



Disclosure of Harm

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Disclosure of Harm

INTRODUCTION

Despite best efforts, patients may incur harm during the delivery of health care. Harm is not always preventable nor is it necessarily an indicator of substandard care.

For the purpose of this policy, “harm” means an unintended outcome arising during the course of treatment, which may be reasonably expected to negatively affect a patient’s health and/or quality of life. This includes outcomes that occur as a result of individual or systemic acts or omissions. This also includes adverse events that result in unintended harm related to the care and/or services provided to the patient rather than to the patient’s underlying medical condition.

For the purpose of this policy, “disclosure” means the acknowledgement and discussion of an outcome with the patient or his or her substitute decision-maker.

The objective of disclosure is not the attribution of blame. Rather, disclosure should provide patients with the information they need to make autonomous, informed decisions about their health care.

PURPOSE

This policy articulates the College’s expectations of physicians for informing patients when harm is sustained in the course of receiving health care.¹

SCOPE

This policy applies to all physicians who become aware, while treating a patient, that the patient has sustained harm in the course of receiving health care.

PRINCIPLES

1. Patients are entitled to information about all aspects of their health care in order to give informed consent to treatment. This requires that they be made aware of any risk of harm associated with treatment, as well as any actual harm that may have occurred during treatment.

2. The obligation to disclose harm flows from the fiduciary nature of the physician-patient relationship. It is part of the physician’s obligation to act in the patient’s best interests, as well as the patient’s entitlement to professional and ethical health care. Disclosure of harm not only respects the autonomy of the patient, it also ensures that the patient can access timely and appropriate interventions for the harm suffered.
3. Disclosure helps foster openness, transparency and good communication, which are integral to maintaining trust in the physician-patient relationship and the medical profession.
4. Disclosure can encourage physicians and health care institutions to improve quality of care and patient safety outcomes.

POLICY

When a patient has sustained harm while under a physician’s care, the physician must ensure that harm is disclosed to the patient or to his or her substitute decision-maker.²

The Legal Basis for Disclosure

Disclosure is a well established legal obligation grounded in the common law doctrine of informed consent.³ The doctrine of informed consent requires physicians to disclose to a patient any fact which a reasonable person in the patient’s position would want to know.⁴ This includes any harm that may have occurred during treatment.⁵

The obligation to disclose also arises from the fiduciary nature of the physician-patient relationship, which compels physicians to act in good faith toward their patients’ best interests.⁶ This includes informing the patient if something goes wrong in the course of treatment.⁷

Regulation 423/07 made under the *Public Hospitals Act*⁸ requires public hospital boards to ensure that an administrator establishes a system for disclosing all “critical incidents”⁹ to the patient or his or her substitute decision-

¹ This policy deals only with disclosure of harm to the patient. It does not address reporting harm to third parties (excluding substitute decision-makers or estate trustees, where applicable), such as health care institutions.

² This is reinforced in Section 14 of the Canadian Medical Association Code of Ethics: “Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.”

³ The statutory basis for informed consent is found in the *Health Care Consent Act*, S.O. 1996, Ch.2, Sched. A. Also see the College’s Consent to Medical Treatment policy.

⁴ *Reibl v. Hughes* [1980] 2 S.C.R. 880; *Arndt v. Smith* [1997] 2 S.C.R. 539.

⁵ *Stamos v. Davies* (1985), 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 (H.C.); *Gerula v. Flores* (1995), 83 O.A.C. 128 (C.A.).

⁶ *McInerney v. MacDonald*, [1990] 2 S.C.R. 138, 93 D.L.R. (4th) 415.

⁷ *Vasdani v. Sehmi*, [1993] O.J. No. 44 (Gen. Div.) (QL).

⁸ R.S.O. 1990, c. P. 40.

⁹ “Critical incident” is defined in the regulation as any unintended event that occurs when a patient receives treatment in a hospital that results in death or serious disability, injury or harm to the patient, and does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing the care.



maker. Pursuant to this regulation, a hospital's disclosure protocol may require physicians to disclose harm to a patient or to his or her substitute decision-maker if the patient sustains harm while under the physician's care.

Physicians who work in hospitals or other health care facilities may be subject to further disclosure requirements established by their particular institution. Physicians are expected to comply with any such requirements, as well as those in this policy.

What to disclose

Disclosure must include:

- the material facts of the incident causing the harm;
- all material consequences for the patient; and
- actions that have already been taken and those that are recommended to address the consequences, including options for follow-up care.¹⁰

Where an incident with the potential for harm does not actually reach the patient because of a timely intervention or good fortune (i.e., a close call or no harm event), the incident need not be disclosed to the patient, although there are certain exceptions to this. The patient should receive knowledge of a close call if there is still an ongoing similar safety risk for the patient, or if the patient is aware of the close call and an explanation will allay concern and promote trust. For further information regarding close call and no harm events, physicians should consult the CMPA publication, *Communicating with Your Patient About Harm: Disclosure of Adverse Events*.

To whom disclosure should be made

Disclosure is typically made directly to the patient. Where the patient is incapable, disclosure can be made to his or her substitute decision-maker.¹¹ If the patient has died, disclosure should be made to his or her estate representative.

When to disclose

Disclosure should generally be made as soon as reasonably possible upon becoming aware of the harm. Until further investigation occurs, disclosure should focus on the incident that brought about the harm and implica-

tions for the patient's treatment plan. More in-depth discussion should be deferred until an investigation of the incident is complete or more facts surrounding the incident are discovered, where applicable.

Disclosure is an ongoing obligation. If additional relevant information becomes available over time, this should be disclosed.

Who should disclose

All physicians involved in the care or treatment of a patient have an obligation to ensure that disclosure of harm is made. The obligation may be fulfilled either by the Most Responsible Physician¹² or another physician who may have more direct knowledge of or involvement in what has occurred.

If care is provided by a team, it is acceptable for one provider to disclose on behalf of the team. However, each physician involved in the care of the patient has a responsibility to ensure that disclosure is carried out.

When it appears that harm has occurred during the course of care delivered by a team, team members should determine who is in the most appropriate position to disclose the harm. Usually this will be the provider most closely connected to the harm. If it is not possible to discern who is most closely connected to the harm, the team may appoint one provider to disclose. In all cases, regardless of who discloses, physicians are expected to ensure that disclosure is made to the patient.

Disclosure discussions may include 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. Ultimately, the onus for ensuring that disclosure is carried out lies with the physician(s) responsible for the patient.

Postgraduate Learners

A postgraduate learner who has advised the Most Responsible Physician and his or her Clinical Preceptor¹³ that a patient has sustained harm has fulfilled his or her obligation for disclosure.

However, in the interest of professionalism and ongoing education, postgraduate learners who are involved in an

¹⁰ This is consistent with the disclosure requirements for hospitals in Regulation 423/07 made under the *Public Hospitals Act*.

¹¹ For information about substitute decision-makers, please see the College's Consent to Medical Treatment policy.

¹² The Most Responsible Physician is the physician who has final responsibility and accountability for the medical care of a patient.

¹³ A clinical preceptor is an individual who serves as a "clinical teacher" (i.e., guides, observes and assesses the educational activities of a physician). Clinical preceptors may or may not be the Most Responsible Physician. Postgraduate learners often serve in the role of clinical teacher, but are not the Most Responsible Physician in patient care.

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event that results in harm should maintain an active involvement in the disclosure process.

The extent of involvement will depend on the circumstances of each case. Postgraduate learners should discuss this with the Most Responsible Physician and his or her Clinical Preceptor.

Subsequent or Non-Treating Physicians

In some instances, a physician who is not treating the patient when the harm is sustained can become aware of the harm. This could occur, for example, where the physician has taken over the patient's care, or is reviewing the patient's medical record as a consulting specialist. If a subsequent or non-treating physician has reason to believe that the patient has not been notified of the harm, the subsequent or non-treating physician should discuss the matter with the previous physician to ensure that harm is disclosed to the patient or his or her substitute decision-maker.

Documenting Disclosure

The clinical event giving rise to the harm, as well as all discussions with the patient, should be recorded in the patient's medical record in accordance with the College's Medical Records policy.

GUIDELINES

Although disclosure is difficult to do, it is required by law and by the College's expectations of professionalism as articulated in the Practice Guide. Moreover, it may help prevent the recurrence of unintended outcomes and promote a culture of patient safety, which reinforces public trust in the profession and the health care system.

Research suggests that prompt disclosure may lessen the risk of the physician being sued for the harm,¹⁴ and that patients are often more forgiving if the physician is forthcoming with them.¹⁵

A sincere expression of apology may be greatly appreciated by the patient and their family. Under the *Apology Act*¹⁶,

apologies made for harm that occurs during treatment cannot be used as evidence of liability against a physician in a civil proceeding, administrative proceeding or arbitration.¹⁷ Physicians should be aware that apologizing does not absolve one of the harm that has occurred, nor does it shield one from a finding of liability.

The College suggests the following additional tips in preparing for a disclosure discussion:

- Disclosure should be made in a sensitive manner taking into consideration the patient's personal, social, religious, and cultural needs.
- Openly communicate the facts as known.
- Provide a short, objective summary of the incident.
- Avoid speculation.
- Reassure the patient or his or her 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 done.
- If possible, transfer the patient to the care of another physician if the patient or his or her substitute decision-maker so desires.
- Physicians may wish to contact the College's Physician Advisory Service for advice before proceeding with disclosure.
- Physicians may wish to contact their medical malpractice provider for advice before proceeding with disclosure.
- Physicians may wish to consult the Canadian Medical Protective Association's publication, *Communicating with Your Patient About Harm: Disclosure of Adverse Events*. This may be particularly helpful with respect to expectations for disclosure of close call events or no harm events (i.e., events which do not reach the patient because of timely intervention or good fortune).

For further information, see the Canadian Patient Safety Institute's *Canadian Disclosure Guidelines*.

¹⁴ See Robertson G. "When Things Go Wrong: The Duty to Disclose Medical Error" *Queens Law J* 2002; 28:353-62 at para 14; Waite M. "To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error" (2005) 13 *Health Law Journal*, p. 1-33 at para. 71-3; Wu, A. "Handling Hospital Errors: Is Disclosure the Best Defense?" (21 December 1999) *Annals of Internal Medicine*, 131:12, 970-2.

¹⁵ Health Quality Council of Alberta, *Disclosure of Harm to Patients and Family (Provincial Framework – July 2006)* at p. 3.

¹⁶ 2009, S.O., c. 3.

¹⁷ The *Apology Act* provides that if a person makes an apology while testifying at an out of court examination in the context of the civil proceeding, administrative proceeding or arbitration, the protection does not apply to the apology for the purpose of that proceeding or arbitration.



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