Community Pharmacy Medication Incident Reporting in Canada

California State Board of Pharmacy

January 23, 2024

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

Session Overview

- Melissa Sheldrick's Story
- Medication Incidents & ISMP Canada's Unique Mandate
- Reporting, Learning & Acting on Med Incidents
- How Each Pharmacy Contributes Their Incident Data
- Provincial and National Shared Learning and Improvements

ISMP Canada Presenters

Melissa Sheldrick,
BA Soc, MSc Ed
Patient and Family Advisor

Sylvia Hyland, RPh, BScPhm, MHSc
Vice President, Operations & Privacy Officer

Enna Aujla
Director, Community Pharmacy Reporting & Learning

Chief Executive Officer

Melissa's Story

Andrew Sheldrick died in 2016 because of errors made during the dispensing process of his compounded medication. The main error was a substitution of Andrew's tryptophan with baclofen.

Prescribed Tryptophan Dose:
3-gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime.

Melissa's Story

What is a medication incident?

A medication incident is a mistake with medicine, or a problem that could cause a mistake with medicine.

Harm Related To Medications

- As many as **1 in 10 hospitalizations** in OECD countries may be caused by a medication-related event
- As many **one in five inpatients** experience medication-related harms during hospitalization
- Together, costs from avoidable admissions due to medication-related events and added length of stay due to preventable hospital-acquired medication-related harms total over **USD 54 billion in OECD countries***

*de Bienassis, K., et al. (2022), "The economics of medication safety: Improving medication safety through collective, real-time learning", *OECD Health Working Papers*, No. 147, OECD Publishing, Paris, https://doi.org/10.1787/9a933261-en.

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

For over 20 years…

Reporting, Learning and Acting

ISMP Canada is a lead partner in the Canadian Medication Incident Reporting and Prevention Program(CMIRPS)

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

CMIRPS collaborates with local, provincial and national partners to prevent and respond to medication incidents across Canada

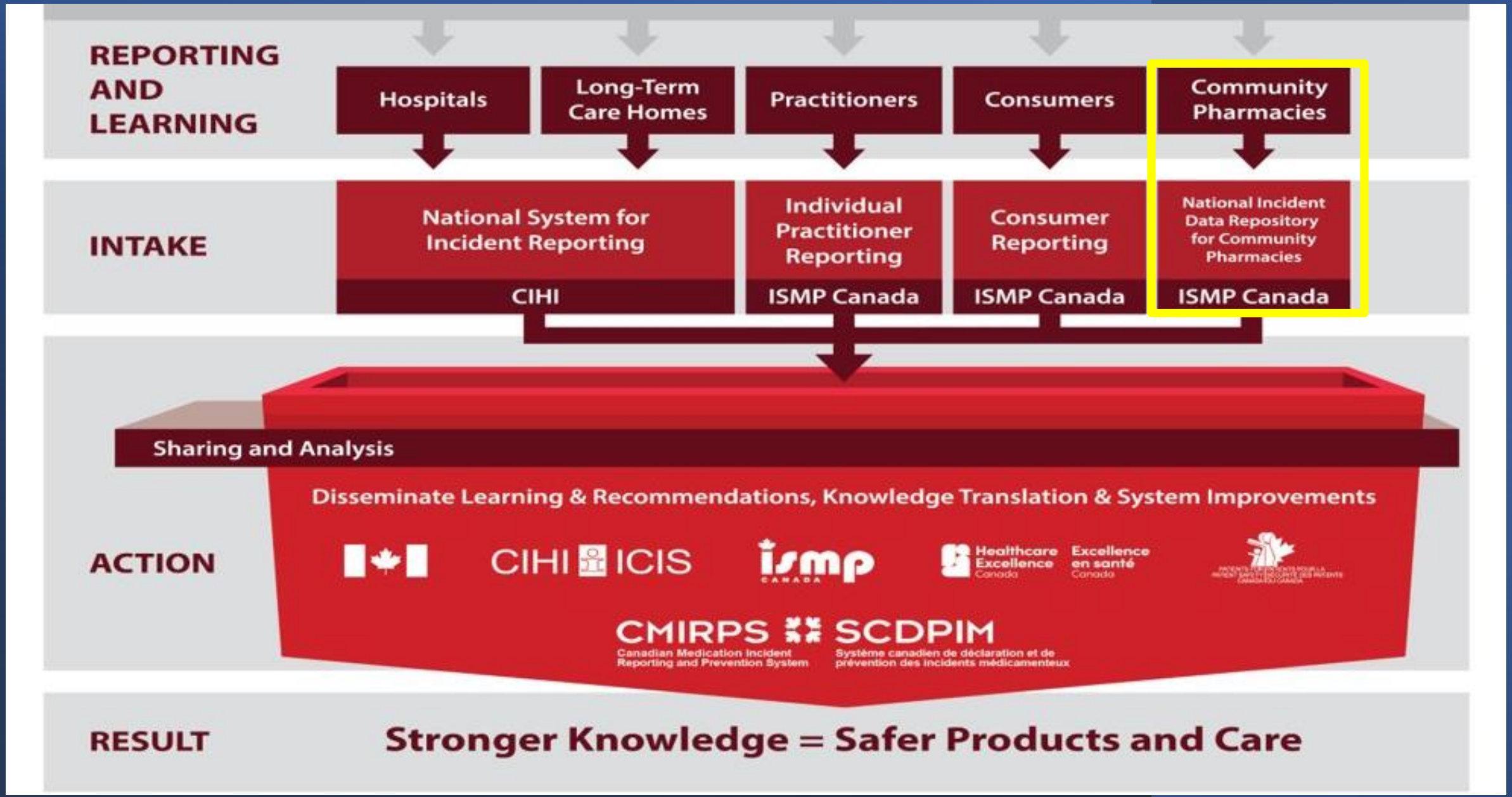
Medication incident occurs (includes harmful events, no-harm events, near misses and underlying conditions that could lead to harmful incidents)

The incident is reported through a CMIRPS channel by healthcare organizations, individual practitioners, consumers

Expert review, analysis & trend identification is conducted by ISMP Canada, including targeted review of additional data from the Canadian Institute for Health Information

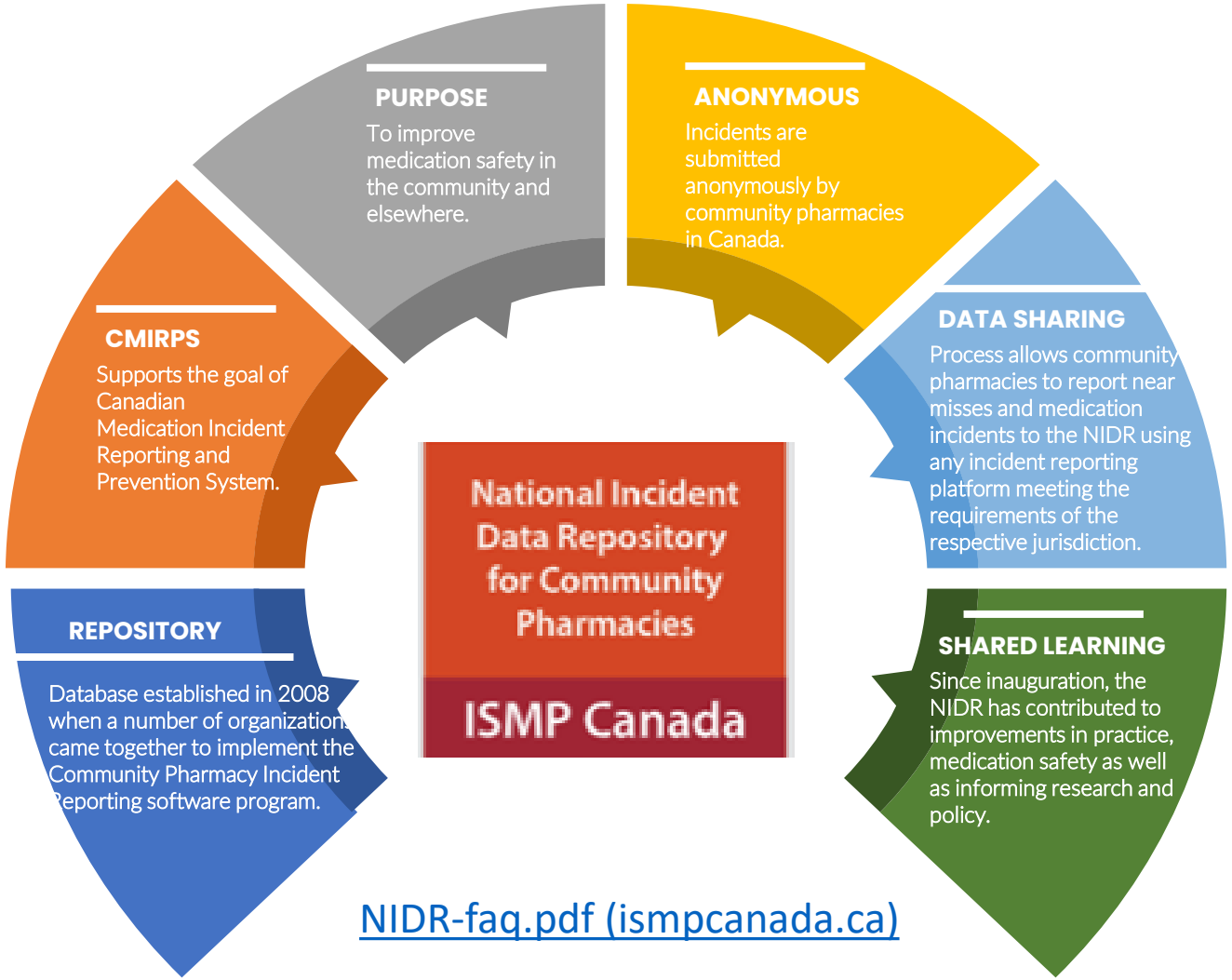
Action & recommendations are made via safety bulletins, alerts, stakeholder communication

Facilitation of change: measures to prevent reoccurrence are put in place

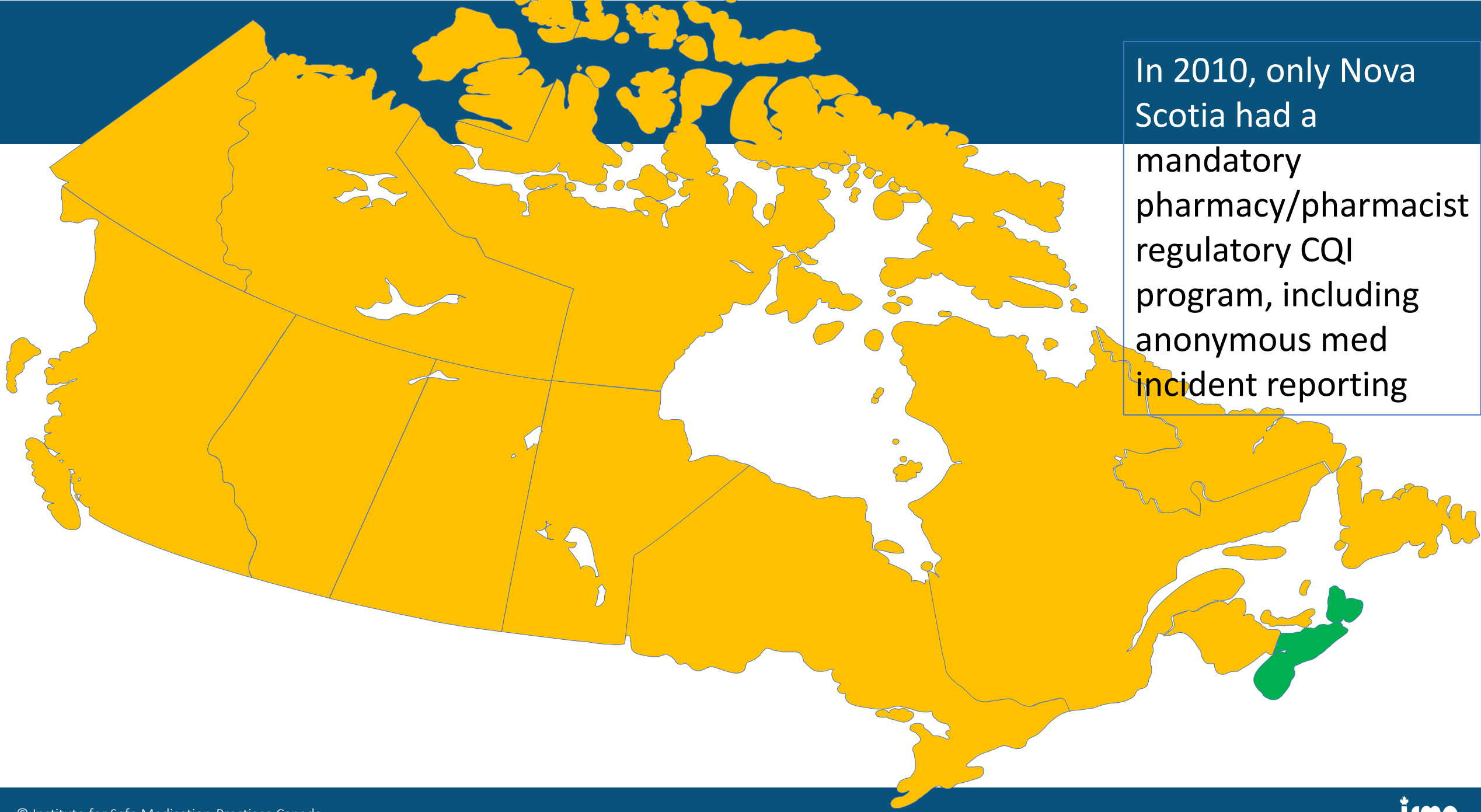

REPORTING AND LEARNING
Hospitals
Long-Term Care Homes
Practitioners
Consumers
Community Pharmacies
INTAKE
National System for Incident Reporting
CIHI
Individual Practitioner Reporting
ISMP Canada
Consumer Reporting
ISMP Canada
National Incident Data Repository for Community Pharmacies
ISMP Canada
Sharing and Analysis
ACTION
Disseminate Learning & Recommendations, Knowledge Translation & System Improvements
CIHI ICIS
ismp CANADA
Healthcare Excellence Canada
Excellence en santé Canada
CMIRPS
Canadian Medication Incident Reporting and Prevention System
SCDPIM
Système canadien de déclaration et de prévention des incidents médicamenteux
RESULT
Stronger Knowledge = Safer Products and Care

National Incident Data Repository for Community Pharmacies (NIDR)

National Incident Data Repository (NIDR)



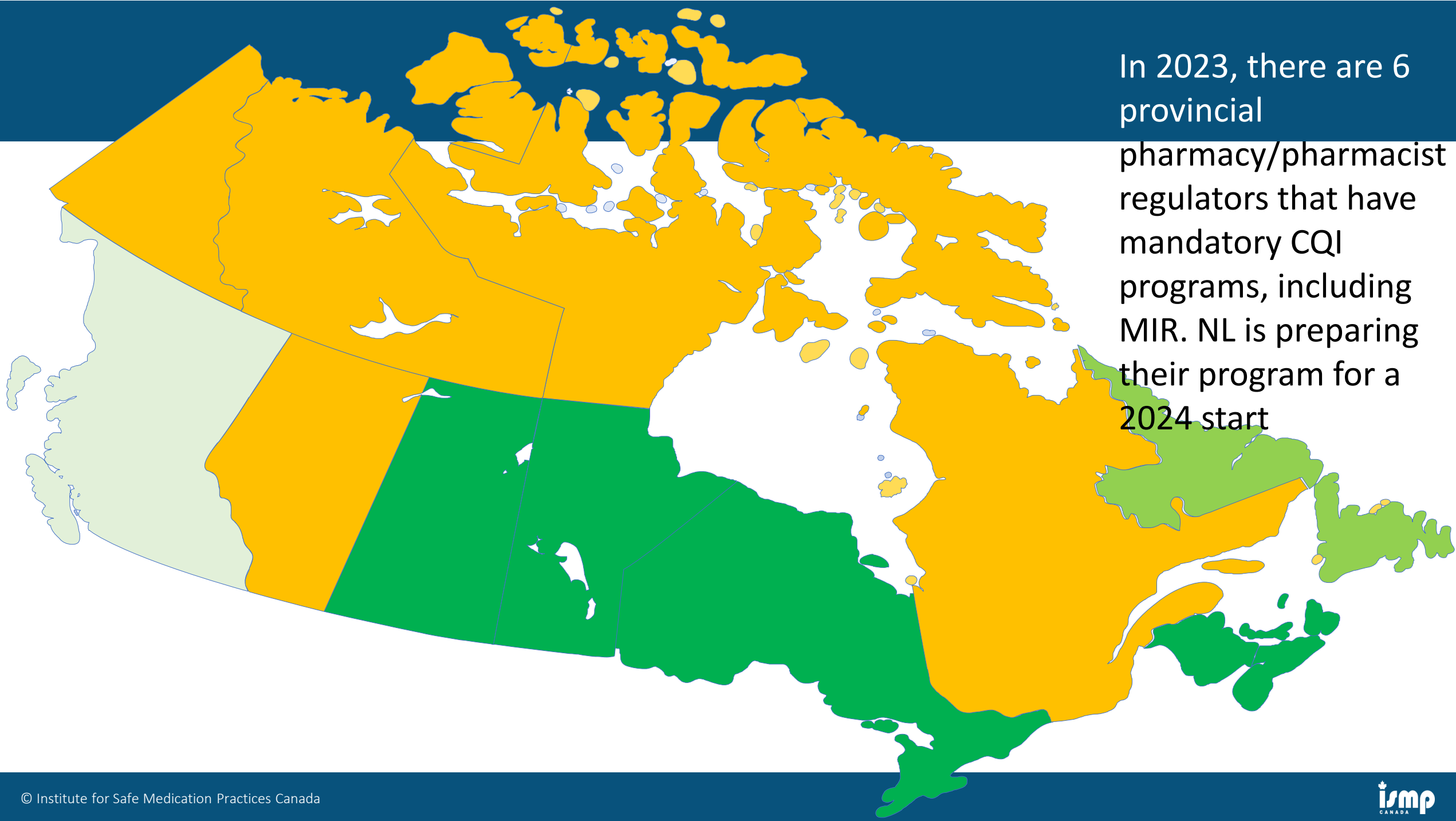
[NIDR-faq.pdf (ismpcanada.ca)]



In 2010, only Nova Scotia had a mandatory pharmacy/pharmacist regulatory CQI program, including anonymous med incident reporting

Innovation

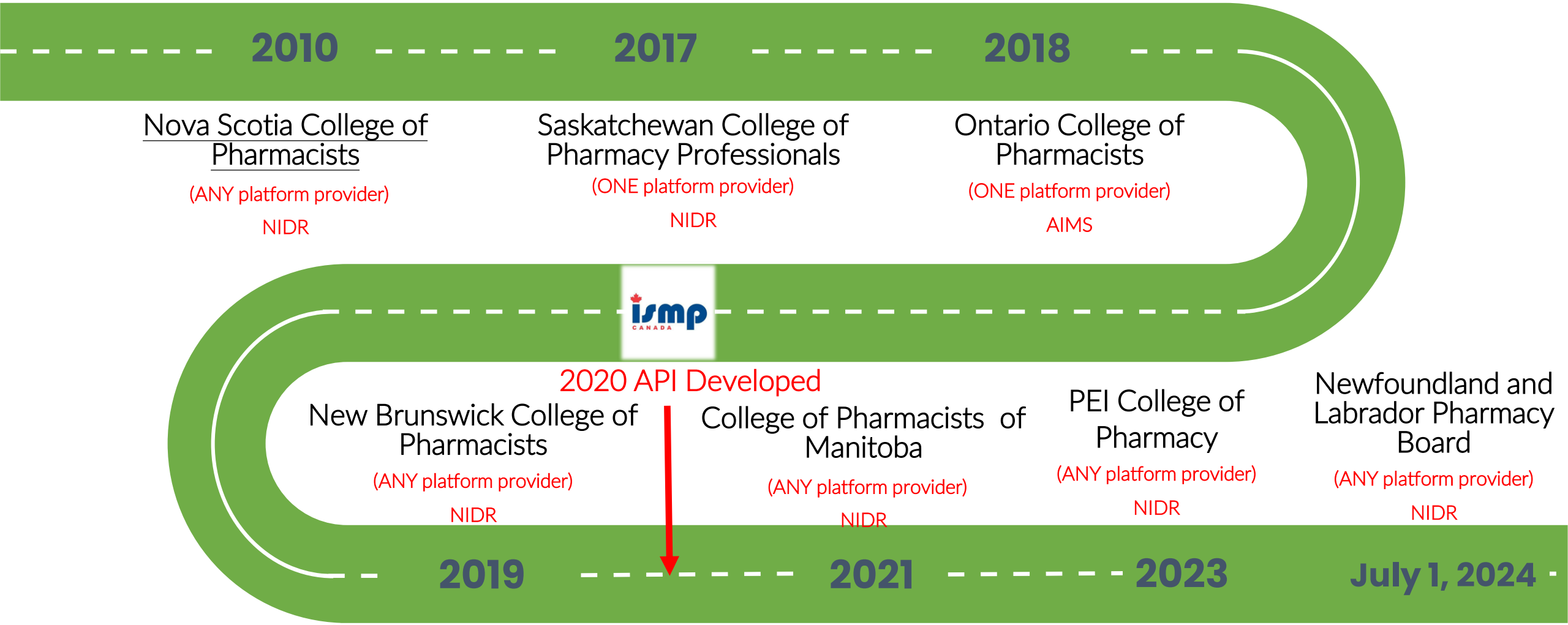
OCP invited Melissa to be part of the initial task force to craft this program and determine its needs. They had never invited a member of the public to be part of this type of task force.



In 2023, there are 6 provincial pharmacy/pharmacist regulators that have mandatory CQI programs, including MIR. NL is preparing their program for a 2024 start

Provincial Regulatory Mandatory Program Timeline

Pan-Canadian (2023)



NAPRA Model Standards

"Continuous quality improvement and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/ territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care."

ISMP Canada collaborating with Provincial Regulators

Saskatchewan College of Pharmacy Professionals – COMPASS

"The strength of the COMPASS program comes from Saskatchewan community pharmacies contributing to a national database called Canada's National Incident Data Repository for Community Pharmacies, which contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS)."

College of Pharmacists of Manitoba - Safety IQ

"Safety expert James Reason argued that "the most detrimental error is failing to learn from an error." **When healthcare professionals share what they learn from incidents within teams and across disciplines, safety improvements are passed along to all Canadians.** Through Safety IQ, community pharmacy teams share valuable learnings to improve patient outcomes on team, provincial, and national levels."

Nova Scotia College of Pharmacists - SafetyNETRx

"By submitting to a national database, pharmacies enable the identification of safety-related trends and patterns that can be communicated across the profession, not just in their own pharmacy.

ISMP Canada collaborating with Provincial Regulators

Newfoundland and Labrador Pharmacy Board - MedSTEP NL

"CQI and mandatory medication incident reporting programs provide pharmacy professionals with information and learning opportunities based on meaningful analysis of both pharmacy-level and national/provincial/territorial-level data, with the goal of reducing the number of medication incidents, mitigating risks to patients, and improving the quality and safety of patient care."

New Brunswick College of Pharmacists

"Pharmacy managers must ensure that **pharmacy professionals anonymously report medication errors (medication incidents that reach the patient) to an external, central Canadian database**."

PEI College of Pharmacy

The Council of the PEI College of Pharmacy has **adopted the NAPRA Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals.**" "The College will receive aggregate data (deidentified and anonymous) to monitor trends and participation in the mandatory medication incident reporting program (at the pharmacy level.)"

How Each Pharmacy Contributes to the NIDR

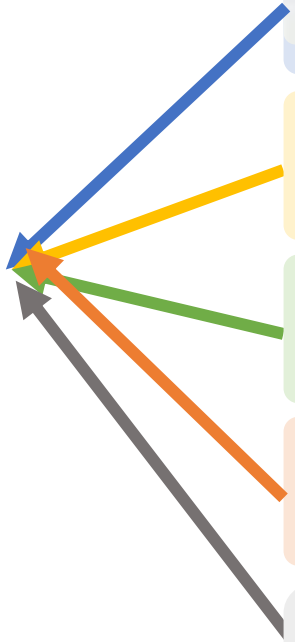
Enabling Data Submission Across Different Reporting Platforms

Platforms Reporting Into NIDR

NIDR

A component of CMIRPS

API



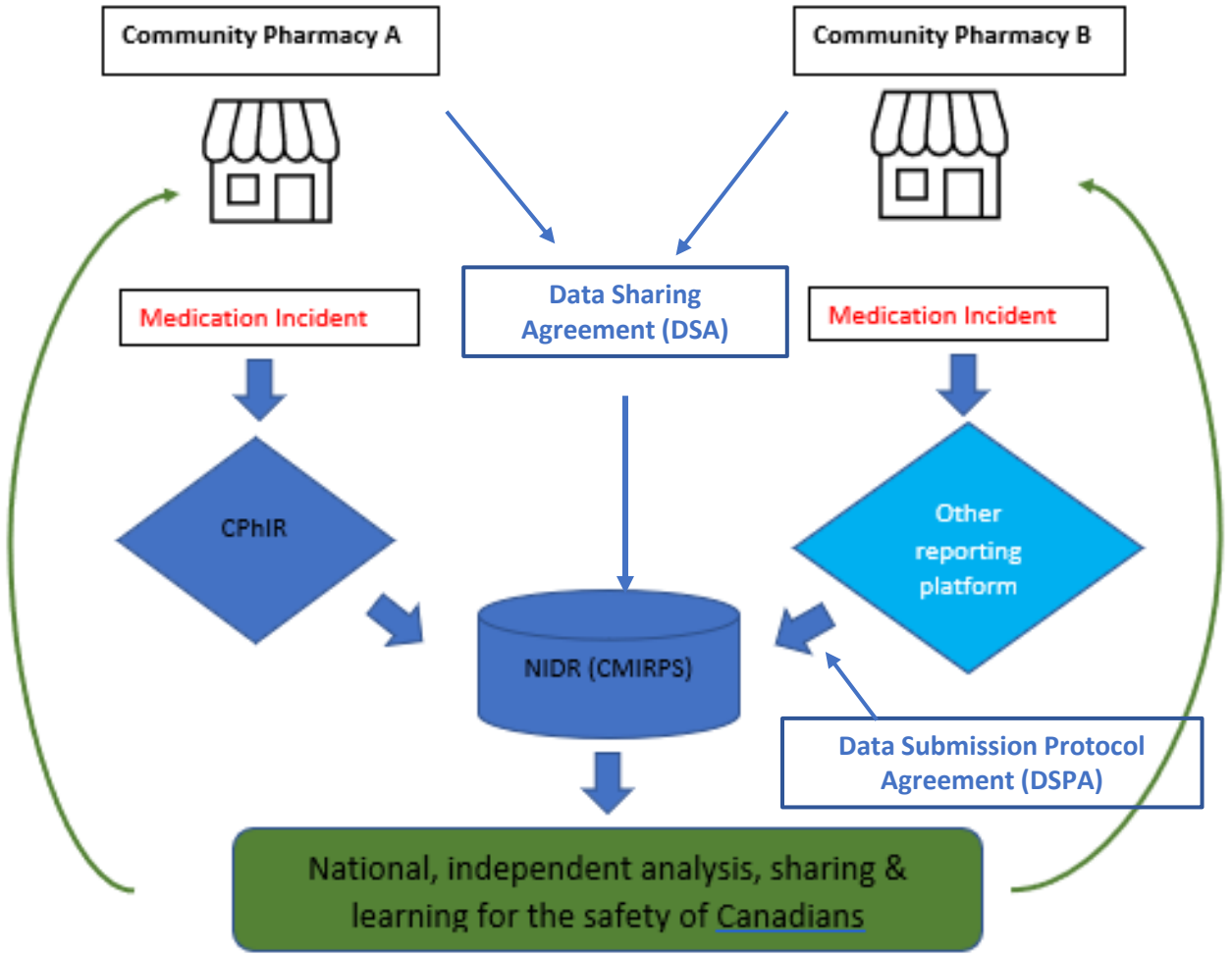
- **Community Pharmacy Incident Reporting (CPhIR)**
- **Third Party Platform Provider** (Vendor 1)
- **Third Party Platform Provider** (Vendor 2)
- **Third Party Platform Provider** (Vendor 3)
- **In-House Corporate Developed Platform**

API = Application Programming Interface

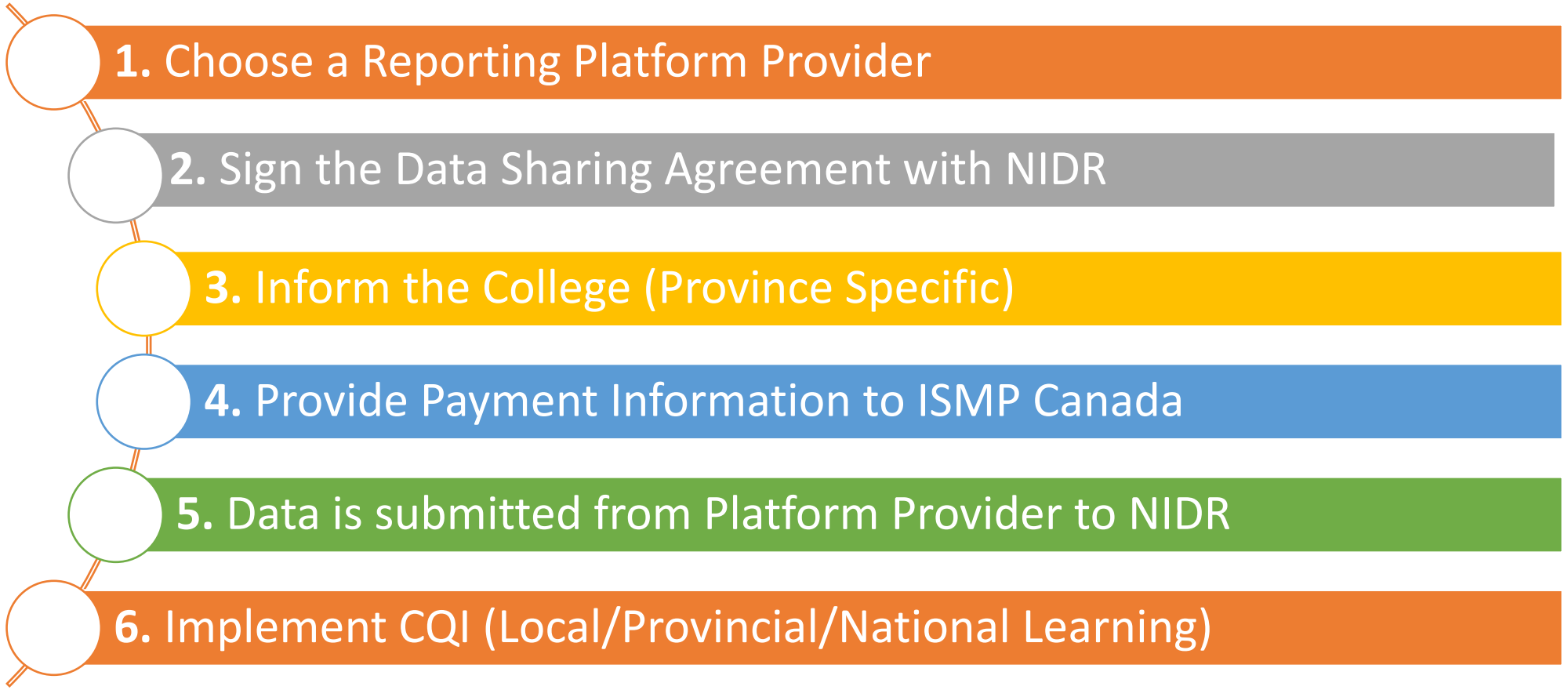
Community Pharmacy Reporting and Learning Process

The Reporting and Learning Process

Community Pharmacy Reporting Processes for Submission of Data to the NIDR



Summary of Pharmacy Steps



What does the Pharmacy Report?
NIDR Minimum Data Set – 7 Mandatory Fields

Mandatory Field	Some Examples of Allowable Responses
Date incident occurred	Year, Month, Day Required
Type of incident	Incorrect patient, incorrect drug, incorrect quantity, drug therapy problem-documented allergy, drug therapy problem-contraindication,
Incident discovered by	Pharmacist, Patient, Prescriber, Caregiver, Pharmacy Assistant, Nurse
Medication System Stages Involved in this Incident	Prescribing, Rx Order Entry, Prescription Preparation/Dispensing, Administration, Monitoring/Follow-up
Medications involved if it was a medication related incident	Drug Product Name, Drug Identification Number (DIN)
Degree of Harm to Patient due to Incident	No Error (Medication Not Dispensed/Near Miss), No Harm, Mild Harm, Moderate Harm, Severe Harm, Death
Incident Description / How the Incident was Discovered	Free Text Field

What does the Pharmacy Report? Examples of Optional Fields

Some Optional Field Examples	Some Examples of Allowable Responses
Contributing Factors	Critical patient information missing-weight, Drug name-look/sound alike names, lack of quality control-independent check system,
Incident Background Information	Hand-written prescription, narcotic/controlled drug, Rx Delivery, Log prescription, e-prescription
Gender	
Age	Ranges: 0-28 days, 28 days-18 years, 18 years-65 years, > 65 years
Time Incident Occurred	Morning, Afternoon, Evening, Overnight, Unknown
Actions Taken at Pharmacy Level	Free Text Field
Shared Learning/Comments	Free Text Field

Data Analysis
Shared Learning
Practice Supports

Analysis by Multidisciplinary Team

Incident reports

Hospitals

Pharmacies

Practitioners

Consumers

Facilities

Multidisciplinary Analysis Team

Pharmacists

Nurses

MDs

Patient & Family Advisor

Others

Outputs

Alerts

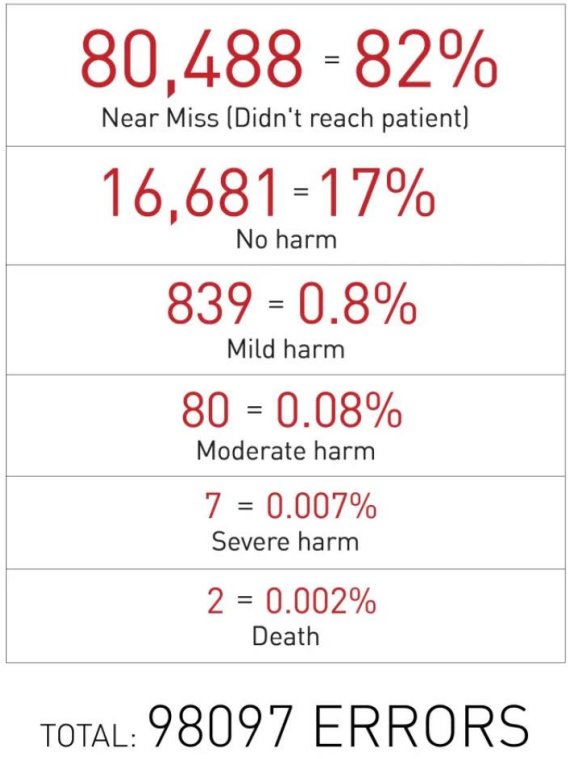
Bulletins

Practice Improvement Tools

Support for Knowledge Translation

Nova Scotia Reporting Over a 7-year Period

NS pharmacy errors, 2010 - 2017



Key Findings

- 301 Community Pharmacies
- 98,097 quality-related events
- 0.95% (*n*=928) were associated with patient harm
- Most common types of quality-related events reported were incorrect dose or frequency, incorrect quantity, and incorrect drug
- Most of the quality-related events occurred at order entry
- There are key differences in the types of reports from community pharmacies and those from other settings

Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis. 2018, CMAJ Open. Boucher, A., et al. Available: Quality-related events reported by community pharmacies in Nova Scotia over a 7-year period: a descriptive analysis (cmajopen.ca)

Data Reports Quantitative

Number of reports

Types of incidents

Levels of harm

Tips from nationally-derived qualitative analyses

ismp CANADA

National Incident Data Repository Safety Brief

Manitoba Data

5,204 reports received from community pharmacies
from April 1, 2017 to September 30, 2022

Reporting period: April 2022 – September 2022

Reports Received	**1,306**
Types of Incidents (including near misses) **(Top 5)**	
Incorrect dose/frequency	263
Incorrect drug	214
Incorrect strength/concentration	180
Incorrect patient	141
Incorrect quantity	106
Levels of Harm	
No Error (e.g., Near Miss)	546
No Harm	674
Mild Harm	81
Moderate Harm	4
Severe Harm	0
Death	1

National Learning

Manitoba community pharmacies contribute to national learning and safety initiatives that incorporate learning from reported medication incidents and suggest system safeguards to prevent patient harm.

One of the most frequently reported types of errors in community pharmacy is incorrect dose/frequency. This is the case for incidents involving direct oral anticoagulants (DOACs).

Thrombosis Canada's monitoring checklist considers several factors to help health care providers optimize the safe and effective use of DOACs.

SAFETY TIP: Confirm the indication and patient-specific factors (e.g., renal function, weight) for a DOAC with the patient or prescriber to assess the appropriate dose, frequency, and duration.

SAFETY TIP: Pharmacists are uniquely positioned to communicate with patients at every refill. Because DOACs, unlike warfarin, do not undergo regular therapeutic monitoring, it is important to emphasize adherence during patient counselling.

Additional safety recommendations can be found in ISMP Canada Safety Bulletins:
https://ismpcanada.ca/safety-bulletins/

LEARN ✓ SHARE ✓ ACT ✓

More than 295,000 reports of medication incidents have been submitted to the National Incident Data Repository for Community Pharmacies (NIDR) since 2008.

Safety. Improvement. Quality.

National Incident Data Repository | Référentiel de données nationales sur les incidents

CMIRPS SCDPIM

National Incident Data Repository for Community Pharmacies
National Snapshot

July 2023

From January 1 to December 31, 2022, a total of 49 650 reports of medication incidents were submitted to the National Incident Data Repository for Community Pharmacies (NIDR) from participating provinces. Most of the reports described near-miss or no-harm incidents; 1.21% (n= 603) of the incidents were associated with mild, moderate, or severe harm, or death. Analysis of incidents has informed the shared learning offered in ISMP Canada Safety Bulletins and provincial NIDR Safety Briefs.

The focus of this NIDR National Snapshot is the 2022 dataset of medication incidents for which "critical patient information missing" was specified as a contributing factor. Reports of 315 incidents with detailed descriptions were included in a multi-incident analysis using the Canadian Incident Analysis Framework.[1] The findings of this analysis (Figure 1) and strategies for improvement (Box 1) are presented here.

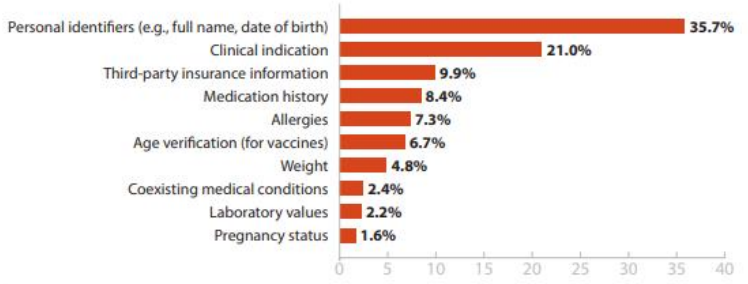


FIGURE 1. Types of critical patient information missed during the processes of prescription order entry, pharmacist clinical check, vaccine administration, and/or prescription delivery.

The National Incident Data Repository for Community Pharmacies (NIDR) is a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

The NIDR contains more than 300 000 reports of medication incidents that have been shared by community pharmacies since 2008. ISMP Canada is committed to analyzing these reports and developing and disseminating learning, with the goal of improving health care systems and medication safety.

Thank you for reporting medication incidents. Your efforts help to inform the "learn, share, and act" cycle!

ismp CANADA

National Incident Data Repository | Référentiel de données nationales sur les incidents

CMIRPS SCDPIM

Working collaboratively to reduce or prevent harm from medication use in Canada.

ismp CANADA

✓To date, over **200 standards, guidelines, and best practices** have been influenced by (e.g., reference) ISMP Canada incident analysis recommendations.

- All nurses (250,616) and pharmacists (6,375) working in accredited hospitals across Canada are required to follow the Medication Safety Standard and/or Required Organizational Practices (ROPs) developed with input from ISMP Canada.

- More than 374,000 reports of medication incidents have been received by ISMP Canada from practitioners, consumers and community pharmacies, to inform shared learning.

Another Example of Practice Change

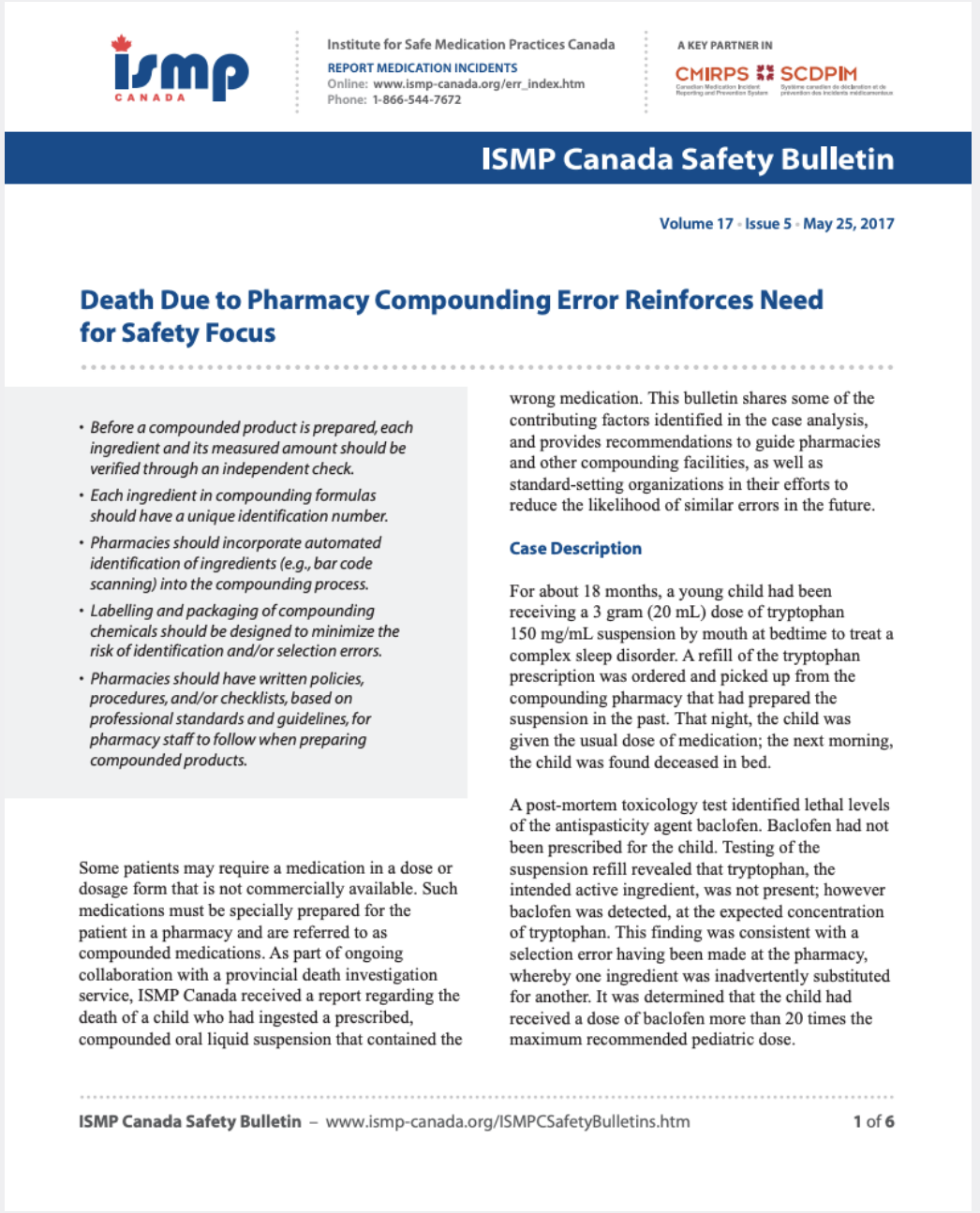
Reports of fatal errors lead to label changes

All products now have the warning "Paralyzing Agent" on the Ferrule/Cap

Local level reports that translated to safety improvement and impact.

Evaluation findings included a decrease in the number of reports of incidents involving inadvertent administration of neuromuscular blocking agents.

Safety Bulletins and Alerts



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 17 • Issue 5 • May 25, 2017

Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus

- *Before a compounded product is prepared, each ingredient and its measured amount should be verified through an independent check.*
- *Each ingredient in compounding formulas should have a unique identification number.*
- *Pharmacies should incorporate automated identification of ingredients (e.g., bar code scanning) into the compounding process.*
- *Labelling and packaging of compounding chemicals should be designed to minimize the risk of identification and/or selection errors.*
- *Pharmacies should have written policies, procedures, and/or checklists, based on professional standards and guidelines, for pharmacy staff to follow when preparing compounded products.*

Some patients may require a medication in a dose or dosage form that is not commercially available. Such medications must be specially prepared for the patient in a pharmacy and are referred to as compounded medications. As part of ongoing collaboration with a provincial death investigation service, ISMP Canada received a report regarding the death of a child who had ingested a prescribed, compounded oral liquid suspension that contained the wrong medication. This bulletin shares some of the contributing factors identified in the case analysis, and provides recommendations to guide pharmacies and other compounding facilities, as well as standard-setting organizations in their efforts to reduce the likelihood of similar errors in the future.

Case Description

For about 18 months, a young child had been receiving a 3 gram (20 mL) dose of tryptophan 150 mg/mL suspension by mouth at bedtime to treat a complex sleep disorder. A refill of the tryptophan prescription was ordered and picked up from the compounding pharmacy that had prepared the suspension in the past. That night, the child was given the usual dose of medication; the next morning, the child was found deceased in bed.

A post-mortem toxicology test identified lethal levels of the antispasticity agent baclofen. Baclofen had not been prescribed for the child. Testing of the suspension refill revealed that tryptophan, the intended active ingredient, was not present; however baclofen was detected, at the expected concentration of tryptophan. This finding was consistent with a selection error having been made at the pharmacy, whereby one ingredient was inadvertently substituted for another. It was determined that the child had received a dose of baclofen more than 20 times the maximum recommended pediatric dose.

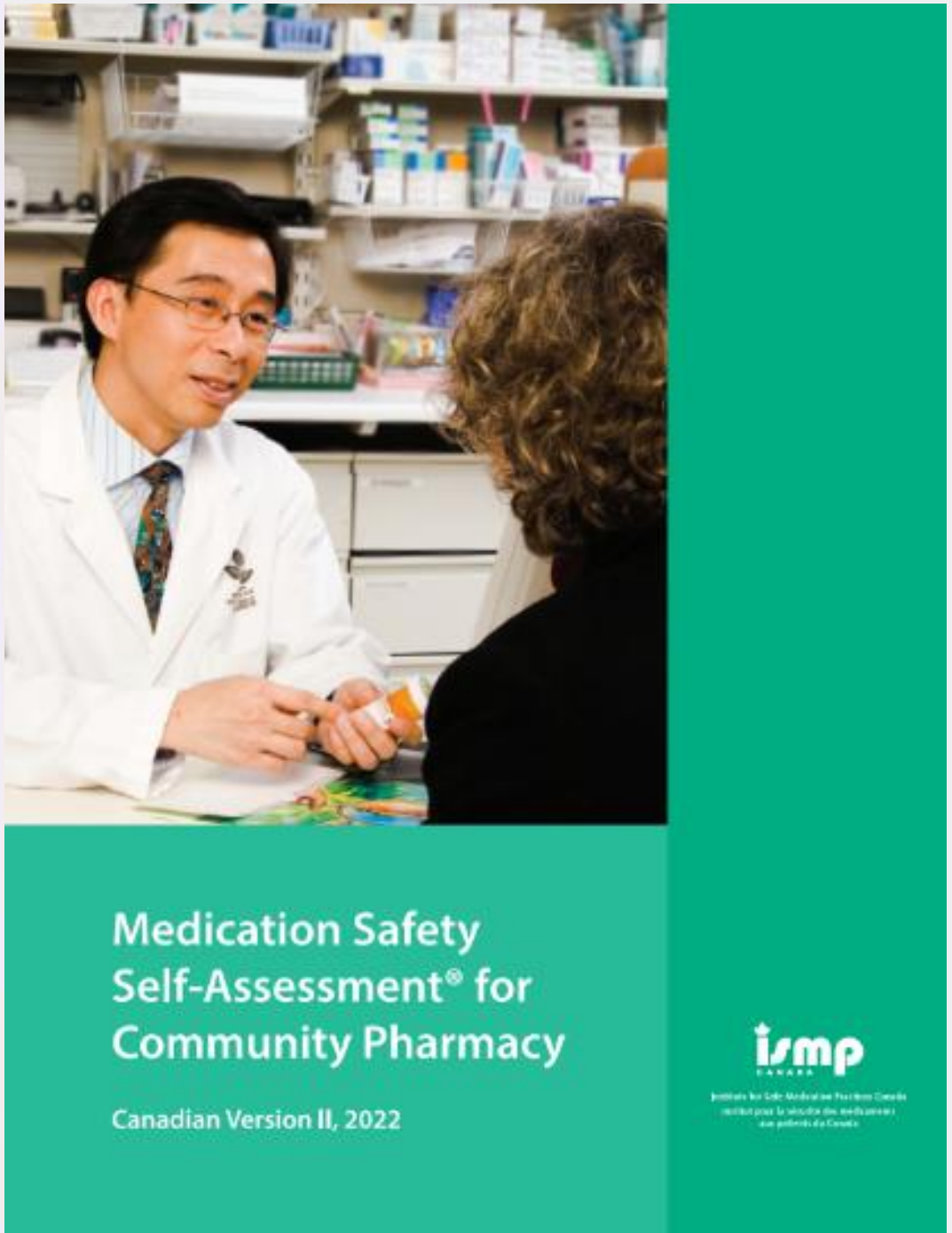
[Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus]

Continuous Improvement

[Safer Labelling of Repackaged Active Pharmaceutical Ingredients for Pharmacy Compounding]

[Tips for Parents When Medications Need to be Compounded]

Medication Safety Self Assessment

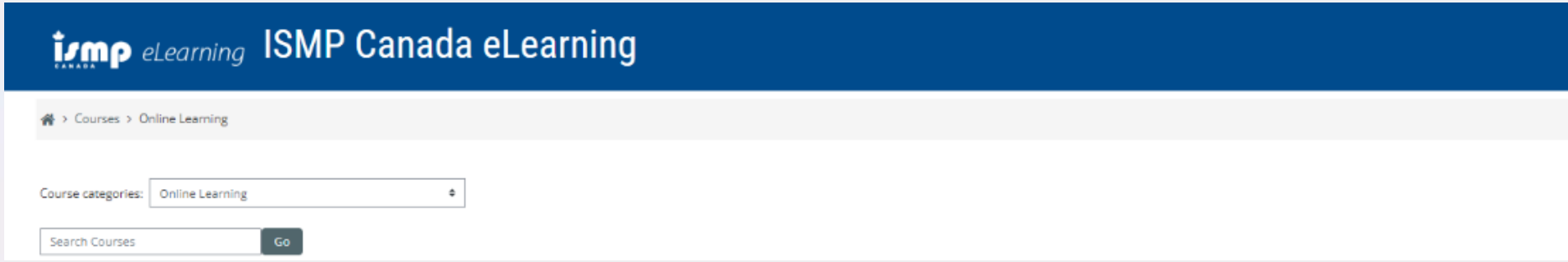


List provinces requiring MSSA

User Fee:

- Cost may include in pricing for platform provider
- Corporate pharmacy arrangements to purchase if platform provider does not provide
- Can be purchased as a separate tool from ISMP Canada for $150

eLearning and Online Modules



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

Education - ISMP Canada

Live Virtual Workshops

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).

5 upcoming dates - **Register**

- 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.

1 upcoming date - **Register**

- 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.

2 upcoming dates - **Register**

- November 17, 2023
- March 2, 2024