NEWFOUNDLAND & LABRADOR PHARMACY BOARD

MedSTEP NL

Continuous Quality Improvement & Medication Incident Reporting

Kelda Newport, Director of Quality & Pharmacy Licensing, NLPB

Enna Aujla, Director of Community Pharmacy Reporting and Learning, ISMP Canada

Land Acknowledgement

We respectfully acknowledge the land on which we gather as the ancestral homelands of the Beothuk. We also acknowledge the island of Ktaqmkuk (Newfoundland) as the unceded, traditional territory of the Beothuk and the Mi’kmaq. And we acknowledge Labrador as the traditional and ancestral homelands of the Innu of Nitassinin, the Inuit of Nunatsiavut, and the Inuit of NunatuKavut. As we open our hearts and minds to the past, we commit ourselves to working in a spirit of truth and reconciliation to make a better future for all.

Outline

1. Describe the concepts of CQI and MIR.
2. Outline elements of MedSTEP NL.
3. Discuss key implementation steps and dates.
4. ISMP Canada Overview.

Continuous Quality Improvement

CQI refers to the structured processes used within the pharmacy, which allows for continual review and improvement of all aspects of the medication dispensing and patient care process, to improve patient safety.

It is about change and increasing the chances that the changes made in pharmacy result in improved patient safety.

To achieve safer care for patients, CQI must focus on both system improvements as well as the tasks performed within each pharmacy.

CQI is an ongoing, collaborative, and iterative process.

Medication Incident Reporting

A medication incident is any preventable event that may cause or lead to inappropriate medication use or patient harm that has reached the patient.

May be related to professional practice, drug products, procedures, and systems, and include prescribing, order communications, product labelling/packaging, compounding, dispensing, distribution, administration, education, monitoring, and use.

All medication incidents that reach a patient need to be reported anonymously to the National Incident Data Repository and should be documented fully in pharmacy records.

Near-Miss Events

An event that could have resulted in unwanted consequences but did not reach the patient either by chance or through timely intervention.

Near misses create opportunities to analyze medication system processes

The pharmacist-in-charge is responsible for establishing policies and procedures related to the documentation and reporting of near-miss events

SAMPLE CRITERIA

Appendix A of the NAPRA Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting

MedSTEP NL

MEDICATION SAFETY THROUGH ERROR PREVENTION

MedSTEP NL is a standardized CQI and MIR program for community pharmacies

- The MedSTEP NL program is mandatory for all community pharmacies as per section 1.3 of the Standards of Pharmacy Operation – Community Pharmacy.

a) Pharmacists-in-charge must implement an ongoing quality management program that:

iii. includes a process for proactive risk assessment, medication incident and near-miss reporting, and continuous quality improvement in accordance with the MedSTEP NL program, including the Model Standards for Continuous Quality Improvement and Medication Incident Reporting and related interpretation guides.

- NLPB's Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting were approved by the Board in June 2023

MedSTEP NL

Incident Discovery and Handling

Investigation and Communication

Documentation and Reporting

Assessment, Prevention & Shared Learning

General Standards

Section 1.1 of the Standards of Practice for CQI & MIR

Policy and Procedure Manual

- Processes for addressing, reporting, investigating, documenting, disclosing, and learning from medication incidents and near-misses;
- Processes for identifying contributing factors for medication incidents and near-miss events and performing an incident analysis;
- the expectations for reviewing and assessing summary reports and analyses of pharmacy-specific data and analyses of shared learnings from the national database;
- the schedule for routine CQI pharmacy staff meetings and for completing a safety self-assessment (SSA).

General Standards

Section 1.2 and 1.3 of the Standards of Practice for CQI & MIR

Expectations for PIC & Pharmacy Professionals

- ensure that a CQI program is developed, documented, and implemented in the pharmacy, and that the requirements of the MedSTEP NL program are met;
- Incorporate CQI within practice, including:
  - contributing to a culture of patient safety;
  - following the pharmacy's CQI-related policies and procedures;
  - engaging in pharmacy staff meetings to discuss summary reports, analyses of pharmacy-specific data, and shared learning from the NIDR;
  - engaging in the pharmacy's SSA process;
  - implementing procedural improvements established by the pharmacist-in-charge.

Incident Discovery & Handling

Sections 2.1 and 2.2 of the Standards of Practice for CQI & MIR

- Pharmacy-specific policy and procedures for handling a medication incident or near-miss event.
- Establish expectations for non-pharmacist staff members to notify a pharmacist staff member.
- Handling the Incident
  - Determine if the patient experienced harm or is at risk for harm.
  - Acknowledge that a medication incident occurred and apologize for distress caused to the patient.
  - Listen, express empathy and concern.
  - Ensure patient receives appropriate consultation in a timely manner.
  - Inform patient of incident follow-up and reporting process (e.g. PIC, National Data Repository, changes to systems and processes).

Investigation & Communication

Section 3.1 of the Standards of Practice for CQI & MIR

Ensure appropriate processes have been followed as described in section 2.2;

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

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

Ensure that the investigation of the contributing factors is done using a systematic process in a transparent and timely manner, engaging pharmacy staff members as appropriate;

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

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

Documentation & Reporting

Section 4.1 of the Standards of Practice for CQI & MIR

- Select a reporting platform that has processes to deidentify patient information and can anonymize data ensuring no patient or pharmacy personnel identifiers once data leaves the platform and can submit data into the national database
- Ensure that pharmacy-specific policies and procedures clearly outline the steps that pharmacy staff must take regarding the documentation and reporting of medication incidents and near-miss events
- Ensure the following documentation is retained in the pharmacy and available for audit, including:
  - all communications with patients and prescribers regarding medication incidents or near-miss events;
  - all CQI improvement plans and outcomes, developed following a medication incident or near-miss event;
  - all CQI improvement plans and outcomes, developed following completion of an SSA; and
  - documentation from formal CQI meetings with pharmacy staff including date, staff members present, topics of discussion and shared learning.

Assessment, Prevention, & Shared Learning

Section 5.1 of the Standards of Practice for CQI & MIR

Pharmacy-specific safety self-assessment

- Existing pharmacy: during the first year of the MedSTEP NL program, and at least every two years thereafter;
- New pharmacy: within the first year of operation, and at least every two years thereafter;
- Change in pharmacy's pharmacist-in-charge: within six months following change.

Assessment, Prevention, & Shared Learning

Section 5.1 of the Standards of Practice for CQI & MIR

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

Process in place for pharmacy staff to review and participate in the analysis of medication incidents to assist with identification of contributing factors;

Pharmacy-level data and national shared learning are reviewed on a quarterly basis to look at trends or opportunities for improvement.

MedSTEP NL:
Phased Implementation

IMPLEMENTATION STEP	IMPLEMENTATION DEADLINE
REVIEW STANDARDS AND RESOURCES	**DECEMBER 31, 2023**
Pharmacist-in-charge (PIC) reviews and understands NLPB's Standards of Practice for Continuous Quality Improvement (CQI) and Medication Incident Reporting (MIR) and CQI and MIR information and resources available on the NLPB website.	
PIC starts to develop a pharmacy policies and procedures manual for MedSTEP NL.	
Pharmacy staff members, including pharmacists, pharmacy technicians, and pharmacy assistants, review and understand NLPB's standards of practice for CQI and MIR and CQI and MIR information and resources available on the NLPB website.	

MedSTEP NL:
Phased Implementation

IMPLEMENTATION STEP	IMPLEMENTATION DEADLINE
CHOOSE A REPORTING PLATFORM AND EXPORT DATA TO THE NATIONAL INCIDENT DATA REPOSITORY (NIDR)	**MARCH 31, 2024**
PIC reviews and understands MedSTEP NL criteria for a MIR platform.	
PIC either: • subscribes to a MIR platform that meets MedSTEP NL criteria; or • ensures existing or in-house MIR platform meets MedSTEP NL criteria.	
PIC signs and submits a data-sharing agreement with NIDR.	
PIC obtains a Medication Safety Self-Assessment tool included in the chosen reporting platform or from another source.	
PIC completes the pharmacy policies and procedures manual for MedSTEP NL.	
Pharmacy staff including pharmacists, pharmacy technicians, and pharmacy assistants reviews and understands the policies and procedures for MedSTEP NL.	

MedSTEP NL:
Phased Implementation

IMPLEMENTATION STEP	IMPLEMENTATION DEADLINE
TRAIN STAFF	**JUNE 30, 2024**
PIC appoints a CQI coordinator (in addition to themselves), if feasible, to help ensure the policy and procedure manual is updated as required, training is ongoing, and medication incidents and near-misses are reported in a timely matter.	
PIC engages with all pharmacy staff in discussions on processes to report incidents and near-miss events and ensures all staff are trained and comfortable with the pharmacy's policy and procedure manual and reporting platform.	
PIC ensures all pharmacy staff have completed the training provided by the MIR platform.	

MedSTEP NL:
Phased Implementation

IMPLEMENTATION STEP	IMPLEMENTATION DEADLINE
COMPLETE IMPLEMENTATION	**JULY 1, 2024**
Pharmacy starts reporting medication incidents and near-miss events as per NLPB's Standards of Practice for CQI and MIR.	JULY 1, 2024
PIC/CQI Coordinator holds and documents a formal CQI meeting within 6 months of MedSTEP NL program implementation and as per NLPB's Standards of Practice for CQI and MIR thereafter.	DECEMBER 31, 2024
PIC/CQI Coordinator completes a Medication Safety Self-Assessment during the first year of the MedSTEP NL program and as per NLPB's Standards of Practice for CQI and MIR thereafter.	JULY 1, 2025

MedSTEP NL

MEDICATION SAFETY THROUGH ERROR PREVENTION

nlpb.ca/medstep-nl

Medication Incident Reporting

Newfoundland and Labrador Pharmacy Board
MedSTEP NL

September 20, 2023

ZERO Preventable Harm From Medications
Institute for Safe Medication Practices Canada

Land Acknowledgement

We acknowledge we are hosted on the lands of the Mississaugas of the Anishinaabe, the Haudenosaunee Confederacy and the Wendat. We also recognize the enduring presence of all First Nations, Métis and the Inuit peoples.[1] We are grateful to live, work and play on this land and we want to contribute to the implementation of the Truth and Reconciliation Commission's eight health-related Calls to Action.

Nous tenons à souligner que nous sommes accueillis sur le territoire traditionel des Mississaugas, des Anichinabés, des Haudenosaunees et des Wendats. Nous voulons également reconnaître la pérennité de la présence des Premières Nations, des Métis et des Inuits. Nous sommes reconnaissants de vivre, de travailler et de jouer sur ce territoire et nous voulons contribuer à la mise en œuvre des huit appels à l'action de la Commission de vérité et de réconciliation en matière de santé.

Find your land acknowledgement at https://native-land.ca/

[1] https://www.tdsb.on.ca/Community/Indigenous-Education/Resources/Land-Acknowledgement

Agenda

ISMP Canada

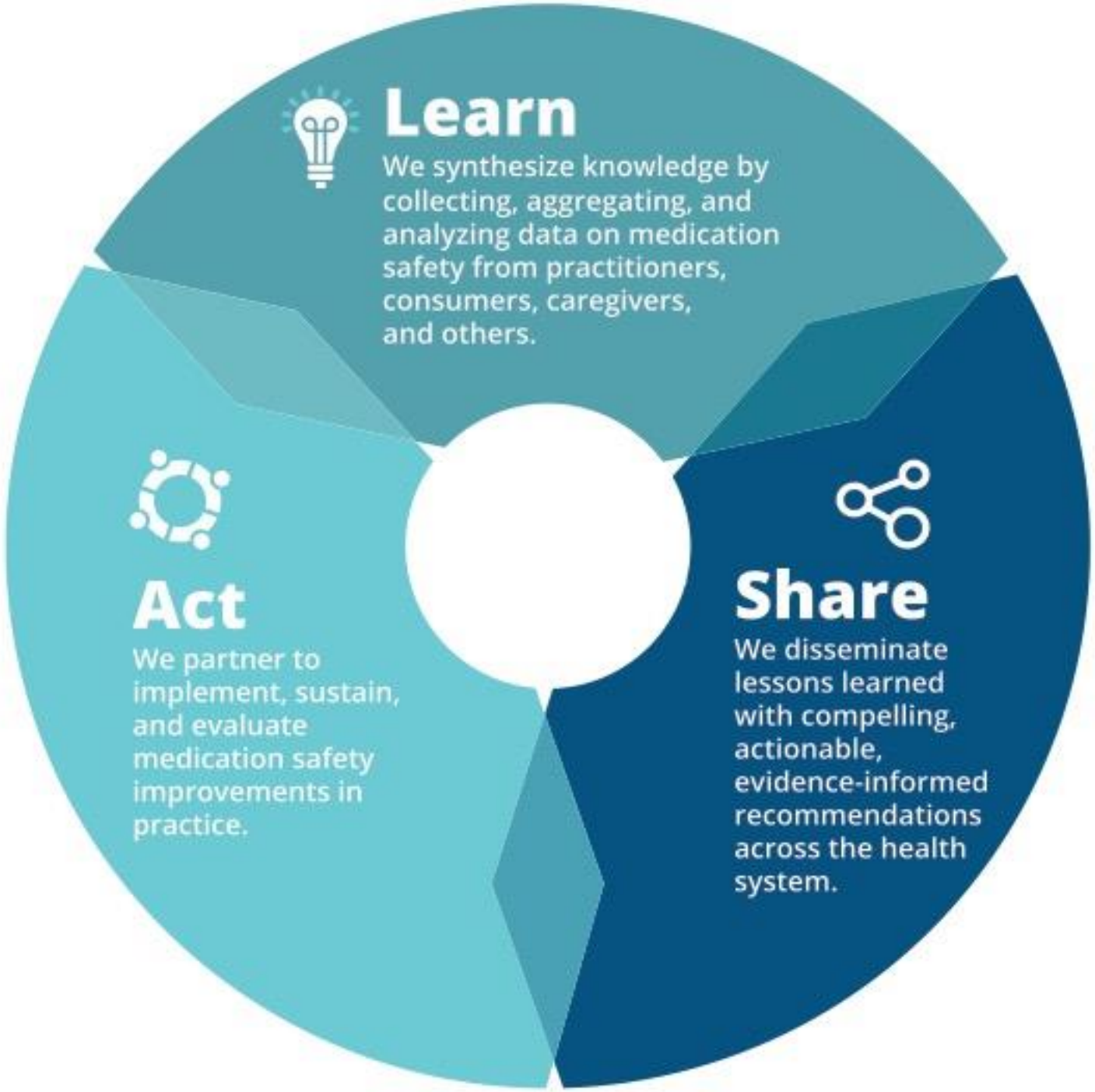
- About Us
- CMIRPS and NIDR
- Pharmacy Steps
- Platform Providers
- Supporting Practice Through Sharing and Learning

A Trusted Partner

Strengthening medication safety through timely learning, sharing, and acting to improve health care.

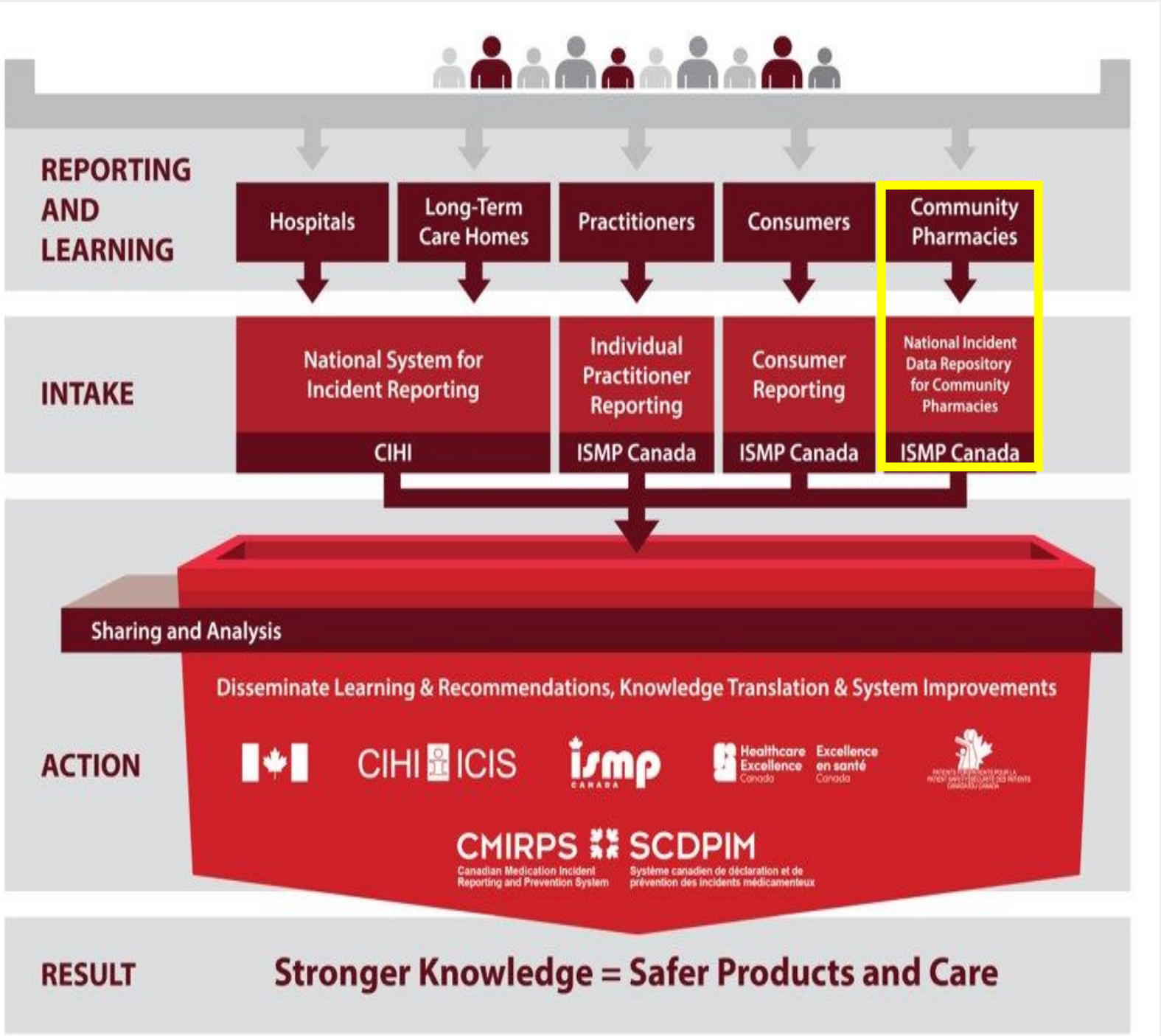
ISMP Canada is a national, independent, not-for-profit organization that purposefully partners with organizations, practitioners, consumers, and caregivers to advance medication safety in all healthcare settings.

ismp CANADA



The Canadian Medication Incident Reporting and Prevention System (CMIRPS) and the National Incident Data Repository (NIDR) for Community Pharmacies

CMIRPS and the NIDR



NIDR FAQ

The National Incident Data Repository for Community Pharmacies (NIDR)

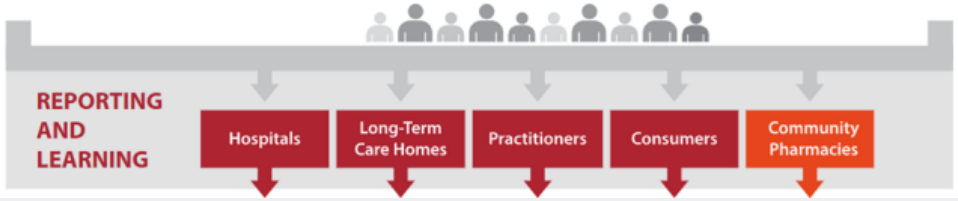
Information and Frequently Asked Questions

Background

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national, not-for-profit organization that is committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes receiving and analyzing medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents.

ISMP Canada is one of the collaborating parties in the Canadian Medication Incident Reporting and Prevention System (CMIRPS), together with Health Canada, Canadian Institute for Health Information (CIHI), Patients for Patient Safety Canada and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

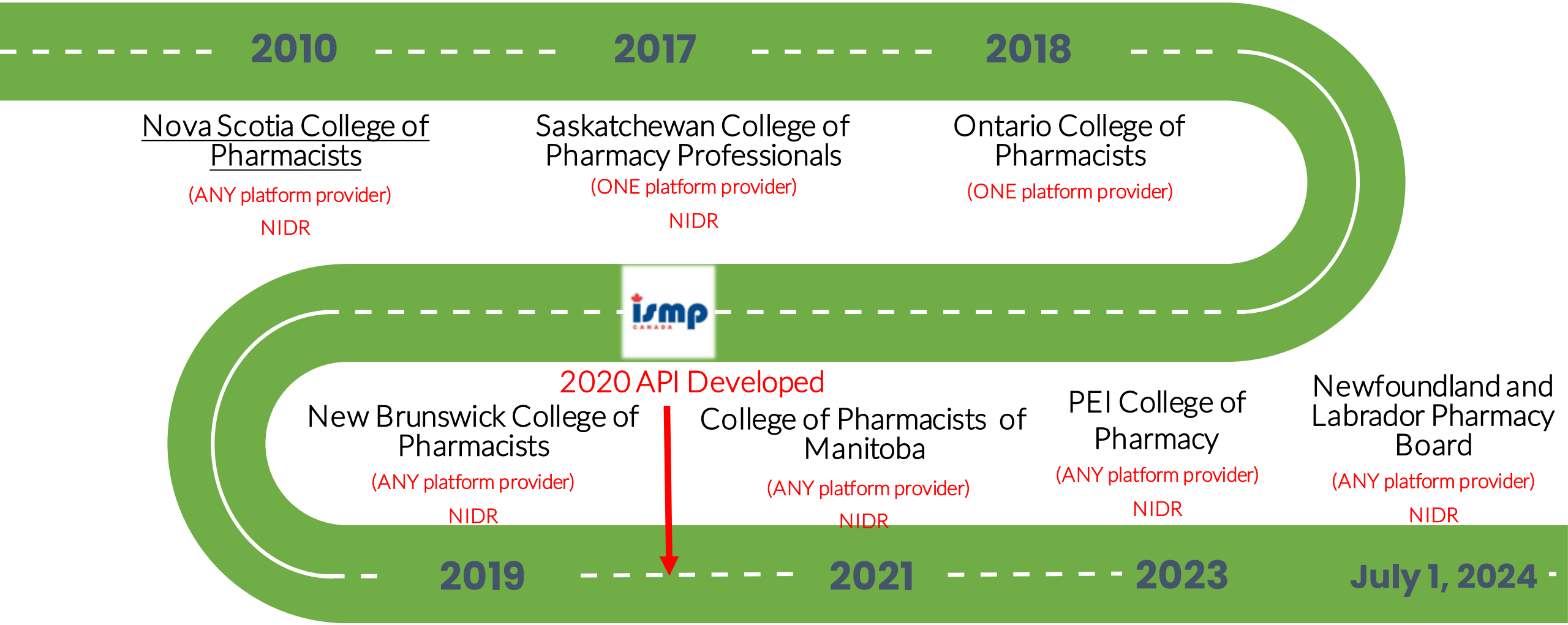
ISMP Canada receives funding from Health Canada for medication safety activities to support the goal of CMIRPS. These activities include the analysis of reports submitted to the: National Incident Data Repository for Community Pharmacies; consumer reporting program, individual practitioner reporting program; and CIHI's National System for Incident Reporting (NSIR). This analysis facilitates the development and dissemination of timely, targeted recommendations designed to improve health care systems and medication safety. See the infographic below for an overview of CMIRPS.



NIDR-faq.pdf (ismpcanada.ca)

Provincial Regulatory Mandatory Program Timeline

Pan-Canadian (2023)



Pharmacy Steps

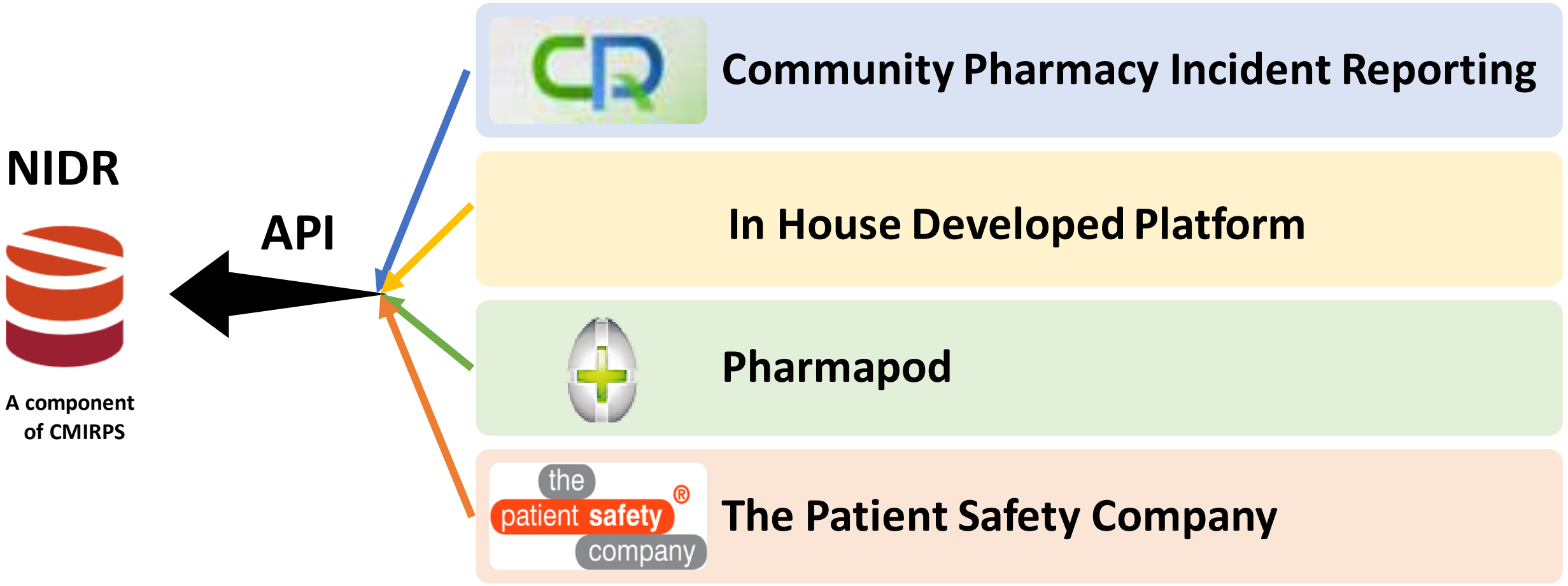
1. Choose a Reporting Platform Provider

What is a Medication Incident Reporting Platform?

- Software program that pharmacy teams use to record data on medication incidents and near-miss events
- Exports de-identified (anonymous) data to the NIDR
    - Work with the NIDR team, if needed, to enable the Reporting Platform Provider to submit data to the NIDR
        - NIDR@ismpcanada.ca
- Meets the MedSTEP NL criteria
- Deadline: March 31, 2024

Platform Providers and the Data Submission Protocol Agreement

Platforms Reporting into the NIDR



API = Application Programming Interface

Note: ISMP Canada cannot provide a recommendation for a platform provider

Data Submission Protocol Agreement (DSPA)

What is a Data Submission Protocol Agreement (DSPA)?

- Agreement between the Platform Provider and ISMP Canada
- One DSPA per Reporting Platform Provider, per province
- Includes list of pharmacies authorizing use of the platform to submit data to NIDR with a signed DSA
- Includes a data-mapping table – maps NIDR data fields with Reporting Platform Provider's data fields
- Provides API terms for use

- API is tested; Live API is provided when the DSPA is signed
- 4 Reporting Platform Providers have DSPAs signed in other provinces

2. Sign the Data Sharing Agreement (DSA) with NIDR

What is a Data Sharing Agreement?

- Data sharing agreement between the data owner (PIC or corporation) and the NIDR housed by ISMP Canada
- Data is collected through a secure transfer protocol for the purpose of analysis and shared learning to advance medication safety in all health care settings in Canada
- Name the chosen Reporting Platform Provider in the DSA

2. Sign the Data Sharing Agreement (DSA) with NIDR

When do I need to submit a DSA?

- The first time the pharmacy wants to submit data into the NIDR
- To notify ISMP Canada of a:
  - Change in Pharmacist-in-charge
  - Change in Community Pharmacy Ownership
  - Change of medication incident Reporting Platform Provider

Where can I find the DSA?

- NIDR-faq.pdf (ismpcanada.ca)
- Contact: NIDR@ismpcanada.ca

3. Provide Payment Information

- To the Reporting Platform Provider
  - Regular subscription fee (differs by provider)

- NIDR (housed by ISMP Canada)
  - Annual data processing fee of $70 + tax per pharmacy*

    **can also be paid by Reporting Platform Provider*
  - Inform the team of any changes in pharmacy details (e.g., change of ownership, change of Pharmacist-in-Charge)

  - NIDR FAQs: NIDR-faq.pdf (ismpcanada.ca)

4. Submit Data

➢ Medication Incident

- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

➢ Near Miss

- An event that could have resulted in unwanted consequences but did not because either by chance or through timely intervention the event did not reach the patient.

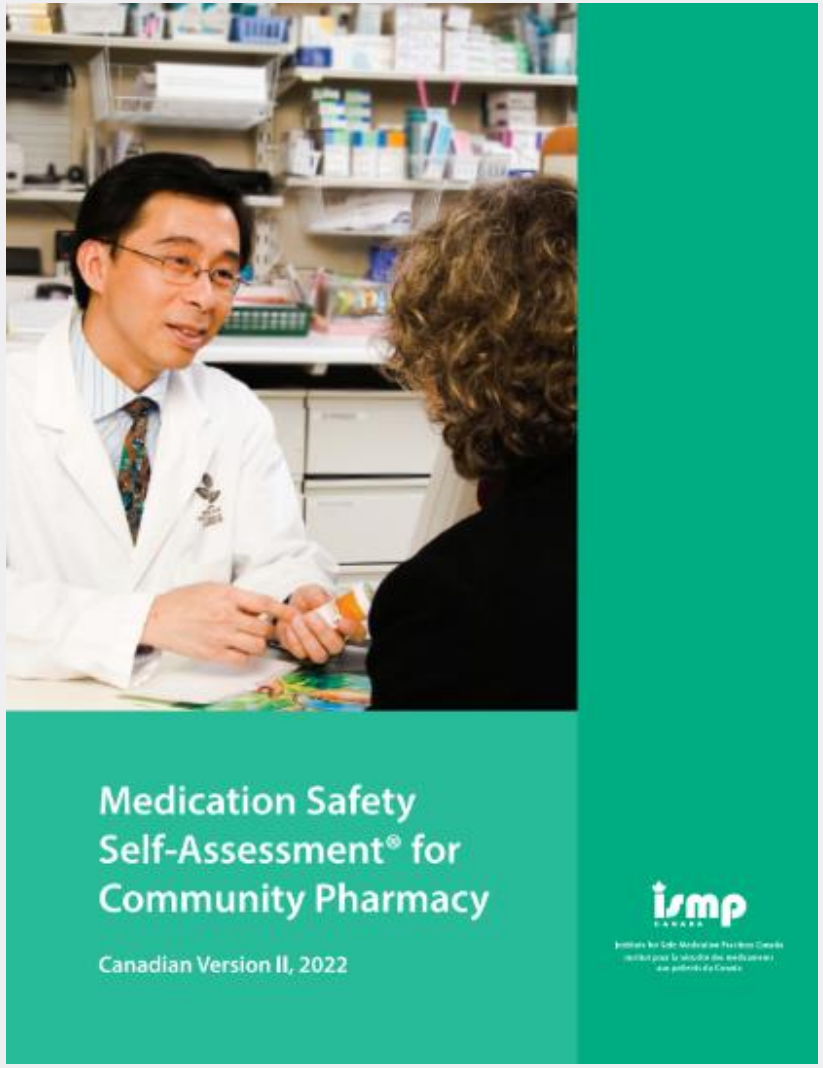
5. Implement MedSTEP NL

Continuous Quality Improvement

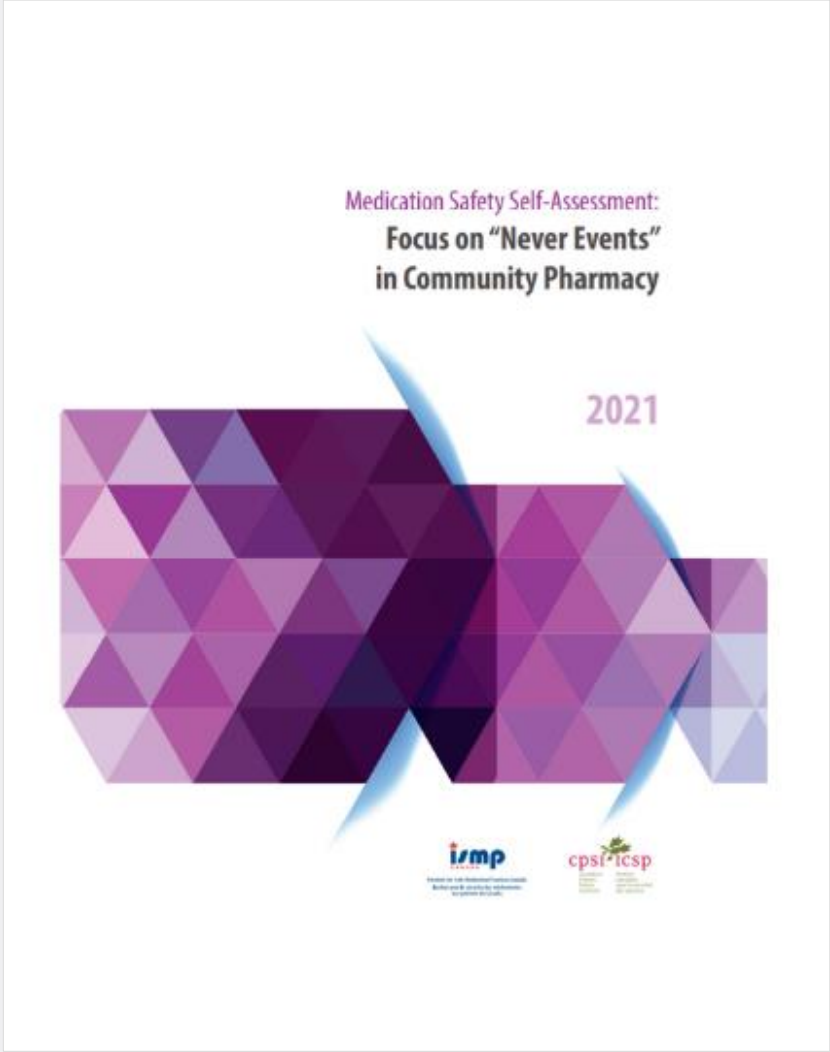
- Retrospective Approach
    - Comprehensive or concise individual incident analysis
    - Multi-incident analysis
    - Staff training and education to support culture of safety

- Prospective Approach
    - Medication Safety Self-Assessment

Medication Safety Self Assessments



User Fee: $150 or cost included in platform provider/corporate pharmacy arrangements



Available from website
[Introduction | ISMP Canada MSSA (ismp-canada.org)](ismp-canada.org)
Free for all pharmacies

Supporting Practice Through Learning

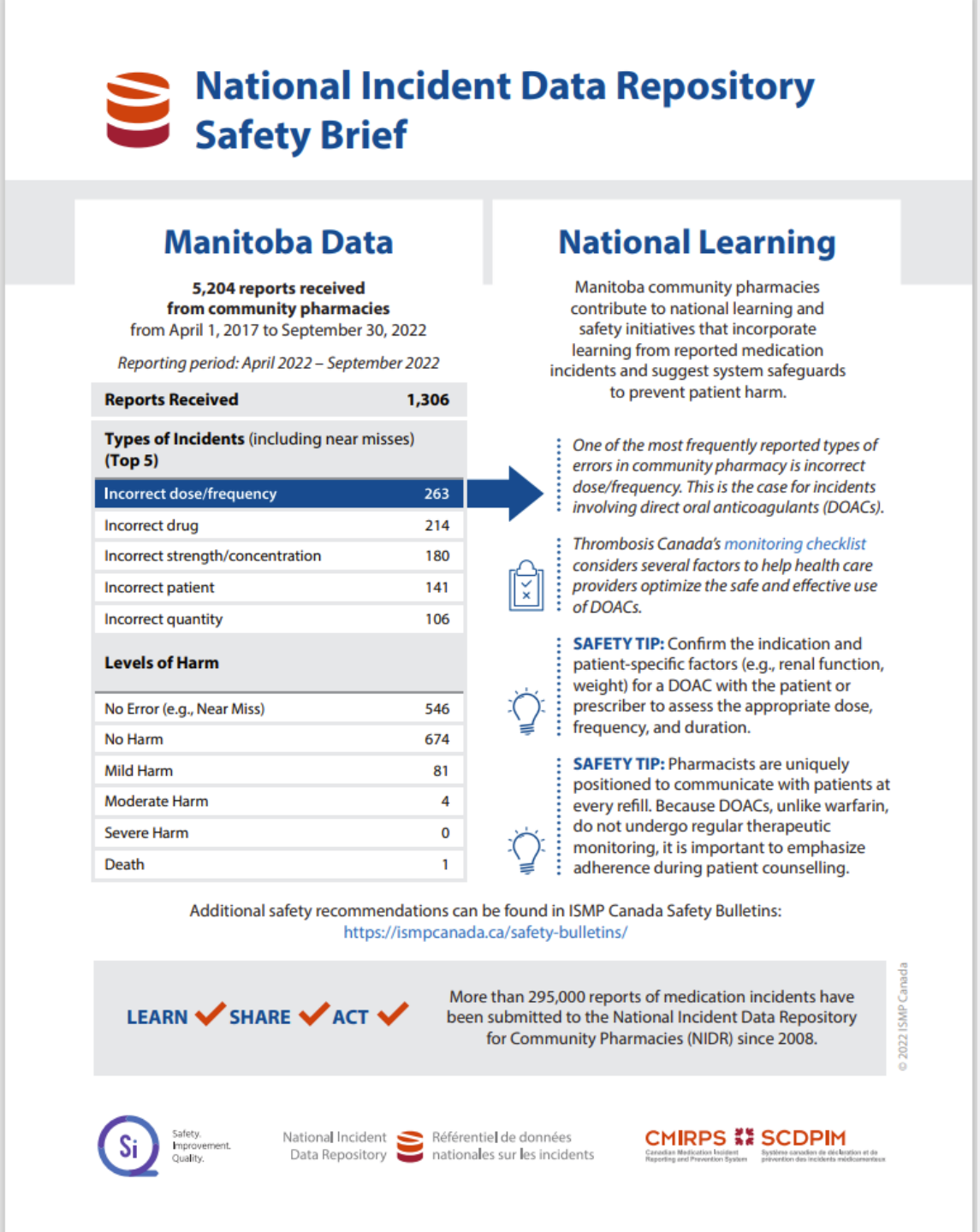
NIDR Safety Brief

*Number of reports

*Types of incidents

*Levels of harm

*Tips from nationally-derived qualitative analyses



National Snapshot

ismp CANADA

National Incident Data Repository for Community Pharmacies

National Snapshot

July 2022

Top 10 Medications Causing Harm (2016-2021)

1. Methadone
2. Levothyroxine
3. Warfarin
4. Furosemide
5. Sertraline
6. Hydrochlorothiazide
7. Citalopram
8. Metformin
9. Hydromorphone
10. Candesartan

Shared Learning from Analyses

Methadone

Analysis Finding: A significant number of errors related to methadone involve giving the drug to the wrong patient.

Safety Strategy: Avoid pre-pouring and always confirm patient identification (with two unique identifiers) and the dose.

Levothyroxine

Analysis Finding: Patient harm can occur when the dosage units of levothyroxine are mixed up or misinterpreted.

Safety Strategy: Standardize the expressions of strength in prescribing and dispensing systems with micrograms (mcg), not milligrams (mg), to align with manufacturer labels.

Warfarin

Analysis Finding: Warfarin's complex dosing regimen can increase the risk of error and harm.

Safety Strategy: Clearly communicate the warfarin dose with the patient based on the most recent INR test, especially when the regimen includes a combination of different strengths and/or varying daily doses.

Metformin

Analysis Finding: The need for frequent metformin dose adjustments and regimen changes can lead to errors and harm.

Safety Strategy: To prevent mix-ups involving metformin, offer patient education as a final check for the correct product and patient understanding.

Hydromorphone

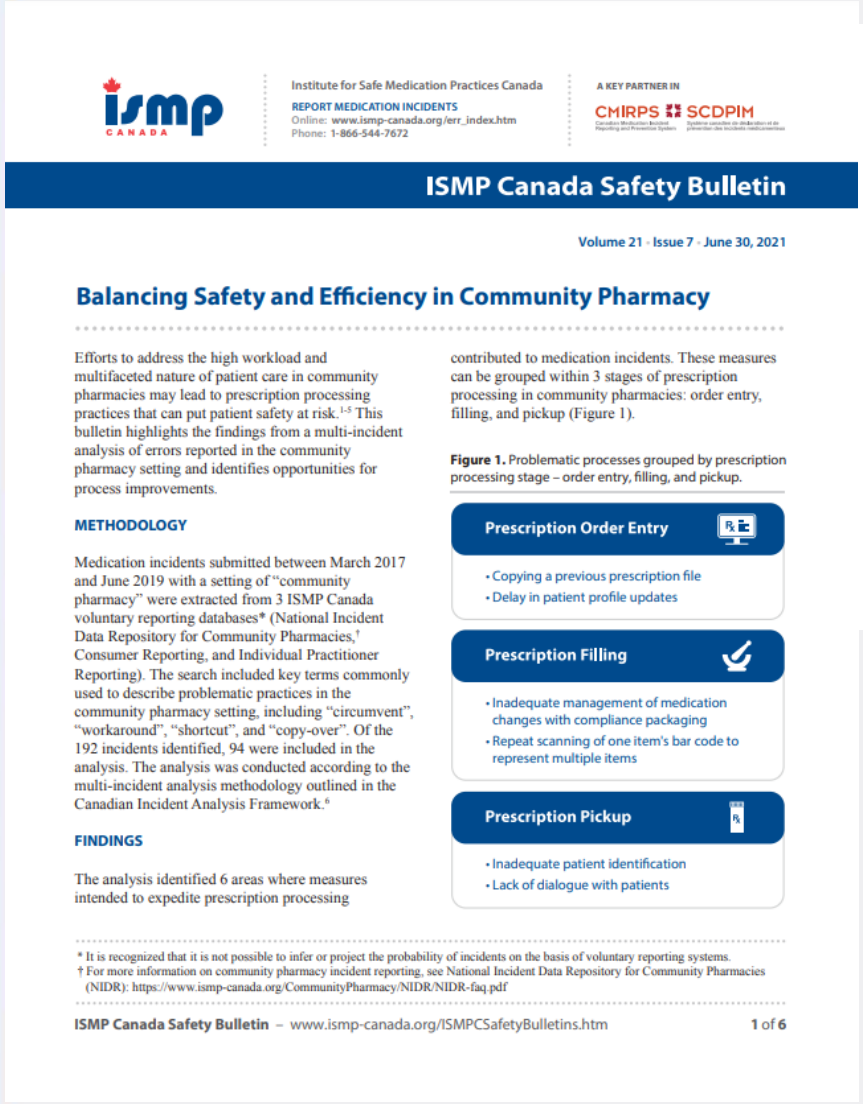
Analysis Finding: Harm can occur when long- and short-acting formulations of hydromorphone are inadvertently interchanged.

Safety Strategy: Include both the generic and brand names throughout the medication-use process to help differentiate between different formulations.

The **NIDR National Snapshot** shares information about the types of medication incidents that have been reported by community pharmacies in Canada. Safety bulletins with detailed analyses and recommendations are available here: https://ismpcanada.ca/safety-bulletins/

ismp CANADA
National Incident Data Repository
Référentiel de données nationales sur les incidents
CMIRPS SCDPIM
Canadian Medication Incident Reporting and Prevention System
Système canadien de déclaration et de prévention des incidents médicamenteux

Safety Bulletin and Med Safety Exchange



Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS SCDPIM

ISMP Canada Safety Bulletin

Volume 21 · Issue 7 · June 30, 2021

Balancing Safety and Efficiency in Community Pharmacy

Efforts to address the high workload and multifaceted nature of patient care in community pharmacies may lead to prescription processing practices that can put patient safety at risk.[1-5] This bulletin highlights the findings from a multi-incident analysis of errors reported in the community pharmacy setting and identifies opportunities for process improvements.

METHODOLOGY

Medication incidents submitted between March 2017 and June 2019 with a setting of "community pharmacy" were extracted from 3 ISMP Canada voluntary reporting databases* (National Incident Data Repository for Community Pharmacies,† Consumer Reporting, and Individual Practitioner Reporting). The search included key terms commonly used to describe problematic practices in the community pharmacy setting, including "circumvent", "workaround", "shortcut", and "copy-over". Of the 192 incidents identified, 94 were included in the analysis. The analysis was conducted according to the multi-incident analysis methodology outlined in the Canadian Incident Analysis Framework.[6]

FINDINGS

The analysis identified 6 areas where measures intended to expedite prescription processing contributed to medication incidents. These measures can be grouped within 3 stages of prescription processing in community pharmacies: order entry, filling, and pickup (Figure 1).

Figure 1. Problematic processes grouped by prescription processing stage – order entry, filling, and pickup.

Prescription Order Entry
- Copying a previous prescription file
- Delay in patient profile updates

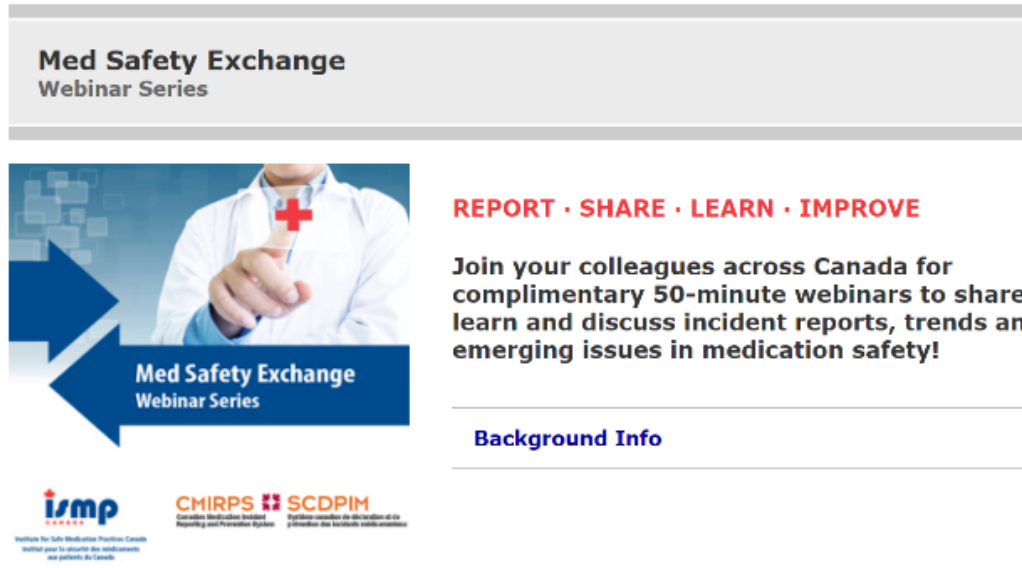
Prescription Filling
- Inadequate management of medication changes with compliance packaging
- Repeat scanning of one item's bar code to represent multiple items

Prescription Pickup
- Inadequate patient identification
- Lack of dialogue with patients

* It is recognized that it is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems.
† For more information on community pharmacy incident reporting, see National Incident Data Repository for Community Pharmacies (NIDR): https://www.ismp-canada.org/CommunityPharmacy/NIDR/NIDR-faq.pdf

ISMP Canada Safety Bulletin – www.ismp-canada.org/ISMPCSafetyBulletins.htm 1 of 6

[Balancing Safety and Efficiency in Community Pharmacy - ISMP Canada]



Med Safety Exchange
Webinar Series

REPORT · SHARE · LEARN · IMPROVE

Join your colleagues across Canada for complimentary 50-minute webinars to share learn and discuss incident reports, trends an emerging issues in medication safety!

Background Info

ismp CANADA
CMIRPS SCDPIM

[Med Safety Exchange - ISMP Canada]

eLearning and Online Modules

- **Keeping Pediatric Patients Safe: Pediatric Safety Considerations for Community Pharmacists**
- **Medication Safety Considerations for Compliance Packaging**
- **Preventing and Analyzing Medication Error A Primer for Community Pharmacies in Ontario**

Education - ISMP Canada

Live Virtual Workshops Education - ISMP Canada

Incident Analysis and Proactive Risk Assessment

▲ Overview

This virtual workshop will provide health care professionals with background theory and hands-on practice in incident analysis using Root Cause Analysis (RCA) and in proactive risk assessment using Failure Mode and Effects Analysis (FMEA).

7 upcoming dates - **Register**

- September 28 & 29, 2023 - **Full**
- October 28 & 29, 2023
- November 23 & 24, 2023
- December 16 & 17, 2023
- January 25 & 26, 2024
- February 24 & 25, 2024
- March 21 & 22, 2024

Multi-Incident Analysis and Medication Safety Culture Assessment

▲ Overview

This virtual workshop will provide participants with background theory and hands-on practice in using a multi-incident analysis to analyze a group of medication incidents that share a common topic on day 1 and introduce a novel tool called the Medication Safety Culture Indicator Matrix (MedSCIM) on day 2.

3 upcoming dates - **Register**

- September 21 & 22, 2023
- November 25 & 26, 2023
- March 23 & 24, 2024

Medication Reconciliation and Best Possible Medication History

▲ Overview

This 1-day live facilitated virtual workshop teaches health care professionals the fundamentals of medication reconciliation (MedRec) and Best Possible Medication History (BPMH) while providing hands-on practice with case scenarios on how to conduct in-person and virtual medication history interviews.

4 upcoming dates - **Register**

- September 23, 2023
- October 20, 2023
- November 17, 2023
- March 2, 2024

Thank you for listening.

Any Questions?

Contact: Enna Aujla, Director of Community Pharmacy Reporting and Learning
enna.aujla@ismpcanada.ca

ZERO Preventable Harm From Medications

Institute for Safe Medication Practices Canada