

International Medication Safety Network

Neuromuscular Blocking Agents (NMBA) Special Interest Group

Update from ISMP Canada

May 31, 2023

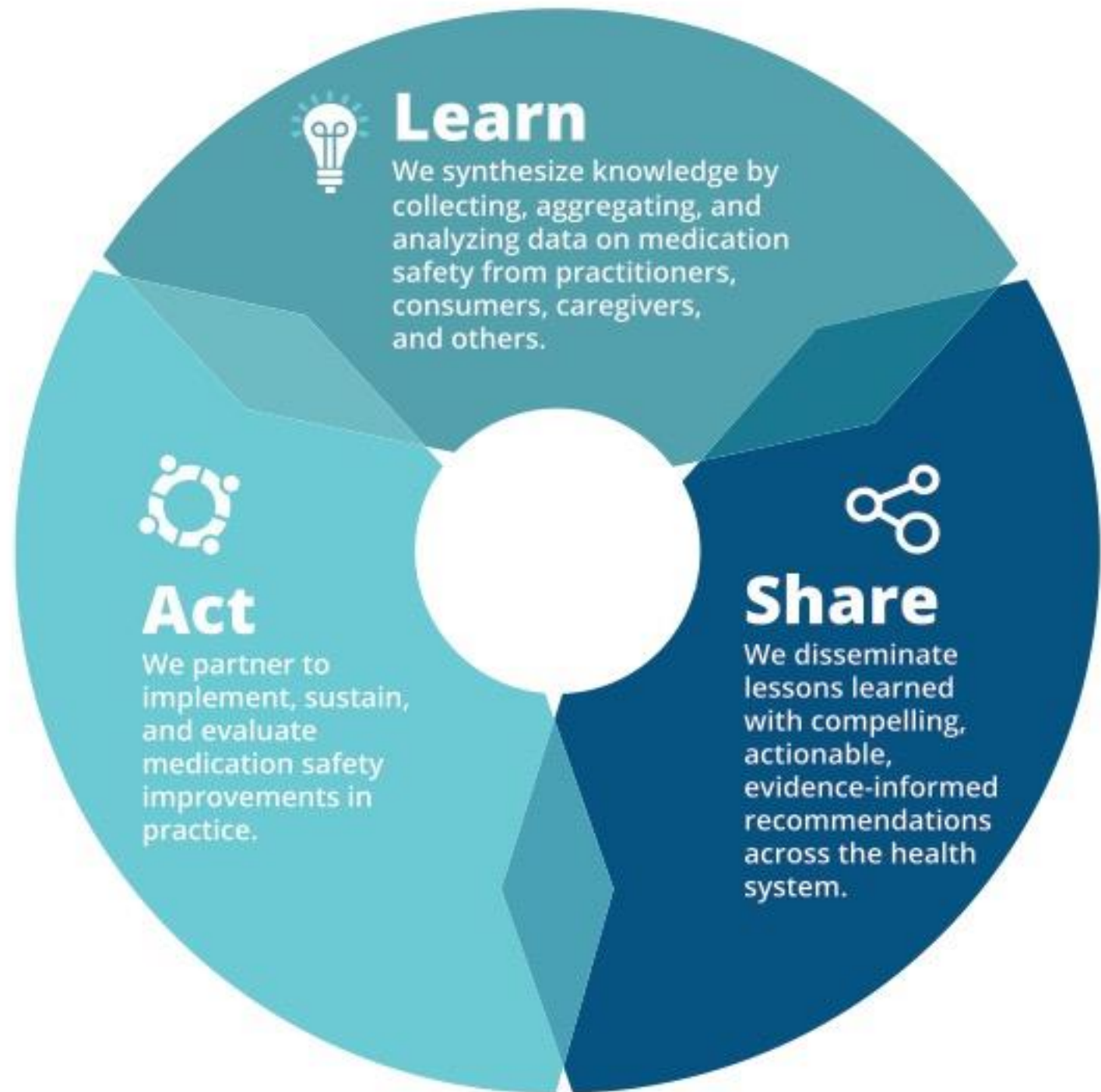


ZERO Preventable Harm From Medications
Institute for Safe Medication Practices Canada

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.

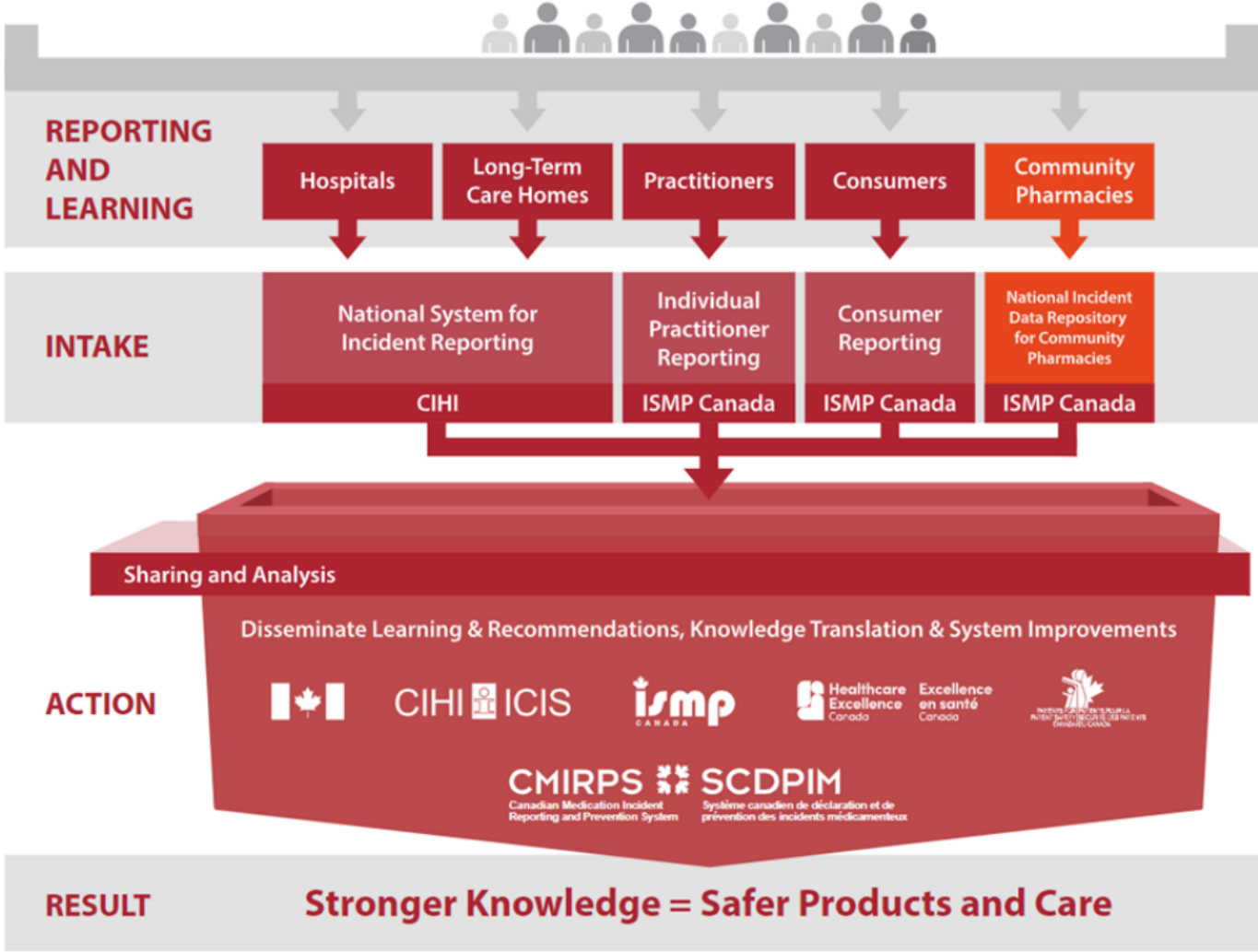


Outline

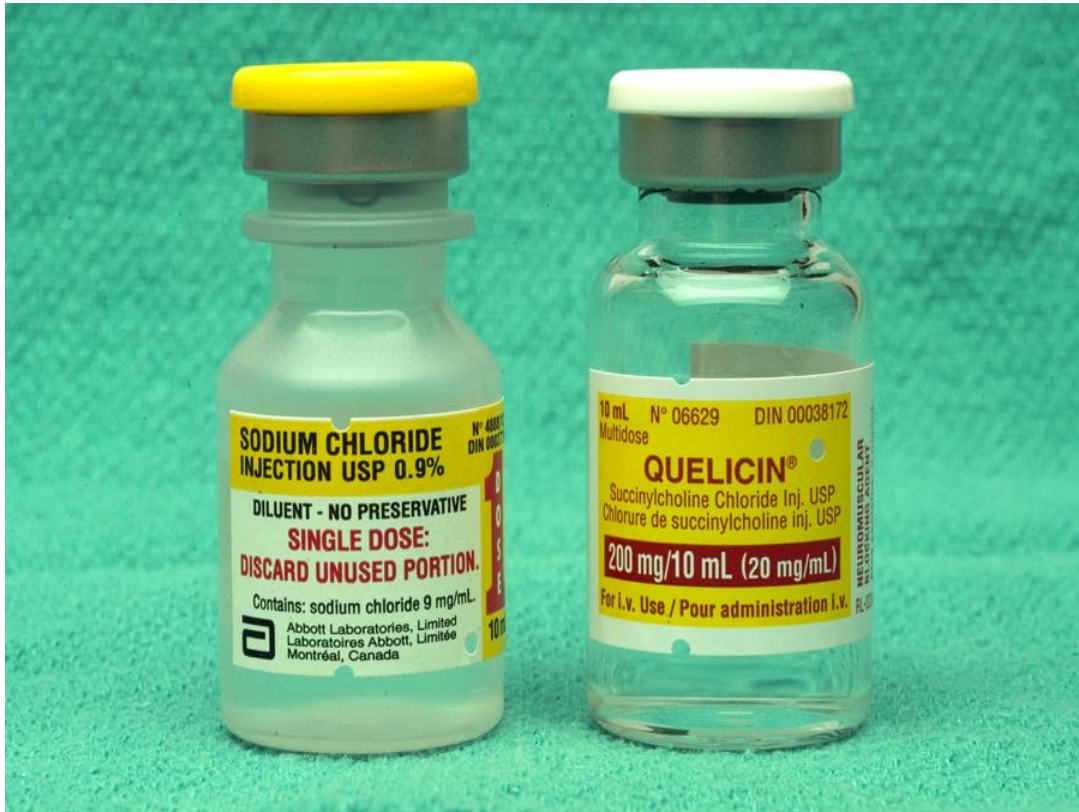
Learn / Share / Act

- 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/ismpcs0212.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/ite
m/37/](https://www.ismp-canada.org/news/item/37/)

Label Improvements Adopted by all Manufacturers



Interim phase

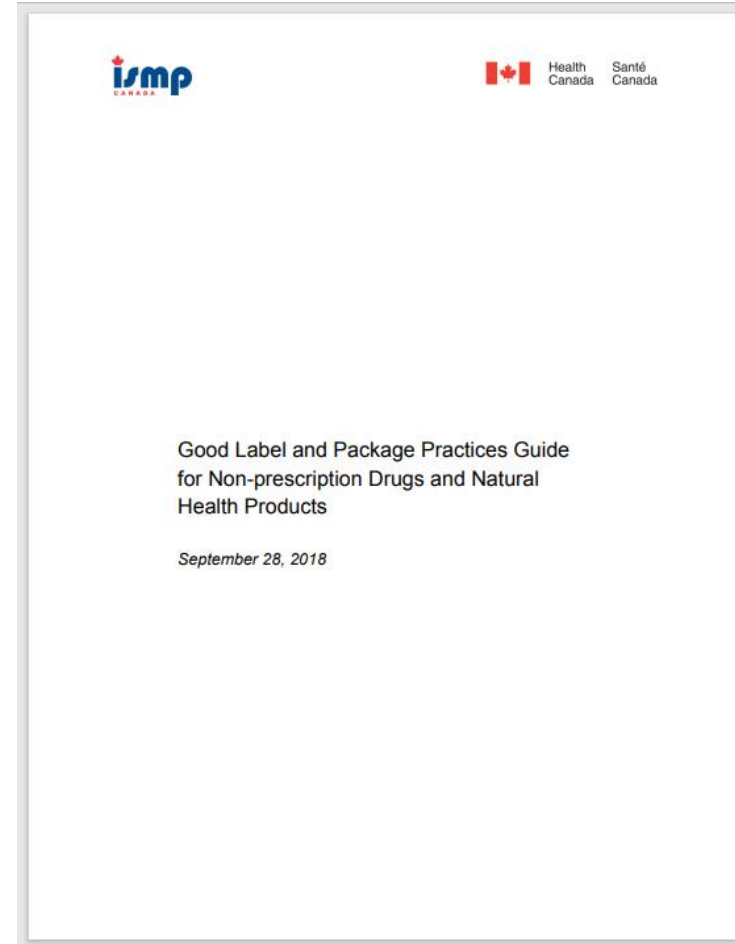


All products now have the warning “Paralyzing Agent” on the Ferrule/Cap

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

A KEY PARTNER IN

CHIRPS SCDPIM
Canadian Incident Reporting System
Canadian Reporting System for Drug Incidents

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.

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



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.)

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

- 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>
- 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
- 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>
- 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/ismpsb0212.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



FREQUENTLY ASKED QUESTIONS (FAQS)

RAPID SEQUENCE INTUBATION

We are in the process of restricting Neuromuscular Blocking agents to only in critical care units. A major concern is that if we have to maintain a “crash intubation” or Rapid Sequence Intubation (RSI) happening in various wards, clinics et

EDITORIAL VIEWS

Perioperative Medication Errors

Building Safer Systems

Beverly A. Orser, M.D., Ph.D., David U, B.Sc.Pharm., M.Sc.Pharm., Michael R. Cohen, M.S., Sc.D. (hon.), D.P.S. (hon.)

IN this month's issue of ANESTHESIOLOGY, Nanji and coworkers¹ present a landmark study that should stimulate discussion and prompt improvements in medication safety in the operating room. The authors performed a prospective, observational clinical trial in a tertiary-care teaching hospital, which measured the frequency of medication errors and adverse drug events during the perioperative period. They reported the numbers of errors and adverse events as percentages



ISMP Canada

Neuromuscular blocking agents: Enhancing safety by reducing the risk of accidental administration

By Christine Koczmara, RN, BScPsy, and Valentina Jelencic, RPh, BScPhm

Abstract

Neuromuscular blocking agents (NMBAs) are often found as ward stock in critical care units to ensure their availability in case of urgent need. The unintentional administration of an NMBA to a non-intubated and non-ventilated patient can result in severe permanent injury or death. Incidents involving mix-ups with NMBAs have occurred within and outside of critical care units. Case reports are highlighted with the intent to increase practitioner awareness of situations that could lead to similar errors and to promote changes in the critical care environment in order to enhance medication safety with NMBAs.

Background

Neuromuscular blocking agents (NMBAs) are considered a common type of error was a labeling error (37 events; 24.2%). There was no difference in event rates for patients who underwent general anesthesia (227 cases, 82.0% of the total, 3,297 medications administered, 5.3% event rate) and those who underwent sedation only (37 cases, 13.4% of the total, 374 medications administered, 4.6% event rate). One third of the anesthesia care providers were house staff (n = 93, 33.6%); however, no differences in event rates were observed

where NMBA medication incidents occur, they can provide valuable lessons for enhancing NMBA safety. The following cases are provided to increase awareness of potential system-based failures.

Reports of inadvertent administration of neuromuscular blocking agents Critical care unit

"Pancuronium [requiring refrigeration] ...was misplaced among heparin flush stock. A nurse inadvertently administered 5 mL of the neuromuscular blocking agent instead of heparin... The patient, who was in the intensive care unit, experienced the effects of the pancuronium administration, but recovered after 10 hours on a respirator." (United States Pharmacopeia [USP], 2000, p. 2).

"A ventilated ICU patient was receiving vecuronium and a potassium chloride infusion. After the patient was extubated, vecuronium was discontinued. The infusion bag containing vecuronium remained in the room and was mistaken to be potassium chloride. Soon after the medication was started, the patient arrested, requiring intubation and ventilation for six hours." (ISMP, 2006, p. 1).

Examples:

Frequently Asked Questions:

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

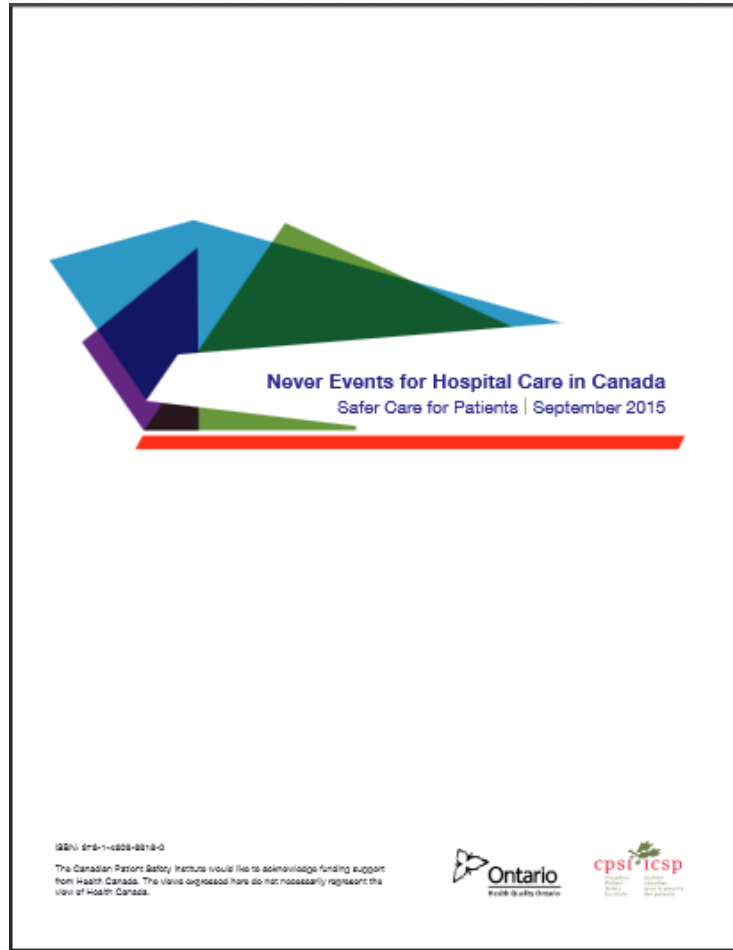
Canadian Association of Critical Care Nurses Journal 2007

<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



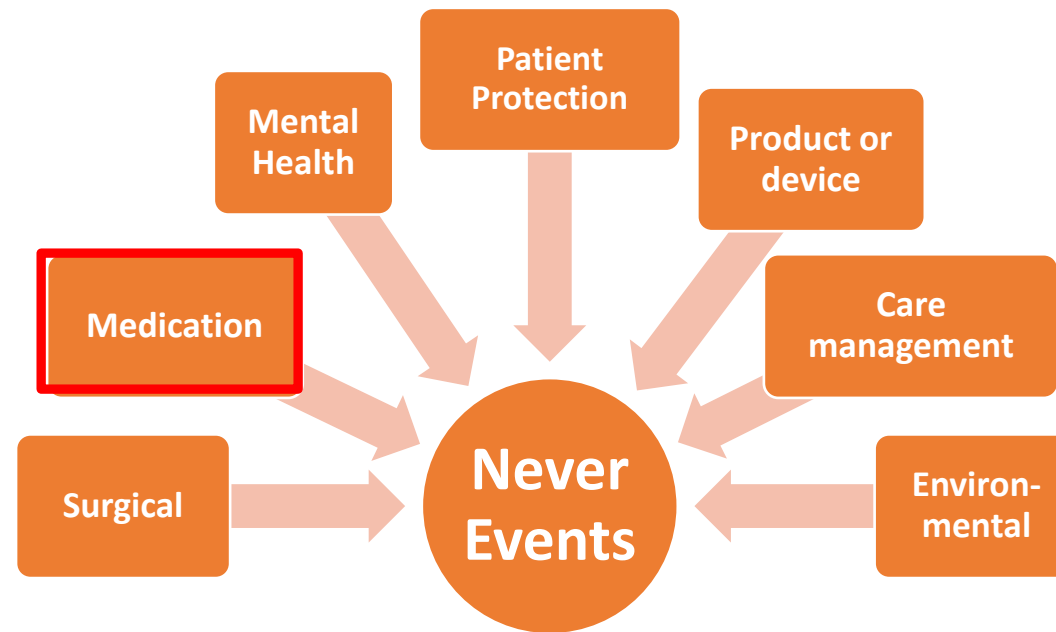
Never Events Include:

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	<p>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).</p> <p>Select NA if paralyzing agents are not used in your facility.</p>
Dispensing	
17.2	<p>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.</p> <p>Select NA if paralyzing agents are not used in your facility.</p>
17.3	<p>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).</p> <p>Select NA if paralyzing agents are not used in your facility.</p>
Administration	
17.4	<p>A standardized process is in place to confirm that patients have been intubated before a paralyzing agent is prepared and administered.</p> <p>Select NA if paralyzing agents are not used in your facility.</p>

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>

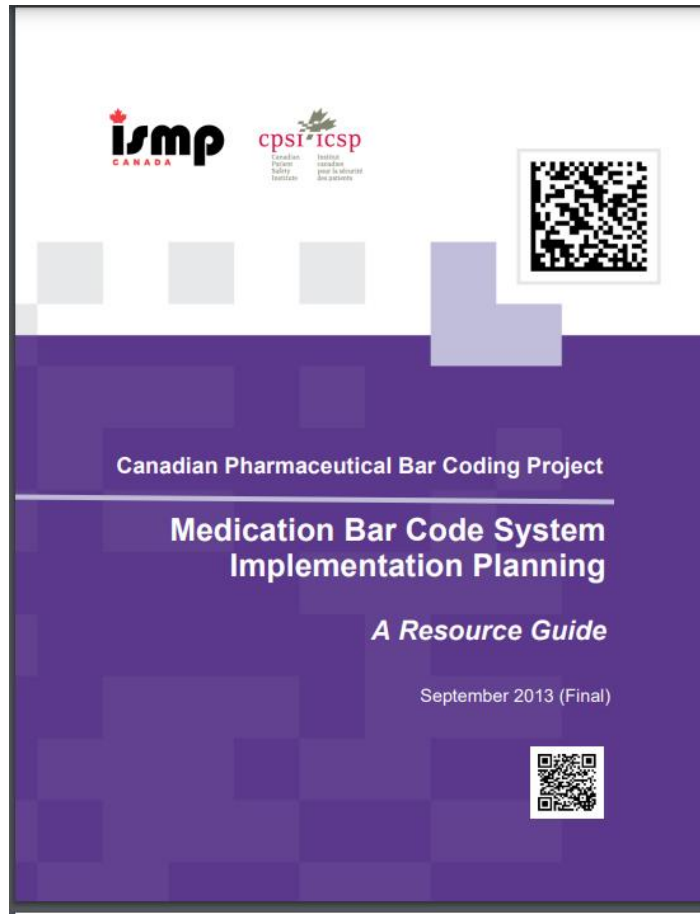
Knowledge Translation through Standards

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/cmirms/rptISMPC_CMIRPS_Final_Report.pdf

Institute for Safe Medication Practices Canada

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Evaluation of Canadian Medication Incident Reporting and Prevention System Services Provided by ISMP Canada—August 18, 2010

Table 9: Changes linked to ISMP Canada recommendations			
Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
NMBAs	<p>Results from the 2007/08 Hospital Pharmacy in Canada Survey showed that 34% of respondents had a policy describing safety procedures for NMBAs.</p> <p>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.</p>	<p>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.</p>	<p>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.</p> <p>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.</p>

