Canada

IMSN Update

November 14, 2022

- Health Canada
- Healthcare Excellence Canada
- Institute for Safe Medication Practices Canada

Health Canada Update

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IMSN Annual Meeting
November 14, 2022



Canada

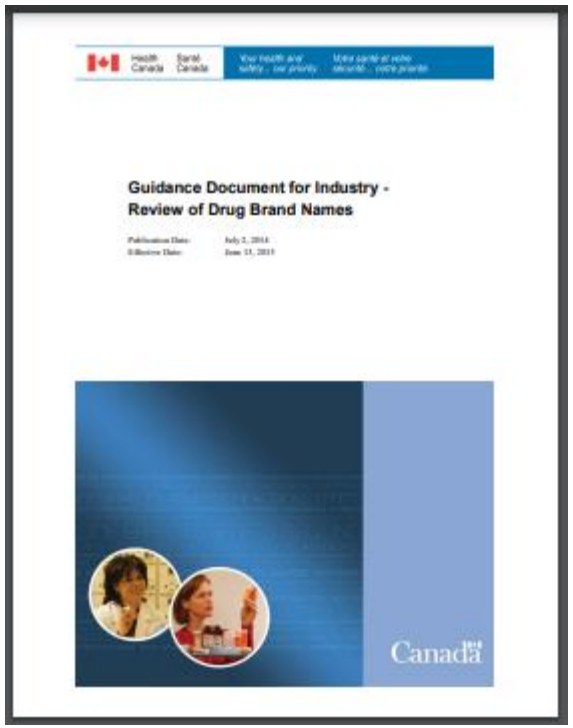
Overview – Health Canada’s Role

- Focus to prevent and manage harmful medication errors that result from a drug's name, package, and label
- Responsible for development of guidance documents and technical statements to provide direction to industry in good practices for naming, packaging and labelling
  - Current priority to update guidance for industry on brand name review
- The prevention and management of medication errors requires a collaborative approach between Health Canada, industry, healthcare professionals and facilities, patient safety organizations, patients and consumers
  - Example of wrong route errors with tranexamic acid




Current Priority - Brand Name Review Guidance

- Outlines procedure for industry to follow to evaluate the potential for a brand name to be misleading or confused with other products on the market
- All brand names subject to review against criteria to address error-prone naming practices
- Required steps:
  - Searches of HC drug databases and medication error reporting databases
  - Process maps
  - Medication-use simulations
  - Failure modes effect analysis






Guidance for Industry - Brand Name Review

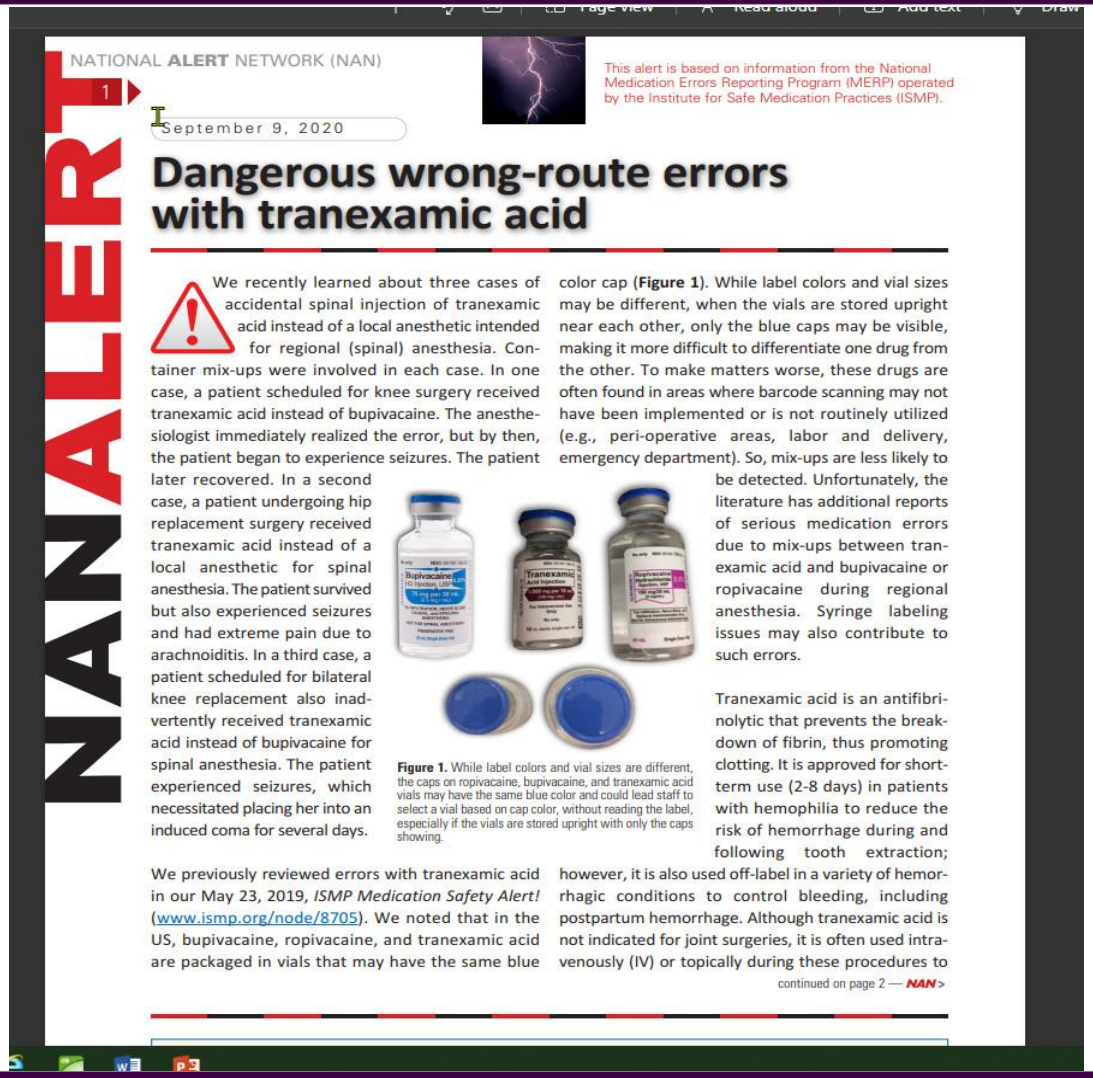
- Health Canada is currently revising the Guidance for Industry – Review of Drug Brand Names to reflect lessons learned since implementation
- Abbreviations & modifiers in brand names create opportunities for medication errors and misinterpretations
- Trends in modifiers proposed by industry:
  - Modifiers to identify package size (e.g., ‘Brandname 2B’)
  - Modifiers to identify strength (e.g., ‘Brandname 30’)
  - Modifiers composed of abbreviations that are defined differently than the usual convention (e.g., ‘Brandname OTC’ where OTC = oral treatment care)




Collaboration on Prevention of Medication Errors

Wrong Route Errors with Tranexamic Acid Injection

- National Alert Network (NAN) issued an alert reporting *"Dangerous wrong-route errors with Tranexamic acid."*
- The alert describes three cases of accidental spinal injection of tranexamic acid instead of local anesthetic intended for regional (spinal) anesthesia.
- Container mix-ups were involved in each case.
- The NAN alert notes that in the US, bupivacaine, ropivacaine and tranexamic acid are packaged in vials that may have the same blue colour cap. While vial label colours and vial sizes may be different, when the vials are stored upright near each other, only the blue caps may be visible, making it more difficult to differentiate one drug from the other.



NATIONAL ALERT NETWORK (NAN)

NANALERT 1

This alert is based on information from the National Medication Errors Reporting Program (MERP) operated by the Institute for Safe Medication Practices (ISMP).

September 9, 2020

Dangerous wrong-route errors with tranexamic acid

We recently learned about three cases of accidental spinal injection of tranexamic acid instead of a local anesthetic intended for regional (spinal) anesthesia. Container mix-ups were involved in each case. In one case, a patient scheduled for knee surgery received tranexamic acid instead of bupivacaine. The anesthesiologist immediately realized the error, but by then, the patient began to experience seizures. The patient later recovered. In a second case, a patient undergoing hip replacement surgery received tranexamic acid instead of a local anesthetic for spinal anesthesia. The patient survived but also experienced seizures and had extreme pain due to arachnoiditis. In a third case, a patient scheduled for bilateral knee replacement also inadvertently received tranexamic acid instead of bupivacaine for spinal anesthesia. The patient experienced seizures, which necessitated placing her into an induced coma for several days.

Figure 1. While label colors and vial sizes are different, the caps on ropivacaine, bupivacaine, and tranexamic acid vials may have the same blue color and could lead staff to select a vial based on cap color, without reading the label, especially if the vials are stored upright with only the caps showing.

We previously reviewed errors with tranexamic acid in our May 23, 2019, *ISMP Medication Safety Alert!* (www.ismp.org/node/8705). We noted that in the US, bupivacaine, ropivacaine, and tranexamic acid are packaged in vials that may have the same blue color cap (**Figure 1**). While label colors and vial sizes may be different, when the vials are stored upright near each other, only the blue caps may be visible, making it more difficult to differentiate one drug from the other. To make matters worse, these drugs are often found in areas where barcode scanning may not have been implemented or is not routinely utilized (e.g., peri-operative areas, labor and delivery, emergency department). So, mix-ups are less likely to be detected. Unfortunately, the literature has additional reports of serious medication errors due to mix-ups between tranexamic acid and bupivacaine or ropivacaine during regional anesthesia. Syringe labeling issues may also contribute to such errors.

Tranexamic acid is an antifibrinolytic that prevents the breakdown of fibrin, thus promoting clotting. It is approved for short-term use (2-8 days) in patients with hemophilia to reduce the risk of hemorrhage during and following tooth extraction; however, it is also used off-label in a variety of hemorrhagic conditions to control bleeding, including postpartum hemorrhage. Although tranexamic acid is not indicated for joint surgeries, it is often used intravenously (IV) or topically during these procedures to

continued on page 2 — NAN>

Canadian Product Monograph Update for Cyklokapron (tranexamic acid)

- Health Canada monitored global alerts and collaborated with ISMP Canada to identify a Canadian report. We then worked with the company to update the Canadian Product Monograph (CPM).
- On November 25, 2021, Cyklokapron (tranexamic acid) CPM was updated. The CPM was revised under the contraindications, dosage & administration, and warning & precautions sections.
- The CPM update was published in HC InfoWatch publication in January 2022 edition.
- ISMP Canada published a safety bulletin on May 26, 2022.

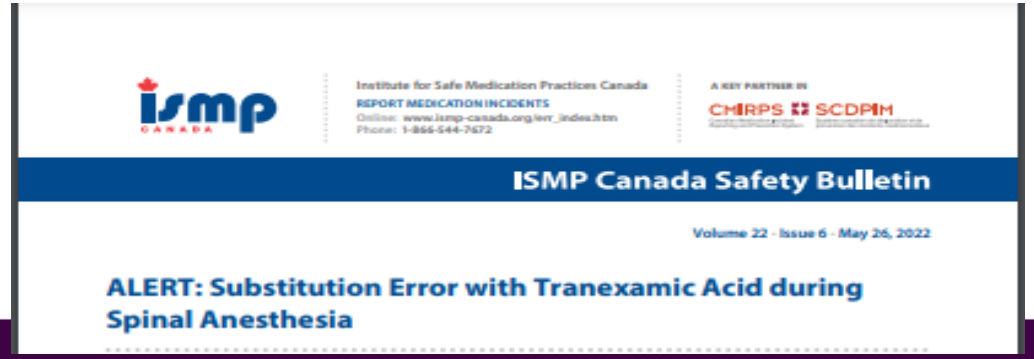
Cyklokapron (tranexamic acid)

The *Contraindications, Warnings and Precautions, Dosage and Administration* and *Patient Medication Information* sections of the Canadian product monograph for Cyklokapron have been updated with the **risk of error(s) due to incorrect route of administration.** The *Warnings and Precautions, Dosage and Administration* and *Patient Medication Information* sections have been updated with the **increased risk for thromboembolic events when used concomitantly with hormonal contraceptives**.

Key messages for healthcare professionals:[1]

- Cyklokapron solution for injection is intended for intravenous injection or infusion only.
- Intrathecal and epidural administration of Cyklokapron is contraindicated.
- Erroneous administration of Cyklokapron solution for injection via intrathecal or epidural routes has resulted in serious harm, including death.
- Care should be exercised to confirm the correct route of administration when other injectable medications are to be administered during the same procedure with Cyklokapron.
- The risk for thromboembolic events may be increased in patients using hormonal contraceptives concomitantly. If Cyklokapron has to be used in these patients, advise them to use an effective, alternative (non-hormonal) contraceptive method.

Health Product InfoWatch – January 2022 7



Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS

ISMP Canada Safety Bulletin

Volume 22 · Issue 6 · May 26, 2022

ALERT: Substitution Error with Tranexamic Acid during Spinal Anesthesia

Healthcare Excellence Canada
Excellence en santé Canada

Country Update - Canada

2022 International Medication Safety Network Annual Meeting

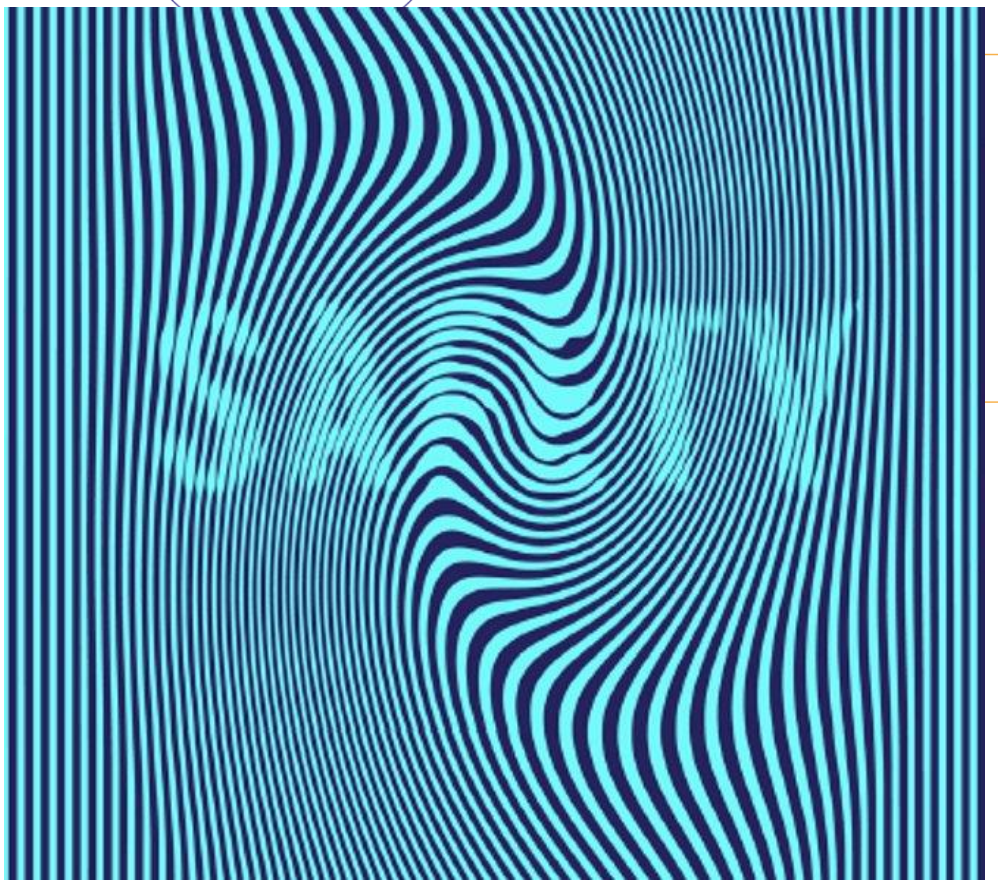
Ioana Popescu, Director, Healthcare Excellence Canada
Kathy Kovacs-Burns, Patients for Patient Safety Canada
Maryanne D'Arpino, VP, Healthcare Excellence Canada (regrets)

Shaping a future where everyone in Canada has safe and high-quality healthcare

[2021-22 Impact Report (healthcareexcellence.ca)]

A safer future

- Defining safety
  - All people
  - All types of harm
  - Creates capacity for safety
  - Incident response restores trust, enables growth
- Creating safety - constant inquiry:
  - Will care be safe in the future?
  - Is care safe now?
  - Has care been safe in the past?
- Capability building
  - Patient safety essentials, effective governance
- Partners in safety
  - With and for more people
  - Patients for Patient Safety Canada



Presence of Safety (healthcareexcellence.ca)

Patients for Patient Safety Canada

- Partnerships
  - Healthcare Excellence Canada – Safety Team
  - Patient Alliance for Patient Safety
  - Institute for Safe Medication Practice Canada
- Medication Safety Events
  - World Patient Safety Day 2022
  - Labelling of non-prescription medications – Health Canada
- Other
  - Safety Conversations
  - Canadian Patient Safety Week
  - Mutual healing demonstration project
  - Antimicrobial resistance and stewardship
  - Art Gallery

PATIENTS FOR PATIENT SAFETY CANADA | PATIENTS POUR LA SÉCURITÉ DES PATIENTS DU CANADA

Contact us

Ioana Popescu – Director, Safety Strategies and Programs, HEC

Maryanne D'Arpino – VP, Programs and System Transformation, HEC

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Healthcare Excellence Canada | Patients for Patient Safety Canada

Healthcare Excellence Canada

Excellence en santé Canada

ISMP Canada Update

Carolyn Hoffman, CEO
IMSN Annual Meeting
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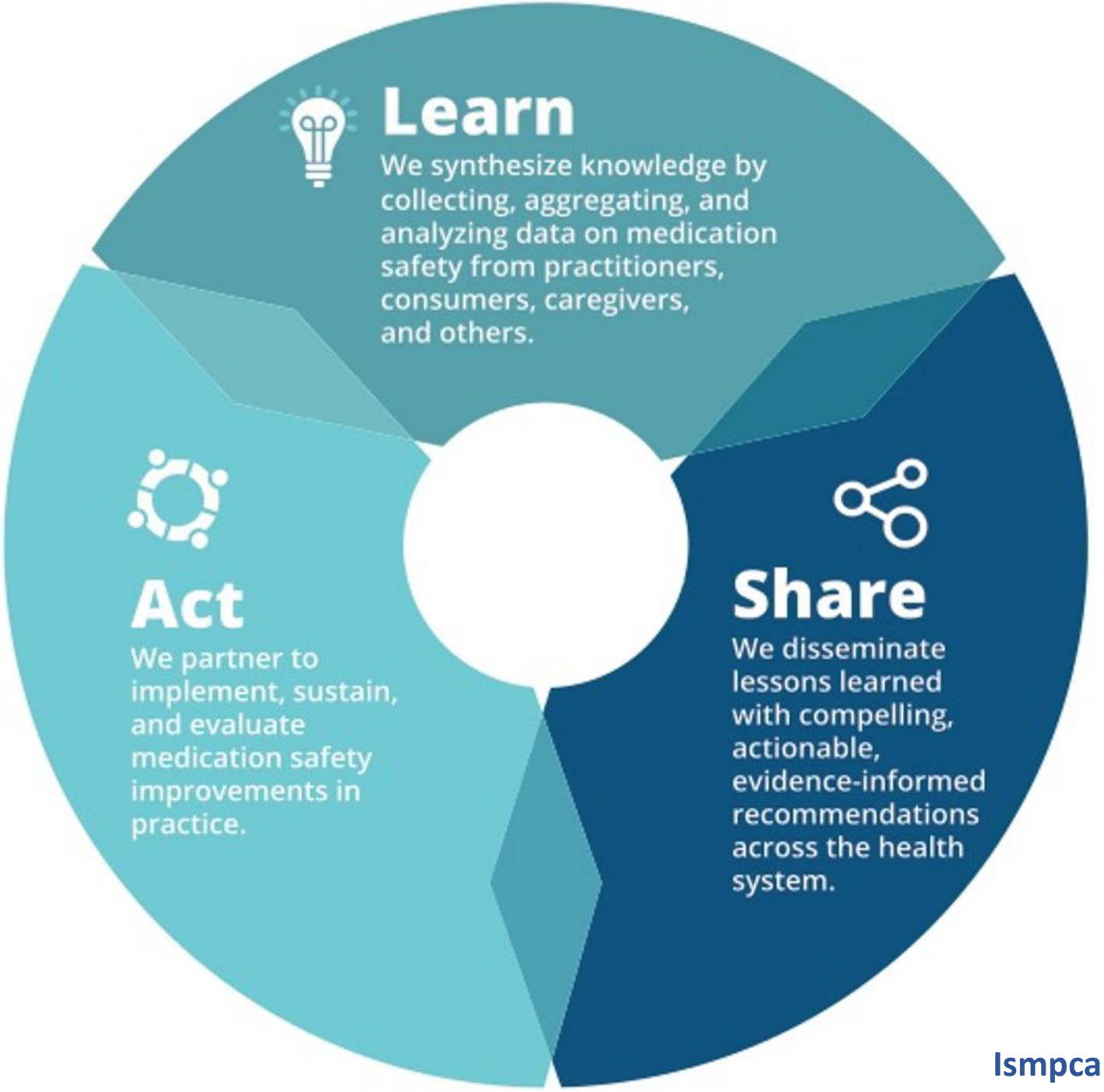
November 14, 2022

ZERO Preventable Harm From Medications
Institute for Safe Medication Practices Canada

A Trusted Partner

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

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



National Incident Data Repository (NIDR)

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

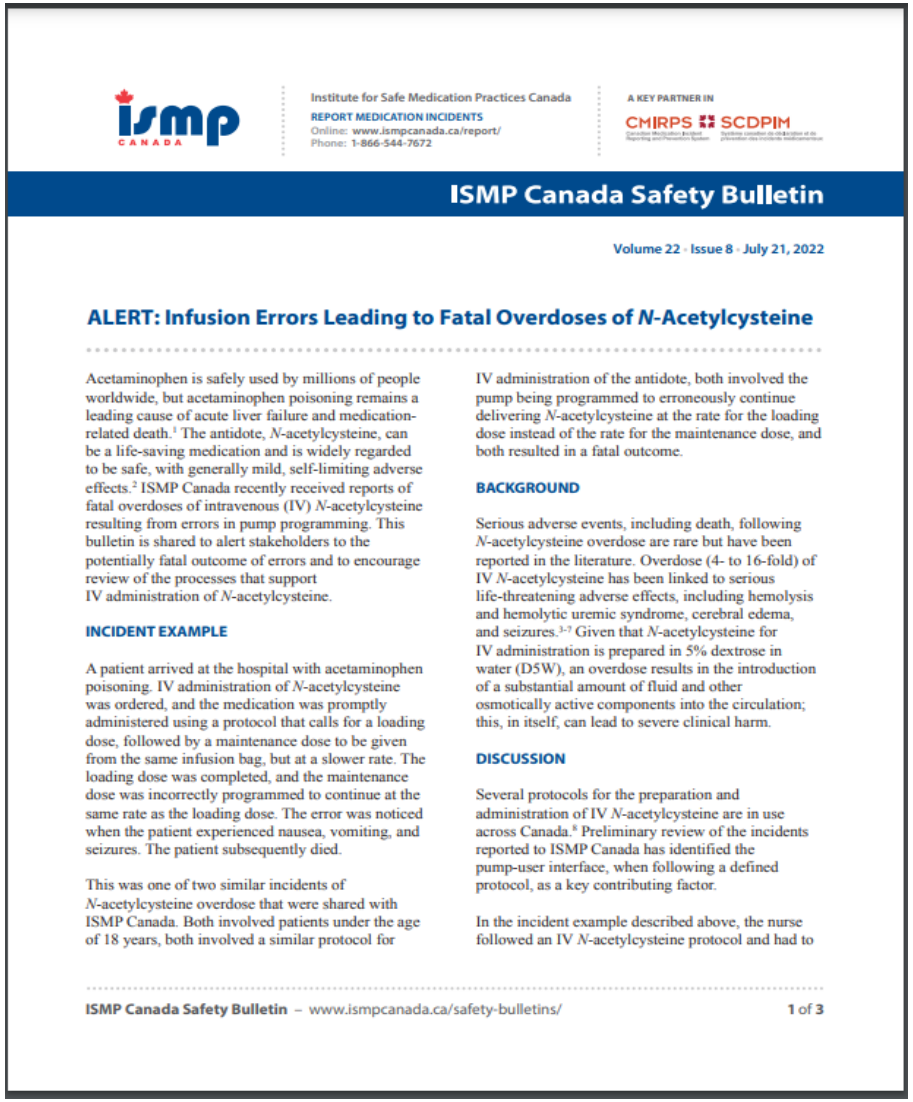
LEARN & SHARE

- ✓ Pharmacist/Pharmacy regulators in 4 Canadian provinces now require anonymous medication incident reporting in community pharmacies with seamless submission to the NIDR that is hosted by ISMP Canada

- ✓ First National NIDR Snapshot issued in July 2022 by ISMP Canada

SCAN ME

Analysis of Fatal Antidote Administration Errors



Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismpcanada.ca/report/
Phone: 1-866-544-7672

A KEY PARTNER IN
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ISMP Canada Safety Bulletin

Volume 22 · Issue 8 · July 21, 2022

ALERT: Infusion Errors Leading to Fatal Overdoses of *N*-Acetylcysteine

Acetaminophen is safely used by millions of people worldwide, but acetaminophen poisoning remains a leading cause of acute liver failure and medication-related death.[1] The antidote, *N*-acetylcysteine, can be a life-saving medication and is widely regarded to be safe, with generally mild, self-limiting adverse effects.[2] ISMP Canada recently received reports of fatal overdoses of intravenous (IV) *N*-acetylcysteine resulting from errors in pump programming. This bulletin is shared to alert stakeholders to the potentially fatal outcome of errors and to encourage review of the processes that support IV administration of *N*-acetylcysteine.

INCIDENT EXAMPLE

A patient arrived at the hospital with acetaminophen poisoning. IV administration of *N*-acetylcysteine was ordered, and the medication was promptly administered using a protocol that calls for a loading dose, followed by a maintenance dose to be given from the same infusion bag, but at a slower rate. The loading dose was completed, and the maintenance dose was incorrectly programmed to continue at the same rate as the loading dose. The error was noticed when the patient experienced nausea, vomiting, and seizures. The patient subsequently died.

This was one of two similar incidents of *N*-acetylcysteine overdose that were shared with ISMP Canada. Both involved patients under the age of 18 years, both involved a similar protocol for IV administration of the antidote, both involved the pump being programmed to erroneously continue delivering *N*-acetylcysteine at the rate for the loading dose instead of the rate for the maintenance dose, and both resulted in a fatal outcome.

BACKGROUND

Serious adverse events, including death, following *N*-acetylcysteine overdose are rare but have been reported in the literature. Overdose (4- to 16-fold) of IV *N*-acetylcysteine has been linked to serious life-threatening adverse effects, including hemolysis and hemolytic uremic syndrome, cerebral edema, and seizures.[3-7] Given that *N*-acetylcysteine for IV administration is prepared in 5% dextrose in water (D5W), an overdose results in the introduction of a substantial amount of fluid and other osmotically active components into the circulation; this, in itself, can lead to severe clinical harm.

DISCUSSION

Several protocols for the preparation and administration of IV *N*-acetylcysteine are in use across Canada.[8] Preliminary review of the incidents reported to ISMP Canada has identified the pump-user interface, when following a defined protocol, as a key contributing factor.

In the incident example described above, the nurse followed an IV *N*-acetylcysteine protocol and had to

ISMP Canada Safety Bulletin – www.ismpcanada.ca/safety-bulletins/ 1 of 3

LEARN & SHARE

- ISMP Canada Safety Bulletin Alert published in July 2022
- Early findings shared from overdoses of N-acetylcysteine used to treat acetaminophen overdoses
- Significant interest within Canada and internationally in this risk
- **Detailed analysis underway – please connect if you have info to share**

Labelling Improvements – Mineral Supplements

LEARN & SHARE

ISMP Canada provided feedback to Health Canada on a Draft Guidance Document: Labelling of Natural Health Products

- Using evidence of error and near miss reports, feedback on specific issues and recommended guidance was provided by ISMP Canada
- Health Canada recently published the updated Guidance Document with the goal of improving the labelling of single-ingredient mineral supplements with a particular focus on calcium, iron, magnesium and zinc
  - New format recommended in which the salt appears on a separate line of text on product labels
  - Notice supported by references to ISMP Canada Safety Bulletins

Figure 1. Examples of zinc products and the different ways the elemental zinc strength is expressed on the front and side labels (images obtained from the internet).

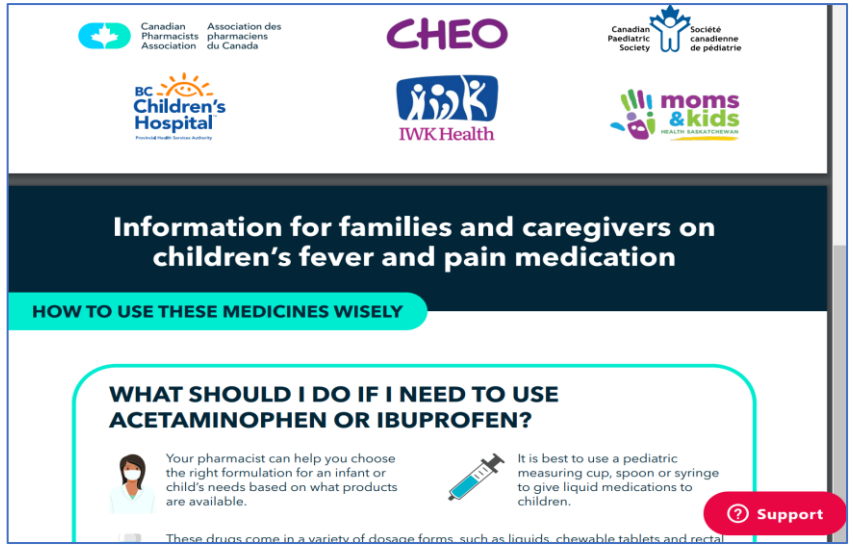
LEARN, SHARE, & ACT

ISMP Canada is partnering with the
Ministry of Long-Term Care in Ontario to provide medication safety tools, facilitation, and coaching support in 4 key areas to long-term care homes

- Resident & Family Engagement
- Measuring & Evaluating
- Quality Improvement
- Report, Learn, & Act After a Medication Incident

Phase 1 Launch (2021 / 2022) – 10 Champion Homes
Phase 2 Spread (2022 / 2023) – up to 100 Trailblazer Homes!

SCAN ME



New and Emerging Risk in Canada