Disclosure of Harm – General Consultation Survey Report

Introduction

The College of Physicians and Surgeons of Ontario (the "College") is currently reviewing its *Disclosure of Harm* policy.

As part of this review, the College has developed an updated draft of the policy and a draft *Advice to the Profession Document*, which were released for external consultation from May to August, 2019.

Invitations to participate in the consultation were sent via email to a broad range of stakeholders, including all Ontario physicians. In addition, a general invitation to provide feedback was posted on the College's website and social media platforms. Feedback was collected via regular mail, email, an online discussion forum, and an online survey.

This report summarises only the stakeholder feedback that was received through the online survey.

Caveats

Participation in this survey was voluntary. As such, no attempt has been made to ensure that the sample of participants is representative of any sub-population.

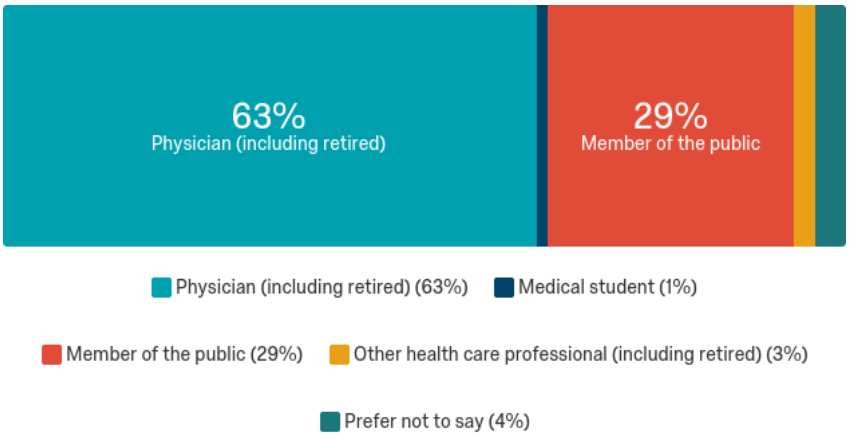
In the interest of space, stakeholder feedback to open-ended questions has been summarised to capture key themes and ideas.

Who we heard from

A total of 73 surveys were received in response to this consultation.

All respondents were from Ontario (100%).

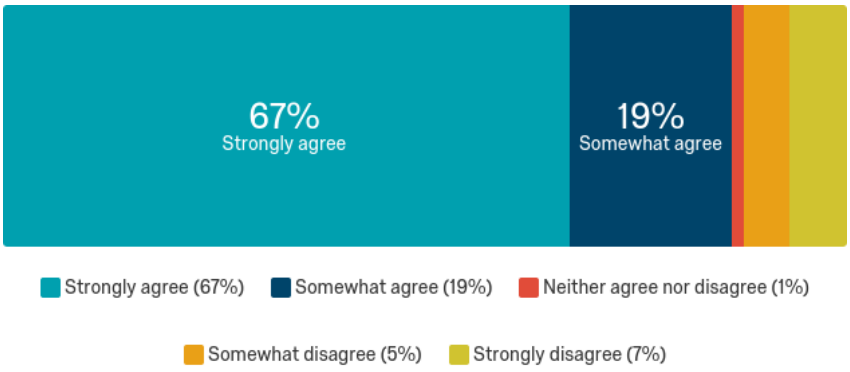
Respondent Demographics



The following questions were posed to all respondents:

Q1: The draft policy includes updated definitions of key terms: "harm," "harmful incident," "no-harm incident," and "near miss incident." These definitions in the draft policy are aligned with those set out by the World Health Organization in its *Conceptual Framework for the International Classification of Patient Safety*. The definitions and the related expectations are pivotal to understanding the draft policy.

"Harm" is defined as "an outcome that negatively affects a patient's health and/or quality of life." Please indicate the extent to which you agree or disagree that the definition of "harm" is clear: (n = 73)

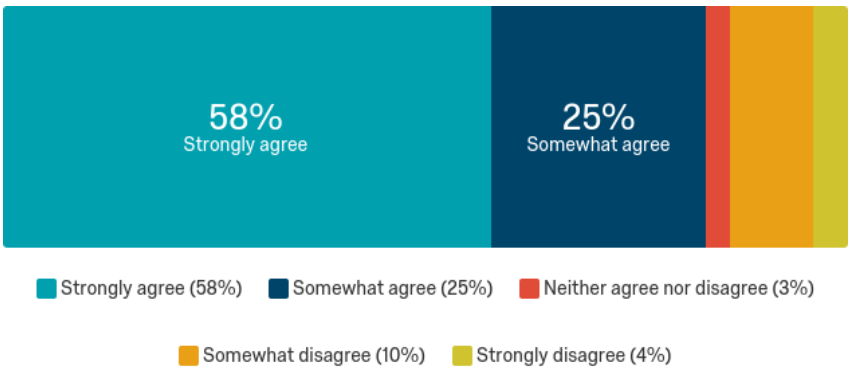


Q2: What, if anything, do you think is unclear about the definition of "harm"? (Optional) (n = 15)

- Several respondents felt examples of "harm" should be added for clarification.
- Physician respondents requested clarification surrounding the definition of "harm." Some were unsure how "harm" is qualified or what it entails, while another felt the definition was too broad by capturing trivial errors and leaves no room for physician discretion.
- Two members of the public questioned who determines whether "harm" has occurred. Another felt it was unclear how harm is related to the physician's action or inaction.

Q3: A "harmful incident" is defined as "an incident that has resulted in harm to the patient (also known as an "adverse event")." In contrast, a "no-harm incident" is defined as "an incident with the potential for harm that reached the patient, but no discernible harm has resulted."

Please indicate the extent to which you agree or disagree that the definition of "no-harm incident" is clear. (n = 71)

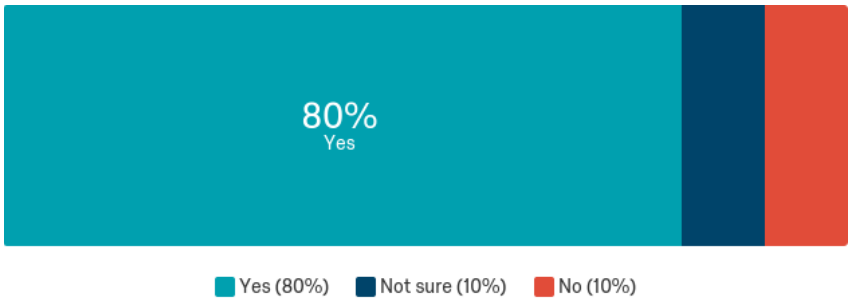


Q4: What, if anything, do you think is unclear about the definition of "no-harm incident?" (Optional) (n = 15)

- Several respondents requested examples of "no-harm incidents." One physician suggested examples would differentiate a "no-harm incident" from a mistake, oversight, or minor error.
- Comments from physician respondents included:
  - "No discernible or clinically apparent harm" may be a more accurate description;
  - How to determine discernible harm when there is a delay in diagnosis; and
  - The definition does not account for potential harm by incorrect laboratory test results.
- One member of the public felt the definition was overly narrow and excludes incidents that affect a patient's prospect of recovery, while another felt the word "discernible" is ambiguous.

Q5: A "no-harm incident" can include a situation where a patient is mistakenly administered the wrong vaccine or an expired vaccine, or where a patient with a known allergy to penicillin is administered penicillin but there is no apparent allergic reaction.

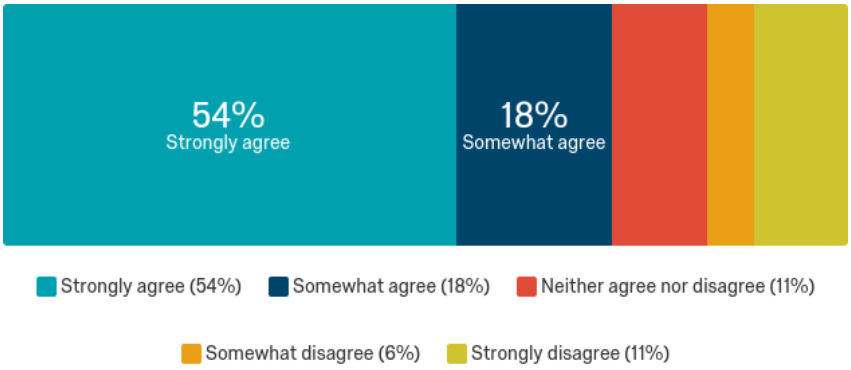
Do these examples help clarify the definition of "no-harm incident"? (n = 71)



Q6: Can you think of any other clear examples of no-harm incidents? If so, please provide a brief description. (Optional) (n = 16)

- Examples of no-harm incidents from respondents included:
  - Medication dosage or prescription errors (inappropriate dosage mistakenly administered);
  - Laboratory or diagnostic testing errors (laboratory tests wrong or wrongly interpreted; mistakes in diagnostic testing; wrong test ordered for patient's clinical problem; lack of appropriate clinical information; or inability to reach most responsible physician with results); and
  - Failure to follow an established treatment protocol or error in selecting the correct protocol.
- Several respondents indicated harm may not be immediately or readily apparent following a "no-harm incident," and noted harm could potentially manifest at a later date where it had previously been erroneously classified as "no-harm."

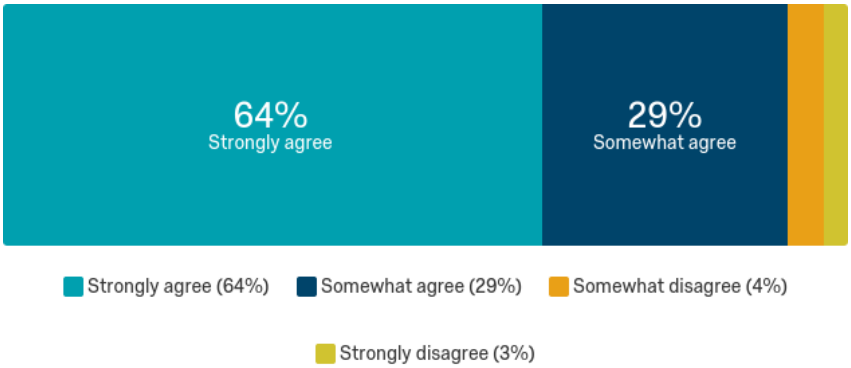
Q7: Do you agree or disagree that physicians should always be required to disclose a no-harm incident to the patient? (n = 71)



Q8: Please briefly describe the kinds of circumstances you think would make disclosure of no-harm incidents appropriate. (Optional) (n = 22)

- Several members of the public felt no-harm incidents should be disclosed in all circumstances:
  - Some members of the public felt the patient has the right to know of any potential harm or if harm has already occurred. Another member of the public highlighted the importance of honesty in the physician-patient relationship.
  - Several respondents believed the process of disclosure may provide a learning opportunity for both the physician and patient. Some felt this education may encourage a patient to assist in preventing harmful incidents from occurring in the future.
  - Other members of the public believed not disclosing could lead to a pattern of incompetence or negatively impact the ability to prevent errors in the future.
- Other respondents felt the disclosure of no-harm incidents to patients should be discretionary or dependent on the circumstances:
  - One physician member indicated there are complex cases where there is a risk disclosure can draw disproportionate attention and concern from the patient, while another felt there could be situations when disclosure would cause more harm than the no-harm (or harmful) incident (particularly in mental health settings).
  - One member of the public suggested that it may be more appropriate to disclose to the patient's family physician when disclosure could cause significant anxiety to the patient.

Q9: A "near miss incident" is defined as "an incident with the potential for harm that did not reach the patient due to timely intervention or good fortune (also known as a "close call")." Please indicate the extent to which you agree or disagree that the definition of "near miss incident" is clear. (n = 69)

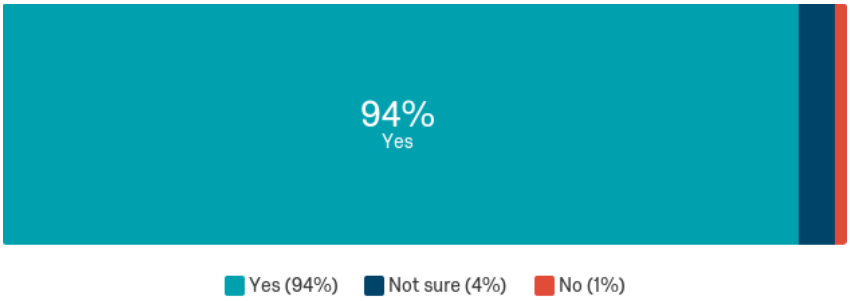


Q10: What, if anything, do you think is unclear about the definition of "near miss incident"? (Optional) (n = 9)

- Several physician respondents felt the definition of "near miss incident" is hard to distinguish from "no-harm incident," and one member of the public felt the definition neglects unanticipated outcomes or outcomes not included in the original patient consent disclosure.
- Some respondents requested examples of "near miss incidents" for clarification.

Q11: A "near miss incident" can include a situation where the wrong unit of blood was being connected to a patient's intravenous line but the error was detected before the infusion began, or where a medication error is made but is caught by the pharmacist prior to dispensing to the patient.

Do these examples help clarify the definition of "near miss incident"? (n = 69)



Q12: Can you think of any other clear examples of near miss incidents? If so, please provide a brief description. (Optional) (n = 13)

The most commonly listed examples from respondents included:

- Medication or prescription errors (e.g. noticing the filled prescription does not match the discharge summary orders before the medication is dispensed; a hospital patient almost given a similarly-named patient's medication instead; the writing of improper prescriptions; or instances of pharmacists catching mistakes in written prescriptions);
- Laboratory errors (e.g. failure to run a test correctly or order the correct panel of tests); and
- Preparing the wrong body part or site for surgery (e.g. the wrong limb was marked for a joint replacement but the mistake was identified during the pre-operative assessment).

Q13: The draft policy expects physicians to use their discretion about whether to disclose a near miss incident to the patient. In what kinds of circumstances do you think a patient would want to know about a near miss? (Optional) (n = 32)

- Many members of the public felt physicians should disclose near miss incidents to patients in all circumstances, and several of these respondents indicated trust and transparency are critical within a physician-patient relationship. Some felt it would be dishonest to not disclose.
- Several respondents believed patients would want to know about a near miss incident if the patient is aware an incident has occurred or if the near miss incident happened in front of them.
- Physician respondents' views on disclosing near miss incidents varied, but several felt patients should be informed of the measures being taken to reduce the risk of the incident recurring.

Q14. The draft policy also addresses the kind of information that a physician must provide as part of the disclosure discussion. The draft policy requires physicians to communicate the following information as part of disclosure:

- **the facts of what occurred and a description of the cause(s) of the incident;**
- **any consequences for the patient, as they become known;**
- **actions that have already been taken and those that are recommended to address any actual or potential consequences to the patient, including options for follow-up care; and**
- **actions being taken, if any, to avoid or reduce the risk of the incident recurring.**

Is there any other important information that patients should be given when harm or potential harm is disclosed? If so, please include a brief description. (Optional) (n = 26)

- Several respondents felt disclosure discussions should address any care implications, including:
    - who the patient can contact for further concerns related to the incident;
    - what the patient can do to monitor for potential consequences;
    - whether there will be any changes to the composition of the patient's care team; and
    - any long-term (non-acute) potential complications.
- Members of the public suggested including the following information during disclosure:
    - an independent third party with expertise in medical error and patient safety;
    - a patient advocate to assist patients in understanding the disclosure communication;
    - the identity of the responsible individual healthcare professional, if requested;
    - access to counselling services; and
    - how and where a patient can submit a complaint to address their concerns.
- Several members of the public indicated disclosure should be provided in writing to ensure patient comprehension and to prevent possible ambiguity surrounding what was disclosed.

Q15. When disclosing harm or potential harm, the draft policy requires physicians to consider whether an apology is appropriate in the circumstances.

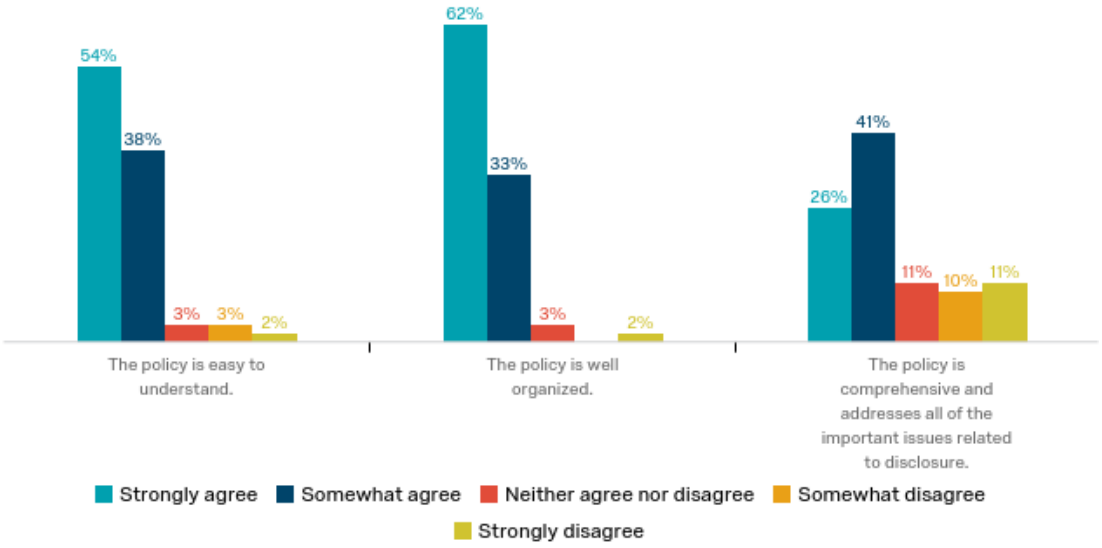
Do you think there are specific instances where an apology should be required? If so, please include a brief description. (Optional) (n = 36)

- Many members of the public thought an apology should always be required if an error occurred. Several of these respondents highlighted the need for the apology to be sincere and genuine.
- Several physician respondents felt apologies are warranted in cases where harm was caused through physician error, if the incident was avoidable, or when there is an intention to treat in the face of known risks that the physician knew were destined to fail or harm the patient.
- One physician respondent indicated that an apology does not have to mean the physician is assuming full responsibility for the event, while another felt apologies should be worded as an acknowledgement and shared human experience and not as a blame assignment.
- One physician questioned whether the term "apology" is appropriate because it implies personal fault and suggested that an explanation of the events and/or an acknowledgement that a harmful incident took place would be suitable in many situations.

The following questions were only posed to respondents who indicated that they read the draft *Disclosure of Harm* policy:

Q16: We'd like to understand whether the draft policy is clear and comprehensive.

Please indicate the extent to which you agree or disagree with the following: (n = 61)



Q17: How can we improve the draft policy's clarity? Please feel free to elaborate on your answers above or touch on other issues relating to clarity. (Optional) (n = 26)

- Several respondents requested additional examples and wording around apologies.
- One member of the public noted the draft policy omitted the consequences of a physician failing to disclose or not doing so in a comprehensive and timely way. Another member of the public felt it was the responsibility of the physician to disclose instances to patients in writing.
- Other suggestions included addressing legal implications or complications of disclosure; providing additional support to disclosing physicians, particularly undergraduate and graduate learners; and acknowledging the role of systems-level gaps that can cause harm.

Q18: How can the draft policy be made more comprehensive? (Optional) (n = 18)

- Several respondents felt physicians should be required to provide disclosure in writing and some members of the public suggested including the consequences for not following the policy.
- Other suggestions from respondents included:
    - Include specific responsibilities for physicians in management or oversight positions to ensure proper disclosure has taken place (i.e. accurate; timely; and fully understood);
    - Potential known or likely harms from treatment should be disclosed to the patient ahead of time as part of the informed consent process; and
    - Include options for rare circumstances where disclosure of harm or no-harm incidents would cause greater harm than not disclosing (e.g. violent or self-harming patients).

The following questions were only posed to respondents who indicated that they read the draft *Advice to the Profession* document:

Q19: Are there issues or topics you think the draft *Advice to the Profession* document should address further? (Optional) (n = 22)

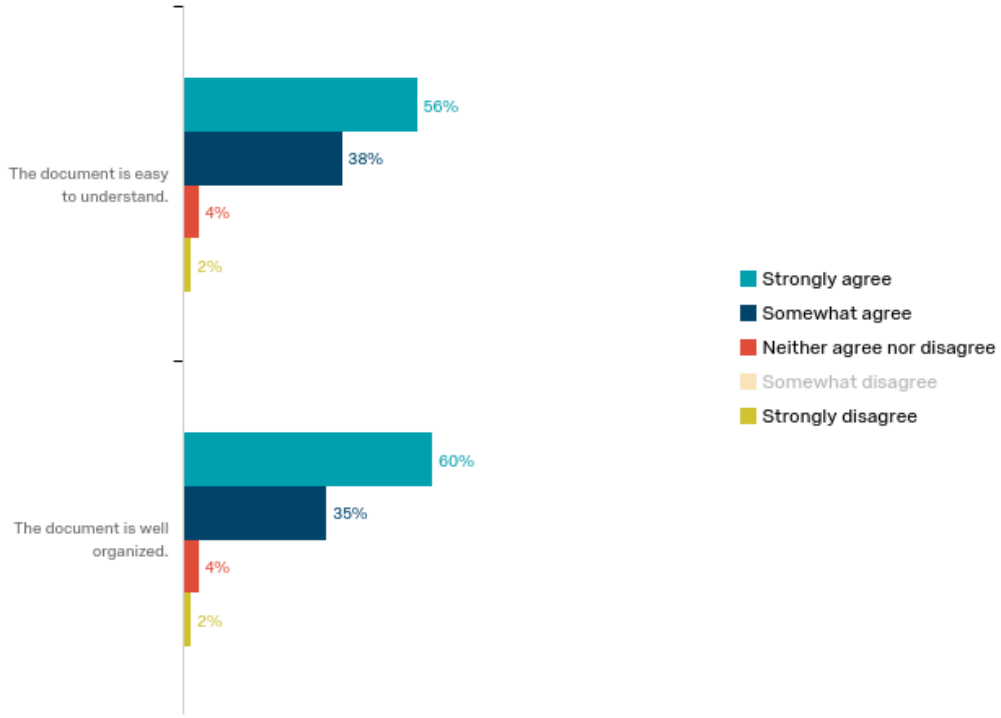
- Some respondents felt the policy should include a section on legal implications or consequences.
- Issues raised by physician respondents included: procedure or surgical incidents; quality improvement processes; obligations of physicians in supervisory roles; and case examples.
- Suggestions from other respondents included: apology and explanation to the patient should be mandatory; provide disclosure in writing or in a way that patients can comprehend; address preventative information in a timely manner; include information around postgraduate learners.

Q20: Is there any information in the draft *Advice to the Profession* document that you think is unhelpful or unnecessary? (Optional) (n = 14)

- Many respondents did not feel any of the information was unhelpful or unnecessary.
- One physician respondent did not believe near misses need to be disclosed while another was unsure if all no-harm incidents should be reported to the patient, especially if there is no current or future clinical impact.

Q21: We'd like to understand whether the draft document is clear.

Please indicate the extent to which you agree or disagree with the following: (n = 55)



The following question was posed to all respondents:

Q22: If you have any additional comments that you have not yet provided on either the draft policy or advice to the profession document, please provide them below: (Optional) (n = 11)

- One physician respondent believed reporting all no-harm incidents to patients would increase bureaucracy and does not serve a useful purpose and felt tracking, reviewing, and acting on all no-harm incidents is more important than disclosure.
- One health care professional respondent felt disclosure to other relevant parties (e.g. within an institution or office practice) should be mandated to ensure corrective actions are undertaken.
- One member of the public felt that if follow-up is needed after disclosure, it would be transparent to offer the patient more information at a later date if the patient is interested.