OHA Submission to the Ontario College of Pharmacists: Implementation of Continuous Quality Assurance for Medication Safety

The Ontario Hospital Association (OHA), on behalf of its member hospitals, is pleased to provide feedback to the Ontario College of Pharmacists (OCP) on its proposed continuous quality assurance (CQA) program for pharmacies, which includes reporting anonymous medication incident data to a third party. The OHA understands that the proposed CQA program standard would apply to all pharmacies in Ontario (e.g., hospital, community). While we appreciate the intent underlying the new standard, we are concerned that new additional reporting requirements may create confusion, duplicate efforts and decrease the impact of existing incident reporting systems.

1. Current Mandatory Reporting to External Bodies

The OCP is proposing to "enable and require anonymous reporting of all medication incidents by pharmacy professionals to an external, independent third-party organization".

Hospitals already report to a number of external organizations to support system learning:

- Ontario hospitals are currently required to report critical incidents relating to medication IV/fluids to the Canadian Institute for Health Information's (CIHI) National System for Incident Reporting.
- Further to the recent *Quality of Care Information Protection Act* (QCIPA) Review recommendations, Health Quality Ontario (HQO) is developing a patient safety learning system that will enable hospitals to report and share recommendations and learnings from their incident reviews, including those relating to medication safety incidents.
- Pharmacy professionals also report to the MedEffect Canada database, Canada Vigilance Program) and provide input into Health Canada's work pertaining to the reporting of adverse drug reactions (Vanessa's Law).

Where a system for reporting exists, as with hospital pharmacies, we recommend that the OCP leverage and consider voluntary reporting into the OCP's system (i.e., at the discretion of the pharmacy professional). Where such systems do not currently exist for incident reporting, such as community pharmacies, making a system available and taking this approach is reasonable.

We believe that there is an opportunity for system partners, including HQO, the OCP, CIHI, and the Institute for Safe Medication Practices (ISMP), to come together to identify a streamlined process, rather than have organizations/providers report to multiple bodies.

Recommendation:

- The OHA recommends the OCP standard complement existing external incident reporting systems, where these are already in place (e.g., hospitals), and not duplicate existing reporting requirements.

2. Hospital Programs to Report and Analyze Incidents

All Ontario public hospitals currently have comprehensive systems in place that would meet the OCP's proposed CQA program. Every hospital has internal processes for flagging incidents that trigger different types of reviews. Some may be completed by the department/unit, others by the program/service, and others may be at the organizational- or multi-organizational level.

A medication-related incident may occur at different points in the course of care, for example, when prescribing, transcribing, dispensing, or administering, and may involve multiple healthcare professionals and factors (e.g., pertaining to the patient, treatment decisions, health care professionals, team, organizational processes). Hospital pharmacies are part of the broader organization, and reporting and reviewing incidents in order to prevent recurrence would take place at the hospital level. Hospitals aggregate incident data to report to operational quality and patient safety committees, along with board committees.

Hospitals have policies and procedures for healthcare professionals, staff, volunteers, etc. to report and notify individuals internally, and to determine any necessary follow-up processes involving the patient and their family, as well as staff involved. Where staff working in the hospital pharmacy become aware of a patient safety incident (e.g., medication incidents, faulty equipment, drug packaging issues), they are expected to report and document details into the hospital incident reporting system. Responses to the incident depend upon its classification (e.g., departmental review, full-scale organizational review) with recommendations for quality improvement and action taken to prevent recurrence considered.

Additionally, there are a number of statutes, regulations and accreditation standards that require hospitals to have comprehensive programs and systems in place for reporting, disclosing, reviewing, and taking action to reduce the risk of recurrence of patient safety incidents, including medication incidents. These include:

- The *Public Hospitals Act* (PHA) Regulation 965 outlines specific requirements for hospitals regarding the review and disclosure of critical incidents.[1] Hospitals must have a system to review every critical incident, as soon as is practicable after the critical incident occurs; and hospitals must develop a plan with systemic steps to avoid or reduce risk of further similar critical incidents. Additionally, the administrator must report aggregate critical incident data to the board quality committee at least twice annually, emphasizing the oversight role; and incident data be taken into consideration by the hospital when developing their annual Quality Improvement Plan (QIP). New amendments come into force on July 1, 2017 to further strengthen these reviews and enable hospitals to share their learnings as a system.

- Accreditation Canada outlines requirements related to patient safety incident disclosure and management process in the governance and leadership standards, as well as a specific Required Organizational Practices (ROP).[2] Tests for compliance require that the patient safety incident management system includes processes for reporting, analyzing, recommending actions, and monitoring improvements to support learning. As well, hospitals are expected to have a

[1] Requirement outlined for patient safety incidents that meet the legislative definition of critical incident as outlined in the *Public Hospitals Act* (PHA) Regulation 965. https://www.ontario.ca/laws/regulation/900965

[2] *Accreditation Canada – Required Organizational Practice Handbook.* https://www.accreditation.ca/rop-handbooks

documented process for reviewing patient safety incidents and established criteria to prioritize those that require further analysis.

Recommendation:

- The OHA recommends that where an organization already has a comprehensive program/system in place (e.g., hospital pharmacy as part of the hospital), the OCP acknowledge that these programs fulfill the OCP's requirements.

3. Clarification of the Terms

Should the OCP proceed with its own medication incident reporting system, it will be critical to align terminology and interpretation to avoid confusion and inconsistent data. The OCP is proposing the reporting of all "medication incident" data, which includes those that reach the patient, as well as near misses. The term "incident" is not defined by the OCP, and therefore, the OHA suggests further clarity on what this encompasses.

The OHA recommends alignment with established definitions of patient safety incidents, such as the Canadian Patient Safety Institute's (CPSI) definition of a patient safety incident: "an event or circumstance, which could have resulted, or did result in harm or an unintended outcome for the patient".[3] Further, the World Health Organization classifies a patient safety incident according to different categories: "near miss", "no harm", "mild harm", "moderate harm", "severe harm", or "death". Some patient safety incidents also meet the legislative definition of a "critical incident", as outlined in the *Public Hospitals Act* (PHA) Regulation 965.

As well, clarifying expectations based upon the specific pharmacy setting is important. Medication incidents in hospitals are very different than those in community pharmacy settings, and as such, the definition of an incident must consider type of setting.

Recommendation:

- The OHA recommends the OCP align any new terminology with provincial definitions and classifications for patient safety incidents, including considerations based on the specific pharmacy setting.

Conclusion

The OHA and our member hospitals are committed to working with the OCP, the Ministry and other key system stakeholders to advance quality and patient safety efforts. To this end, we would be pleased to discuss the proposed CQA model in greater detail and answer questions on the recommendations outlined above.

If you have any questions, please do not hesitate to contact Karen Sequeira, Senior Lead, Quality, Risk, and Patient Safety, at the OHA (email: ksequeira@oha.com).

[3] Canadian Patient Safety Institute's (CPSI). http://www.patientsafetyinstitute.ca/en/Topic/Pages/Patient-Safety-Incident.aspx