POLICY

Disclosure of Harm

STATUS:
Approved by Council:
Amended:
To be reviewed:

1. Preamble

Despite the best efforts of health professionals, the delivery of medical care can sometimes result in unexpected outcomes and expose a patient to harm or potential harm. Harm is not always preventable, nor is it necessarily an indicator of substandard care, but its impact can deeply affect patients and their families.

Physicians may also be significantly impacted when their patients experience negative health care outcomes. Physicians sometimes feel ill equipped to disclose and discuss the harm that has occurred with patients and families, and may also struggle to find the support they need to conduct these conversations effectively.

2. Definitions

For the purposes of this policy, the following definitions apply:

Apology: an expression of sympathy or regret; a statement that one is sorry for what has happened.

Disclosure: the acknowledgement and discussion of a harmful incident, a no-harm incident, or a near miss incident with the patient, substitute decision-maker, and/or estate trustee, as the case may be.

Harm: an outcome that negatively affects a patient's health or quality of life. Harm may or may not relate to material risks discussed during the informed consent process.

Harmful incident: an incident that has resulted in harm to the patient (also known as an "adverse event").

No-harm incident: an incident with the potential for harm that reached the patient, but no discernible or clinically apparent harm has resulted.

Near miss incident: an incident with the potential for harm that did not reach the patient due to timely intervention or good fortune (also known as "close call")

3. Purpose of this policy

Physicians have a legal duty to disclose errors made in the course of medical treatment. Where a medical error is not fully disclosed, courts have held that may negate the patient's consent. Gerula v. Flores, 1995 CanLII 1096 (ON CA)

Full disclosure helps foster openness, transparency, and good communication in the delivery of medical treatment. These are integral to promoting patient autonomy and maintaining trust, both in the physician-patient relationship and the medical profession generally.

On a practical level, disclosure can help physicians and health care institutions prevent future incidents, thereby improving over all quality of care and patient safety outcomes. Disclosure also ensures that the patient can access, and make informed decisions about, timely and appropriate interventions that may be required as a result of an unexpected health care outcome.

4. The College's Position

Obligation to Disclose

1. Physicians must ensure that harmful incidents are disclosed.
2. Physicians must ensure that no-harm incidents are disclosed.
3. Physicians must consider whether to disclose near miss incidents, taking into account whether:
    a. the patient is aware of the incident and an explanation will reduce concern and promote trust;
    b. the patient should be educated to monitor for future similar incidents; and
    c. a reasonable person in the patient's position would want to know about the incident.

To whom to disclose

4. Physicians must disclose directly to the patient or, where the patient is incapable with respect to the treatment, to the patient's decision-maker.
5. If the patient has died, the physician must disclose to the patient's estate trustee (or if there is no trustee the person who has assumed responsibility for the administration of the patient's estate)

When to disclose

6. Physicians must disclose as soon as possible after the incident occurs.
7. Disclosure is an ongoing obligation, and physicians must disclose additional relevant information as soon as possible once it becomes available.

What to disclose

8. As part of disclosure physicians must communicate the following information:
    a. the facts of what occurred and a description of the cause(s) of the incident;

b. any consequences for the patient, as they become known;
c. actions that have already been taken and those that are recommended to address any actual or potential consequences to the patient, including any steps the patient can take to monitor for potential consequences of similar incidents, as well as options for follow up care;
d. actions being taken, if any, to avoid or reduce the risk of the incident recurring; and
e. who the patient may contact for further information.

9. Avoid speculation. If a physician speculates about what occurred and that information later turns out to be inaccurate it can harm patient confidence.
10. Avoid blaming others.
11. Physicians must consider whether an apology is appropriate, taking into consideration the nature of the incident and the consequences of the incident for the patient.

Who must disclose

12. Where a sole physician is directly involved in the patient's care at the time of the incident, that physician must disclose.
13. Where multiple physicians are directly involved in the patient's care at the time of the incident, the physician must:

a. assess who is the most appropriate physician to disclose; and
b. ensure that disclosure occurs, regardless of who conduct the disclosure.

14. Physicians must use their professional judgement in determining whether to include in the disclosure, as appropriate, other health care providers involved in the patient's care, someone trained in the disclosure process, and/or someone with particular expertise in the patient's condition.

Postgraduate trainees

15. Postgraduate trainees must inform the Most Responsible Physician (MRP) and their clinical preceptor in a timely manner of any harmful, no-harm or near miss incidents.
16. In the interest of professionalism and ongoing education, MRP's must encourage the postgraduate trainees' active involvement in the disclosure process to the extent the MRP determines is appropriate in the circumstances.

Documentation

17. Physicians who disclose an incident must capture the following in the patient's medical record:

a. the facts of what occurred;
b. a description of the cause(s) of the incident; and
c. the relevant details of all discussions and communications with the patient relating to disclosure of the incident.

Subsequent physicians

18. Where a subsequent physician has reason to believe that an incident warranting disclosure has not in fact been disclosed, they must:

a. discuss the matter with the previous physician, where it is possible to do so; and

b. where appropriate, ensure that disclosure takes place at the first reasonable opportunity, which may require the subsequent physician to disclose the incident to the extent that they have the appropriate knowledge about the incident to do so.

5. What types of incidents must be disclosed?

In considering what kinds of incidents must be disclosed, remember that the purpose of disclosure is not to attribute blame. Rather, disclosure aims to provide patients with a full understanding of all aspects of their health care, as well as the information they need to make autonomous, informed medical decisions.

Harm to patients may arise in a number of ways including through:

- The natural progression of the patient's medical condition;
- A recognized risk inherent to the investigation or treatment; and
- Events or circumstances, such as individual or systemic failures, that resulted in unnecessary harm to the patient (also known as "patient safety incidents").

The cause of harm is often complex and may arise out of multiple contributing factors. This policy is primarily meant to navigate disclosure discussions in situations where something has gone wrong with a patient's care, rather than situations where the patient's condition worsens due to a progressive illness.

Harmful incidents

A harmful incident is an incident that led to patient harm. Patients expect, and are entitled to know about any harm they have experienced. Physicians must disclose all incidents that have resulted in harm to the patient, no matter the cause. These situations are also sometimes known as "adverse events". Some examples include:

- The wrong unit of blood was infused and the patient died from a haemolytic reaction.
- A patient with a known allergy to penicillin is administered penicillin and suffers an allergic reaction.
- A cancer patient was inadvertently administered too much opioid medication, and requires an opioid antagonist and temporary respiratory support.

No-Harm incidents

A "no harm incident" is a situation where an incident with the potential for harm has reached the patient, even though the patient has not experienced any immediate, discernible, or clinically apparent harmful effects. Some examples include:

- A patient is mistakenly administered the wrong vaccine.
- A relevant finding in the body of a laboratory report is missed, although there had been no clinically apparent effect on the patient's health at the time the mistake was discovered.

No harm incidents must be disclosed to patients because of the potential that harm might manifest in the future. Where a potentially harmful incident has reached a patient, there must be certainty about whether harm has occurred, and this certainty can only be achieved by discussing the incident with the patient. Acknowledgement of the incident will also allow the patient, family, and health care team to monitor and potentially intervene to prevent potential future harm. Disclosure may also be necessary to the informed consent process to ensure that the patient can make fully informed decisions with respect to any subsequent treatment.

Near miss incidents

A "near miss incident" is a potentially harmful incident that did not reach the patient due to timely intervention or good fortune. These are also called close calls. Some examples include:

- The wrong unit of blood was issued to a patient but the error was detected before the infusion began.
- A medication error is made – for example, the prescription does not match the discharge summary order or a patient with a similar name is almost dispensed another patient's medication – but the error is caught by the pharmacist prior to dispensing to the patient.
- The wrong site is prepared for surgery but the mistake is found while completing the pre-operative checklist.

In each instance of a near miss, the physician must consider whether it needs to be disclosed to the patient, using their professional judgement in the specific clinical context and taking into account the factors set out in the policy.

6. Disclosure as an on-going obligation

Disclosure is an on-going obligation, which means that physicians must disclose relevant information as soon as possible when it becomes available. Full disclosure may therefore require a series of discussions, depending on the nature and complexity of the incident, and taking into account the time it could take for harm to develop following the incident.

The nature of the information disclosed will depend on how much time has passed since the incident occurred, the stage of the investigation, and the condition of the patient. For example, at an early stage, physicians might choose to focus on the circumstances that caused the incident and any immediate implications for the patient's treatment plan, with a commitment to follow up once further investigation occurs or more facts are discovered. At all stages, it is important for physicians to communicate only what is known and to avoid speculation.

Subsequent physicians are also subject to disclosure obligations. Where you are concerned that an incident warranting disclosure has not been disclosed, you must discuss the matter with the previous physician. A constructive and respectful discussion may help clarify the particular facts and circumstances of the incident, the evolution of the case, and the obligations of the previous physician around disclosure. If you continue to have concern about the clinical care or outcome, consider working with the previous physician in a sensitive manner to create a plan

for disclosure. It is strongly recommended to document your conversations with the other physician. Ultimately, you may be responsible for disclosure to the extent that you have sufficient knowledge about the incident to do so.

7. The role of apologies

A full and sincere apology may contribute to a successful disclosure discussion. Section 23.1 of The Evidence Act in Saskatchewan states that an apology does not constitute an express or implied admission of fault or liability and must not be taken in account in any determination of fault or liability.

An apology can be greatly appreciated by patients and their family, and can assist in promoting trust and reducing litigation and complaints. The manner in which an apology is delivered can be extremely important. The most effective apologies demonstrate sincerity, empathy, and genuine concern for the patient's well-being. Apologies should be tailored to each individual circumstance, avoiding a formulaic approach.

Physicians have identified a number of additional barriers to an apology, including lack of training and self-confidence in conducting the disclosure effectively. It is common, in the context of a difficult disclosure conversation, to feel uncertain about what to say to patients and their families. The confidence required to conduct these conversations effectively is often obtained through practice and training. Some references include: the Canadian Patient Safety Institute's Canadian Disclosure Guidelines: Being Open with Patients and Families and the Canadian Medical Protective Association's Disclosing harm from healthcare delivery: open and honest communication with patients.

The following tips and guidance may be helpful:

- Try to reassure the patient or substitute decision-maker that you will do everything you can to address their concerns.
- Outline a plan for prompt and thorough intervention to mitigate the harm.
- Where multiple physicians are involved in a hospital setting, note that ultimate responsibility will generally lie with the Most Responsible Physician as the physician with primary responsibility for managing the medical care of a patient at a specific point in time.
- Consider whether it would be appropriate to transfer the patient to the care of another physician and make the patient aware of any changes to their health care team.
- Consider the patient's cultural and ethnic identity, as well as their language of choice, and enable access to family and/or interpretive support where possible.
- Convey sincerity through tone of voice, body language gestures, and facial expression.
- Consider contacting the CMPA for advice or speaking with a colleague prior to proceeding with a disclosure.

8. Critical incident regime

Physicians working in hospitals will also be subject to the Critical Incident Regulations, 2016 and the Saskatchewan Critical Incident Reporting Guideline, 2004 which contains a list of events required to be reported to the Minister of Health. "Critical incident" is defined as:

> A serious adverse health event, including, but not limited to, the actual or potential loss of life, limb or function relation to a health service provided by, or a program operated by a health care organization (HCO).

The scope of incidents which fall under this Disclosure of Harm Policy is therefore broader than those included in the definition of critical incident in the Saskatchewan Guideline.

9. Acknowledgement

The College gratefully acknowledges the College of Physicians and Surgeons of Ontario for permitting their documents 'Disclosure of Harm' and 'Advice to the Profession: Disclosure of Harm' to be adapted in preparing this policy.

10.. Other Resources

Canadian Medical Protective Association: Disclosing adverse events to patients: strengthening the doctor-patient relationship

Canadian Medical Protective Association: Will you be sorry for saying "I'm sorry"?

Canadian Medical Protective Association: Learning from adverse events: Fostering a just culture of safety in Canadian hospitals and health care institutions