



British Columbia's Draft Template Policy for Disclosure of Adverse Events

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1. Policy Purpose

- To assist physicians, managers and other health care providers in disclosing adverse events to patients or their representatives.

2. Definitions

- **Adverse Event^[1]:** An injury caused by health care management rather than the patient's underlying disease; also called harm, injury, or complication. Health care management refers to all aspects of the health care system, not just the actions or decisions of physicians or nurses. (Example: The side rails were left down on the bed of a patient suffering from epileptic seizures and the patient fell and was injured).

- ^[1] Guidance Note: Consider adapting definitions to suit your facility's experience and practice.

Definitions

- **Most Responsible Physician:** The physician who has the day-to-day responsibility for the patient's health.^[1]

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^[1] Guidance Note: Modify this definition to accord with any existing MRP policy.

Definitions

- **Near Miss:** An event or circumstance which has not affected the patient nor caused harm but where the potential for harm exists. Disclosure is not required unless it would assist the patient in avoiding harm in the future. (For example, "this is a type of medication that should only be given orally, and we nearly gave it by another route. You should always check with your nurse when you are getting this medication.")

Definitions

- **Preventable Adverse Event:** An injury (or complication) that results from an error or systems failure, such as giving the wrong medication or misreporting a test result, or leaving the side rails down.

Definitions

- **Unpreventable Adverse Event:** An injury (or complication) that was not due to an error or systems failure and is not always preventable given the current state of scientific knowledge, such as the hazards of high risk therapies or the rare but known risks of any treatments.

3. Policy Statement

- 3.1 Health care providers have an ethical obligation to be honest with their patients and patients are entitled to the facts about their care and treatment. Honestly discussing the difficult truth with a patient when an Adverse Event has occurred demonstrates respect for the patient, professionalism, and a commitment to improving care.

Policy Statement

- 3.2 Health care providers and administrators must work together to ensure that appropriate disclosure to patients or their representatives is a routine part of the response to a harmful or potentially harmful Adverse Event. More broadly, information about Preventable Adverse Events or Near Misses should be shared between facilities and health authorities (on an anonymized basis) in order to increase patient safety throughout the health care system.

Policy Statement

- 3.3 Disclosure of Adverse Events and the reporting of Adverse Events or critical incidents are separate requirements. Critical incident reporting should continue to be done according to [1] and, where applicable, in a manner consistent with the requirements for protection from disclosure under section 51 of the *Evidence Act* of British Columbia, which protects quality assurance documents. Quality assurance records may not be used as the source of information communicated to a patient or their representative when disclosing an adverse event.

- [1] Guidance Note: Identify facility incident reporting policy here by name and number.

Policy Statement

- 3.4 The information that is communicated in a discussion about an Adverse Event must come from the information already recorded in a patient's hospital record and/or from those involved in the event itself and must be factual, not speculative.

Policy Statement

- 3.5 Disclosure of Near Misses or non-significant incidents is a matter of clinical and professional judgment. If it would assist the patient in the future to know that a mistake in relation to their care was nearly made, then it should be disclosed. Certainly, the broader health care team should be made aware of Near Misses in order to learn and prevent future Adverse Events.

4. Responsibilities

- 4.1 All staff should report adverse events to the Most Responsible Physician or senior administrator immediately and should assist them in gathering the facts. All staff should refer to the Incident Reporting Policy with respect to completing an incident report.

Responsibilities

- 4.2 The patient's Most Responsible Physician or the Senior Administrator in consultation with the health care team will determine the appropriate person to disclose to the patient.
- 4.3 Generally, the Most Responsible Physician and Senior Administrator should be involved in the discussion with the patient or their representative. One of the two should take notes of the discussion.

Responsibilities

- 4.4 The Most Responsible Physician/Senior Administrator should ensure that the site administrator, senior medical director and risk management are aware of the event immediately.^[1]
- ^[1] Guidance Note: Consider if this should depend on severity and ensure these responsibilities align with your critical incident policies.

5. Procedure

- 5.1 Disclosure should be done as soon as practicably possible after the harm has been identified unless the patient's condition presents compelling reasons not to disclose at that time or more investigation is required to ascertain significant facts. Disclosure may have to be done on more than one occasion, depending on the circumstances.

Procedure

- 5.2 Empathize with the patient and express appropriate regret about their circumstances. Do this before providing an explanation where possible. Apologize if you are the provider who made an error. Discuss this with risk management if you are unsure about how to conduct such a discussion.

Procedure

- 5.3 Provide the facts only during any explanation of the events. The nature of the event, the level of severity and outcomes if known can be discussed. Do not attribute blame to any individual. Do not express personal opinions about fault. If some facts are as yet unknown, identify this without assuming liability.

Procedure

- 5.4 The team should communicate ownership of the event to the patient. This is separate and distinct from an assumption of liability. The patient must feel confident that the team takes responsibility for determining the causes of the event, ensuring the patient's care is managed and any future complications are communicated to the patient.

Procedure

- 5.5 If the Adverse Event was clearly not due to an error, or the cause is unclear, that is, if it was an Unexpected Adverse Event, make sure the patient understands that the injury is not the result of a failure of care, but an inherent risk.

Procedure

- 5.6 Allow the patient or representative to absorb the information they have just heard. Listen carefully to any questions they may have and clarify their understanding. Respect should be given to a patient's educational level, cultural background and disabilities.

Procedure

- 5.7 Let the patient know the steps that are being taken to deal with the Adverse Event. If there are particular questions or issues which cannot be dealt with at the time, let the patient know that they will be followed up and set a time line for further contact. Designate a person within the disclosure team that the patient can contact if further questions arise so that there is a central line of communication. Do not promise to provide the patient with any quality assurance report or review that is protected under section 51 of the *Evidence Act*. Nor can you disclose any information about disciplinary steps taken regarding staff as this is governed by the personal privacy sections of the *Freedom of Information and Protection of Privacy Act*. You can assure the patient that they will be advised of any recommendations or changes in policy or procedure that are adopted and implemented by the facility following the review.

Procedure

- 5.8 Support in the form of counseling, spiritual services, or other forms of available support within the organization should be offered to the patient or family regardless of whether they make the request. Should the patient or family request more detailed long-term support, information must be provided to the patient on how to facilitate this request. Support should also be offered to the staff involved in the Adverse Event where appropriate.

Procedure

- 5.9 Record a complete, accurate and factual account of the disclosure discussion in the patient's medical record including the following: objective details of the event, the patient's condition immediately before and after the time of the event, medical intervention and patient response, and notification of the physician(s). The individual most involved with the adverse event should be responsible for documentation. This is not an incident report, which is dealt with in policy [identify].

Procedure

- 5.10 Consider if others in the health care system could learn from the Adverse Event or Near Miss and contact the Health Care Protection Program to discuss whether an anonymized report can or should be circulated.

Procedure

- 5.11 When disclosing information to anyone other than the patient or the patient's legally authorized representative, health care providers must also be mindful of their obligations to protect personal information with respect to a patient and staff as set out in the *Freedom of Information and Protection of Privacy Act*. Rarely, there may be a requirement to consider a broader notification of risks to the public or a large number of patients pursuant to the "public interest" section of that Act (i.e., SARS exposure, infected medical devices). It is important that there be a careful expert assessment of the risks and benefits to the public and that the appropriate contingency plans of the organization be in place (i.e., helplines, testing information) before such public disclosures are made, unless the emergency nature of the circumstances do not permit any delay.