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The College of Pharmacists of Manitoba's mandate is to protect the health and well-being of the public by ensuring and promoting safe, patient-centred, and progressive pharmacy practice in collaboration with other health-care providers. One of the examples of how this mandate manifests itself is through Safety IQ, a standardized continuous quality improvement (CQI) program that will enable pharmacists in Manitoba to further increase patient safety and ensure better patient health outcomes. Its elements include reporting, analyzing, documenting, and sharing learning from medication incidents and near miss events to improve patient safety.

This guidance document is designed to be read alongside the Practice Direction on Medication Incidents and Discrepancies or Near-Miss Events.

How does Safety IQ work?

In September 2017, the College implemented a project called Safety Improvement in Quality (Safety IQ) with 20 participating community pharmacies across Manitoba. Participants in Safety IQ anonymously report medication incidents and near misses for analysis nationally and by their team, leading to suggestions for improvement. Through open discussion and sharing of medication errors, pharmacies can create a culture where patient safety is a mindset for all pharmacy staff.

On October 15, 2018, upon review of the assessment of the Safety IQ pilot by St. Francis Xavier University and recommendations of the College’s Quality Assurance Committee, Council has approved the implementation of Safety IQ within all community pharmacies in Manitoba. Council also directed that an Advisory Committee for Safety IQ be created to develop a plan for implementation, including considerations for different options for reporting technology providers, program requirements, training and education, and timelines for the provincial roll-out of Safety IQ.

This Advisory Committee has been meeting regularly to continue the process of implementation. Like any change in pharmacy practice, there are multiple layers of changes that must be made. Working in collaboration with the Standards of Practice and Quality Assurance committee, College Council, and other various stakeholders, the College hopes to begin implementation of the program in summer 2020.

Safety IQ consists of three fundamental tools to improve patient safety:

1. Anonymous reporting of medication incidents and near misses to a third party and national database to support shared learning within the pharmacy and with other pharmacies and healthcare professionals
2. Medication safety self-assessment, a proactive assessment of pharmacy processes to identify areas of improvement, which is done at the start of Safety IQ and then once every three years
3. Quality improvement meetings to review incidents among pharmacy staff and develop improvement plans as well as assess practice changes that have been implemented
A safety culture is the shared belief and the practice of healthcare providers that makes safety the first priority when providing care to patients. According to the US Institute of Medicine, “The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm.”

For community pharmacies, a safety culture optimizes learning from medication incidents and near misses to prevent future errors and improve patient safety.

Medication errors are rarely caused by a single event or the actions of a single person. Analysis of medication incidents and near-misses often reveals a system failure or environmental factors that must be changed to prevent medication incidents.

A safety culture encourages healthcare providers to be open about medication incidents and near-misses so they can be reported, analyzed, and changes in practice can be made. This will help prevent re-occurrences and the information can be shared with others.

Healthcare providers are still held accountable when errors are the result of neglect or incompetence, but these situations are rare. Healthcare providers and patients benefit from understanding why an error occurred and knowing that new safeguards have been put in place to prevent the error from happening again.

**Elements of Safety IQ**

**SHARE**
Pharmacies share learnings with their team during CQI meetings and huddles. The national database provides recommendations based on analysis from pharmacies across Canada.

**ANALYZE**
Using Safety IQ tools, pharmacies can analyze their medication incidents and learn from them. The information reported to the platform vendor as well as the national database is analyzed by their teams. The purpose of this analysis is to identify the possible causes of a near miss or medication incident and to find ways to prevent a similar error from happening in the future.

**DOCUMENT**
Detailed documentation and regular pharmacy team meetings ensure tracking and implementation of new or improved safety measures. In other words, a pharmacy team can figure out what works and what doesn’t in their continuous quality improvement program.

**REPORT**
Participating community pharmacies anonymously report medication incidents and near misses to a College-approved vendor.

**IMPROVE**
Safety IQ Program Requirements

Report

Community pharmacies anonymously report medication incidents and near misses to an independent external reporting platform provider to support quality improvement within the pharmacy. The platform provider then exports the anonymous and de-identified incident data to a National Incident Data Repository to allow for shared learning from incident data from across Canada.

Pharmacies provide information on the incident such as the date, type of incident, medication(s) involved, degree of harm and a description of the incident. Information on the contributing factors and actions and changes made in the pharmacy as a result of the incident can also be submitted. All this data provides for quantitative and qualitative analysis at a national level.

Analyze

Continuous Quality Improvement (CQI) is an ongoing approach to problem-solving and harm-prevention that focuses on identifying root causes of a problem and introducing ways to eliminate or reduce the problem.

In the pharmacy profession, CQI focuses on preventing medication incidents and continually looking for ways to improve medication dispensing, therapy management, and patient counseling. The Safety IQ approach to CQI combines proactive and reactive elements to improve patient safety.

Analysis should be undertaken with the goal of improvement rather than goal of identifying who is at fault. A complete analysis of medication incidents and near misses will often discover a chain of critical events that contributed to the incident. Changes to existing systems must be developed and implemented to minimize recurrent incidents or near misses.

Reactive Elements

Each individual pharmacy can analyze their own incident and near miss reports utilizing the tools within the reporting platform. When doing so, consider contributing factors and develop changes in systems or processes to prevent recurrence of errors.

Proactive Elements

Each participating pharmacy conducts a medication safety self-assessment at the start of Safety IQ and at least once every three years. The assessment is designed to empower community pharmacy professionals to ask ‘what are we doing now and how can we do better?’ It helps pharmacy teams evaluate the level of safety in their practice and determine areas to focus on for improvement. Medication safety self-assessments commonly address core areas within the pharmacy system, such as patient information, drug labelling/packaging, drug storage and distribution, and patient education.

The self-assessment helps pharmacies evaluate changes over time, as subsequent self-assessments will reveal the extent to which improvement occurs in the core areas of the assessment.
Share

Each pharmacy conducts at least one formal staff meeting, where a majority of staff are present, per year to analyze and discuss medication incidents and near misses as well as the practice changes that have been implemented. The College recommends informal meetings/huddles throughout the year as necessary to review incidents.

Some reporting platform providers also share reports and recommendations from incident data collected within their platform to help pharmacies with their practice improvements.

By contributing incident data to a National Incident Data Repository, experts in incident analysis can review trends and patterns nationally and study contributing factors to develop recommendations to share with all pharmacy professionals. There are a number of examples of this already being done. ISMP (Institute for Safe Medication Practices) Canada, for instance, provides multiple tools through which pharmacy professionals can learn from incident data. These include the ISMP Safety Bulletin, Med Safety Exchange Webinar Series, and SMART Pharmacist Podcasts.

Rather than only the individual pharmacy learning from their own incidents, through Safety IQ, pharmacy professionals will share their experiences with their colleagues across the country. Critical incidents that occur can be analyzed promptly and recommendations shared widely to improve awareness of possible safety issues and prevent patients from experiencing a similar event.

Document

Discussions and Improvement Plans

CQI is a continuous cycle of reviewing what you are doing, making changes and also, most importantly, evaluating the changes to see if they are effective. Therefore, it is important to document discussions with staff and keep track of the improvement plans that are decided upon. This allows you to then evaluate the efficacy of these improvement plans at a later date.

At a minimum, teams within each pharmacy including pharmacy managers, staff pharmacists, pharmacy technicians and pharmacy assistants should meet at least once a year to discuss the previous year’s medication incidents and formulate strategies to reduce the likelihood of similar incidents or near misses recurring in the future. Any recent medication safety self-assessments would also be reviewed during the formal staff meeting. Depending on the frequency and severity of the medication incidents and near misses occurring at the pharmacy, the pharmacy manager may decide that such meetings should take place more frequently or hold informal meetings when incidents occur.

All formal CQI meetings should be documented and include the date, staff present, and discussion topics.
Do all medication incidents need to be reported?

All medication errors that reach a patient must be both reported anonymously into the reporting database and be documented fully and identifiably within readily retrievable records in the pharmacy.

What is a near miss and when should it be reported?

A near miss event is an error that could have resulted in inappropriate medication use or patient harm, but was discovered before reaching the patient. Pharmacy professionals excel at catching errors before the medication is released to the patient. Near miss reporting provides an opportunity to consider possible gaps in existing systems that could place patients at risk. If near misses are not addressed, an error that is a near-miss at a pharmacy today could be a medication incident tomorrow.

Not all near misses will provide an opportunity to learn and improve pharmacy processes. The pharmacy manager and team should consider if the error was not caught could have harmed the patient. If a near miss is occurring repeatedly, this may indicate a gap in your pharmacies processes and procedures.

Examples:

- A prescription is received from a doctor’s office with the wrong dose. The pharmacist catches this error during the therapeutic check. This does not need to get reported, since it is well within the established processes and procedures to check dosage before dispensing a prescription.
- While filling blister packs, two pills are accidentally dropped into the wrong section. This error is caught immediately by the person filling the blister pack. Blister packs are also routinely checked again before dispensing. This does not need to get reported, since the error was caught immediately and would have been caught during subsequent checks as well.
- A pharmacist notices that the prescription medication in a bottle looks different than usual. The pharmacist investigates this and discovers that the bottle was filled with a sound-alike prescription drug. The pharmacist then re-fills the prescription with the proper medication and the patient receives the correct medication. Reporting of this near miss would be beneficial to report.
- A pharmacy technician notices that when blister packs are filled, it is common for two pills to be accidentally dropped into the wrong section. While this is usually discovered immediately and corrected, it tends to be a common occurrence in the pharmacy. This needs to be reported, since it occurs commonly and a more proactive solution can be established to prevent it.

Frequently Asked Questions

CQI Coordinator

Each pharmacy should appoint a CQI Coordinator to lead the implementation and elements of Safety IQ at the pharmacy. While in some cases the CQI Coordinator may be the pharmacy manager, it is not necessary that this be the case. Anyone who feels competent and confident in their understanding of Safety IQ elements and processes may be the CQI Coordinator. The Coordinator leads CQI meetings, trains other pharmacy professionals on using the CQI reporting platform, and ensures that a consistent, regular, and effective system is in place for reporting incidents and implementing positive changes in the interest of patient safety.
What is the purpose of CQI Meetings?

CQI meetings are an important component of Safety IQ. They provide an opportunity for the CQI Coordinator to share with the entire pharmacy team what medication incidents occurred and to describe any trends they can find. It is also a great opportunity to brainstorm potential systemic changes that would reduce the number of incidents and increase patient safety.

Furthermore, CQI meetings are a setting in which pharmacy staff can review and discuss national shared learnings. This proactive education component is critical to preventing medication incidents in the pharmacy.

What data will the College have access to? What is done with this data?

The data reported to an external reporting platform is analyzed by the reporting platform and remains at an arm's length from the College. The College will not see any specific incident information from pharmacies, but will be able to see anonymous de-identified aggregate data from across the province. This can be helpful in determining systemic factors that cause medication incidents. By discovering these systemic factors, the College can develop tools or resources for pharmacies to close gaps in pharmacy practice and improve patient safety by minimizing the recurrence of near misses and medication incidents. Collection of this data is non-punitive unless it is determined it is negligent behaviour.

Where does the data go? What is done with this data?

The external reporting platform may analyze the data to find key trends. The data is also sent to a national medication incident database, a single national data repository that is independent of a reporting platform provider and has the ability to accept anonymous reporting data from multiple providers using a common set of standards. Contribution to a national database allows for population of national aggregate data in which learnings arising from trends and patterns can be communicated across the profession.

Is there any other medication incident documentation that the College requires?

Incident reports to an external reporting platform will contain pertinent details similar to the current College incident report form, such as the type of incident, incident description, contributing factors, extent of harm, and action taken. It is still important to document communication with the patient and prescriber. This way, in the rare instance when a complaint related to the incident is presented to the College, your pharmacy would be equipped with relevant documentation and records. Once an incident is submitted online, the pharmacy can print it and add further information related to the incident including communications with those involved.
Pharmacy’s Role in Safety IQ

Pharmacy Managers

Pharmacy managers must ensure the pharmacy has written policies and procedures for addressing, reporting, investigating, documenting, disclosing, and learning from medication incidents. They should ensure all staff are trained in reporting incidents and near misses. They must also ensure that the pharmacy appoints one of the members of the pharmacy team to be a CQI Coordinator. In some cases, it may make most sense for the pharmacy manager to assume this role, though delegating it to another pharmacy professional is perfectly acceptable.

Pharmacy managers also have a responsibility to develop and foster a culture of safety that allows for open discussion and learning from medication incidents.

Pharmacists

In the case of a medication incident, pharmacists must determine if the patient has experienced harm or is at risk of possible harm. They should provide care to the patient and ensure the incident is mediated in a timely manner. They should also notify the pharmacy manager, prescriber, and any other personnel deemed necessary about the medication incident.

Pharmacy Staff

Pharmacy staff should be knowledgeable about the pharmacy procedures to follow in the event of a medication incident in order that the event is handled in a professional and thoughtful manner.

All pharmacy staff must understand the reporting tool that the pharmacy uses and be aware of procedures for medication incident and near miss reporting to comply with Safety IQ. Everyone should play an active role in the reporting work flow and in identifying potential safety issues and solutions.

College’s Role in Safety IQ

While the College will not have access to individual incident information, the College will have access to anonymous, de-identified aggregate data from which key trends can be discovered and used to create proactive tools and systems to enhance patient safety.

The College Field Operations officers will also assess how pharmacies utilize and engage with Safety IQ.

Finally, the College has a key role in promoting Safety IQ, developing criteria for third party reporting platforms, and using the aggregate data to fulfill its mandate to protect the health and well-being of the public.
Disclosure and Communication

Disclosure can be one of the most difficult aspects of working in a pharmacy. However, it is one of the most critical skills pharmacy staff should possess, in case a medication incident occurs. The College receives complaints regarding poor communication skills during disclosure. Many of these complaints could have been prevented if pharmacy staff were equipped with meaningful disclosure practices. When done in a sensitive and empathetic manner, disclosure can prevent exacerbation of the shock caused by a medication incident.

The third volume of the eQuipped newsletter contains a great resource from ISMP Canada regarding pharmacist-patient communication and disclosure.

Section 3.2.2 of the Incidents and Discrepancies practice direction discusses disclosure and communication with patients. The Standards of Practice committee and Safety IQ Advisory Committee collaborated to outline a constructive process when it comes to disclosing a medication error with a patient. When a medication incident occurs, patients want to know the following:

1. That the pharmacy acknowledges and apologizes for the incident
2. That the pharmacy understands what happened and why
3. That the pharmacy will implement practices that prevent a similar medication incident from occurring in the future

Ensuring that these three principles are included in the pharmacy’s disclosure process can help pharmacy staff address the patient’s concerns involving medication incidents.

Value of Safety IQ and Reporting

Across Canada, programs similar to Safety IQ, have demonstrated positive, practical, and tangible results. Participants in the Safety IQ Pilot Project have also credited the Safety IQ tools with making it easier to find and address incident trends. Overall, Safety IQ has proven to be a valuable resource.

Manitoba pharmacists are committed to patient-centred care and safety. As we strive towards continuous quality improvement, Safety IQ, when used in meaningful ways, will be an asset to community pharmacies. Safety IQ helps pharmacies gain valuable insights on which to build better structures for improving quality and safety.