



National Association of Pharmacy Regulatory Authorities [®]
Association nationale des organismes de réglementation de la pharmacie

Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals



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Pharmacy Professionals

Approved by the National Association of Pharmacy Regulatory Authorities' (NAPRA) Board of Directors May 2021, published July 2021.

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Introduction

Background

Medication incident reporting has long been a recommended part of the practice of pharmacy in Canada to protect patients' health and well-being. In recent years, it has been a priority of provincial/territorial pharmacy regulatory authorities (PRAs) to move towards implementing mandatory reporting programs. These programs improve the ability to analyze and learn from medication incidents and near misses, so that pharmacy professionals may continually improve the quality of pharmacy practice to prevent and mitigate risks to patients.

As part of the National Association of Pharmacy Regulatory Authority's (NAPRA's) 2019–2023 Strategic Plan, the need for the development of national standards of practice for reporting, analyzing, preventing, and learning from medication-related incidents was identified. As many of the stakeholders involved in medication incident reporting are national in scope, it was felt that national standards of practice would help to facilitate continuous quality improvement and medication incident reporting across Canada and would improve the ability to share learnings across the country. Sharing learnings across the country will increase the richness and volume of the data available to improve pharmacy practice in the best interest of the Canadian public.

NAPRA formed a working group consisting of PRA representatives and practising pharmacy professionals with expertise in medication incident reporting in their respective jurisdictions. An environmental scan was conducted, including a review of the literature on medication incident reporting and quality improvement in pharmacy practice and existing national and international standards. A draft document was then developed and revised through a series of consultations with NAPRA's membership, as well as key stakeholders related to medication incident reporting. The final document was approved by the NAPRA Board of Directors in May 2021.

Objective

This document has been developed by NAPRA as a supplement to the model standards of practice for Canadian pharmacists and pharmacy technicians. The objective is to promote patient safety in Canada through reporting and learning from medication incidents and near misses, in accordance with federal/provincial/territorial requirements.

As with all NAPRA documents, these supplemental standards of practice serve as a model, which can be adopted or adapted for implementation as seen fit by the PRA in each province/territory, based on the needs in that jurisdiction. Once these standards are implemented by the PRA in a particular jurisdiction, pharmacy professionals will be expected to follow them in the development of their pharmacy's continuous quality improvement processes and in the event of a medication incident or near miss. These standards represent the minimum expected standards of practice for continuous quality improvement and medication incident reporting. Other practices may be acceptable, but only if the pharmacy manager and/or pharmacy professional is able to demonstrate their equivalency or superiority to the practices outlined herein to the PRA in their jurisdiction.

Introduction

These standards are based on the principles of a culture of patient safety and a just culture within the pharmacy practice environment, wherein learning is promoted through reporting without fear of punitive action. It is important to note that the goal of these standards of practice, and of medication incident reporting in general, is to promote continuous quality improvement processes that contribute to patient safety and enhance patient trust in the safety of pharmacy practice. Continuous quality improvement and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care.

The data gathered from medication incident reporting is not used to trigger disciplinary or punitive action, but rather is used to promote continuous learning and quality improvement that enhance patient safety. The need to share anonymous data with a national and/or provincial database is important, as this will facilitate the sharing of learnings from medication incident reporting across the country. It is important to note that data submitted to a PRA through the medication incident reporting system, in jurisdictions where this is required, will not include any information that could be used to identify the patient, the individual who completed and/or submitted the report, nor any pharmacy personnel involved in the incident or near miss.

The goal of these standards of practice, and of medication incident reporting in general, is to promote continuous quality improvement processes that contribute to patient safety and enhance patient trust in the safety of pharmacy practice.

Glossary

Anonymized reports

Reports that do not include any information that could be used to identify the individual who completed and/or submitted the report, nor any pharmacy personnel involved in the incident or near miss, in accordance with federal and/or provincial/territorial privacy laws.

Contributing factor¹

A circumstance, action or influence that is thought to have played a part in the origin or development of an incident or near miss, or to increase the risk of an incident or near miss.

Culture of patient safety²

A component of organizational culture, which includes the shared beliefs, attitudes, values, norms and behavioural characteristics of employees, and influences staff member attitudes and behaviours in relation to their organization's ongoing patient safety performance. An enabling patient safety culture is characterized by leadership that leads by example, transparent communication, psychological safety facilitating reporting of errors, patient and family engagement, and a commitment to ongoing improvement.

De-identified report

A report that does not include any information that could be used to identify patients, in accordance with federal and/or provincial/territorial privacy laws.

Just culture³

The environment of a workplace in which consideration is given to wider systemic issues when things go wrong, enabling professionals and those operating the system to learn without fear of retribution. To encourage reporting of safety issues, inadvertent human error, freely admitted, is generally not subject to sanction. However, people are held to account where there is evidence of unprofessional conduct or deliberate acts.

Medication incident⁴

Any preventable event that may cause or lead to inappropriate medication use or patient harm that has reached the patient. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

National database

A repository of medication incident and near miss reporting data submitted from across Canada. The data contained in a national database is de-identified and anonymized.

Near miss⁵

An event that could have resulted in unwanted consequences but did not because, either by chance or through timely intervention, the event did not reach the patient.

1 Definition derived from the Canadian Patient Safety Institute's glossary (Canadian Patient Safety Institute n.d.).

2 Definition obtained from Royal College of Physicians and Surgeons of Canada (n.d.).

3 Definition derived from National Health Service (2018).

4 Definition derived from Institute for Safe Medication Practices Canada (n.d.).

5 Definition obtained from Institute for Safe Medication Practices Canada (n.d.).

Glossary

Peer support⁶

Emotional and practical support between two people who share a common experience, such as a mental health challenge or illness.

Pharmacy manager

The pharmacy professional recognized as being in charge of the operations of a specific pharmacy and who is held accountable by the pharmacy regulatory authority for the operations of that pharmacy.

Pharmacy professional

A person authorized to practise as a pharmacist or pharmacy technician by the pharmacy regulatory authority in one of the provinces or territories of Canada. This term includes pharmacy managers. For the purposes of this document, a pharmacy manager would be expected to meet the standards of practice for pharmacy professionals in addition to the standards for pharmacy managers.

Provincial database

A repository of medication incident and near miss reporting data submitted from across a particular province. The data contained in a provincial database is de-identified and anonymized.

Reporting platform

The computer software used by pharmacy professionals for recording medication incidents and near misses at the pharmacy level and reporting them to a national and/or provincial database.

Root cause⁷

The most fundamental reason (or one of several fundamental reasons) a suspected failure, a medication incident, a near miss, or a situation in which performance does not meet expectations has occurred.

Root-cause analysis⁸

An objective analytical process that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans. (Similar term: incident analysis⁹)

Safety self-assessment

A process used by pharmacy professionals to proactively identify potential safety concerns. Regular use of this process may help decrease the number of medication incidents and near misses and identify opportunities for improvement at a pharmacy in order to mitigate risks to patients. The frequency of use may vary depending on province, territory, or organization.

6 Definition obtained from Canadian Mental Health Association (2018).

7 Definition derived from Joint Commission (2015).

8 Definition derived from Institute for Safe Medication Practices Canada (n.d.).

9 The term incident analysis is used in the [Canadian Incident Analysis Framework](#) (Canadian Patient Safety Institute 2012).

Standards of practice for pharmacy professionals

1. Pharmacy manager standards

The pharmacy manager ensures safe care for their patients through oversight of the continuous quality improvement processes within their pharmacy team and ensuring the competent management of medication incidents and near misses.

1.1 Continuous quality improvement

- 1.1.1 The pharmacy manager works with owners, employers, and pharmacy personnel to foster a culture of patient safety and a just culture in the workplace environment in order to promote learning and quality improvement that supports patient safety.
- 1.1.2 The pharmacy manager ensures that pharmacy-specific policies and procedures for continuous quality improvement are developed, documented, and implemented and include the processes for:
 - 1.1.2.1 Identifying root causes and contributing factors for medication incidents and near misses and performing a root-cause analysis as appropriate
 - 1.1.2.2 Reviewing and assessing summary reports and analyses of pharmacy-specific data
 - 1.1.2.3 Reviewing and assessing objective analyses from regional-, provincial/territorial-, and/or national-level data
 - 1.1.2.4 Holding routine¹⁰ team meetings to discuss summary reports and analyses and determine how to address them
 - 1.1.2.5 Completing a safety self-assessment on a routine¹⁰ basis

¹⁰ Note: Routine team meetings and safety self-assessments should be held/completed as often as necessary to address issues identified by the pharmacy. The minimum frequency of routine team meetings and safety self-assessments will depend on the requirements set by the PRA in each province and territory.

Standards of practice for pharmacy professionals

- 1.1.3 The pharmacy manager ensures that a continuous quality improvement program for the pharmacy is developed, documented and implemented and includes the processes for:
 - 1.1.3.1 Following up with team members involved in medication incidents and near misses and encouraging them to seek peer support when appropriate
 - 1.1.3.2 Ensuring that pharmacy policies and procedures are reviewed and updated based on the pharmacy's root-cause analyses, safety self-assessments, summary reports and analyses, and objective analyses from regional-, provincial/territorial-, and national-level data
 - 1.1.3.3 Implementing improvements to the pharmacy's procedures in accordance with the pharmacy's continuous quality improvement plan
 - 1.1.3.4 Developing a monitoring process to determine the efficacy of implemented improvements to the pharmacy's procedures
 - 1.1.3.5 Implementing further updates to the pharmacy's procedures if previous improvements are not effective

1.2 Management of medication incidents and near misses

- 1.2.1 The pharmacy manager ensures that pharmacy-specific policies and procedures are developed, documented, and implemented that clearly outline the steps that pharmacy personnel must take when a medication incident or near miss occurs, including the steps for disclosure.
- 1.2.2 The pharmacy manager ensures that a pharmacy-specific policy is developed, documented, and implemented that clearly outlines the pharmacy's criteria for determining whether a near miss must be reported to a national/provincial database.¹¹
- 1.2.3 The pharmacy manager works with owners and employers to ensure that appropriate resources are in place to enable pharmacy personnel to devote time to continuous quality improvement and reporting activities.

¹¹ Note: The pharmacy manager should align the pharmacy's criteria with the guidance provided by the PRA in their jurisdiction. In provinces and territories where the PRA defers the decision on when to report near misses to the pharmacy manager, they may refer to Appendix A for sample criteria that can be used to determine whether a near miss should be reported.

Standards of practice for pharmacy professionals

- 1.2.4 The pharmacy manager works with owners and employers to select a reporting platform that:
 - 1.2.4.1 Has processes in place to de-identify patient information and anonymize data, ensuring there are no patient or pharmacy personnel identifiers once data leaves the platform;
 - 1.2.4.2 Is able to integrate with a national/provincial database to share anonymous and de-identified medication incident and near miss reports; and
 - 1.2.4.3 Is able to integrate with the systems in place to share anonymous and de-identified data with the PRA, when required in that jurisdiction.



Standards of practice for pharmacy professionals

2. Pharmacy professional standards

Pharmacy professionals ensure safe care for their patients by committing to continuous quality improvement and appropriate handling of medication incidents and near misses.

2.1 Continuous quality improvement

2.1.1 Pharmacy professionals must incorporate continuous quality improvement within their practice, including:

2.1.1.1 Contributing to a culture of patient safety and a just culture in the workplace environment

2.1.1.2 Familiarizing themselves with the pharmacy's policies and procedures for continuous quality improvement

2.1.1.3 Engaging in determining root causes and contributing factors for medication incidents and near misses and in performing a root-cause analysis as appropriate according to the pharmacy's policies and procedures¹²

2.1.1.4 Engaging in team meetings to discuss summary reports and analyses of pharmacy-specific, regional-level, and national-level data

2.1.1.5 Engaging in the pharmacy's safety self-assessment process

2.1.1.6 Engaging in reviewing and updating the pharmacy's policies and procedures in response to the pharmacy's root-cause analyses, safety self-assessments, and summary reports and analyses

2.1.1.7 Implementing procedural improvements established by the pharmacy manager

¹² See Appendix B for levels of harm.

Standards of practice for pharmacy professionals

2.2 Handling medication incidents and near misses

- 2.2.1 Pharmacy professionals handle medication incidents openly and transparently according to the established policies and procedures of the pharmacy, including:
 - 2.2.1.1 Disclosing the incident to the patient or patient's agent and other health professionals involved in the patient's circle of care, in accordance with a patient-centred approach and provincial/territorial or national disclosure guidelines
 - 2.2.1.2 Following up with the patient or patient's agent to monitor for effects of the incident on the patient¹³
 - 2.2.1.3 Sharing information about the incident and follow-up plan with other health professionals involved in the patient's circle of care as appropriate
 - 2.2.1.4 Documenting the incident and follow-up plan and submitting a report to a national/provincial database using the pharmacy's reporting platform
 - 2.2.1.5 When appropriate, sharing information with the patient or patient's agent about how the pharmacy will improve and how the pharmacy will share learnings to prevent recurrence
- 2.2.2 Pharmacy professionals handle near misses according to the established policies and procedures of the pharmacy, including:
 - 2.2.2.1 Documenting the near miss using the pharmacy's reporting platform
 - 2.2.2.2 Determining if the near miss must be reported to a national/provincial database according to the pharmacy's policies and procedures¹⁴
 - 2.2.2.3 When required, submitting a report of the near miss to a national/provincial database using the pharmacy's reporting platform

¹³ Note: May be outside of the pharmacy technician scope of practice in some jurisdictions.

¹⁴ See 1.2.2.

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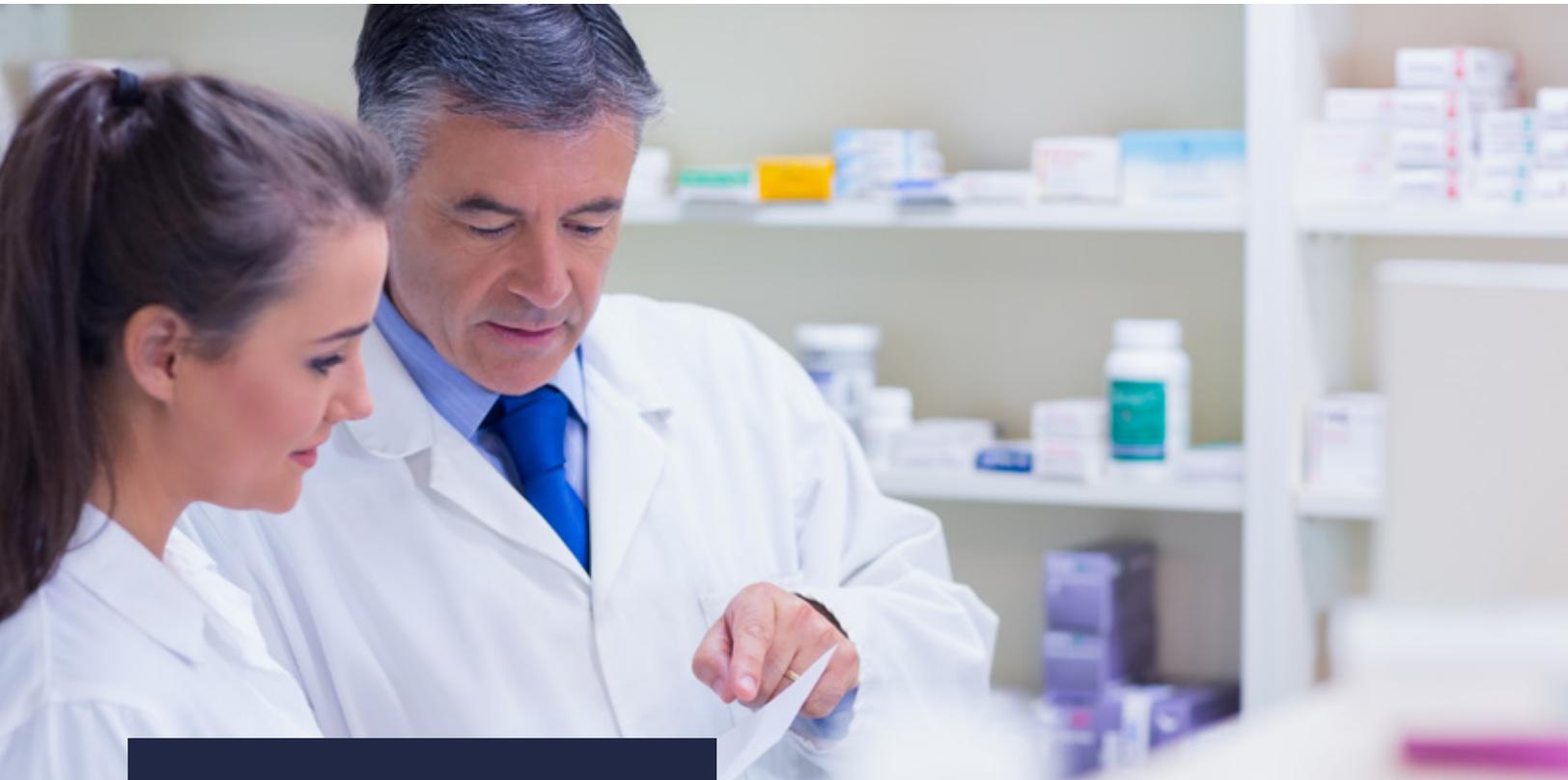
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Appendix A: Sample criteria for defining a reportable near miss

The following list is a sample of criteria that may be used to determine whether a near miss should be reported to a national/provincial database:

- Were it to reach the patient, the near miss may cause harm.
- The near miss has been a recurrent issue in the pharmacy.
- The near miss provides a learning opportunity for the particular pharmacy or for pharmacy practice in general.
- Reporting the near miss aligns with the guidance set out by the PRA in that province/territory.



Appendix B: Levels of harm

No harm (medication dispensed)

No symptoms detected; no treatment required

Mild harm

Symptoms were mild, temporary, and short term; no treatment or minor treatment was required

Moderate harm

Symptoms required additional treatment or an operation; the incident kept the patient in hospital longer than expected; or caused permanent harm or loss of function

Severe harm

Symptoms required major treatment to save the patient's life; the incident shortened life expectancy; or caused major permanent or long-term harm

Death

There is reason to believe that the incident caused the patient's death or hastened the patient's death



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