International Medication Safety Network

Neuromuscular Blocking Agents (NMBA) Special Interest Group

Update from ISMP Canada

May 31, 2023

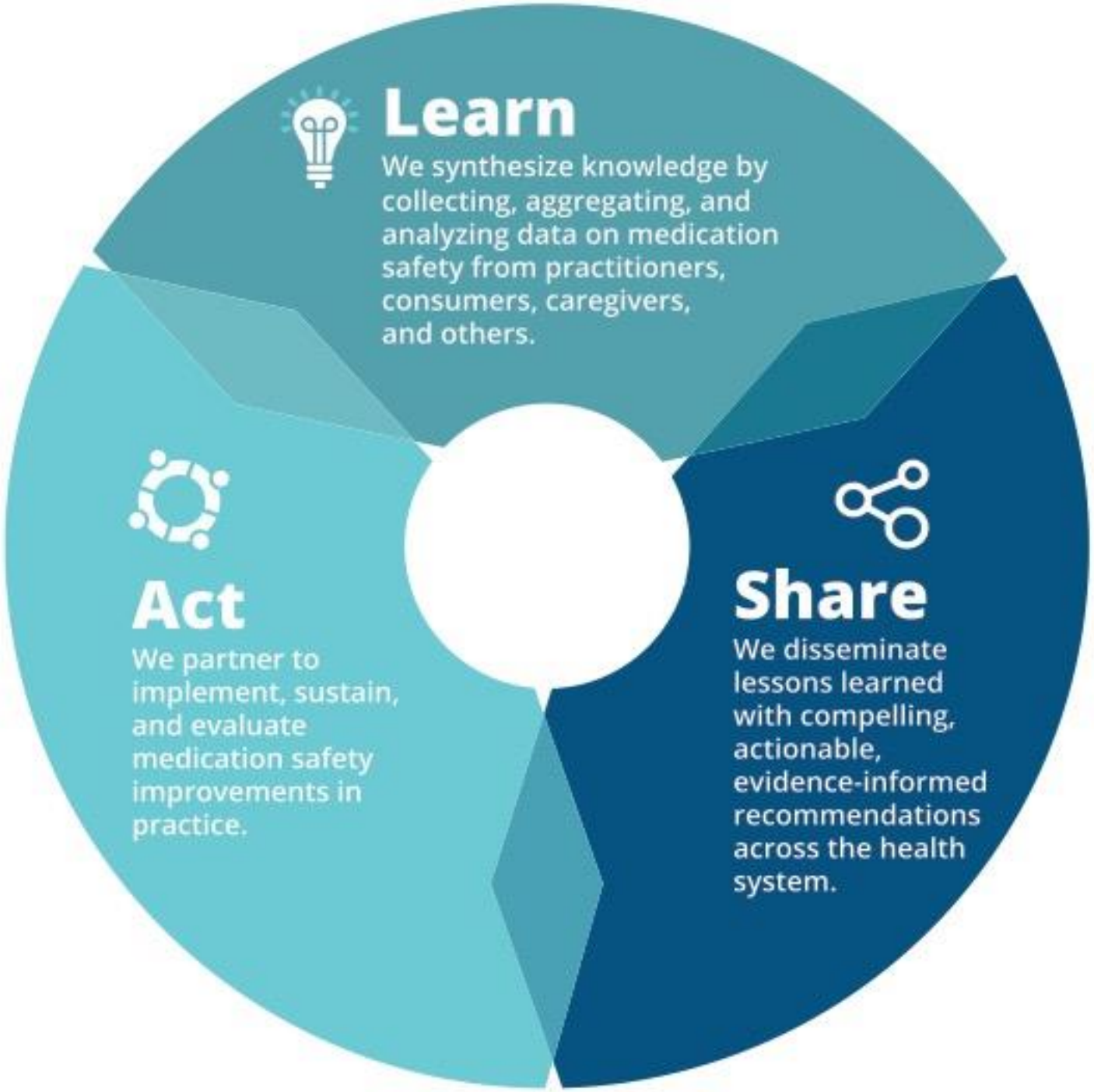
ZERO Preventable Harm From Medications
Institute for Safe Medication Practices Canada

A Trusted Partner

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

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

ismp CANADA

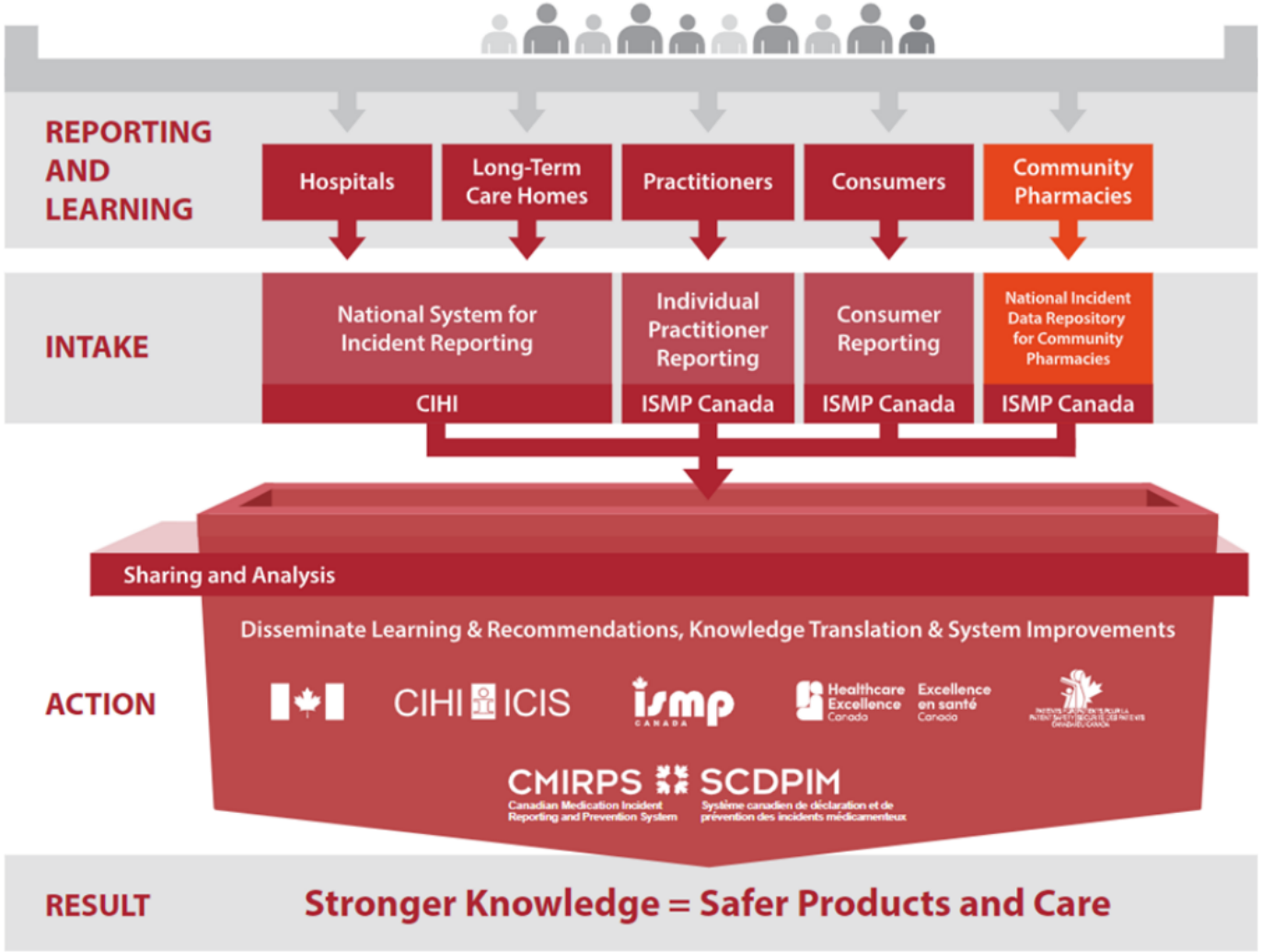


Outline

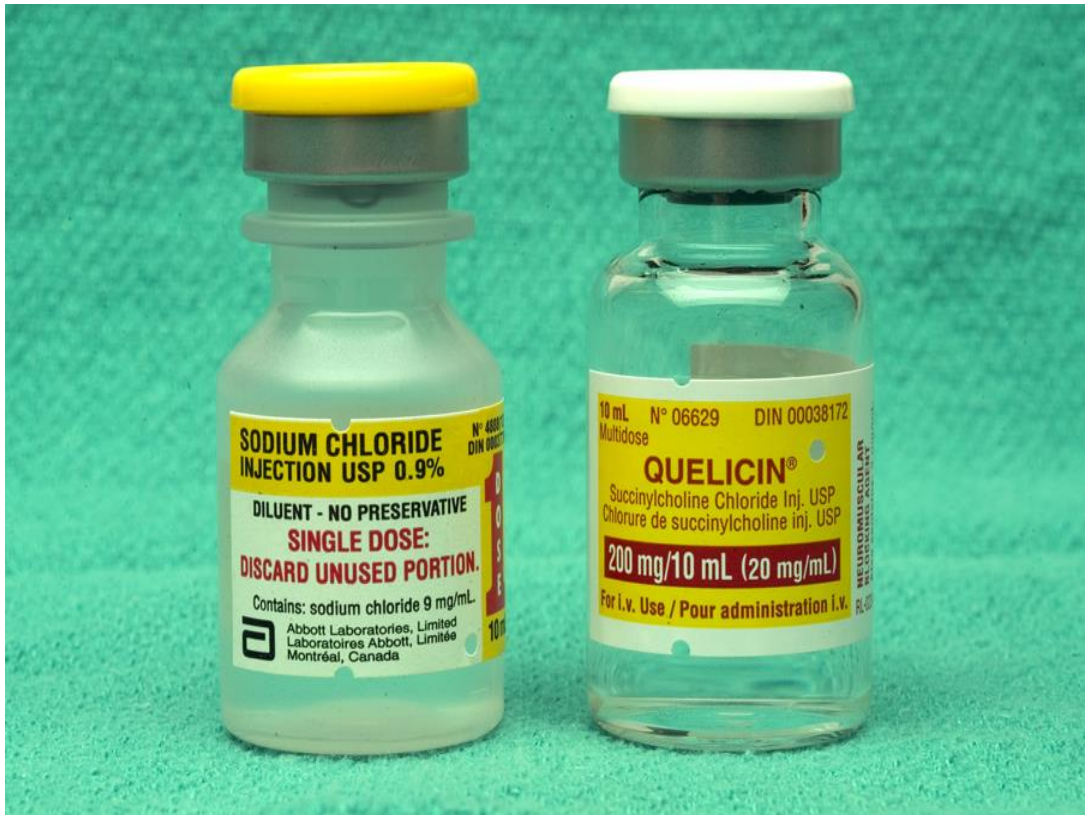
Learn / Share / Act

- Reporting and Learning Program in Canada
- Analysis
- Knowledge Dissemination
- Knowledge Translation
- Sustaining Improvement
- Evaluation

Canadian Medication Incident Reporting and Prevention System



Example Error Report and Action



Succinylcholine (right) was mistaken for sodium chloride (left) and used to reconstitute a medication.

Succinylcholine package and label changes (right) with Warning “Paralyzing Agent”.

Safety Bulletin described warning

ISMP Canada is an independent Canadian non-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

ISMP Canada Safety Bulletin

Volume 2, Issue 12 December, 2002

Neuromuscular Blocking Agents – Time for Action

A potentially life-threatening, near miss incident in the emergency department of a Canadian general hospital raises a warning flag. The sequence of events is as follows and, as will be discussed below, many Canadian hospitals are at risk for a similar incident:

- An order for intravenous "acyclovir 1 g IV q8h" was written in an emergency department where medications

Possible contributing factors to the error described:

- Vecuronium vials that had previously been returned to the pharmacy (from the operating rooms) were inadvertently put into the acyclovir stock container.
- Although the neuromuscular blocking agents were segregated in the Pharmacy, this area happened to be in

December 2002: Neuromuscular Blocking Agents – Time for Action https://www.ismp-canada.org/download/safetyBulletins/ismpcsb0212.pdf

Safety Bulletin described initiative

Neuromuscular Blocking Agent Labelling and Packaging Initiative

A collaborative meeting of representatives of pharmaceutical manufacturers of neuromuscular blocking agents was convened by ISMP Canada in Toronto on February 27th, 2006. The foremost outcome was agreement among the attending stakeholders on the "ideal features" for packaging and labeling of neuromuscular blocking agents:

1. Red cap with white lettering: "Paralyzing agent" or "Warning: Paralyzing Agent"
2. Red ferrule with white lettering: "Paralyzing agent"
3. Red lettering on the product label: "Paralyzing agent" or "Warning: Paralyzing Agent"
4. Peel-off label, using the colour scheme and content information recognized by the ASA/CAS recommended standards, for application to a prepared syringe (ASA = American Society of Anesthesiologists (www.asahq.org); CAS = Canadian Anesthesiologists' Society (www.cas.ca)
5. Space on the product label for bar code application
6. Development of a universal symbol for neuromuscular blocking agents and proposal for global use: placement of this symbol (e.g., on the label), to be determined
7. Review of potential benefit of using TALL-man lettering for generic names of neuromuscular blocking agents

Participating manufacturers (Sandoz Inc, Hospira, Organon, and Abbott) are evaluating the feasibility of incorporating some or all of these features.

February 2006: Neuromuscular Blocking Agent Labelling and Packaging Initiative https://www.ismp-canada.org/news/item/37/

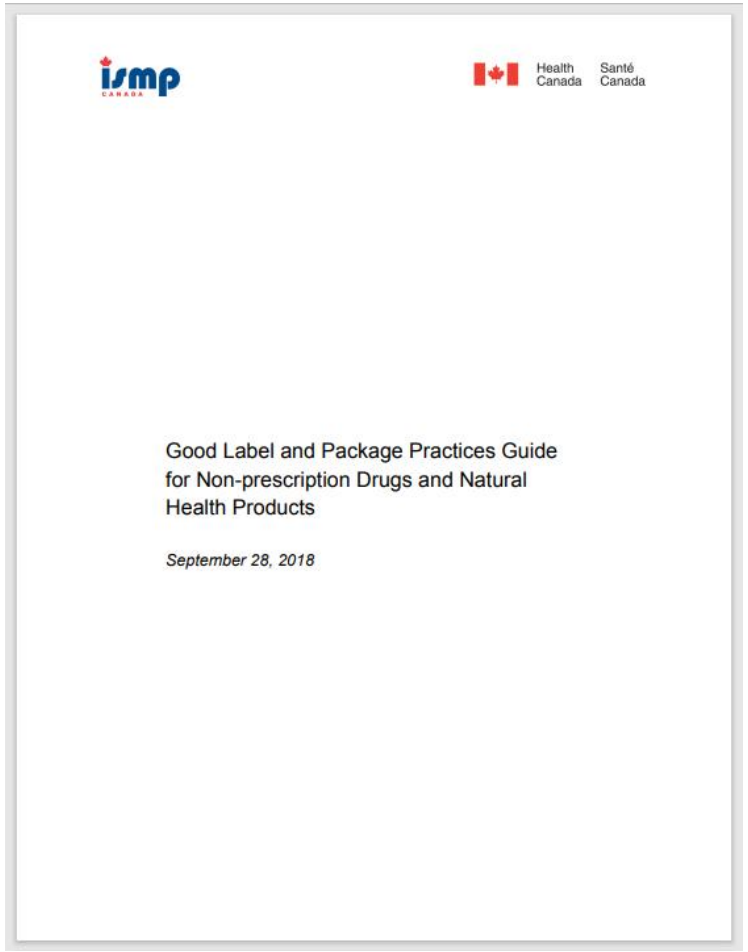
Label Improvements Adopted by all Manufacturers

Interim phase

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

Sustaining Learning in Practice

Guide for Prescription Drugs



Guide for Non-prescription drugs

Safety Bulletin Describes Monitoring

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

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ISMP Canada Safety Bulletin

Volume 21 • Issue 5 • May 6, 2021

ALERT: Rocuronium Vials Lack Recommended Warning on Ferrule

- Rocuronium 50 mg/5 mL (from Auro Pharma Inc.) has the warning "**Paralyzing Agent**" on the cap but lacks this warning on the ferrule (Figure 1); this is inconsistent with safety recommendations designed to mitigate the risk of errors with neuromuscular blocking agents.
- The warning on the vial label is hidden behind a peel away label (Figure 1) instead of being prominently displayed on the principal display panel.
- Risk reduction strategies are needed—in particular, applying end-user warnings to the vial and alerting staff—until planned changes are made by the manufacturer and the existing supply is depleted.

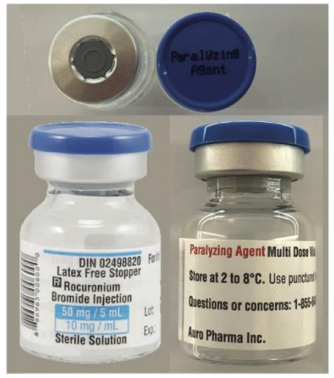


Figure 1. Auro rocuronium vials without the "Paralyzing Agent" warning on the ferrule, nor prominently displayed on the principal display panel. (Image courtesy of Auro Pharma Inc.)

BACKGROUND

The current COVID-19 pandemic has increased the demand for certain critical medications. The neuromuscular blocking agent rocuronium is one such medication. Neuromuscular blocking agents are high-alert medications and, when used in error, can lead to devastating injuries or death.[1]

SAFETY CONCERN

In accordance with recommendations established to address selection errors at the point of care,[2,3] neuromuscular blocking agents in Canada should carry a prominent warning on the vial labels, cap, and ferrule.[3] The Auro product does not carry the recommended warning on its ferrule, nor does it prominently display the warning on the principal display panel. It also lacks the recommended red cap and red ferrule with the warning in white lettering. This deviation from safe labelling and packaging recommendations increases the risk that this product may be misidentified and inadvertently administered.[4]

RESPONSIVE ACTION

HealthPRO Procurement Services Inc. has communicated with Auro about the risk. The company has indicated that they will be changing the cap and ferrule to red, both of which will display the warning "Paralyzing Agent" in white letters (Figure 2). Auro will redesign the vial label to prominently display the warning on the principal display panel (Figure 2). The company will also provide an auxiliary label that includes the warning, for application to syringes. Auro has submitted the label changes to Health Canada for approval; however, until the new format becomes available, hospitals may be accessing the original supply. Auro and other Canadian manufacturers are to be commended for voluntarily implementing safety recommendations for labelling and packaging of neuromuscular blocking agents.[2]

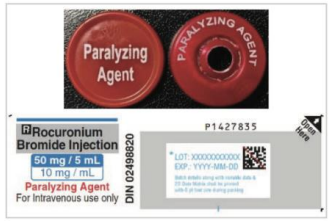


Figure 2. Proposed improvements for Auro rocuronium vials: the "Paralyzing Agent" warning in white lettering on the red cap and red ferrule, and prominently displayed on the principal display panel (Images courtesy of Auro Pharma Inc.)

RISK MITIGATION STRATEGIES

In the interim, until the current supply is exhausted AND the new stock is in use, hospitals that purchase the Auro rocuronium product should take the following precautions:[1,4]

- Apply end-user warnings, such as an auxiliary label indicating "Paralyzing Agent", on the vial.
- Review how and where the product is stored, to ensure that such warnings are clearly visible.
- Assess the risk of a look-alike mix-up with existing products in the pharmacy, intensive care unit, or other areas where rocuronium would be used.
- Where available, use bar-code scanning technology throughout the medication-use process.
- Alert staff about the risk of errors.

ACKNOWLEDGEMENTS

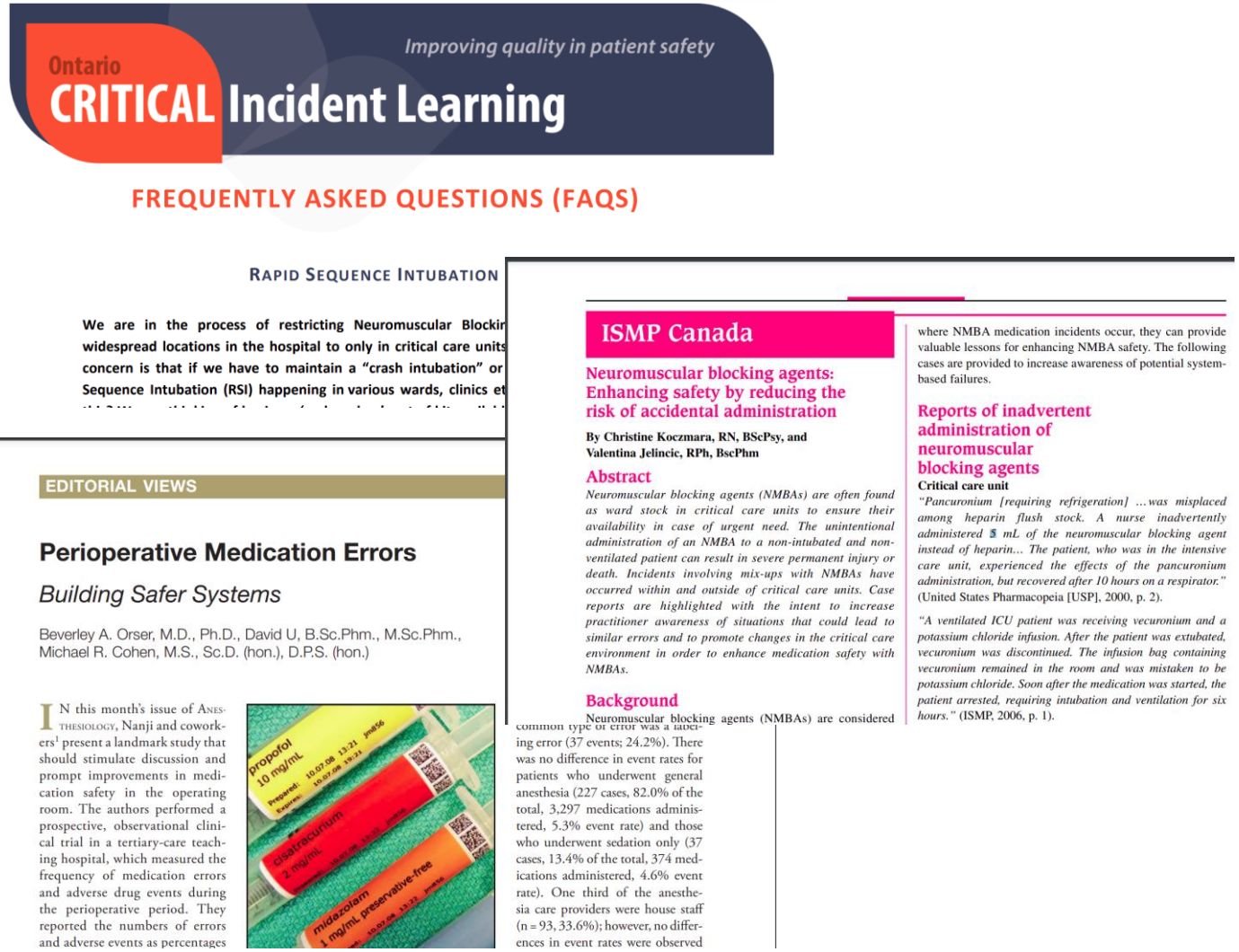
ISMP Canada gratefully acknowledges HealthPRO Procurement Services Inc. for identifying the risk and for their contributions to this alert.

REFERENCES

1. Special alert! Prepare for vials of neuromuscular blocking agents without cap warnings. Horsham (PA): Institute for Safe Medication Practices; 2020 Jun 4 [cited 2020 Apr 22]. Available from: https://ismp.org/resources/special-alert-prepare-vials-neuromuscular-blocking-agents-without-cap-warnings
2. Neuromuscular blocking agents: sustaining packaging improvements over time. ISMP Can Saf Bull. 2014 [cited 2021 Apr 21];14(7):1-5. Available from: https://www.ismp-canada.org/download/safetyBulletins/2014/ISMPCSB2014-7_NeuromuscularBlockingAgents.pdf
3. Good label and package practices guide for prescription drugs. Toronto (ON): Institute for Safe Medication Practices Canada; 2019 Jun [cited 2021 Apr 21]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs-profile/guidance-document.html
4. Neuromuscular blocking agents—time for action. ISMP Can Saf Bull. 2002 [cited 2021 Apr 22];2(12):1-3. Available from: https://www.ismp-canada.org/download/safetyBulletins/ismpcsb0212.pdf

May 2021: Safety Bulletin - ALERT: Rocuronium Vials Lack Recommended Warning on Ferrule
https://ismpcanada.ca/wp-content/uploads/ISMPCSB2021-i5-ALERT-Rocuronium.pdf#page=1

Additional Publications to Share Learning



Examples:

Frequently Asked Questions:

https://www.ismp-canada.org/download/ocil/FAQ-restrict-neuromuscular-blocking-agents-accessible-rapid-sequence-intubation-kits.pdf

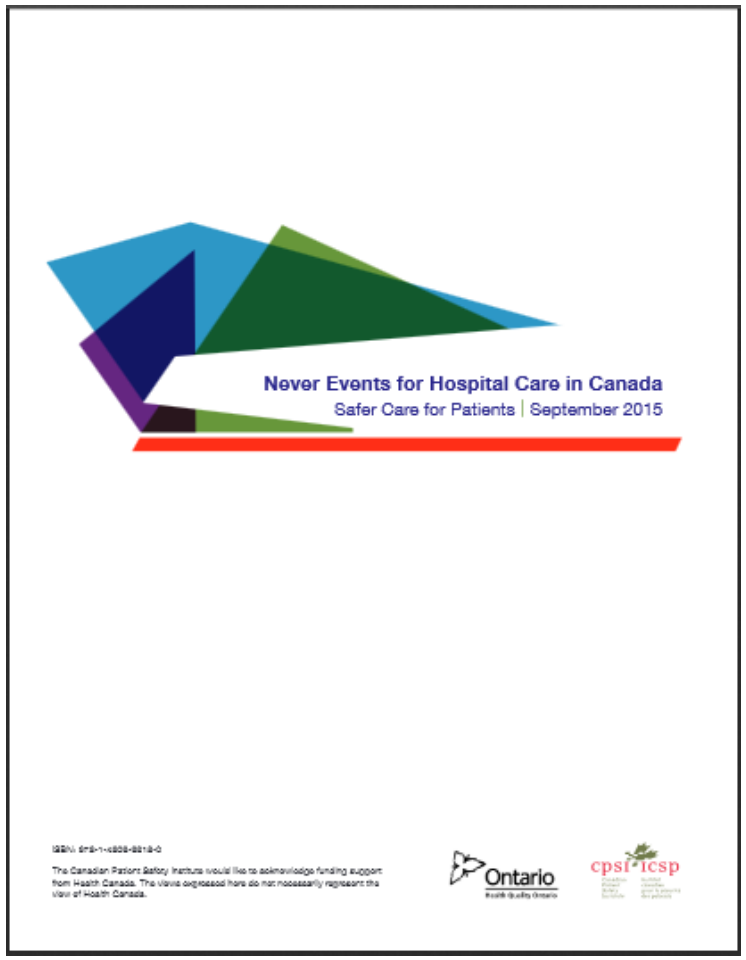
Canadian Association of Critical Care Nurses Journal 2007

https://www.ismp-canada.org/download/caccn/CACCN-Spring07.pdf

Anesthesiology Journal 2016

https://www.ismp-canada.org/download/PerioperativeMedicationErrors.pdf

Never Events for Hospital Care in Canada



Never Events Include:

Patient death or serious harm as a result of neuromuscular blockade without sedation, airway control and ventilation capability.

http://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/

Never Event Definition

Patient safety incidents in a healthcare facility that result in serious harm or death, and are preventable using organizational checks and balances.

Never Events Medication Safety Self-Assessment (MSSA) (2019)

Self-Assessment Items	
Prescribing	
17.1	A standard protocol or order set is used when paralyzing agents are prescribed for ventilated patients outside of the operating room (OR) and post-anesthesia care unit (PACU). ***Select NA** if paralyzing agents are not used in your facility.*
Dispensing	
17.2	Paralyzing agents are only available in rapid sequence intubation kits, surgical suites, post-anesthesia care unit/anesthesia stock, the emergency department and critical care units, where patients can be ventilated and monitored by practitioners with demonstrated competencies. ***Select NA** if paralyzing agents are not used in your facility.*
17.3	Storage bins and ADC pockets or drawers containing paralyzing agents include an auxiliary label to clearly communicate that respiratory paralysis will occur and ventilation is required when administering these agents (e.g., WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST; WARNING: CAUSES RESPIRATORY PARALYSIS—PATIENT MUST BE VENTILATED). ***Select NA** if paralyzing agents are not used in your facility.*
Administration	
17.4	A standardized process is in place to confirm that patients have been intubated before a paralyzing agent is prepared and administered. ***Select NA** if paralyzing agents are not used in your facility.*

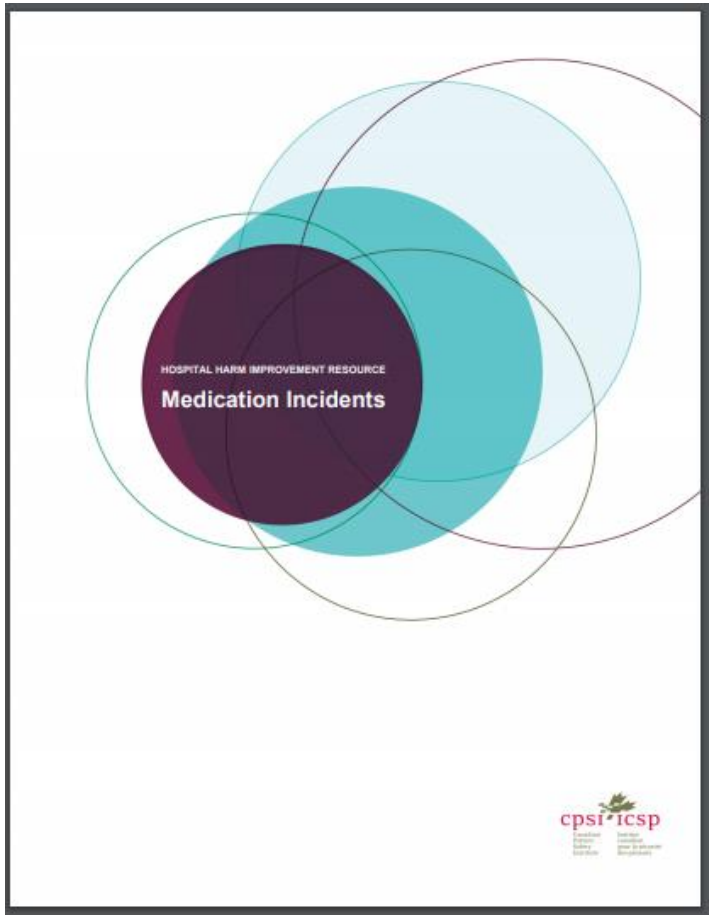
Available from: https://mssa2.ismp-canada.org/never-events-hosp-amb

MSSA For Paramedics (2022)

4.5	Neuromuscular blocking agents include warnings that clearly identify the medications as respiratory paralyzing agents that require mechanical ventilation when used, and auxiliary labels are added as required prior to stocking in response vehicles or paramedic kits. *Select NA if neuromuscular blocking agents are not used by your paramedic organization.*

6.19	Neuromuscular blocking agents are only available in rapid sequence intubation kits with additional safeguards (e.g., auxiliary warnings, containers with lids). *Select NA if your paramedic organization does not stock neuromuscular blocking agents.*

Resource Guide for Practice Improvements



Hospital Harm Improvement Resource Guide

http://www.patientsafetyinstitute.ca/en/toolsResources/Hospital-Harm-Measure/Improvement-Resources

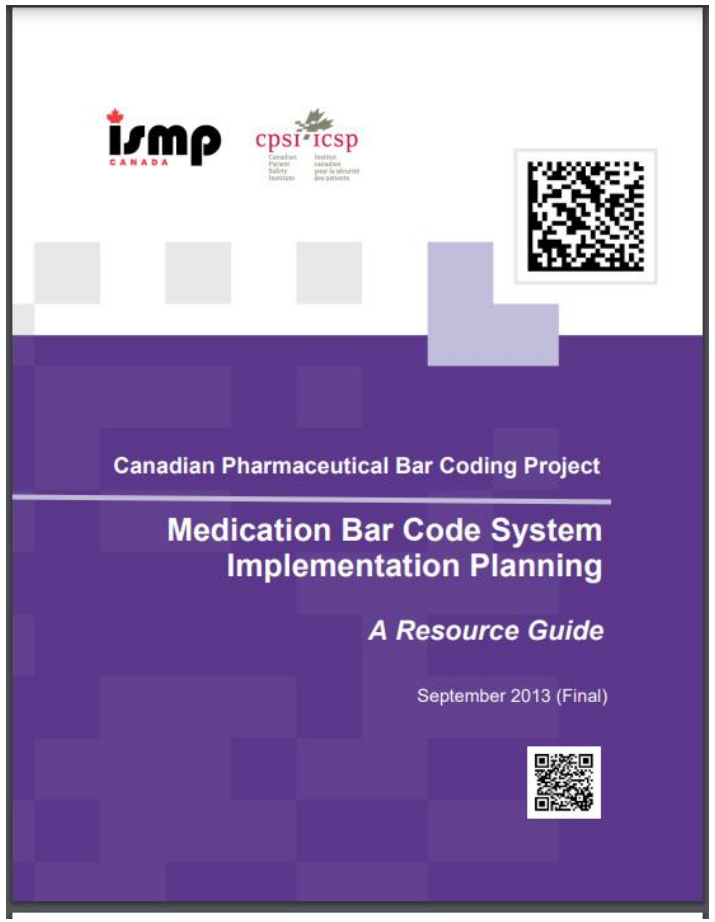
Knowledge Translation through Standards

Medication Management Standards and Required Organizational Practices

***High-Alert Medications*:**

Organizations are required to implement a comprehensive strategy to manage high-alert medications, based on the ISMP list of high-alert medications.

Pharmaceutical Bar Coding Support



Aim:

Create a national environment for automated identification at each point of medication flow chain (from manufacturer to patient administration).

Evaluation to Capture Results

Impact captured in Evaluation work.

https://www.ismp-canada.org/download/cmirps/rptISMPC_CMIRPS_Final_Report.pdf

Table 9: Changes linked to ISMP Canada recommendations

Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
NMBAs	Results from the 2007/08 Hospital Pharmacy in Canada Survey showed that 34% of respondents had a policy describing safety procedures for NMBAs. Similarly, in the evaluation survey, 42% of respondents working in community hospitals and 32% of respondents in teaching hospitals reported changes to practices in response to ISMP Canada recommendations.	Beginning in 2005/06, manufacturers began making changes to their products. As of May 2010, the manufacturers of all NMBA products distributed within Canada have made changes to their products that are consistent with ISMP Canada's recommendations on packaging and labelling, including, at a minimum, a warning on the cap. Manufacturers are waiting for further recommendations around the addition of a universal symbol for NMBAs.	In a near-miss incident reported to ISMP Canada in 2007, the nurse involved credited the newly-introduced packaging and labelling features with preventing the inadvertent use of NMBAs. In addition, ISMP Canada reports that all 20 reported medication incidents involving inadvertent use of NMBAs occurred before 2008. Since 2008, no incidents have been reported.