adverse event. This may be the attending physician or a consultant. For the purposes of disclosure, MRP is not synonymous with the admitting physician in a hospital setting.

INVITE TRAINEES

Medical residents involved in an adverse event should report it to their supervising physicians and be encouraged to be present to observe the disclosure discussion as a learning experience.

ARRANGE FOR LANGUAGE TRANSLATION IF REQUIRED

Anticipate any language barriers and arrange for translation as necessary to facilitate proper understanding of the facts. It is best to use a translator other than a family member. The translator needs to be briefed on the nature of the meeting and approach that will be taken.

CONSIDER ANY OTHER NEEDS OF YOUR PATIENT

Try to be sensitive to the cultural background of your patient. Knowledge of the beliefs, values and customs of the many cultures in Canada is important in patient-centred communication. Communication styles vary across cultures and members of any cultural group. Consider seeking advice from those knowledgeable in a given cultural group's expectations. While this may involve some additional time and effort, it can also help to prevent misunderstandings.

Consider whether additional supports for those with visual, hearing or other impairments are required.

SET THE TIME: WHEN WILL THE INITIAL MEETING OCCUR?

It is best if the preliminary disclosure occurs as soon as is reasonably possible after an adverse event. Waiting for your patient or family to ask for explanations will only increase the stress for all concerned.

Set aside an appropriate amount of protected time. These discussions should not be interrupted or rushed.

Even if an adverse event is discovered well after the time of the actual patient encounter, disclosure should still occur.

DECIDE WHERE TO MEET

To the extent possible, disclosure discussions are best accomplished face-to-face in a clean, comfortable and private area to maintain confidentiality. Cell phones and other communication devices should be turned off to ensure you will not be interrupted. Choose a setting that preferably allows the participants to sit at eye level with you. Be prepared to respond to any physical or emotional reactions.

PLANNING WHAT YOU WILL SAY

This is one of the most important steps.

Take the time you need to organize your thoughts before you approach your patient. While recognizing that disclosure should not be scripted, the following are things to think about while planning what to say at the initial disclosure meeting.

Plan what you will say about the clinical situation

Think about what clinical information you should provide to your patient, such as what has happened and the clinical nature of his or her condition as it now exists.

Be prepared to provide recommendations on how to deal with the medical condition, including alternate treatments, and the risks and benefits of any investigations and treatments. This is an informed consent discussion on how to move forward.

Anticipate and answer questions about any proposed care.

Plan what you will say about the adverse event

Consider what information is available and appropriate to discuss at this stage and point in time. Limit the discussion to the facts.

Patients will likely want to know why something happened. Be ready to answer the difficult questions that are likely to arise, even if the answer is “I do not know but will try to find out and let you know.” Remember not to prejudge the reason(s) for an adverse event. Do not speculate or blame others.

A NOTE ON THE TERM “ERROR”: The term error should be avoided in disclosure discussions (see the Canadian Disclosure Guidelines, CPSI, 2008) because it often misrepresents the reasons for an adverse event, and the word carries with it a sense of blame for an individual that is often inappropriate, especially before all the facts are known.

An adverse clinical *outcome or event* does not mean there has been an error. In fact, most adverse clinical *outcomes* result from the progression of the patient’s underlying medical condition. Adverse *events* are most often the result of inherent risks in investigations or treatments, and a small number are the result of a series of system failures linking together to result in harm, or are related to issues in provider performance or a combination of these.

An inappropriate focus on provider error (“blame and shame”) and punitive approaches is now recognized as being unfair. Such an approach will ultimately inhibit the reporting of adverse events and therefore the system changes required to prevent other similar events will not happen as they should.

Furthermore, the use of the term “error” may be misunderstood to mean the care provided was substandard or negligent in law. Errors may or may not be negligent.

Commit to providing answers if possible. In a hospital/institution setting, it is helpful to know the policies for reporting of adverse events and the likely approach to the analysis. This information will help you answer questions about any analyses that might follow. Determine what and how information related to these investigations will be provided to your patient, but be aware that there usually are limitations on information flow.

Although it may seem obvious an adverse event is linked directly to poor provider performance, seldom are all of the important system or other contributing factors immediately recognized. If it is clear from the beginning that provider performance contributed to the harm, then this should be acknowledged in the initial disclosure discussion, although the use of the word error is generally not recommended. However, it is most often the case that all of the system contributors to the harm will not have been identified and this should be stated.

BRIEF OTHER HEALTH CARE PROVIDERS

Brief the health care team who will be caring for your patient as soon as reasonably possible. All members of the treating team should be aware of the patient's care needs and the facts which have been communicated to the patient. It is important all health care providers give consistent information regarding the facts to the patient and family, using the same medical terms. This helps avoid misunderstanding.



THE INITIAL DISCLOSURE MEETING

Meeting the information needs of patients. The principles of good communication during disclosure meetings, how to conclude meetings, and the importance of follow-up

COMMUNICATION SKILLS FOR DISCLOSURE MEETINGS

Having planned the content of what to say to your patient (see **Tab 3** — Planning the initial disclosure), the following provides practical suggestions on how to communicate effectively with your patient.

Although the focus for this section is on the initial disclosure discussions, these suggestions will also be helpful when giving “bad news” to any patient about serious clinical conditions.

Whatever the reason for the harm, good communicators recommend the following approaches to content, manner and listening.

CONTENT

- Introduce those present as required;
- Introduce the topic for discussion with words such as: “Something has happened and we need to talk about it.” In other circumstances, it may be appropriate to thank the patient for bringing a problem to your attention;
- Ask your patient if there is someone else whom he or she would like present;
- Use plain language, and avoid using medical terminology and jargon. Even common medical terms may cause confusion and may need explanation;
- Describe the clinical condition as it now exists;
- Express your regret as appropriate. An expression of regret for what has happened will convey your concern in an empathetic manner (see “*Expressions of regret*” on page 26);
- Find out what your patient already knows and is experiencing. It is helpful to determine if your information is consistent with that already given by others. Different health care providers may convey the same clinical information using different medical terms and this sometimes leads to misunderstanding;
- Present the existing facts. Be careful not to jump to conclusions before all the facts are in. Be sensitive to how much information is being provided, and what your patient is ready to hear. Patients should be allowed to absorb information at a rate they are comfortable with;
- Do not speculate or blame others. Self-serving defensive statements accompanied by blame for others will only increase tensions and are not helpful;
- Impress on your patient how seriously you are taking the situation; and
- Allow your patient time to express his or her feelings. Emotional reactions by the patient and family, including crying, anger and silence, are normal. Do not presume you understand how the patient feels but let the patient know you understand why they are upset.

MANNER

- Be professional in appearance and demeanour;
- Whenever possible sit at eye level or a little lower. This helps convey respect and avoids the impression you are talking down to your patient. Do not dominate the meeting;
- Avoid barriers between you and your patient, such as a desk. Tissues should be readily available;
- Speak at a comfortably slow rate. It is a common observation in such situations that many health professionals are uncomfortable with even short periods of silence and therefore may speak too much;
- Be aware of your own non-verbal communication, including body language. Much of communication is by body language. Appropriate eye contact and a forward sitting posture will reflect your concern;
- Focus on your patient's needs. One cannot anticipate how a patient will react, even if the patient is well known to you. How you react to your patient's emotional responses is important. If patient anger or another emotion is met with resentment or defensiveness on your part, then the remaining discussion is unlikely to go well; and
- Touching a hand or forearm may be therapeutic for some patients, but may not be welcomed by others depending on the extent of your previous patient-doctor relationship, what has happened, or the patient's cultural background.

LISTENING

- Be attentive, genuine and convey your concern;
- Be sensitive to any language barriers and your patient's cultural background; value what is said by your patient or others present;
- Allow time for your patient to reflect on the information;
- Welcome questions;
- Check for understanding frequently by asking for questions, and acknowledge the importance of these appropriately. You may need to repeat the same information several times as patients may have difficulty understanding or hearing you; and
- Be aware of your patient's non-verbal communication, including body language. Patients may not voice frustrations about unmet expectations, so if you sense an unspoken concern, gently seek clarification.

ENDING THE MEETING

It is important to do what you can to make sure your patient has all the information he or she wants before you end the meeting. Consider the following:

- Do not put a time limit on the meeting;
- Ask if there are more questions;
- Confirm the clinical next steps, such as investigations, treatments, consultations or a transfer of care to another physician or facility;
- Summarize your discussion of the facts and again test for your patient's understanding;

- Define the nature and timelines of any analysis that will be undertaken to answer how or why the event occurred. If appropriate, explain what further information your patient might receive and when in a post-analysis disclosure. Don't make promises to provide information unless you are certain you can fulfill that promise;
- Provide contact information about how you or others can be reached for further information or answers to your patient's questions. Keep the lines of communication open;
- If your patient wishes, arrange a follow-up meeting to discuss progress and discuss any new facts; and
- In particular, consider making your patient's family physician aware of what has happened.

A NOTE ON EXPRESSIONS OF REGRET

At every disclosure meeting, an expression of regret or sympathy regarding the condition of the patient and for what has happened is important. Genuine concern and regret by a caring physician and the health care team will be appreciated by most patients and families.

Your choice of words is important and should reflect your genuine feelings. An example is: "I feel badly that this has happened to you." Such expressions are often helpful emotionally for the patient and the physician, and may help restore or strengthen the patient-doctor relationship.

DOCUMENTATION OF INITIAL DISCLOSURE MEETING(S)

It is recommended to include in your progress notes:

- The time, location and date of meeting;
- The name and roles of those present;
- The facts presented in the discussion;
- The participants' reactions and responses;
- Questions raised by your patient and the family, and the answers given;
- The agreed-upon next steps;
 - Any plan for providing follow up and further information to your patient and the family, if appropriate; and
 - Who will be your patient's contact, and the contact information

AS ADDITIONAL INFORMATION BECOMES KNOWN

If you work in an office or clinic in the community practice setting, the MRP will likely follow up with the patient to monitor clinical progress and provide more information on the adverse event.

In a hospital/institution setting, depending on what has happened, others in leadership and administrative positions may be following up with your patient to meet his or her information needs. There should be an opportunity provided for you to be involved in these subsequent discussions if you and your patient wish.

POST-ANALYSIS DISCLOSURE

After an appropriate analysis, the additional facts related to the reasons for the harm are discussed with the patient.

As described in **Tab 1** “The stages of disclosure,” an unexpected poor clinical outcome may result from an underlying medical condition or an adverse event. The reasons for an adverse event may range from the recognized and unavoidable risks inherent in an investigation or treatment, to system failures, to problems in provider performance, or a combination of any of these.

POST-ANALYSIS DISCLOSURE IN COMMUNITY PRACTICE

If you work in an office or clinic in the community, you are likely to be leading this discussion. The patient will also usually appreciate learning of any changes you have made to your practice to prevent future reoccurrences of the event, if any.

POST-ANALYSIS DISCLOSURE IN HOSPITAL/INSTITUTIONAL PRACTICE

Depending on the outcome of the analysis of an adverse event, it may be that a provider has a limited or no role in the post-analysis disclosure meeting with the patient.

Where the analysis reveals that the adverse event was the result of a system failure, the hospital/institution's leadership and management will likely be responsible for the post-analysis disclosure and will determine what information will be disclosed to the patient at this stage. However, the hospital/institution should still provide you with an opportunity to be involved in these subsequent discussions, if you and your patient so choose.

There may be limitations in hospitals and institutions on what information can be shared with patients.

Those providing the post-analysis disclosure in hospitals/institutions 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 federal or provincial/territorial legislation, regulations or local institutional/hospital by-laws and policies, and legal privilege.

Quality of care information and the recommendations from quality improvement (Quality of Care, Critical Incident Review, Risk Management) committee investigations are protected by provincial/territorial laws to varying degrees. General access, even to patients, may not be permitted.

Leadership/management must comply with provincial/territorial legislation and determine on a case-by-case basis if any information from a quality improvement committee may be disclosed.

Patients wish to learn of safety improvements to prevent similar events. Sometimes such improvements may not be possible. Those responsible in leadership/management must

QUALITY IMPROVEMENT COMMITTEES: A quality of care committee, as part of a quality improvement program in a hospital/institution, contributes to improvements in patient care through the analysis of clinical outcomes, adverse events and close calls, with the purpose of providing recommendations to help correct any system failures that are identified.

Depending on the province or territory, quality improvement committees may have different titles, for example: Quality of Care, Critical Incident Review, Risk Management committees.

All Canadian provinces/territories have some legislated protection for information reported to quality of care committees to prevent the information from being used in subsequent legal or disciplinary proceedings. This encourages the full participation of health care providers in quality improvement.

Following the analysis of an adverse event, patients often want to learn of what steps have been implemented to prevent similar harm to others. However, some jurisdictions explicitly prohibit the sharing of any findings, conclusions or recommendations of a quality improvement committee to persons other than to those in management responsible for their implementation. You should therefore ensure that the disclosure of quality improvement information to the patient does not contravene any relevant legislation that specifically protects this type of information.

decide, on a case-by-case basis, if a system (or *health care delivery*) change actually made based upon a recommendation is appropriate for discussion with a particular patient at the post-analysis stage.

THE ROLE OF APOLOGY

At the post-analysis disclosure stage, after the analysis of the adverse event is complete and it is clear that a health care provider or health care organization is responsible for or has contributed to the harm from an adverse event, it is appropriate to acknowledge that responsibility and to apologize.

How should you say you are sorry for a poor clinical outcome? The answer depends on the reason for the outcome:

- If it is the result of the progression of the underlying medical condition: *An expression of concern and sympathy is sufficient and will be appreciated by your patient and the family.*
- If it is the result of an adverse event related to an inherent risk of an investigation or treatment: *An expression of regret should be provided, such as "I feel badly that this happened to you." An apology (with acceptance of responsibility) should not be provided.*




Apology:

A genuine expression of sympathy or regret, a statement that one is sorry for what has happened. An apology includes an acknowledgement of responsibility if such responsibility has been determined after the analysis of the adverse event.

- If it is the result of an adverse event related to system failures or provider performance, as determined after careful analysis: *An apology should be considered by the responsible provider or responsible organization.*

The use of words that express or imply legal responsibility, such as negligence or fault, or reference to failing to meet the standard of care, should be avoided and are not part of disclosure. Such legal determinations are complex, and independent bodies such as the courts and regulatory authorities (Colleges) have the responsibility to make these determinations fairly.

As a patient's physician, it is not your responsibility to apologize on behalf of another health care provider or an organization. Where a hospital or institution is responsible in part or fully for what has happened, the leadership/administration should decide on the appropriate action to take on behalf of the organization.


Acknowledge responsibility with an apology when it is appropriate to do so.

Prior to an apology, CMPA members may wish to contact the CMPA.

DOCUMENTATION OF POST-ANALYSIS DISCLOSURE MEETING(S)

In addition to the basic documentation of the time, location and date of meeting, and name and roles of those present⁵, it is suggested to include in the progress notes:

- The facts presented to explain what happened. Provincial/territorial laws may require that facts not already in the medical record discovered in quality improvement (Quality of Care, Critical Incident Review, Risk Management) committee reviews be disclosed and placed in the medical record. There may be limitations in hospitals and institutions on what information can be shared with patients;
- Whether an apology was provided for what happened, and what was said;
- The participants' reactions and responses to the discussion;
- Questions raised by the patient and family, and the answers given; and
- The plan for any further follow-up as necessary.

A patient, although he or she does not own the medical record, has the right to a copy of it.

DOCUMENTATION FROM QUALITY IMPROVEMENT COMMITTEES OR ACCOUNTABILITY/PERFORMANCE REVIEWS

Information collected during legally protected quality of care or risk management investigations or in performance reviews of health care providers is confidential and therefore must be kept in secure separate locations, and not in the medical record.

⁵ If you work in an office or clinic in the community practice setting, generally initial and post-analysis disclosure discussions are your responsibility. In hospitals and institutions, leadership/management may lead at the post-analysis stage (see page 12).

CHECKLIST FOR DISCLOSURE

A checklist summary of the key elements of disclosure for quick reference

The CMPA encourages you to call for advice, assistance and support — 1-800-267-6522

FIRST THINGS FIRST: ATTEND TO CLINICAL CARE (TAB 2)

- Try to fix or limit any further harm to your patient
- Make the environment safe (remove any biohazards, malfunctioning equipment, etc.)
- Facilitate any required investigations, treatments and/or consultations
- Consider whether you are the best individual to provide further care
- Brief any other health care providers who may be required to provide further care
- Make sure someone — such as a nurse, social worker or spiritual advisor — is available to comfort your patient as needed
- Document the clinical condition, recommendations and decisions for further care in a timely fashion
- For quality improvement investigations:
 - As required, report what has happened (for example to the hospital/institution, or to a coroner/medical examiner in the event of a death)
 - If appropriate, collect any tissue samples or clinical material for future analysis

PLANNING THE INITIAL DISCLOSURE (TAB 3)

Remember you may only know what has happened, not how or why the adverse event occurred. Therefore, **before you speak** with your patient:

Gather the facts

- Begin to gather the facts in an organized manner and review the medical record
- Consult with the health care providers who were involved to establish a consistent understanding of the facts
- Avoid speculation and do not blame others

Consider who should be present at the meeting

- Family members (with consent of your patient)
- Other health care providers directly involved with the care
- Skilled communicators, as necessary
- Translator if required; generally not a family member
- Those required to meet any special needs of your patient (e.g. cultural, vision, hearing, spiritual needs)
- Decide who will lead the discussion

Set the time and place for the meeting

- Meet as soon as is reasonably possible
- Provide sufficient uninterrupted time
- Choose a setting where you can meet face to face
- To the extent possible, preserve confidentiality and privacy in a comfortable environment

Plan what you will say

Disclosure cannot be scripted. However, before you meet with your patient, organize your thoughts and consider how you will:

- Manage your own emotions
- Acknowledge that something unexpected has happened
- Express your concern and regret
- Respond to your patient's emotional reactions
- Respond to questions your patient is likely to ask
- Explain the process for any analysis of the adverse event
- Explain if and what additional information about the event may be forthcoming

THE INITIAL DISCLOSURE MEETING (TAB 4)**During the meeting**

- Introduce the topic for discussion with words such as "something has happened and we need to talk about it"
- Present the existing facts. Don't speculate
- Describe both the clinical condition as it now exists and any future care requirements
- Express your regret as appropriate
- Find out what your patient already knows and is experiencing
- Be sensitive to how much information is being provided; try not to overload your patient
- Communicate in a clear, sensitive and empathetic manner
- Welcome questions
- Impress on your patient how seriously you are taking the situation

Ending the meeting

- Confirm the clinical next steps
- Summarize the discussion and again test for understanding
- As appropriate, define what the next steps will be to answer any questions about how or why the event occurred
- Provide contact information about how you or others can be reached
- Consider arranging a follow-up meeting with your patient

Follow through after the meeting:

- Make other members of the health care team (in particular, the family physician) aware of your patient's clinical condition
- As appropriate, continue to monitor your patient's condition

POST-ANALYSIS DISCLOSURE (TAB 5)

(In a hospital or institution, leadership/management may lead)

- Continue to provide clinical and emotional support
- If appropriate, convey newly uncovered facts to your patient if any, including what steps have been taken to prevent similar harm to others
- Provide a further expression of regret that may include an apology with acknowledgement of responsibility for what has happened if this is appropriate
- Consider arranging appropriate emotional support for all those involved, including yourself
- Document the clinical care and discussions in a factual way

FREQUENTLY ASKED QUESTIONS (FAQs)

The following are questions members often ask the CMPA about disclosure

What are my obligations to disclose?

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

Section 14 of the Canadian Medical Association’s Code of Ethics

All of the medical regulatory licensing authorities (Colleges) in Canada would view the disclosure of adverse events to patients as an ethical and professional obligation, although some may not have formally defined policies. Furthermore, although specific legislation mandating disclosure may not exist in a particular province or territory, disclosure will likely be seen as a legal professional obligation in all of the jurisdictions.

What is the difference between disclosure and reporting?

Disclosure to a patient of the occurrence and facts of an adverse event, as defined in this document, must be distinguished from reporting the occurrence to a hospital/institution or other bodies.

Many hospitals require that a medical director or others, such as patient safety officers or risk management coordinators, be notified depending on the severity and perceived preventability of an event. This is called “reporting.”

Physicians, medical directors or other administrators may have further responsibility, depending on the circumstances, to investigate and to make further reports to other bodies, depending on the province/territory. In addition, leadership/management will be responsible to make system improvements to try to prevent similar problems in the future and for seeing that issues of professional accountability are addressed.

If I say “I’m sorry” will I get sued?

Litigation may or may not result after poor clinical outcomes, including adverse events, irrespective of how well the facts are communicated or disclosed. Some patients and families have said they may even be forgiving of preventable adverse events but are less inclined to be so if they perceive that a physician or hospital is evasive or dishonest in communicating with them.

Expressions of genuine concern and regret by a caring physician or health care professional are usually appreciated by the patient. Unfortunately, an inappropriate acknowledgement of responsibility or fault prior to a complete analysis may lead to unwarranted litigation.

Negligence/fault:

Negligence/fault occurs when harm to the patient is caused by the failure to exercise a reasonable and acceptable standard of care. The standard of care is not perfection. (For a more detailed explanation of negligence/fault, see the eLearning activity on negligence on our website at www.cmpa-acpm.ca)

In the event of litigation, the CMPA provides medico-legal advice and defence to members, and appropriate compensation to patients who have been harmed by the care they received by member physicians if it is proven the care was negligent.

What should I consider when discussing the care provided by others with my patient?

A patient or family will sometimes ask a physician about the quality of care previously provided by another physician or other health professionals.

Many complaints and lawsuits start after ill-considered comments on the care provided by someone else, especially when the facts and circumstances are unknown. A single thoughtless comment often forms the basis for dissatisfaction and/or complaint by patients and their families, especially when the clinical outcome is poor or unexpected. Remember that at some time in the future, you may have to stand by statements you have made. Prior to commenting on the care provided by others, consider if you know enough of the facts to be in a position to offer a view of whether the care was reasonable at the time. In most instances the other health care provider should be the one discussing his/her care directly with the patient if there is concern about the care or outcome.

A chief of department or clinical supervisor may be helpful in giving valuable perspective or in resolving disputes.

I am aware of a possible adverse event that occurred under the care of another physician or health care provider. Should I provide disclosure to the patient directly?

The ethical and professional obligation to discuss an adverse event with a patient rests primarily with the most responsible physician (MRP) at the time of the adverse event.

Focus on the needs of your patient as they now exist. Your comments should be limited to the facts you know and when you knew them. Refer your patient back to the other physician or other provider for a discussion of what happened previously. Notify the other physician or other provider that your patient will be seeking information.

Patients do not benefit from speculation and innuendo. However, there are times when the quality of the care provided by another should be questioned, but addressed constructively. This is best accomplished through an established administrative process, for example notifying the chief of a department to review the care.

Health care providers who comment on the care provided by others without knowing all of the facts and circumstances run the risk of being unfair to both patients and health care providers.

What do I do if my patient wants a lawyer at the disclosure meeting, or is threatening to sue me?

Please contact the CMPA for advice on how to proceed.

Disclosure should be about patient care and addressing the clinical and information needs of your patient. If those present are attending for other reasons or are threatening legal action, this will impede frank and open discussion and may put you at medico-legal risk.

How can leadership/management support health care providers affected by adverse events?

The occurrence of an unanticipated poor patient outcome will be stressful for everyone involved. It is well known that health professionals care deeply when one of their patients is harmed. This is especially true if they believe they could have done something to prevent the harm. Health care providers often blame themselves, and may feel guilty and embarrassed. As a result, they may have difficulty asking for assistance and often feel isolated. Many have not been trained in disclosure or gained experience in communicating effectively with patients following adverse events.

As a physician, it is also important to extend your understanding and support to others on the health care team.

If you are administratively responsible for other health professionals, thought should be given to ensuring they have the appropriate and timely informal and formal support not only for the disclosure communications (at initial disclosure stage see **Tabs 3** and **4**, or at post-analysis disclosure stage see **Tab 5**) but also for addressing the emotional stress evoked by the event.

Some individuals may require a redistribution of their work responsibilities or time off so they can recover with the goal of returning to full productivity and job satisfaction.

How do I deal with my own stress?

If you are involved in the adverse event, consider your own emotional and physical health. It is important to recognize early you do not have to “go it alone,” or self-treat, and you can seek out appropriate support when needed. If you do talk about what you are going through with colleagues, be sure not to discuss clinical details or make assumptions of fault or blame.

Help is available from a number of sources, including your own personal physician or by accessing the services of the Canadian Physician Health Network which has programs available in all provinces and territories. The Canadian Medical Association website (cma.ca) or your provincial/territorial medical organization website will have contact information for these programs. CMPA physicians are also available to discuss the case with you.

Should a patient be offered money after an adverse event?

Some advocate for the provision of monetary payments to patients as part of the disclosure process. In some instances, this may place CMPA members under pressure to provide or arrange a monetary payment to the patient. Such an approach should raise a number of real concerns for both patients and physicians. There is concern that such payments may not appropriately compensate those patients who deserve compensation. In addition, physicians should be aware that any such payments could later be advanced as an admission of liability if a legal action occurs. Furthermore, these payments may need to be reported on your own professional record, for example when reapplying for provincial/territorial medical licensure or in applications for hospital privileges.

Compensation of patients who have allegedly been harmed by negligent medical care is best dealt with through the existing Canadian civil legal system. The CMPA is working to improve the medico-legal liability system. This includes efforts to affect a timely settlement of worthy claims to meet the needs of patients and reduce the stress on both patients and providers.

IMPORTANT: Members who are asked or required to participate in a compensation scheme as part of the disclosure process should be wary, and should contact the CMPA immediately for advice and possible legal assistance.

ARE EDUCATIONAL TRAINING SESSIONS ON DISCLOSURE AVAILABLE?

CMPA physicians are available to present rounds or workshops on disclosure of adverse events or any other medico-legal topic.

Contact education@cmpa.org or telephone for more information.



TERMINOLOGY

A glossary of common terms

Many of the following terms and definitions are recommended by the Canadian Patient Safety Institute (see Disclosure Working Group. *Canadian Disclosure Guidelines*. Edmonton, AB: Canadian Patient Safety Institute; 2008). The terms used in organization policies and provincial/territorial legislation may vary.

- Adverse event*** An event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition.
- Apology**** A genuine expression of sympathy or regret, a statement that one is sorry for what has happened. An apology includes an acknowledgement of responsibility if such responsibility has been determined after the analysis of the adverse event.
- Close call*** An event with the potential for harm that did not result in harm because it did not reach the patient due to timely intervention or good fortune (sometimes called a near miss).
- Disclosure*** The process by which an adverse event is communicated to the patient by health care providers.
Initial disclosure: The initial communications with the patient as soon as reasonably possible after an adverse event, focusing on the known facts and the provision of further clinical care.
Post-analysis disclosure: Subsequent communications with a patient about known facts related to (the harm and) the reasons for the harm after an appropriate analysis of the adverse event.
- Error**** An act (plan, decision, choice, action or inaction) that when viewed in retrospect was not correct and resulted in an adverse event or a close call.
- provider (medical) error**
- Event**** A significant occurrence.
- Harm*** An outcome that negatively affects the patient's health and/or quality of life.
- Most responsible physician (MRP)**** The physician most directly involved in the patient's care at the time of the adverse event. This may be the attending physician or a consultant. For the purposes of this booklet, MRP is not synonymous with the admitting physician in a hospital setting.

- Negligence/fault**** A legal concept. In all provinces/territories of Canada except Québec, to establish negligence by a physician, a plaintiff patient must prove to the satisfaction of a court that harm to the patient was caused by the failure to exercise a reasonable and acceptable standard of care by the physician. In the courts, the medical standard of care to determine negligence is not one of perfection but rather the standard of care that might reasonably have been applied by a colleague in similar circumstances.
- In Québec, the concept of fault is at the heart of civil liability. Every person has a duty to abide by certain rules of conduct or standards, and if a person does not, he or she has committed a fault. The plaintiff must demonstrate the physician committed a fault, that is, did not act as a reasonably prudent physician of similar training and experience would have under the circumstances. The plaintiff must also have suffered an injury as a result of the fault committed, and the plaintiff must establish the fault caused the injury.
- (For a more detailed explanation of negligence/fault, see the eLearning activity on negligence on our website at www.cmpa-acpm.ca)
- Reporting*** The communication of information about an adverse event or close call by health care providers through appropriate channels inside or outside of health care organizations for the purpose of reducing the risk of adverse events in the future.
- Substitute decision maker (SDM)**** An SDM is a person who is legally authorized to make decisions on behalf of the patient. This authority may be granted through a legal document such as an advance directive, by legislation, or by the courts.
- System failure**** The lack, malfunction or failure of policies, operational processes, or the supporting infrastructure for the provision of health care.

* CPSI definition

**CMPA definition

THE CMPA IS AVAILABLE TO PROVIDE ADVICE

If an adverse event occurs, CMPA members are encouraged to call the Association as soon as possible. CMPA physicians are available to provide advice and support on how to effectively communicate with patients in these circumstances.

Contact the CMPA at **1 800 267-6522**



THE CANADIAN
MEDICAL
PROTECTIVE
ASSOCIATION

L'ASSOCIATION
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DE PROTECTION
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ABOUT THIS PUBLICATION:

Health care providers seek the best possible clinical outcomes for their patients. However, even with the best of medical care, a patient's outcome may not be what was originally desired or anticipated, and in some cases may be entirely unanticipated. Some unexpected outcomes are unfortunately related to health care delivery itself, despite the dedication, training and professionalism of the health care providers.

Patients expect to be informed about harm they have experienced, whatever the reason for it, and this information needs to be delivered in a caring manner.

This resource provides advice on communicating with your patient if an unanticipated poor clinical outcome has occurred during care, particularly in the difficult circumstances in which health care delivery is suspected or known to have contributed to that poor outcome.



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THE CMPA

The vision of the CMPA is to be valued as a vital component of the Canadian health care system, as a world class provider of medical liability protection, and as a champion of medical risk reduction.

The CMPA is a not-for-profit mutual defence organization that extends assistance to most Canadian physicians. The Association provides compensation to patients who have been harmed through the proven medical negligence of its physician members.

Safer medical care is a priority for the CMPA. The CMPA, based on its extensive experience of helping physicians involved in medico-legal difficulties, is increasingly expanding its role in the education of physicians, medical students and other health care providers to improve both the safety and quality of health care in Canada.