The College of Physicians and Surgeons of Ontario

Advice to the Profession: Disclosure of Harm

Advice to the Profession companion documents are intended to provide physicians with additional information and general advice in order to support their understanding and implementation of the expectations set out in policies. They may also identify some additional best practices regarding specific practice issues.

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.[1]

This document is intended to help physicians interpret their disclosure obligations as set out in the *Disclosure of Harm* [hyperlink] policy and provide guidance around how these obligations may be effectively discharged.

Why disclose? Legal and ethical imperatives

Physicians have a legal duty to disclose errors made in the course of medical treatment. The courts have also found that where a medical error is not fully disclosed, the non-disclosure can negate the patient's ability to provide valid consent for subsequent treatment.[2]

The professional expectations set out in the policy build upon these legal obligations. The expectations reflect the underlying principle that 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.

Physicians and other health care practitioners may often feel that disclosure may decrease trust in the profession and increase the likelihood of litigation. However, the opposite appears to be the case:

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[1] Canadian Patient Safety Institute, *Canadian Disclosure Guidelines: Being Open with Patients and Families* (2011) p. 16.

[2] *Gerula v. Flores*, 1995 CanLII 1096 (ONCA). Physicians who work in hospitals or other health care facilities may be subject to additional disclosure requirements as established by their particular institution, as well as the requirements of Regulation 965, made under the *Public Hospitals Act*, relating to the disclosure of "critical incidents."

28 research suggests that an open, honest disclosure discussion – including an apology, where appropriate
29 – can have a positive impact on patient trust and reduce the risk of litigation.[3]

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

34 ***What incidents must be disclosed?***

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

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

40 • the natural progression of the patient's medical condition;
41 • a recognized risk inherent to the investigation or treatment; and
42 • events or circumstances, such as individual or systemic failures, that resulted in unnecessary
43 harm to the patient (also known as "patient safety incidents").

44 While harm can occur in many ways, the policy expectations and this advice document are primarily
45 meant to help physicians navigate disclosure discussions in situations where something has gone wrong
46 with a patient's care, rather than situations where the patient's condition worsens due to a progressive
47 illness.

48 *1) Harmful incidents*

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

53 2) *No-harm incidents*

54 A "no-harm incident" is a situation where an incident with the potential for harm has reached the
55 patient, even though the patient has not experienced any immediate or discernible harmful effects. For
56 example:

57 • A patient is mistakenly administered the wrong vaccine or an expired vaccine.

[3] Gerald B. Robertson and Justice Ellen I. Picard, *Legal Liability of Doctors and Hospitals in Canada*, 5th Ed. (2017), p. 263; American Academic of Pediatrics, "Policy Statement: Disclosure of Adverse Events in Pediatrics" (December 2016) *Pediatrics*, 138:6.

58 - A patient with a known allergy to penicillin is administered penicillin, but there is no allergic
59 reaction.

60 No-harm incidents must also be disclosed to patients in order to promote the principles of honesty and
61 respect for patient autonomy in health care, as well as the physician's duty to act in the patient's best
62 interests. Where a potentially harmful incident has reached a patient, there must be certainty about
63 whether harm has occurred, and this certainty can only be achieved by discussing the incident with the
64 patient. Acknowledgment of the incident will also allow the patient, family, and health care team to
65 monitor and potentially intervene to prevent potential future harm.

66 Moreover, disclosure may be necessary to the informed consent process to ensure that the patient can
67 make fully informed decisions with respect to any subsequent treatment.

68 3) *Near miss incidents*

69 A "near miss incident" is a potentially harmful incident that did not touch the patient due to timely
70 intervention or good fortune. These are also known as "close calls." For example:

71 - The wrong unit of blood was being connected to a patient's intravenous line, but the error was
72 detected before the infusion began.
73 - A medication error is made but is caught by the pharmacist prior to dispensing to the patient.

74 Physicians must consider whether a near miss needs to be disclosed to the patient, using their
75 professional judgment in the specific clinical context, taking into account the factors set out in the
76 policy.

77 ***Disclosure as an ongoing obligation***

78 Disclosure is an ongoing obligation, which means that physicians must disclose relevant information on a
79 timely basis. As required by the policy, the initial disclosure must occur as soon as possible, with
80 additional information being disclosed as it becomes available.

81 Full disclosure may therefore require a series of discussions, depending on the nature and complexity of
82 the incident, and taking into account the time it could take for harm to develop following the incident.

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

89 Subsequent and non-treating physicians are also subject to disclosure obligations. Where you are
90 concerned that an incident warranting disclosure has not been disclosed, you must discuss the matter
91 with the previous physician. A constructive and respectful discussion may help clarify the particular facts

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and circumstances of the incident and the evolution of the case. 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. Ultimately, you may be responsible for disclosure to the extent that you have sufficient knowledge about the incident to do so.

The role of apologies

A full and sincere apology may contribute to a successful disclosure discussion.[4] Such an apology can be greatly appreciated by patients and their family, and can assist in promoting trust and reducing litigation risk.[5] Patients also say that 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.[6] Apologies should therefore be tailored in each individual circumstance, avoiding a formulaic approach.

Physicians sometimes hesitate to apologize to patients because of concern about legal implications. It is important to note that an apology is not an admission of legal liability. In Ontario, the law states that 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.[7] At the same time, apologizing does not absolve physicians of harm that has occurred, nor does it shield them from a finding of liability in the future.

Aside from potential litigation, physicians have identified a number of additional barriers to an apology, including a lack of training and self-confidence in conducting the disclosure discussion effectively. It is common, in the context of a difficult disclosure conversation, to feel uncertain about what to say to patients and their families, and the confidence required to conduct these conversations effectively is often obtained through practice and training. You may wish to access further educational resources and materials regarding the delivery of apologies (and disclosure generally), including the following:

- *Canadian Disclosure Guidelines: Being Open with Patients and Families*, Canadian Patient Safety Institute (2011)
- *Disclosing harm from healthcare delivery: Open and honest communication with patients*, Canadian Medical Protective Association (2015)

Additional tips: Disclosing and apologies

- 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.

[4] McLennan et al., "Apologies in medicine: Legal protection is not enough" (2015) *CMAJ*, 187(5), p. E157; Wolk et al., "Institutional disclosure: Promise and problems" (2014) *Journal of Healthcare Risk Management*, 33:3, p. 30.
[5] Levinson et al., "Disclosure of Medical Error" (2016) *JAMA*, 316:7, p. 765; American Academic of Pediatrics.
[6] McLennan et al, p. E157; Wolk et al., p. 30.
[7] *Apology Act, 2009*, S.O. 2009, c. 3.

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123 • Consider whether it would be appropriate to transfer the patient to the care of another
124 physician.
125 • Consider the patient's cultural and ethnic identity, as well as their language of choice, and
126 enable access to family and/or interpretive support where possible.
127 • Convey sincerity through tone of voice, body language, gestures, and facial expression.
128 • Consider contacting your medical malpractice provider and/or the CPSO's Physician Advisory
129 Service for advice prior to proceeding with disclosure.

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