Supplemental Standard of Practice: Mandatory Standardized Medication Safety Program in Ontario Pharmacies

Purpose

To provide further clarity regarding practice expectations for pharmacy professionals in Ontario, in order to meet the Standards as outlined under Section 3 (Safety and Quality) of the National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards of Practice (for (pharmacists and pharmacy technicians).

Introduction

The aim of the Ontario College of Pharmacists' medication safety program is to improve patient safety through the identification of medication incident trends and workflow issues leading to medication incidents, in order to support Continuous Quality Improvement (CQI) in pharmacy practice. CQI involves an ongoing and systematic examination of an organization's work processes to identify and address the root causes of quality issues and implement corresponding changes.[1] Effective CQI programs involve implementation of quality improvements resulting from both proactive review of work processes to identify areas of risk, and retrospective review of specific medication incidents. The objective of CQI is to ensure that all pharmacy professionals learn from medication incidents, and review and enhance their policies and procedures to reduce the chances of recurrence, thereby improving patient safety.

To achieve safer care for patients, CQI must focus on both system improvements as well as the tasks that individual practitioners perform. The medication safety program is based on a CQI approach. It supports shared accountability and holds pharmacy owners and managers accountable for creating a work culture that supports staff in engaging in CQI and holds pharmacy professionals accountable for the quality of their choices. To enable a culture that supports learning and accountability over blame and punishment, individuals must be comfortable to discuss medication incidents without fear of punitive outcomes.

A critical element in safe medication practices is the sharing of lessons learned from medication incidents through recording of medication incidents and near misses, to support sustainable changes in practice. The lessons learned from both medication incidents and near misses enable continuous process improvements to minimize future incidents and maximize health outcomes to improve the quality of care provided in pharmacies.

[1] Boyle TA, Bishop AC, Duggan K, Reid C, Mahaffey T, MacKinnon NJ, et al. Keeping the "continuous" in continuous quality improvement: Exploring perceived outcomes of CQI program use in community pharmacy. *Res Social Adm Pharm* 2014 Jan-Feb; 10(1): 45-57.

Supplemental Standard of Practice (sSOP)

An effective standardized medication safety program for pharmacies must address both medication incidents that reach the patient, as well as near misses intercepted prior to dispensing. Pharmacy professionals must meet all of the following *requirements* of the Mandatory Medication Safety Program, and pharmacies must enable and support pharmacy professionals in meeting these requirements:

Report

- A*nonymous* recording of all medication incidents and near misses by pharmacy professionals to a specified independent, objective third-party organization to support quality improvement within the pharmacy, and for population of an aggregate incident database to facilitate *anonymous* reporting that will identify issues and incident trends to support shared learnings.

Document

- Documentation of appropriate details of medication incidents and near misses in a timely manner to support the accurateness of information reported.
- Documentation of CQI plans and outcomes of staff communications and quality improvements implemented.

Analyze

- Analysis of incidents and near misses in a timely manner for causal factors and implementing appropriate steps to minimize the likelihood of recurrence of the incident.
- Completion of a pharmacy safety self-assessment (PSSA) within the first year of implementation of the Standard, then at least every 2-3 years. The Designated Manager may determine a PSSA is required more frequently if a significant change occurs in the pharmacy.
- Analysis of individual and aggregate data to inform the development of quality improvement initiatives.

Share Learning

- Prompt communication of appropriate details of a medication incident or near miss to all pharmacy staff, including causal factors and actions taken to reduce the likelihood of recurrence.
- Regular scheduling of CQI communication with pharmacy staff to educate pharmacy team members on medication safety, encourage open dialogue on medication incidents, and complete a PSSA (when required).
- Development and monitoring of CQI plans, outcomes of CQI communications and quality improvements implemented.

Responsibilities of Pharmacy Professionals in Meeting the sSOP

Pharmacy professionals must practice in accordance with all of the *requirements* of the medication safety program, as outlined above.

According to the Standards of Practice, all pharmacists and pharmacy technicians have the responsibility and obligation to manage medication incidents and address unsafe practices. This includes documenting and communicating all medication incidents and near misses with the entire pharmacy staff, and as appropriate to the patient and other health care providers (e.g. if the incident reaches the patient).

There is an expectation that pharmacy professionals will record medication incidents and near misses, and engage in continuous quality improvement planning and initiatives to improve system vulnerabilities.

Responsibility of Pharmacy Owners and Designated Managers (DMs) in Meeting the sSOP

Pharmacy owners and DMs must enable a culture that supports learning and accountability over blame and punishment, and encourages individuals to discuss medication incidents without fear of punitive outcomes. It is an expectation that all pharmacy operations are conducted in a manner that supports the aim of the medication safety program (as outlined in the introduction), and the *requirements* outlined in the sSOP that were designed to enable pharmacy professionals to meet this goal.

It is the responsibility of pharmacy owners and DMs to ensure that the work environment is conducive to, and incorporates, the appropriate process and procedures to support pharmacy professionals in meeting the *requirements* of the Medication Safety Program. This includes ensuring that pharmacy staff are able to *anonymously* record medication incidents, and have implemented processes to continually document, identify, and apply learnings from medication incidents to improve workflow within the pharmacy.