Newfoundland and Labrador Pharmacy Board

Standards of Practice

Continuous Quality Improvement and Medication Incident Reporting in Community Pharmacies

August 2023

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Introduction

Section 1.3 of the NLPB *Standards of Pharmacy Operation for Community Pharmacy* refers to the requirement for pharmacies to have a program in place that ensures continuous quality improvement (CQI). These standards describe the minimum acceptable standards for this program and are intended to promote consistency in this area throughout the province.

These standards are based on *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals* developed by the National Association of Pharmacy Regulatory Authorities in response to an identified need for consistent national standards of practice for reporting, analyzing, preventing, and learning from medication-related incidents. They are centred on the principles of a culture of patient safety and ensuring a just culture within the pharmacy practice environment, wherein learning is promoted through reporting without fear of punitive action. CQI 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 anonymized 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 across the country.

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

In this document,

- "Anonymized report" means a report that does 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.
- "Continuous quality improvement (CQI)" refers to the structured processes used within the pharmacy which allows for continual review and improvement of all aspects of the medication dispensing process, to improve patient safety.
- "Contributing factor" means 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.
- "Critical incident" means an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.
- "Culture of patient safety" means 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" means 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.
- "Incident analysis" (also known as "root-cause analysis") means an objective analytical process that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the contributing factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness and feasibility of the plans.

- "Just culture" means 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 incident" means 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.
- "MedSTEP NL" is the standardized CQI and medication incident reporting program approved by the NLPB board for community pharmacies and includes elements of reporting, analyzing, documenting and shared learning from medication incidents and near-miss events with the objective to continuously review and improve the quality and safety of pharmacy practice in the province.
- "National database" means the National Incident Data Repository (NIDR) for Community Pharmacies, a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). The NIDR is a repository of medication incident and near-miss reporting data submitted from across Canada. The data contained in the national database is de-identified and anonymized and can provide provincial reporting.
- "Near-miss" means 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.
- "Peer support" means emotional and practical support between two people who share a common experience, such as a mental health challenge or illness.
- "Pharmacy professional" means a person registered to practice as a pharmacist or pharmacy technician in Newfoundland and Labrador. This term includes pharmacists-in-charge. For the purposes of this document, a pharmacist-in-charge would be expected to meet the standards of practice for pharmacy professionals in addition to the standards for pharmacists-in-charge.
- "Reporting platform" means the computer software used by pharmacy professionals for recording medication incidents and near misses at the pharmacy level and reporting them to the national database.
- "Safety self-assessment (SSA)" means 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 to mitigate risks to patients.

1) General Standards

1.1. Policy and Procedure Manual

The pharmacy must have a well-organized and easily accessible policy and procedure manual specific to the CQI program that all pharmacy staff are aware of and familiar with. The pharmacist-in-charge is expected to ensure that the manual is regularly reviewed and updated as required. At a minimum, this manual should include information related to:

a) processes for addressing, reporting, investigating, documenting, disclosing, and learning from medication incidents and near-miss events;

b) processes for identifying contributing factors for medication incidents and near-miss events and performing an incident analysis, as appropriate;

c) the expectations for reviewing and assessing summary reports and analyses of pharmacy-specific data;

d) the expectations for reviewing and assessing objective analyses of shared learnings from the national database;

e) the schedule for routine CQI pharmacy staff meetings; and

f) the schedule and process for completing a safety self-assessment (SSA).

By definition, policies are clear statements that guide processes, procedures, and decision-making related to the CQI program. Procedures describe how each policy will be put into action in the pharmacy. For example, procedures should outline:

- who will do what;
- what steps they need to take;
- when (or how often) the steps need to be completed;
- which forms or documents to use; and
- how documentation is retained.

1.2. Expectations of the Pharmacist-in-Charge

Pharmacists-in-charge are expected to:

a) ensure that a CQI program is developed, documented, and implemented in the pharmacy, and that the requirements of the MedSTEP NL program are met;

b) ensure all dispensary staff are trained in, and are required to comply with, systems, policies, and procedures related to the pharmacy's CQI program as well as the MedSTEP NL program; and

c) implement a CQI plan that includes:

   i) reviewing and making improvements to the pharmacy's policies and procedures based on the incident analyses, SSAs, summary reports and analyses, and objective analyses from regional-, provincial-, or national-level data;

   ii) developing monitoring processes to determine the efficacy of implemented improvements to the pharmacy's policies and procedures; and

   iii) implementing further updates to the pharmacy's policies and procedures if previous improvements are not effective.

1.3. Expectations of Pharmacy Professionals

Pharmacy professionals are expected to incorporate CQI within their practice, including:

a) contributing to a culture of patient safety and a just culture in the workplace environment;

b) familiarizing themselves with and following the pharmacy's CQI-related policies and procedures;

c) engaging in determining contributing factors for medication incidents and near-miss events and in performing incident analyses as appropriate according to the pharmacy's policies and procedures;

d) engaging in pharmacy staff meetings to discuss summary reports and analyses of pharmacy-specific data, and shared learning from the national database;

e) engaging in the pharmacy's SSA process;

f) engaging in reviewing and updating the pharmacy's policies and procedures in response to the pharmacy's incident analyses, SSAs, and summary reports and analyses; and

g) implementing procedural improvements established by the pharmacist-in-charge.

2) Incident Discovery and Handling

2.1. Expectations of the Pharmacist-in-Charge

The pharmacist-in-charge must ensure that pharmacy-specific policies and procedures clearly outline the steps that pharmacy staff must take when a medication incident or near-miss event occurs.

2.2. Expectations of Pharmacy Professionals

a) If a non-pharmacist staff member discovers or is made aware of a medication incident or near-miss event, they must immediately notify a pharmacist staff member or the pharmacist-in-charge.

b) If a pharmacist discovers or is made aware of a medication incident, they must:
   i) determine if the patient has experienced harm or is at risk of possible harm;
   ii) acknowledge that a medication incident has occurred and apologize for the distress the incident has caused the patient;
   iii) listen to the patient, express empathy, and concern, do not minimize what happened;
   iv) provide care for the patient to the best of their ability to protect their health and safety;
   v) ensure the patient receives the appropriate medication or consultation in a timely manner;
   vi) take reasonable steps to ensure that the inappropriate medication is quarantined and/or returned to the pharmacy to avoid risk of harm or further harm, if relevant;
   vii) inform the patient that:
      - the medication incident will be reported to the pharmacist-in-charge;
      - the medication incident will be anonymously reported to the national database to allow other pharmacies to learn from the incident; and
      - an investigation will take place, and that, based on the outcome of the investigation, changes to systems and processes may be implemented to minimize the recurrence of a similar incident in the future;
   viii) notify the pharmacist-in-charge of the medication incident;
   ix) notify the prescriber and any other personnel deemed necessary about the medication incident;
   x) document the incident and follow-up plan in the pharmacy; and
   xi) submit a report to the national database using the pharmacy's reporting platform in accordance with established policies and procedures.

c) If a pharmacist discovers or is made aware of a near-miss event, they must follow established policies and procedures related to the documentation and reporting of near miss events including:
   i) documenting the near miss using the pharmacy's reporting platform;
   ii) determining if the near miss must be reported to the national database according to the pharmacy's policies and procedures; and
   iii) when required, submitting a report of the near miss to the national database using the pharmacy's reporting platform.

3) Investigation and Communication

3.1. Expectations of the Pharmacist-in-Charge

If notified that a medication incident has occurred, the pharmacist-in-charge must:

a) ensure that the appropriate processes have been followed as described in section 2.2;

b) communicate with the patient to ensure they are kept informed as new information develops including any changes to systems or processes that have been implemented after analysis of the medication incident;

c) communicate with pharmacy staff members involved in the incident, ensuring they have access to peer or other support as needed;

d) ensure that the investigation of the contributing factors associated with the medication incident is done using a systematic process in a transparent and timely manner, engaging pharmacy staff members as appropriate;

e) ensure that any necessary changes to systems or processes are developed and implemented to minimize recurrence of the medication incident or near miss event; and

f) ensure that findings from the investigation and necessary changes to policies and/or procedures are shared with pharmacy staff and reflected in the policy and procedure manual as appropriate.

4) Documentation and Reporting

4.1. Expectations of the Pharmacist-in-Charge

The pharmacist-in-charge must:

a) collaborate with the pharmacy owner to select a reporting platform that:
   i) 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;
   ii) can submit to the national database to share anonymous and de-identified medication incident and near miss reports; and

b) ensure that pharmacy-specific policies and procedures clearly outline the steps that pharmacy staff must take regarding the documentation and reporting of medication incidents and near-miss events, including:
   i) the expectations for what information related to medication incidents and near-miss events is to be documented and retained onsite;
   ii) the requirement for medication incidents to be promptly and anonymously reported to the national database using the pharmacy's reporting platform; and
   iii) the pharmacy's criteria for determining when a near-miss event is to be reported to the national database.

c) ensure the following documentation is retained in the pharmacy and available for audit, including:
   i) all communications with patients and prescribers regarding medication incidents or near-miss events (this is not limited to the information that is reported to the medication incident reporting platform);
   ii) all CQI improvement plans and outcomes, developed following a medication incident or near-miss event;
   iii) all CQI improvement plans and outcomes, developed following completion of an SSA; and
   iv) documentation from formal CQI meetings with pharmacy staff including date, staff members present, topics of discussion and shared learning.

5) Assessment and Prevention

5.1. Expectations of the Pharmacist-in-Charge

The pharmacist-in-charge must ensure that:

a) a pharmacy-specific SSA is completed:
   i) for an existing pharmacy - during the first year of the MedSTEP NL program, and at least every two years thereafter;

ii) for a new pharmacy - within the first year of operation, and at least every two years thereafter;

iii) within six months following a change in the pharmacy's pharmacist-in-charge. In these cases, the outgoing pharmacist-in-charge should share the most recent SSA with the new pharmacist-in-charge.

b) formal CQI meetings to educate on medication safety and encourage open dialogue are conducted with pharmacy staff at least every 6 months with informal huddles occurring as medication incidents or near-miss events occur;

c) there is a process in place for pharmacy staff to review and participate in the analysis of medication incidents and recurrent or potentially harmful near miss events to assist with the identification of contributing factors; and

d) both pharmacy-level data and national database shared learning are reviewed on a quarterly basis to look at trends or opportunities for improvement.