

Guide to CQI+

A continuous quality improvement program for pharmacy teams





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Acknowledgements

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The college also acknowledges the work of the <u>National Association of Pharmacy Regulatory Authorities</u> (NAPRA) with respect to the development of the Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals.



Welcome to CQI+

The Alberta College of Pharmacy's (ACP's) continuous quality improvement program, CQI+, is an evolution of quality in Alberta pharmacy care. CQI+ aims to support community pharmacy teams in preventing harm to patients and responding appropriately when it does occur. It builds upon key quality activities already familiar to pharmacy teams:

- · documenting when practice incidents occur,
- · analyzing practice incidents to identify root causes, and
- creating action plans to address risks identified through this process and prevent recurrence.

CQI+ focuses on enhancing the safety and quality of pharmacy care in Alberta by enabling pharmacy teams to be proactive when it comes to patient safety, facilitating broader learning and sharing when practice incidents or close calls do occur, and strengthening the safety culture of pharmacy in Alberta.

Central to CQI+ will be the use of technology to enhance pharmacy teams' abilities to record and analyze practice incidents and close calls, and anonymously share those details to a national database: the National Incident Data
Repository for Community Pharmacies (NIDR). In turn, pharmacy teams and patients will benefit when proactive safety strategies can be implemented based on the insights gained from collective experiences across Canada.

CQI+ consists of five key activities:

- · Prevent,
- Respond,
- Analyze,
- Improve, and
- Communicate.

At its core, each key activity is enabled by a strong **safety culture** – a genuine commitment to patient safety by the entire pharmacy team.

- Prevent Action will be taken by pharmacy teams to minimize risks to patients before a practice incident or close call occurs.
- Respond Pharmacy teams will respond appropriately and in a timely fashion when practice incidents or close calls occur to meet the needs of patients.
- Prevent Respond
 Safety
 culture
 Improve Analyze
- Analyze Pharmacy teams will identify contributing factors and root causes when practice incidents and close calls occur.
- **Improve** Pharmacy teams will take steps to improve the safety of their practices based on their analysis of practice incidents and close calls.
- Communicate Essential to the success of all activities within CQI+ is comprehensive, open communication with
 patients, caregivers, other healthcare providers, and within the pharmacy team. This will ensure everyone can
 learn from concerns that are identified, and that patients are appropriately informed and engaged in addressing
 risks.



Who must participate in CQI+?

For continuous quality improvement in pharmacy to be effective, everyone must be meaningfully engaged in the process and the safety culture. The requirements of the CQI+ program are mandatory for all regulated members practicing in a pharmacy with a community, compounding and repackaging, or satellite pharmacy license. Licensees of these pharmacies must ensure all members of the pharmacy team meaningfully participate in continuous quality improvement activities.

Proprietors must ensure their pharmacy team, including the licensee, are sufficiently resourced to meet the requirements of the CQI+ program. This includes ensuring adequate staffing to support continuous quality improvement activities and to minimize risks in the pharmacy. It may also include financial investment and access to necessary resources identified by ACP or the pharmacy team.

Why is continuous quality improvement important?

When a practice incident occurs in a pharmacy, it can have significant impacts on the patient as well as the individuals and organizations involved. That is why it is critical that pharmacy teams commit to the ongoing evaluation of their processes to proactively identify and minimize risk.

This approach is the basis of continuous quality improvement – a structured process used within a pharmacy, which allows for the ongoing review and improvement of all aspects of the delivery of care, to ensure quality and safety. It addresses quality concerns when they arise but prioritizes being proactive in assessing risk and taking action before harm can occur.

Updated terminology and concepts

CQI+ introduces several updated concepts that pharmacy teams must be aware of.



¹ Health Quality Council of Alberta. <u>Just Culture: Glossary: Terms to Avoid</u>.



Definitions

Unless otherwise noted, definitions are the same as those used in the <u>Standards of Practice for Pharmacists and Pharmacy Technicians and Standards for the Operation of Licensed Pharmacies.</u>

- Close call 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 a patient.
- Continuous quality improvement means a structured process used within a pharmacy, which allows for the
 ongoing review and improvement of all aspects of the delivery of care, in order to ensure patient safety and
 satisfaction. It is reactive when quality concerns arise, but also proactive in assessing risk and taking action
 before harm can occur.
- Contributing factor² means a circumstance, action, or influence that is thought to have played a part in the origin or development of a practice incident or close call, or to increase the risk of a practice incident or close call.
- **Just culture** means an atmosphere of trust in which healthcare workers are supported and treated fairly when something goes wrong with patient care. Just culture is important to patient safety as it creates an environment in which people (healthcare workers and patients) feel safe to report errors and concerns about things that could lead to patient adverse events.
- Pharmacy team means the regulated members practising in the licensed pharmacy, other regulated health
 professionals practising collaboratively with the regulated members, and unregulated employees who provide
 support. Pharmacy team members work cohesively within the licensed pharmacy under the oversight of the
 pharmacy licensee.
- Practice incident means an event that may lead to inappropriate drug use or patient harm that has reached a
 patient. Practice incidents may be related to professional practice, drugs, procedures, and systems, and include
 prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing,
 distribution, administration, education, monitoring, and use.
- Root cause³ means the most fundamental reason (or one of several fundamental reasons) a suspected failure, a practice incident, a close call, or a situation in which performance does not meet expectations has occurred.
- Safety culture means the underlying beliefs and values of an organization as they relate to safety as a priority.

² Adapted from NAPRA's Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals.

³ See footnote 2.



CQI+ program requirements summary

Further details related to each requirement can be found in subsequent sections of this guide.

Practice incident and close call management

- 1. Each pharmacy must procure access to an online practice incident management platform that meets the requirements outlined in this guide.
- 2. The practice incident management platform must be used to document practice incidents and close calls that occur in the pharmacy, including their associated analysis and action plans.
- 3. Details of all practice incidents and close calls meeting ACP criteria must be documented.
- 4. Anonymous detail of practice incidents and close calls must be submitted to the National Incident Data Repository for Community Pharmacies, and this must be facilitated by the practice incident management platform.

Safety self-assessment

- 5. Each pharmacy must procure access to an online safety self-assessment tool.
- 6. Each pharmacy must complete and document a safety self-assessment at least every two years, or within six months of a licensee change, whichever is sooner.
- 7. The results of the safety self-assessment must be used to inform continuous quality improvement activities in the pharmacy that proactively address risks identified.

Site-specific continuous quality improvement (CQI) program

- 8. Each pharmacy must have site-specific policies and procedures in place to guide their pharmacy's continuous quality improvement program. They must be reviewed by the licensee at least annually and updated as required.
- 9. All pharmacy team members must be trained on the pharmacy's specific policies and procedures for continuous quality improvement in the pharmacy.
- 10. Practice incidents and close calls must be analyzed to identify and document contributing factors and root causes.
- 11. Based on the analysis of a practice incident or close call, an action plan must be documented and implemented to prevent it from occurring again.
- 12. Action plans must be routinely evaluated to assess their effectiveness and make changes, if required.
- 13. Pharmacy teams must convene at least every three months for a continuous quality improvement meeting, the results of which must be documented.



Practice incident management platform

Each pharmacy must have access to a practice incident management platform that facilitates the CQI process in the pharmacy, including

- · documentation and analysis of practice incidents and close calls,
- documentation of action plans; and
- anonymous reporting of practice incidents and close calls to the national database.

The practice incident management platform is used internally by the pharmacy team to document practice incidents and close calls. These practice incidents and close calls are then anonymously submitted to the NIDR. Details of practice incidents and close calls submitted to the NIDR will not include any identifying information so, while ACP may be provided with aggregate data from the NIDR, it will not allow ACP to identify individual pharmacies or registrants who have submitted reports. **ACP will not have access to individual practice incident and close call details submitted to the NIDR.**

Note that ACP field officers and inspectors will still review practice incidents and close calls with regulated members when on site.

Access to the platform must not be shared between pharmacies, except through the use of valid licences that allow for the management of multiple locations. In all cases, the pharmacy licensee must oversee access to the platform for their individual pharmacy. Each pharmacy team member using the platform must have a unique login.

There are several platforms available in the Canadian marketplace. The pharmacy team's choice of platform must ensure that all of the CQI+ practice incident management platform requirements⁴ are satisfied.

The *Health Information Act* requires licensees to submit a site-specific privacy impact assessment (PIA) to the Office of the Information and Privacy Commissioner (OIPC) any time they implement a system that collects, uses, or discloses patient-identifying information. Licensees should work with their practice incident management platform provider and OIPC to understand how information is collected, used, and disclosed to determine whether a PIA is required.

Known providers

ACP recognizes the availability of the following commercially available platforms in Canada (in alphabetical order):

- Community Pharmacy Incident Reporting (CPhIR) ISMP Canada
- <u>Pharmapod</u> ThinkResearch
- TPSC Cloud The Patient Safety Company

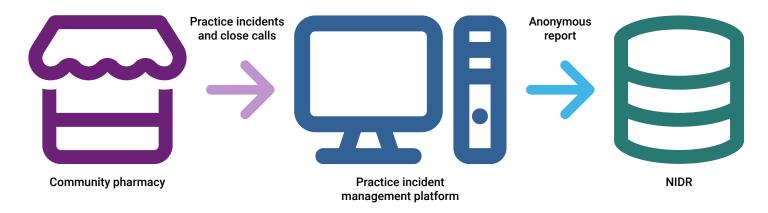
This list is not intended to be exhaustive, and ACP does not approve or endorse individual platforms. Pharmacy teams may use another platform, including a proprietary system, provided that they can demonstrate it meets ACP's CQI+ practice incident management platform requirements as defined in <u>Appendix A</u>.

⁴ See Appendix A – CQI+ practice incident management platform requirements.



Mandatory reporting to the NIDR

After a practice incident or close call is documented in the practice incident management platform, it must be transmitted anonymously to ISMP Canada's <u>National Incident Data Repository for Community Pharmacies</u> (NIDR) to contribute to broader analysis of safety trends in pharmacy care. It is mandatory that the practice incident management platform facilitate this process automatically.



What is the NIDR?

The NIDR is a component of the <u>Canadian Medication Incident Reporting and Prevention System</u> (CMIRPS), a collaborative pan-Canadian program designed to reduce and prevent harmful medication incidents.

The NIDR creates a cohesive, information-sharing system that facilitates the understanding of medication incidents and close calls and the development of robust strategies to prevent patient harm.

Information from the NIDR, in addition to information from healthcare facility, practitioner, and consumer reporting programs of CMIRPS, is analyzed and targeted recommendations are shared with all healthcare professionals through <u>Safety Bulletins</u> and other <u>quality improvement education opportunities</u>. Safety Bulletins offer medication system improvement strategies for improving patient safety on a wide variety of practices, processes, and medications. The bulletins will also share alerts and warnings specific to the Canadian marketplace.

ISMP Canada also produces publications specific to the NIDR, including National Snapshots, provincial Safety Briefs, and Medication Safety Self-Assessment Data Spotlights.

Regardless of the practice incident management platform selected, pharmacies are required to establish a Data Sharing Agreement with ISMP Canada to facilitate submission of anonymous reports to the NIDR.

What information does ACP have access to?

Practice incident and close call information is submitted to the NIDR directly from the practice incident management platform. The NIDR does not collect details identifying the pharmacy, any involved pharmacy team members, or any involved patients. Reports submitted to the NIDR are anonymous and held by an independent third party, ISMP Canada.

While ACP does not have access to individual practice incident and close call reports submitted to the NIDR, ACP may be provided with de-identified, anonymous, aggregate data analyses intended to identify opportunities to improve patient safety and support pharmacy team members in Alberta.



Safety culture

CQI+ was developed through the lens of safety culture, so this concept is central to all activities required by CQI+. It is a licensee's responsibility to not only ensure compliance of their pharmacy team with the CQI+ program requirements, but also to make efforts to foster a strong safety culture. It is critical for all pharmacy team members to truly understand and embrace safety culture when considering the broader CQI+ program requirements and how they apply within their own practices.

What is safety culture?

Safety culture in pharmacy relies on the pharmacy team
having shared beliefs and values about patient safety. In
safety culture, pharmacy team members share openly about
the quality of care provided and seek to learn from each other.
Pharmacy team members also view practice incidents, close
calls, and other concerns about patient safety as indicators of
potential system weakness that may need to be addressed to improve safety.

The Health Quality Council of Alberta (HQCA) identifies three building blocks that are necessary to the success of safety culture:

- just culture,
- · reporting culture, and
- learning culture.

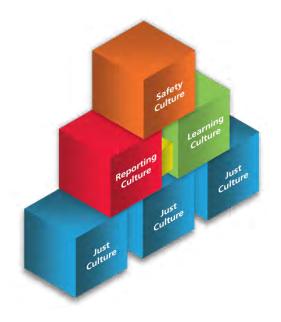
A just culture enables a reporting and learning culture and, together, these components enable a strong safety culture.

What is a just culture?

A foundational component of a safety culture is a just culture, in which pharmacy team members are treated with respect and feel supported when something goes wrong or nearly goes wrong with patient care. Shared values, beliefs, and attitudes about safety guard against naming, shaming, and blaming people if something goes wrong with care delivery.

This is important because individuals will feel less comfortable raising concerns or reporting an error when they fear backlash. As a result, the environment can become even more unsafe.







How can regulated members facilitate a just culture?

The Health Quality Council of Alberta outlines several behaviours associated with a just culture:

- Support and treat healthcare workers with respect, dignity, and compassion when they are involved in situations
 where a patient was harmed or nearly harmed.
- Avoid blame and quick judgements about the actions of an individual.
- Proactively inform healthcare workers about what it means to be held appropriately accountable for one's actions.
 Actions stemming from reckless behaviour may be subject to discipline; intent to harm will result in legal action.
- Hold people appropriately accountable for their actions by assessing their accountability in the context of the situation including contributing system factors.
- Follow a systematic approach to understanding why people took the actions they did in the context of the situation.
- Be aware and take steps to minimize hindsight bias ("If I knew then what I know now") or outcome bias (the greater the harm, the greater the consequence) when assessing a person's actions.
- Actively look for system factors that contributed to the situation where a patient was harmed or nearly harmed, and make changes to reduce the risk of the same problem happening again.

Just culture and accountability

A just culture does not mean that individuals are not accountable for their actions. In fact, accountability is an important component of a just culture, and is essential in maintaining trust with patients after an incident has occurred. In a just culture, the actions of people involved when something goes wrong are assessed fairly. The process focuses on understanding why people acted the way they did by considering the context and contributing system factors while minimizing the influence of bias. Further, pharmacy team members are only held accountable for their actions. Accountability is always assessed in the context of the situation including contributing system factors.

Licensees should have a clear, transparent process in place to address the concept of accountability in a pharmacy team when a practice incident occurs. One tool that can help licensees achieve this is the Health Quality Council of Alberta's Just Individual Assessment (JIA). Several additional resources are available to support decision-making at each of the steps identified in the JIA.

What is a reporting culture?

A reporting culture is an organizational climate in which people willingly report practice incidents and close calls. Reporting culture depends on a just culture where people feel safe and supported to raise concerns, and are confident that their feedback will be acted upon.

The pharmacy's practice incident management platform should make it easy for pharmacy team members to report practice incidents and close calls, and it should be clear to reporters how their reports are used to improve a policy, procedure, or process.



What is a learning culture?

A learning culture is the will of an organization to embrace change when it is needed. To know what is needed, an organization must strive to be informed. For a pharmacy team to have a strong learning culture, they must view the documentation and analysis of practice incidents and close calls as opportunities to learn and improve.

The pharmacy's practice incident management platform is a critical tool to help pharmacy teams identify trends and insights from their practice incident and close call documentation.

Enabling a safety culture in the pharmacy

Licensees should review HQCA's <u>Safety Culture Fact Sheet</u>, which outlines barriers and facilitators of just, reporting, and learning cultures as components of a safety culture.

Licensees should work with their team to reflect on whether these features are present within their practice environment, and regularly take steps to enhance the safety culture.

Certain team members may take a specific interest in the pharmacy's approach to safety and quality. Delegating components of the pharmacy's CQI program to another regulated member on the pharmacy team is an excellent way to strengthen the safety culture by building engagement and encouraging collaboration amongst the pharmacy team. It is nonetheless important to remember that, while a pharmacy team may have leaders in their CQI program, safety culture is everyone's responsibility.



Prevent

Activities undertaken within a pharmacy team's CQI program are all done with the aim of preventing practice incidents. Risks must be actively identified, analyzed, and mitigated, and procedures must be constantly reviewed and updated in response. Staff members, regulated and unregulated, must be trained and possess the knowledge and skills to participate in these activities.

Pharmacy teams will use several strategies to ensure they proactively address safety considerations in their pharmacy, including

- · policies and procedures,
- · safety self-assessment,
- · comprehensive training, and
- regular continuous quality improvement meetings.



Policies and procedures

A safety culture depends on all pharmacy team members having clear expectations about how safety and quality concerns are addressed. To support this, licensees must ensure that site-specific policies and procedures are in place outlining each aspect of the pharmacy's CQI program. These policies should be updated regularly – at least annually – based on learnings from reviews of practice incidents and close calls, safety self-assessments, and information obtained from other sources. Policies should be reviewed with all pharmacy team members upon commencing employment, and whenever changes are made.

For sample (template) policies and procedures, see ACP's general policies and procedures manual template, located on the <u>Licensee resources</u> section of the ACP website.

Communication reminder



- Pharmacy team members should be involved in developing, updating, and implementing new policies and procedures.
- Any policy changes must be communicated effectively to all team members.



Safety self-assessment

To support a proactive review of safety in the pharmacy environment, each licensed pharmacy must have individual access to an online safety self-assessment tool.

A safety self-assessment is a tool that supports a pharmacy team – not just the licensee – in reflecting on their practices and proactively identifying processes which may contribute to patient risk. This tool is not a test, and it is not expected that a pharmacy will score highly in all areas. The results are not shared or provided to ACP. Instead, they are intended to help pharmacy teams identify opportunities to improve safety and the quality of the care they provide. All team members should be encouraged to contribute to the safety self-assessment, and risks identified in the safety self-assessment should be mitigated through the creation of action plans (see Improve).

There are two safety self-assessment products currently available in Canada:

- Medication Safety Self-Assessment (MSSA) from ISMP Canada
 - This product may be purchased separately or may be included for pharmacy teams using ISMP Canada's
 CPhIR software for the documentation of practice incidents and close calls.
- Pharmacy Safety Self-Assessment (PSSA) from ThinkResearch
 - This product may be purchased as a standalone offering or may be included for pharmacy teams using ThinkResearch's Pharmapod software for the documentation of practice incidents and close calls.

If the pharmacy's practice incident management platform does not have an included safety self-assessment tool, the pharmacy must subscribe to one of these standalone safety self-assessment products in addition to the platform.

A pharmacy review by corporate management does not satisfy the safety self-assessment requirement for CQI+, nor does a casual observance of pharmacy practice.

Documentation of a safety self-assessment

A safety self-assessment, including actions taken as a result, must be documented by the licensee at least every two years. If the licensee of a pharmacy changes, the safety self-assessment must be conducted within six months of the new licensee being instated. While the results of the self-assessment do not need to be reported or submitted outside of the pharmacy, records must be retained for inspection by ACP.

Communication reminder

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Licensees should ensure the safety self-assessment is completed in collaboration with the pharmacy team. The results of the self-assessment and the risks identified also need to be shared with the team.



CQI+ training

Each pharmacy must have a documented training plan in place to ensure all pharmacy team members are able to participate in the continuous quality improvement activities of the pharmacy and meet the requirements of CQI+. Records must be retained for inspection by ACP.

Training of pharmacy team members must include, at a minimum, a review of

- · all materials on ACP's CQI+ website,
- Domain 6 (Continuous Quality Improvement) of both the Standards of Practice for Pharmacists and Pharmacy
 Technicians and the Standards for the Operation of Licensed Pharmacies,
- their pharmacy's policies and procedures related to CQI, and
- all resources provided by their pharmacy's practice incident management platform.

Licensees must regularly evaluate the need for additional or repeated training for pharmacy team members.

Continuous quality improvement meetings

To support the safety culture in the pharmacy, the licensee must provide regular opportunities for discussion and reflection on safety. These meetings must occur, at a minimum, every three months and should involve as many pharmacy team members who support patient care as possible. Every attendee should be encouraged to voice their perspectives, opinions, and ideas, and they should be supported when they do.

Quality improvement meetings should include

- If recently completed, a review of the pharmacy's latest safety self-assessment and an evaluation of any associated action plans. It may be valuable to revisit this from time to time, especially when meetings include new pharmacy team members.
- A discussion about any practice incidents and close calls that have occurred since the previous meeting, including
 any contributing factors or root causes identified, and steps taken to address them.
- An evaluation of action plans developed as a result of analyzing practice incidents and close calls, making adjustments as needed.
- An assessment of the pharmacy team's engagement with the pharmacy's CQI processes (e.g., the team's
 involvement in documenting and analyzing practice incidents and close calls). This is not to blame anyone; rather,
 this will help to identify any barriers to participating, and provide an opportunity to brainstorm solutions to
 increase engagement by the entire pharmacy team.
- A review of relevant information from external sources (e.g., ISMP Canada publications, information from ACP, learnings shared by other pharmacies) that could proactively inform safety strategies in the pharmacy.
- Importantly, a discussion about safety successes! The continuous quality improvement meeting is also an opportunity to celebrate when the team's actions have had a positive impact on patient safety, the quality of care the pharmacy team provides, or pharmacy team member satisfaction.



Document the results of the meeting, preferably within the pharmacy's practice incident management platform if possible. Documentation should reflect

- · the date of the meeting,
- who was in attendance,
- what was discussed during the meeting, and
- · any action plans developed as a result of the meeting.

Safety huddles

Safety huddles are short, informal CQI meetings that allow sharing of timely information about quality or safety concerns, or to celebrate successes. An opportune time to conduct a safety huddle is following the discovery a practice incident or close call; however, pharmacy teams should also consider conducting them more routinely. For example, many healthcare teams conduct a safety huddle at the beginning of each day or at "shift change."

Communication reminder



CQI meetings and safety huddles are an excellent opportunity to reinforce the safety culture of the pharmacy team. Licensees should use these opportunities to actively seek feedback and engagement from their pharmacy team. Pharmacy teams should have open communication about recent practice incidents and close calls with the aim of collaboratively learning from them, developing action plans together, and evaluating successes and challenges with existing policies and procedures.



Respond

The focus of CQI+ is to enable proactive interventions to reduce the risk of practice incidents occurring in a pharmacy practice; however, it is equally important to respond appropriately when practice incidents occur. These unfortunate events are upsetting to patients, their caregivers, and pharmacy team members alike, particularly when patients experience harm, and our subsequent actions can play an important role in minimizing both physical and psychological harm to all individuals involved.

Each element of the pharmacy team's expected response must be documented in the pharmacy's policies and procedures so all team members can participate in a consistent response.

A comprehensive response to a practice incident includes

- first ensuring the immediate safety of the patient and others who may be affected,
- · disclosure and apology,
- gathering of information about the incident and discussion with the pharmacy team,
- documentation of the incident details,
- analysis of the incident to determine contributing factors and root causes,
- development of action plans to address the contributing factors and root causes, and
- providing feedback to the patient or their agent(s) about the results of the analysis and the specific actions taken as a result.

The pharmacy's chosen practice incident management platform should support these activities.

Example of a practice incident

Mrs. Shevchenko calls the pharmacy to report that, last night, her husband experienced symptoms of confusion, sweating, and dilated pupils after taking his regular insulin. Ms. Shevchenko took him to the hospital, where he was treated in the emergency department for hypoglycemia. Once stabilized, he was discharged the next morning.

The pharmacist who answered the phone, Farida, quickly reviews the patient's profile and sees that he picked up three boxes of long-acting insulin earlier in the day yesterday. After double-checking the pharmacy's insulin inventory, Farida suspects that one box of rapid-acting insulin may have been incorrectly dispensed along with two long-acting boxes.





Disclosure and patient care

"Disclosure is an open discussion with a patient and identified support person(s) about an incident that harmed the patient. It typically involves an ongoing exchange of information over a period of time. Disclosure is not simply a one-way sharing of information. It is intended to be a meaningful dialogue and must include the patient perspective and their experience of the incident."⁵

When a practice incident occurs, regulated members must disclose the incident to the patient, their agent, and/or their caregiver. This disclosure will likely need to be supported by conversations among pharmacy team members to better understand the circumstances surrounding the incident. However, if patient safety is at risk, disclosure must begin as soon as possible and the patient must be advised what steps are necessary, including emergency measures, to ensure that harm is minimized.

Even in the event that no physical harm occurs, regulated members should consider the psychological, financial, and social impacts of a practice incident and seek to undertake restorative actions where appropriate.

Disclosure is a process and may occur over a period of time rather than a single interaction. For example, as the pharmacy team learns more about the contributing factors of the incident, they may engage the patient again to provide additional details. This ongoing engagement can restore trust and rapport.

Elements of disclosure

A comprehensive disclosure involves sharing the following information:

- · acknowledgement that a practice incident has occurred;
- a genuine and sincere apology;
- an explanation of what happened and, to the degree it is known, why it happened; and
- actions that have been or will be taken to improve safety in the future.

Apologies and the Alberta Evidence Act

Pharmacy teams may be hesitant to apologize to patients when a practice incident occurs. They may be concerned that an apology is an admission of fault or liability; however, a genuine and sincere apology demonstrates compassion, validates the experience of the patient, and helps restore the relationship of trust.

An apology is not considered an admission of liability. In Alberta, Section 26.1(2)(a) of the *Alberta Evidence Act* (RSA 2000, C.A., 18) states that "an apology made by or on behalf of a person in connection with any matter does not constitute an express or implied admission of fault or liability by the person in connection with that matter" and "shall not be taken into account in any determination of fault or liability in connection with that matter."

For detailed advice on disclosure, review the Health Quality Council of Alberta's "A Guide to Disclosure of Harm" document.

⁵ Health Quality Council of Alberta. A Guide to Disclosure of Harm (2023).

⁶ See footnote 5.



Notification of health professionals involved in the patient's care

When a practice incident occurs, regulated members must notify any health professionals involved in the patient's care. Consideration should be given to how and when this notification should occur, based on the severity of the incident and the potential for it to impact the health professional's ongoing care of the patient.

Communication reminder



- Timely disclosure of a practice incident and honest, open communication about what happened can support trust and rapport in the patient relationship.
- Consider asking the patient for ideas for addressing the incident and preventing similar incidents from occurring in the future.
- Document the disclosure conversation in the patient record to support fellow pharmacy team members in following up with the patient as needed.
- When notifying relevant members of the patient's healthcare team (e.g. family physician, nurse practitioner)
 of the practice incident, consider what role they might play in identifying or addressing the contributing
 factors.

Example of a practice incident, continued



The pharmacist first confirms with Mrs. Shevchenko that her husband is no longer experiencing symptoms. However, because Farida suspects that a practice incident may have occurred, she asks Mrs. Shevchenko to inspect each box of insulin that was picked up from the pharmacy yesterday. Her suspicion is confirmed: one of the three boxes is rapid-acting insulin. Mrs. Shevchenko describes that the three boxes were taped together and that the box in the middle was incorrect.

Farida explains what she believes has happened and apologizes for the error. Mrs. Shevchenko offers to bring the rapid-acting insulin back to the pharmacy later in the day.

Farida explains, "In the meantime, we are taking this error very seriously and will notify your husband's doctor of what has occurred. We will also begin our analysis of how this might have happened. Our goal is to make sure it doesn't happen again. I will update you with more details as soon as we know more."

Mrs. Shevchenko is thankful for the apology and agrees with the planned next steps.



Information gathering

When a practice incident occurs, the analysis of the event must begin as soon as possible. This process often starts with open and honest communication with the pharmacy team to learn more about the circumstances surrounding the event. The focus of a quality discussion is not to assign blame but, rather, to understand the timeline of events and to dig deeper into the contributing factors and root causes of the incident. The licensee is responsible to ensure this occurs, but any pharmacy team member may initiate it when they become aware of an incident.

Regulated members must use their clinical judgement to balance the urgency of this discussion with the potential for patient harm, in which case disclosure to the patient and necessary clinical follow up should take priority.

Psychological safety

The notion of healthcare professionals as second vic~tims (the patient and their family being the first victims) in practice incidents is well accepted. One systematic review found that physicians involved in medical errors expressed emotional distress that seemed to increase their risk for burnout and depression, potentially leading to an increase in future errors. Substance use, depression, suicide, quitting the medical field, and litigation stress have also been reported as outcomes of practice incidents affecting healthcare professionals.⁷

Therefore, it is critical that pharmacy licensees, proprietors, and regulated members recognize and mitigate potential psychological harm resulting from a practice incident by offering support. Support can take many forms. The following list of support measures have been identified in the literature,⁸ in order of importance to healthcare workers:

- talk to a colleague,
- conduct a formal debrief with other individuals involved in the incident,
- designate a mentor/colleague to speak to,
- talk to a friend or family member,
- · discuss with manager or supervisor,
- get support through a workplace Employee Assistance Program,
- · access counselling support,
- · take time away, and
- talk to the patient involved in the incident.

This list is not intended to be exhaustive, and the measures that are most appropriate or effective in one scenario may differ greatly from those used in another. Pharmacy proprietors and licensees should consider having multiple sources of support available to their team members, and tailor them as required based on the affected individual's needs. Regulated members must also ensure that confidential patient information is not disclosed with any unauthorized individuals (e.g., family member, counsellor).

⁷ Carolanne Caron, Mélanie Joanisse, Christine Landry, Mikaela Ney, and Melanie Trinacty. "Emotional Impact of Medication-Related Patient Safety Incidents on Canadian Hospital Pharmacists: A Mixed-Methods Study." The Canadian Journal of Hospital Pharmacy. Volume 76, Number 4.
8 See footnote 7.



Documentation of a practice incident

Once steps have been taken to prioritize the health and safety of the patient, documentation should begin as soon as possible within the pharmacy's practice incident management platform. This information is a component of the patient record, so the pharmacy's policies and procedures must ensure that the entire history of a practice incident can easily be located, tracked, and cross-referenced for each patient involved. This might include, for example, noting the incident number from the practice incident management platform directly in the patient record in the pharmacy's dispensing software or in a practice incident log.

The following elements must be included in the documentation of a practice incident, at a minimum:

- the date the incident occurred,
- the type of incident,
- who the incident was discovered by,
- the medication system stages involved in this incident,
- · whether the incident was medication related,
- · the medication(s) involved in the incident,
- the degree of harm to the patient due to the incident,
- · an incident description including how the incident was discovered,
- the contributing factors identified, and
- · all actions taken at the pharmacy level.

Optional data fields include the

- · time the incident occurred,
- · patient's gender,
- patient's age,
- · incident background information, and
- shared learning/comments.

While these fields are optional, it is important for pharmacy team members to document as much information as possible about the incident to support its analysis and the opportunities for learning.

Entry options for each field must conform to those accepted by the National Incident Data Repository. Platform providers must work with ISMP Canada to ensure appropriate mapping of fields in a manner that is acceptable.

The practice incident management platform should enable thorough documentation of all the above elements and support all requirements for record retention as outlined in the *Health Information Act*.



Documentation and anonymity

Practice incident documentation is a component of the patient record; therefore, documentation may contain patient identifying information, pharmacy team member identifying information, and identifying information of other healthcare professionals involved in the incident.

However, any practice incident or close call documentation that is submitted outside of the practice incident management platform to the NIDR must be de-identified. Pharmacy team members must pay special attention to ensure that information entered in free-form text fields that will be submitted to the NIDR does not contain any individually identifying information (e.g., patients, pharmacy team members, healthcare providers, others).



Example of a practice incident, continued

Example of a practice incident, continued

Farida discusses the practice incident with the pharmacy team and learns

- A pharmacy technician, Jenna, processed the prescription refill request in the computer and left the label in a basket for filling.
- A pharmacy student, Toby, prepared the prescription for dispensing.
- He obtained five boxes of insulin from the fridge, scanned the top box five times, and taped all five boxes together.
- The rapid-acting insulin and the basal insulin are stored beside each other.
- The licensee, a pharmacist named Yan, checked the prescription.
- He remembers that the insulin boxes looked the same, so he just checked the DIN on the top box. The insulin was placed in a bag in the refrigerator for pickup by the patient.
- Yan remembers chatting with Mr. Shevchenko when he picked up the insulin. Since he checked the prescription, Yan didn't open the bag to show it to him.

Farida begins her documentation of the practice incident in the pharmacy's practice incident management platform.

Date of discovery: October 8, 2024

Date incident occurred: October 7, 2024

Type of incident: Incorrect drug

Incident discovered by: Patient's family member

Medication system stages involved in this incident: Prescription preparation/dispensing

Medication related: True

Medication(s): Rapid-acting insulin (DIN 12345678), long-acting insulin (DIN 87654321)

Degree of harm to patient due to incident: Moderate harm

Incident description / how the incident was discovered: The patient picked up a refill of his insulin yesterday, which included three boxes of long-acting insulin. One box was replaced with short-acting insulin inadvertently. The patient ended up experiencing hypoglycemia, was hospitalized, and was discharged upon recovery the next day. The incident was discovered by the patient's wife in conjunction with me, the pharmacist. I confirmed that our insulin inventory was out – one more box of long-acting insulin and one less box of short-acting insulin. The patient's wife confirmed that they had received one incorrect box.

Contributing factors: TBD

Actions taken at the pharmacy level: TBD

Farida saves, but does not submit, her documentation so she can begin analysis of the contributing factors and root causes of the incident. She will document the contributing factors and actions taken at the pharmacy level when this has been completed.



Communication reminder

All pharmacy team members should be encouraged to contribute to the documentation of the practice incident. This contributes to a safety culture that demonstrates value in everyone's perspectives.

Close calls

What is a close call?

A close call is 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 a patient. Other sources may refer to close calls as "near misses" or "good catches."

Close calls allow pharmacy teams to recognize risks in their processes before they have an opportunity to impact patient safety. Importantly, pharmacy teams must also recognize the learning value of close calls and analyze them accordingly.

Example of a close call

Mr. Jones arrives at the pharmacy to pick up his monthly blister packs. As John, the pharmacist, retrieves them from the pickup drawer, he recalls a recent telephone conversation with Mr. Jones' family physician in which she discontinued Mr. Jones' metoprolol due to hypotension. John quickly looks at the blister pack and, to his surprise, he notices that the metoprolol is still included. He advises Mr. Jones to sit down for a moment while he reviews his patient profile. After confirming that the medication indeed should have been discontinued, John quickly fixes the blister pack.

Reflecting on the circumstances, John recalls discontinuing the metoprolol in the pharmacy dispensing software; however, he didn't realize at the time that his blister packs were already made and ready for pickup. The pharmacy's policies and procedures do not outline a specific process for discontinuing medications for blister pack patients.

Documenting and reporting a close call

Documentation, analysis, and reporting of close calls is a mandatory component of ACP's CQI+ program. Close calls must be documented, analyzed, and actioned in the same manner as practice incidents.

However, it can be difficult to identify when a close call has occurred, since many standard pharmacy processes (e.g., double checks, barcode scanning) are specifically designed to catch errors or otherwise mitigate incidents before they occur. Typically, errors detected through these processes would not be considered close calls. Instead, close calls are events detected outside of established, routine pharmacy processes.









Licensees must document site-specific policies and procedures to ensure close calls are identified and actioned appropriately. Use the following criteria9 to determine when a close call has occurred:

- Were it to reach the patient, the close call may have caused harm.
- The close call has been a recurrent issue in the pharmacy.
- The close call provides a learning opportunity for the pharmacy or for pharmacy practice in general.

If the event meets any of these criteria, it must be documented, analyzed, actioned, and reported to the national database.

Example of a close call, continued

In the above example, at least two of the criteria were met. If Mr. Jones had inadvertently taken the metoprolol, he could have been at risk of a fall or other adverse outcomes. The close call also provides a learning opportunity for the pharmacy team, likely resulting in a new or updated process around discontinuations.

This close call must therefore be documented in the practice incident management platform, analyzed, and actioned. It must also be reported to the NIDR to share the learning opportunity with others across the country.

⁹ Adapted from NAPRA Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals.



Analyze

Each practice incident and close call provides an opportunity for learning and implementation of changes to prevent recurrence.

To understand what went wrong, the pharmacy team must analyze the event to identify the contributing factors and root causes of the practice incident or close call. This process allows the pharmacy team to move beyond what happened, and to focus on why it happened. There are no right or wrong answers – it is simply important that the team think critically about the potential contributors to the practice incident or close call.

One of the most straightforward concepts that is employed in various methodologies is diagramming. Diagramming involves asking "why" to visualize the relationship between contributing factors and the outcome being analyzed, such as patient harm, or potential patient harm in the case of a close call.



Example of a practice incident, continued

Farida creates a cause-and-effect diagram to help the pharmacy team identify the various contributing factors to this practice incident.

She starts with the outcome: the patient experienced a hypoglycemic episode.

Then she identifies the practice incident that led to the outcome: the patient received rapid-acting insulin instead of long-acting insulin.

Then she works with the team to explore why this incident happened. Two conditions are identified: the incorrect product was selected, and the checking process was ineffective.

In evaluating why the incorrect product was selected, the team brainstorms potential contributing factors:

- Jenna notes that the two types of insulin are stored right next to each other in the fridge.
- Yan identifies that the product packaging is very similar.
- Toby shares that only one insulin box was scanned during the verification step.

In evaluating why the checking process was ineffective, the team identifies several contributing factors:

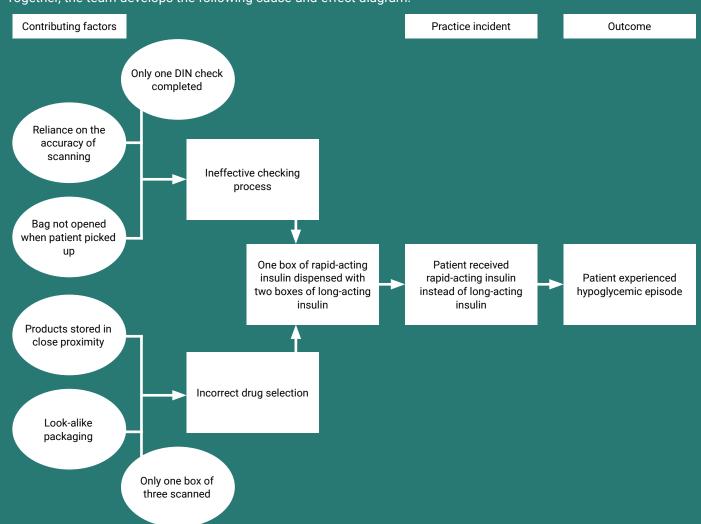
- Farida highlights that the boxes were taped together, so it was not possible to check each DIN.
- Yan suggests that he tends to rely on the accuracy of the scanning process.
- Yan also describes that the pharmacy's policy of opening the bag when the patient picks up was not followed.





Example of a practice incident, continued

Together, the team develops the following cause-and-effect diagram:



After reviewing the diagram together, the team agrees that look-alike packaging and storage of the drugs in close proximity are potential root causes, fundamental reasons this practice incident occurred.

Farida returns to her saved documentation in the pharmacy's practice incident management platform to update the contributing factors. Her platform also allows her to upload a copy of the cause-and-effect diagram she created.

Farida selects the following contributing factors:

- drug name, label, packaging problem look-alike packaging;
- drug name, label, packaging problem faulty drug identification;
- environmental, staffing, or workflow problem inefficient workflow;
- lack of quality control or independent check systems independent checks for high alert drugs/high risk patient population drugs; and

lack of quality control or independent check systems - equipment quality control checks.



Several tools are available to support pharmacy teams in the exercise of identifying contributing factors and root causes (see Appendix B – Resources), and various options will be included within the pharmacy's practice incident management platform. Regardless of the tool(s) used, licensees must ensure that the process for analyzing practice incidents and close calls to determine contributing factors and root causes is clearly documented in the pharmacy's policies and procedures.

The results of the pharmacy team's analysis must be documented in the practice incident management platform and used to inform improvement activities.

Communication reminder

- The whole pharmacy team should be included in the analysis of a practice incident or close call. Each team member will have a different experience of the systems and processes in the pharmacy and may be able to identify unique risks and contributing factors within their own role.
- Pharmacy teams should evaluate whether patients and their agents should also be involved in the analysis of
 practice incidents, and in determining action plans to address the contributing factors and root causes. This
 exercise validates the patient's experience of the event and helps to build (or re-build) trust through
 accountability.



Improve

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies that address the contributing factors or vulnerabilities leading to the incidents. In turn, improvement strategies enable further preventative actions.

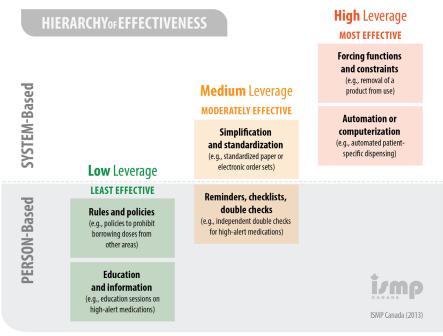
Licensees must work with the pharmacy team to identify and document action plans in their practice incident management platform to address the risks identified.

Hierarchy of effectiveness¹⁰

Certain types of risk-mitigation strategies have been shown to be more effective than others. In general, system-based approaches yield the most effective results, while personbased approaches can be least effective. With that said, system-based strategies are often the most complex – and resource intensive – to implement. In contrast, person-based



strategies can usually be implemented quickly and with minimal impact on resources.¹¹ Pharmacy teams will be faced with the challenge of identifying opportunities for improvement that will have a tangible impact on safety while balancing the practicality of the proposed solutions. Pharmacy teams can consider implementing several strategies simultaneously, both system-based and person-based, to achieve maximum effectiveness.



Designing effective recommendations. Toronto (ON): Institute for Safe Medication Practices Canada. Ontario Critical Incident Learning. 2013[cited 2023 Sept 8];4:1-2. Available from: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4 EffectiveRecommendations.pdf

¹⁰ ISMP Canada. Hierarchy of Effectiveness.

¹¹ Health Quality Council of Alberta. Systematic Systems Analysis: A Practical Approach to Patient Safety Reviews. 2022.



SMART action plans

When developing action plans for improvement, pharmacy teams must ensure their plans are SMART (Specific, Measurable, Attainable, Relevant, Time-bound).

- Specific What exactly do we intend to do? Who does this initiative apply to?
- Measurable How will we know we've succeeded?
- Attainable Do we have the resources to achieve our goal?
- Relevant Will this action plan make a difference?
- **Time-bound** When will this start? When will it end?

Example of a practice incident, continued

The pharmacy team agrees that addressing the storage of the refrigerated products is a priority. While this is likely a medium-leverage change, it is simple and quick to implement. Jenna remarks that this strategy could be applied to other look-alike drugs in the fridge. The team works to re-organize the fridge inventory so look-alike products are kept apart, and are stored within dedicated, well-labelled baskets. Not only will this strategy seek to prevent recurrence of the insulin incident, it will prevent occurrence of other incidents related to look-alike refrigerated drugs.

Farida calls the Shevchenkos and suggests a meeting to discuss the outcome of the pharmacy team's analysis of the practice incident. They agree and come into the pharmacy the next day to meet with Farida and Yan, the licensee. The Shevchenkos are appreciative that the pharmacy team has taken the practice incident seriously, and agree with the suggested course of action. Farida also asks if they have any ideas for improvement, at which time Mr. Shevchenko suggests that the pharmacy team show him his medications when he picks them up, so everyone can be sure they're correct.

After the meeting, Yan logs into the pharmacy's practice incident management platform and updates the "Actions taken at pharmacy level" section, using the SMART format:

Right away, we will organize the fridge to ensure all insulin products are stored in distinct bins, not in close proximity to look-alike products. Within a week, we will update our policies and procedures to reflect the new storage system for refrigerated products and ensure all staff are trained on the new procedures. We will seek to have zero practice incidents related to look-alike refrigerated products moving forward.

Yan enters additional actions taken and completes the report. He checks it over one last time to ensure no individually identifying information is contained within fields that will be submitted to the national database. Once he's satisfied with his documentation, Yan submits the report, and it is automatically transmitted securely to the NIDR by the practice incident management platform.

The team uses their next safety huddle to discuss and reinforce the importance of adhering to their existing policies around barcode scanning and showing patients their medications at the pickup counter. Yan congratulates the team on working together to analyze this practice incident and make the pharmacy environment safer.





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Communication reminder

- Involving patients in reviewing, or even contributing to, action plans to improve safety can help support the patient relationship by building trust and rapport.
- Ensure all members of the pharmacy team are aware of action plans and their role in achieving them.

 Pharmacy team members should be given an opportunity to contribute to and evaluate the plans based on their unique perspectives.

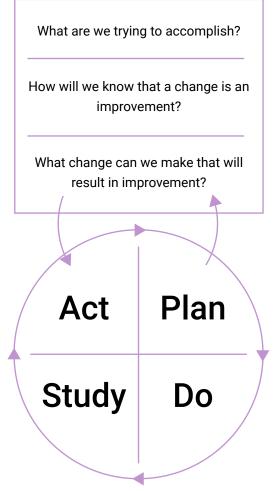
Monitoring change

The pharmacy team's safety journey doesn't end with implementing change. Opportunities for learning remain, and they can be identified through continuous evaluation of the new processes that have been implemented. One tool that can be used to support the continuous evaluation of change is the Plan-Do-Study-Act (PDSA) cycle.¹²

The PDSA cycle is a useful tool for evaluating change. To conduct a PDSA cycle, develop a plan to test the change (Plan), carry out the test (Do), observe, analyse, and learn from the test (Study), and determine what modifications, if any, to make for the next cycle (Act).

In a healthy safety culture, the PDSA cycle continues as the pharmacy team continues to evolve its policies, processes, and systems to make care safer and more effective.

Incorporate PDSA into the pharmacy's CQI meetings and huddles.



¹² Institute for Healthcare Improvement. Plan-Do-Study-Act (PDSA) Worksheet.



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Communication reminder

- When implementing change in the pharmacy, the entire pharmacy team should be involved in the
 development, implementation, and evaluation of the plan. Pharmacy team members can help identify
 practical barriers and opportunities for implementation, and participation in this process can build
 engagement and strengthen the safety culture.
- Pharmacy teams must consider when patients should be involved in the evaluation of action plans. Patients
 affected by a practice incident may appreciate knowing what specific steps have been taken to prevent
 recurrence, and this may help to strengthen trust in the patient relationship.



Appendix A – CQI+ practice incident management platform requirements

Requirement	Detail
Privacy and security	 Data collected by the platform must be physically stored on servers located in Canada.
	 Data stored (at rest) and transmitted must be encrypted with industry standard best practices.¹³
	 The platform must be able to transmit anonymized practice incident data securely to the National Incident Data Repository (NIDR).
	 The custodian of the pharmacy's practice incident, close call, and related continuous quality improvement data (e.g., root cause analysis, action plans) is the pharmacy licensee, not the platform vendor.
	 A common agreement must be established between the platform provider and the pharmacy outlining roles and responsibilities.¹⁴
Anonymity	 All information submitted outside of the pharmacy platform must be de- identified.
	 No patient-identifying information can be transmitted to the national database.
	 No other individually identifying information can be transmitted to the national database (e.g., caregivers, healthcare professionals)
	 All practice incident and close call information submitted outside of the pharmacy platform must be anonymous.
	The pharmacy involved must not be identified.
	 Pharmacy team members involved must not be identified.
	 Pharmacy team members reporting must not be identified.
Support	 Platform vendors must provide pharmacy teams with comprehensive training on the use of the platform to support continuous quality improvement activities.
	 Platform vendors must provide technical support services that are readily accessible to pharmacy team members encountering difficulties accessing or using their platform.

ACP recommends following common industry best practices for data security. Minimally, data at rest should be encrypted with AES and a 128-bit key. Data in transit should be wrapped in the most recent versions of a secure protocol such as HTTPS, TLS, or SSH, or over a VPN.

4 Agreement as specified by the platform vendor.



Practice incidents and close calls	 Platforms must allow for a distinction between practice incidents and close calls. Importantly, all functionality associated with practice incident documentation must be in place for close calls.
Continuous quality improvement tools	processes through analysis of contributing factors and root causes, and documentation of action plans.
	 The platform must provide summary reports and tools to facilitate pharmacy team members in identifying and analyzing safety trends within their pharmacy practice.
Mandatory data fields	 Data collected by the platform must include, at a minimum, date incident occurred, type of incident, incident discovered by, medication system stages involved in this incident, medication related, medications, degree of harm to patient due to incident, incident description/how the incident was discovered, contributing factors of this incident, and actions taken at pharmacy level. Entry options for each field must conform to those accepted by the National Incident Data Repository.
	 Platform providers must work with the national database provider to ensure appropriate mapping of fields in a manner that is acceptable to the national database provider.



Optional data fields	Incident Data Repository.
Users and shared entry	pharmacy team to contribute to the documentation of each practice incident or close call. Each team member must have individual login access, with permissions customized as needed based on the team member's role. Onboarding and offboarding procedures must include management of users within the practice incident management platform.
Engagement	In the event it is not available from the national database, platform vendors must agree to provide ACP with de-identified engagement information, including the number of unique pharmacies reporting at least one incident or close call, incidents or close calls reported, and unique system users reporting. Frequency: monthly and annual summaries

Note: If the platform provider does not have a safety self-assessment tool available within their platform, the licensee must separately subscribe to a safety self-assessment tool.



Appendix B - Resources

This appendix contains links to resources referenced within the body of the guide, as well as additional resources identified for the public.

Resources for regulated members

- <u>CQI+ webpage</u>, Alberta College of Pharmacy
- <u>CQI+ quick start checklist</u>, Alberta College of Pharmacy
- CQI+ Q&A, Alberta College of Pharmacy
- <u>CQI+ practice incident management platform requirements</u>, Alberta College of Pharmacy
- Data Sharing Agreement, ISMP Canada (coming soon)
- Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals, NAPRA
- Glossary: Recommended Terms, Health Quality Council of Alberta
- Glossary: Terms to Avoid, Health Quality Council of Alberta

Safety culture

- Just Culture, Health Quality Council of Alberta
- Safety Culture Fact Sheet, Health Quality Council of Alberta

Prevent

- General policies and procedures manual template, Alberta College of Pharmacy
- Patient Concerns Management A Framework for Alberta, Health Quality Council of Alberta
- Advice to the professions: Licensees' roles in responding to patient concerns, Alberta College of Pharmacy
- Medication Safety Self-Assessment (MSSA), ISMP Canada
- Pharmacy Safety Self-Assessment (PSSA), ThinkResearch

Respond

- A Guide to Disclosure of Harm, Health Quality Council of Alberta
- <u>Just Individual Assessment</u> (JIA), Health Quality Council of Alberta
 - JIA tool directory



Analyze

- <u>Canadian Incident Analysis Framework</u>, ISMP Canada
- Virtual Workshops, ISMP Canada
- <u>Patient Safety Essentials Toolkit</u>, The Institute for Healthcare Improvement
- Quality Improvement Essentials Toolkit, The Institute for Healthcare Improvement
- Systematic Systems Analysis (SSA), Health Quality Council of Alberta

Improve

- Hierarchy of Effectiveness, ISMP Canada
- <u>Plan-Do-Study-Act (PDSA) Worksheet</u>, The Institute for Healthcare Improvement

Resources for the public

- <u>SafeMedicationUse.ca</u>, ISMP Canada A website for consumers to report medication incidents and to get information about using medication safely.
- Public reporting of a medication error or adverse reaction to a medication, ISMP Canada
- When Something Goes Wrong Information for patients who've been harmed during healthcare, Health Quality Council of Alberta