



Key Findings from the ISMP Canada Safety Bulletins

Drugs: Oversight, Safety and Supply

**OHA Educational Event
November 20, 2015
Toronto, ON**

David U
President & CEO ISMP Canada

Ontario Critical Incident Reporting

- ECFAA, 2010: requiring hospitals to report critical incidents related to medications and IV fluids
- ISMP Canada supports the implementation of the critical incident reporting
- Analysis of critical incidents
- Disseminating findings

What Have We Learned

- From critical incident reports to the National System for Incident Reporting (NSIR)
- From non-critical incidents reported through NSIR and ISMP Canada databases

What is a Critical Incident?

Severe harm incident is:

- symptomatic, requiring life-saving intervention or
- major surgical/medical intervention, or
- shortening life expectancy or
- causing major permanent, long-term harm or loss of function.

Death incident is:

- selected if on the balance of probabilities, the incident was considered to have played a role in the patient's/resident's death

Critical Incident?

Case:*

- Naloxone given to patient experiencing morphine overdose
- Patient recovered, no longer monitored
- Patient experienced another opioid overdose

Severe harm outcome is:

- symptomatic, requiring life-saving intervention or
- major surgical/medical intervention, or
- shortening life expectancy or
- causing major permanent, long-term harm or loss of function.

Insulin



- High-alert drug, risk for hypoglycemia requiring intervention
- No critical incident reports in 2014

Ontario Critical Incident Learning

www.ismp-canada.org/ocil

Ontario Critical Incident Learning
Improving quality in patient safety

Home Collaboration

To advance the patient safety agenda, in August 2011 the Ontario Ministry of Health and Long-Term Care issued a directive that hospitals must report critical incidents involving medications and intravenous fluids to the Canadian Institute for Health Information National System for Incident Reporting (NSIR). A critical incident is an "unintended event that occurs when a patient receives treatment in the hospital that results in death, or serious disability, injury or harm, and does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing treatment".

ISMP Canada has been identified as the lead organization for analysis of the reported incidents. A multidisciplinary team reviews each submitted critical incident report to ensure effective identification of the contributing factors. In addition, ISMP Canada will periodically conduct aggregate analysis of reported incidents to provide a more in-depth assessment of events involving a particular medication or care setting. On the basis of these analyses, ISMP Canada will develop and disseminate outcome-directed recommendations, with an emphasis on high-leverage actions that take into account human factors engineering principles and the need to design systems with integrated safeguards.

Bulletins:

- Resources to Sustain Incident Learning - Iss. 13/2015
- Fluid Management - Iss. 12/2015
- Multiple IV Infusions: Risks and Recommendations - Iss. 11/2014
- Naloxone Saves Lives - Iss. 10/2014
- Sharing Insulin Pens is a High-Risk Practice - Iss. 9/2014
- Safe Pain Control in the Emergency Department - Iss. 8/2014
- Smart Pumps Need Smart Systems - Iss. 7/2014
- Monitoring Processes Contribute to Safe Use of Warfarin - Iss. 6/2013
- Promoting the Safe Use of Insulin in Hospitals - Iss. 5/2013
- Designing Effective Recommendations - Iss. 4/2013
- Quality Medication Reconciliation Processes Are Critical - Iss. 3/2013
- HYDRomorphine remains a high-alert drug - Iss. 2/2013
- Mandatory Reporting—Can We Do Better? - Iss. 1/2012

Analysis Report:

- Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report - 2015
- Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report - 2014

- Multidisciplinary team analyzes Ontario critical incidents related to medication and IV fluids
 - Safety bulletins
 - Annual analysis reports
 - Webinars
 - KT projects

Designing Effective Recommendations

Ontario
CRITICAL

Improving quality in patient safety
Incident Learning

Issue 4
April 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

- Circulate bulletin to front-line staff and physicians
- Refer bulletin to quality and safety committees to encourage appraisal of effectiveness of hospital's recommendations and assessment of hospital's quality improvement initiatives
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies to mitigate the contributing factors leading to the incidents.

Advice for Hospitals

- Review patient safety incidents using a systematic, team-oriented approach, as described in the Canadian Incident Analysis Framework.¹
- Recognize that certain types of risk-mitigation strategies are more effective than others. Mitigation strategies can be ordered by hierarchy of effectiveness:²

The diagram illustrates the Hierarchy of Effectiveness for medication incidents, categorized into Person-Based and System-Based strategies. The strategies are ordered from Least Effective to Most Effective.

Category	Least Effective	Moderately Effective	Most Effective
Person-Based	Low Leverage Rules and policies (e.g., policies to prohibit borrowing doses from other areas)	Medium Leverage Simplification and standardization (e.g., standardized paper or electronic order sets)	High Leverage Forcing functions and constraints (e.g., removal of a product from use)
System-Based	Education and Information (e.g., education sessions on high-alert medications)	Reminders, checklists, double checks (e.g., independent double checks for high-alert medications)	Automation or computerization (e.g., automated patient-specific dispensing)

HIERARCHY OF EFFECTIVENESS

- Identify higher leverage strategies
 - System-based
 - More effective
- Often used in combination with lower leverage strategies (e.g., education)

ISMP Canada Ontario Critical Incident Learning



Issue 8
April 2014

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee with a recommendation to examine pain order sets used in the emergency department
- Refer bulletin to nursing leadership committees
- Refer bulletin to chief of staff and physician leaders for review of safe prescribing practices
- Circulate bulletin to physicians and other front-line staff
- Use bulletin as an educational resource in your hospital's safety huddles or rounds



Institute for Safe Medication Practices
Canada
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Safe Pain Control in the Emergency Department



Issue 9
June 2014

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee and nursing leadership committees with a recommendation to examine the use of insulin pens for inpatients
- Circulate bulletin to physicians and front-line staff
- Use bulletin, in addition to other tools such as the insulin pen e-Learning module, as an educational resource in your hospital's safety huddles or rounds



Institute for Safe Medication Practices
Canada
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Sharing Insulin Pens is a High-Risk Practice

Insulin pens are injection devices that are designed to help patients administer their own insulin with greater ease, convenience, and accuracy relative to the traditional insulin vial, needle, and syringe.¹ These advantages have led to a rise in the popularity of insulin pens in facilities, which has been paralleled by an increase in concerns about the high-risk practice of sharing insulin pens between different patients.² Since insulin cartridges and reservoirs can be contaminated with blood and other biologic material after their first use, sharing insulin pens carries the potential for transmission of blood-borne pathogens (e.g., HIV, hepatitis B, hepatitis C).^{3,4}

ISMP Canada, with support from the Ontario Ministry of Health and Long-Term Care, led a knowledge translation project to develop evidence-based interventions and resources promoting the safe use of these devices. A key resource developed is the "Safe Use of Insulin Pens" e-Learning module. The module is intended to help healthcare providers recognize the advantages and disadvantages of insulin pens, understand the risks associated with the use of these devices, and develop best-practice administration techniques while learning to use insulin pens safely.⁵

Call to Action for Hospitals

Make system-based changes to ensure insulin pens are used safely:

- Prohibit the sharing of insulin pens between patients.
- Dispense insulin pens with cartridges already inserted.
- Label insulin pens with pharmacy-generated, patient-specific labels, for single-patient use only.
- Place patient-specific labels on the barrel of the insulin pen, not on the cap.
- Use insulin cartridges only with an insulin pen. Do not use a needle and syringe to withdraw insulin from a cartridge.
- Use educational tools such as the ISMP Canada e-Learning module, along with hands-on training, to educate healthcare providers on the potential risks associated with using these devices, as well as on best-practice techniques.

Sustain high-quality practice:

- Ensure that staff members have access to relevant information about best-practice techniques and potential risks of insulin pens at all points of care.
- Reinforce safe insulin practices by providing education on an ongoing basis.
- Perform regular audits to assess compliance with best-practice administration techniques and recommended labelling practices and provide feedback to staff by sharing audit results.
- Actively seek feedback from insulin pen users as part of continuous quality assessment.
- Report medication incidents related to insulin pens internally and to patient safety organizations (e.g., ISMP Canada).
- Develop a long-term medication safety plan that uses high-leverage risk reduction strategies to ensure that insulin products are not shared amongst multiple patients.



Issue 10
September 2014

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee with a recommendation to evaluate naloxone availability and usage as well as existing naloxone protocols.
- Refer bulletin to nursing leadership and practice committees suggesting review of opioid monitoring practices to ensure that appropriate triggers are identified for naloxone use.
- Refer bulletin to interdisciplinary safety committee with a recommendation to review the types of incidents where naloxone is used.
- Use bulletin as an educational resource in your hospital's safety huddles or rounds.



Institute for Safe Medication Practices
Canada
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Naloxone Saves Lives



Issue 11
December 2014

Distributed to:

- Directors of nursing
- Directors of pharmacy
- Education coordinators
- Directors of biomedical engineering
- Clinical informatics managers
- Procurement managers
- Quality/patient safety leads

Suggested action items:

- Refer bulletin to director of biomedical engineering, clinical informatics manager, and procurement manager to take actions that upgrading personnel projects involving IV equipment (small container lines associated with administering multiple IV infusions).
- Refer bulletin to safety committees with suggestions that they consider the role of multiple IV infusions in investigations of current and future medication incidents, so that key risks are understood.
- Refer bulletin to nursing and pharmacy leadership (or equivalent) and staff levels and to education committees to take awareness of suggested strategies to minimize or prevent risks associated with multiple IV infusions.



Institute for Safe Medication Practices
Canada
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Multiple IV Infusions: Risks and Recommendations

Despite growing awareness of the factors that lead to errors in programming a single intravenous (IV) infusion, minimal research has been conducted into the errors that can result from administering multiple IV infusions¹ to a single patient (Figure 1). The use of multiple IV infusions is often unavoidable, and the complexity of the processes involved in managing these infusions contributes to the risk for medication errors. The Ontario Critical Incident Learning program recognizes the challenges that front-line practitioners face in managing multiple IV infusions and in preventing these types of errors.

Over the long term, improvements in the design of infusion systems are needed to solve problems associated with administering multiple IV infusions to individual patients. However, over the short term, supporting clinicians with targeted strategies can reduce inherent hazards and improve safety. The following are examples of errors and selected strategies designed to reduce or eliminate the risks associated with managing multiple IV infusions.



Figure 1. Managing multiple IV infusions

Identifying IV Infusions:

A nurse misidentified an infusion pump administering insulin, confusing it with one administering sodium chloride. The nurse unintentionally titrated the insulin pump's flow rate to the desired rate for the sodium chloride (i.e., from 3 mL/h to 75 mL/h). The patient received an overdose of insulin.²

Recommended Strategies:

1. Label primary IV tubing with the name of the infusate, just above the injection port closest to the patient and near the infusion pump (i.e., on the IV tubing just below the pump).³
2. Map the IV container to the corresponding IV pump/channel⁴ particularly where:
 - programming the infusion pump;⁵
 - changing IV solutions;⁶
 - transferring care of the patient (e.g., at shift change or on transfer to another care location).

Managing "Dead Volume":⁷

After administering an IV push dose of barbiturate slowly over 1 minute, a nurse flushed the line with sodium chloride as quickly as possible. As a result, most of the barbiturate dose (which was still in the IV tubing and catheter) was administered faster than the intended rate.⁸

Recommended Strategies:

1. Minimize "dead volume" by connecting IV infusions as close as possible to the patient's access port; use a single multiport connector (e.g., a manifold) when connecting more than 2 infusions.⁹
2. Minimize the clinical impact of "dead volume" by doubling the line after administration of an intermittent medication, using the recommended rate for that intermittent medication, to ensure administration of the complete dose at the intended rate.⁷

¹ In this publication, the term "multiple IV infusions" refers to the administration of 2 or more separate, continuous IV infusions to a single patient. It does not include the administration of a single IV infusion to multiple patients (e.g., in a group setting).

Opioid Overdoses

- #1 from 2012-14
 - Opioids (class)
 - HYDROmorphine (drug)
- High-alert medications
- Represents opportunities for better management of opioid overdoses

Ontario
CRITICAL Incident Learning

Improving quality in patient safety

Issue 10
September 2014

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee with a recommendation to evaluate naloxone availability and usage as well as existing naloxone protocols
- Refer bulletin to nursing leadership and practice committees suggesting review of opioid monitoring practices to ensure that appropriate triggers are identified for naloxone use
- Refer bulletin to inter-disciplinary safety committee with a recommendation to review the types of incidents where naloxone is used
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

Naloxone Saves Lives

Opioids constitute a class of high-alert medications whose toxic effects can cause sedation, confusion, and respiratory compromise and can lead to death. Fortunately, an effective and life-saving reversal agent—naloxone—is available. Naloxone temporarily replaces the opioid at the site of action of the drug, counteracting the toxic effects. With appropriate monitoring, patients known or suspected to be experiencing toxicity can be identified and rescued from the effects of opioid overdose with timely administration of naloxone and the initiation of other medical interventions.

Naloxone has a shorter duration of effect than some opioids, and once it has been metabolized by the body, there is a risk that the pharmacological effects of the opioid will re-emerge, causing harm to recur.¹ Therefore, patients receiving naloxone must be monitored closely for a prolonged period to ensure that any re-emergence of toxic effects is immediately addressed. Further administration of naloxone along with a higher level of care and medical intervention may be required.

Naloxone also antagonizes the opioid's analgesic benefits, potentially inciting severe pain or withdrawal effects. Health care providers must be aware of these attributes and must manage these variables to safely mitigate the toxicity of opioids while maintaining their desired effects.¹ Predefined naloxone protocols can help practitioners to balance conflicting clinical priorities and address the potential for unfamiliarity with appropriate dosing of naloxone because of infrequent use. Such protocols are an important tool for safe opioid management.

Call to Action for Hospitals

Make medication safety a strategic priority:

- Review the availability of specific antidotes and rescue agents within the facility generally and in each clinical area.
- Ensure that naloxone, along with appropriate medical directives and protocols for its use, are available to practitioners in all care areas.

Make systems-based changes to enhance safety:

- Ensure that opioid-related protocols have appropriate monitoring parameters to enhance the identification of opioid toxic effects and include medical directives for the immediate use of naloxone by all front-line practitioners that administer opioids.
- Create rescue protocols for the use of naloxone in cases of opioid overdose or toxicity. These rescue protocols should take into account the pharmacological properties of different opioids and the relatively shorter duration of effect of naloxone.

Sustain high-quality practice:

- Conduct mock overdose sessions to test the use of naloxone protocols.
- Solicit feedback from users of the medical directives and protocols.
- Analyze each episode of naloxone use to evaluate the opioid use that led to the incident.

ISMP

Institute for Safe Medication Practices Canada
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Learning from Analysis



Include in pain protocols/
order sets:

- Patients at risk
- Monitoring
 - Respiratory rate
 - Sedation
- Parameters for triggering naloxone use

Learning from Analysis

Develop and implement a naloxone protocol / rescue directive.

Include:

- Monitoring parameters
- Monitoring duration
- Need to reinstitute naloxone



Fluid Management

Ontario

CRITICAL Incident Learning

Improving quality in patient safety

Issue 12
February 2015

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy
- Directors of nursing

Suggested Action Items

- Ask the Pharmacy and Therapeutics Committee to evaluate protocols and order sets developed for fluid and electrolyte management on a regular basis.
- Ensure that clinical leadership committees review protocols to ensure that staff members are able to identify and safely manage the risks associated with fluid and electrolyte therapy.
- Review off-hour laboratory service demands and resources to ensure timely and effective responses.



**Institute for Safe
Medication Practices
Canada**
www.ismp-canada.org
1-866-544-7672
info@ismp-canada.org

Fluid Management

Most patients who are receiving inpatient care require fluid and electrolyte management, a process that is often thought of as simple and routine. However, evaluation of fluid status and replacement of fluids are complex activities, and there can be profound clinical consequences for patients if these tasks are not well managed. Electrolyte disturbances and pulmonary edema are but a few of the potential adverse sequelae that may develop while managing a patient's illnesses, comorbid conditions, and requirements for hydration.

Determining an optimal regimen for replacing fluids and electrolytes involves clinical assessment of fluid volume status and measurements of fluid input and fluid loss. Appropriate imaging and laboratory measurement of electrolytes and organ function are also required.

The safe use of replacement fluids and electrolytes requires a respect for the unique needs of each patient. It also demands a systematic approach to assessment, monitoring, and correction of any deficits.

Call to Action for Hospitals

Make fluid-related safety a priority:

- Recognize that the complexity of the processes associated with fluid and electrolyte management is widely underappreciated.
- Ensure that laboratory infrastructure supports timely collection and transportation of samples, and measurement and reporting of electrolytes and other indicators of fluid status.

Make systems-based changes to enhance safety:

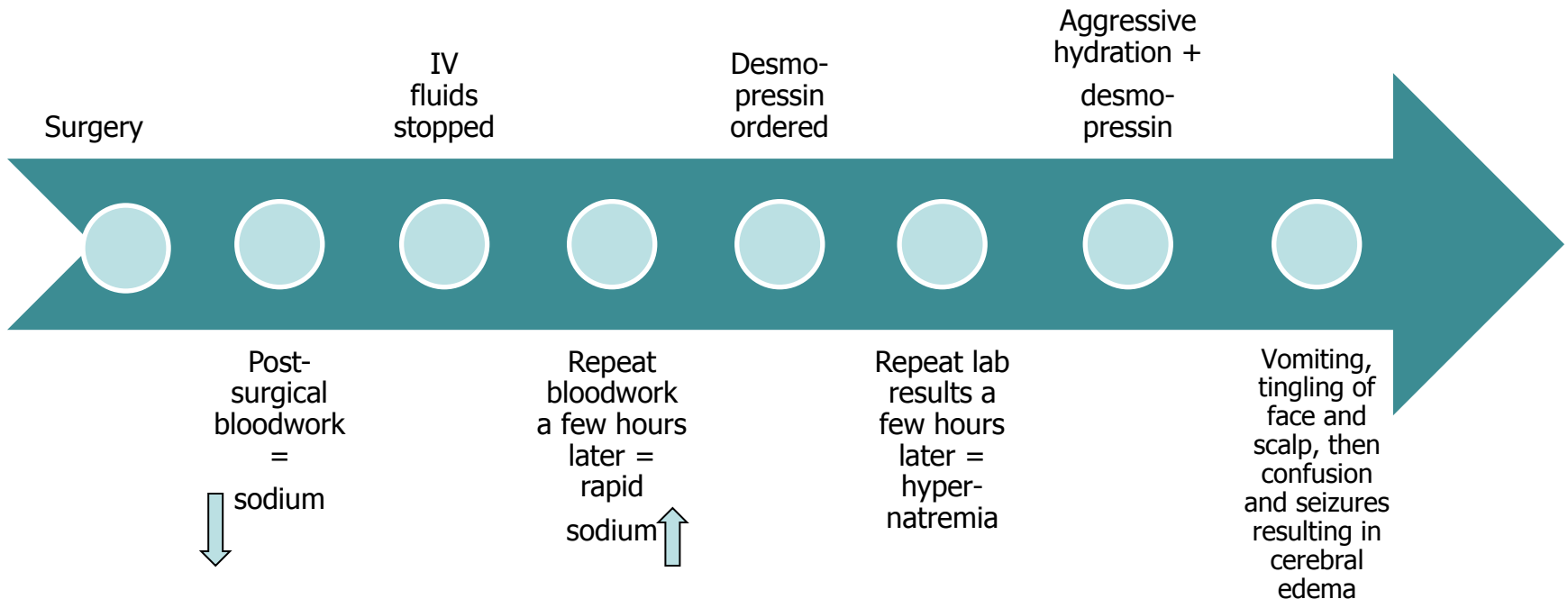
- Anticipate procedures or clinical conditions that may require enhanced observation of fluid status, and create standardized protocols and processes to support this heightened awareness.
- Create protocols and order sets for fluid and electrolyte management, ensuring that they include appropriate laboratory testing and monitoring.

Sustain high-quality practice:

- Make the assessment of fluid status a regular part of clinical practice and vital-sign monitoring.
- Ensure that organizations have a robust process that monitors staff competence and compliance in executing protocols/order sets consistently.

Fluid Management Case

Actions



Signs and Symptoms

Learning from Analysis

- Anticipate procedures or clinical conditions that may require enhanced patient observation
- Develop order sets for fluid and electrolyte management (including monitoring parameters)

Learning from Analysis

Laboratory Infrastructure

- Timely
 - collection and transportation of samples
 - analysis and measurement
 - reporting of all abnormal results back to care team

Education

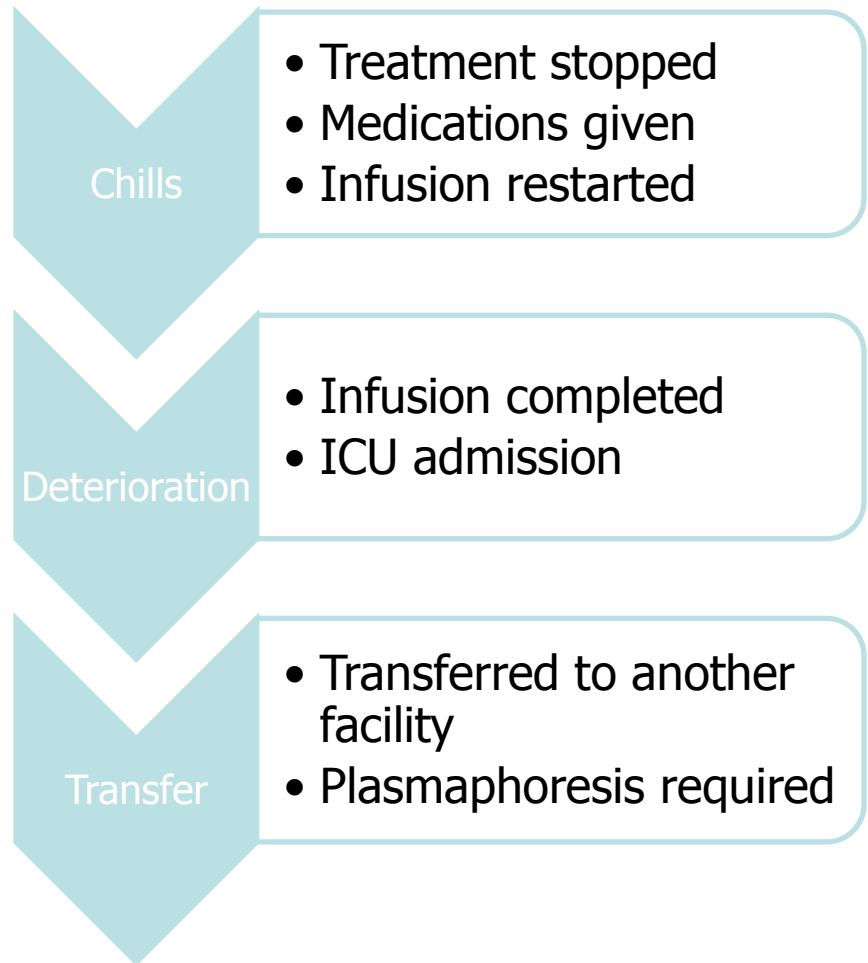
- Signs and symptoms
- Recognizing seriousness of hyponatremia
- Understanding of rationale behind management

Amphotericin B

Bulletin to be distributed Nov 16 or 17 –
picture to come

Amphotericin B

- Amphotericin B (liposomal) 5 mg/kg/day ordered
- Incorrect selection at order entry for regular Amphotericin B at 5 mg/kg/day
- MAR transcription did not include “liposomal”



Learning from Analysis

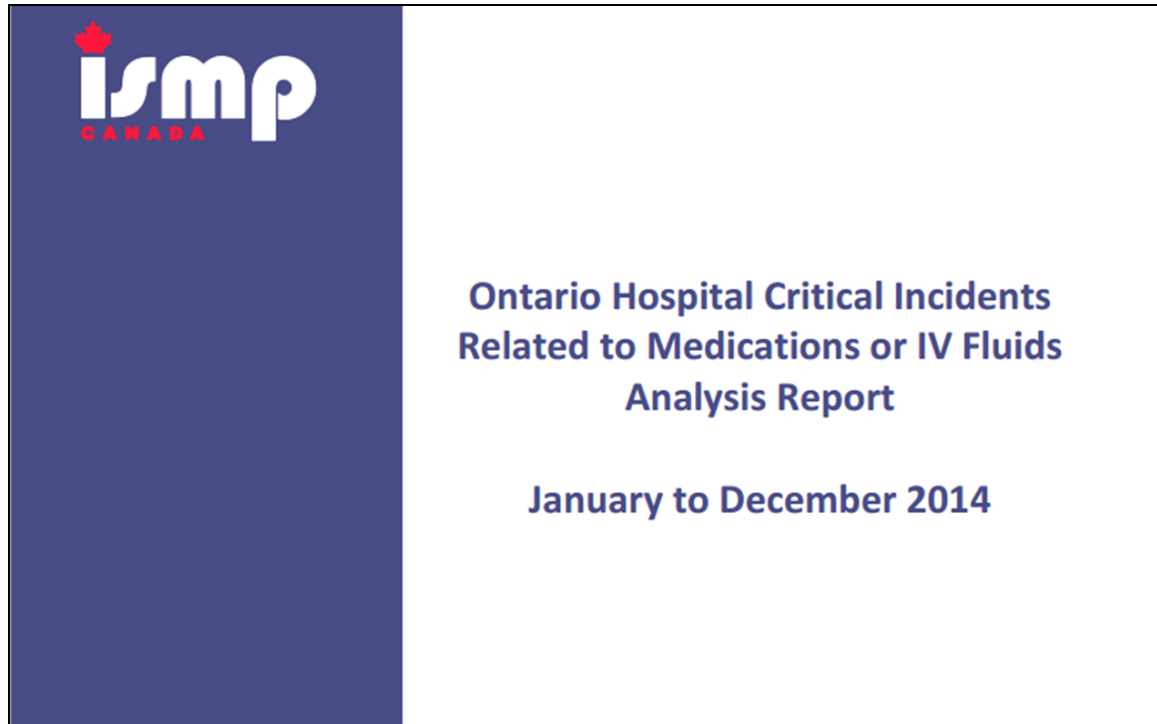
- Consider carrying 1 formulation, if clinically appropriate
- Restrict the dispensing of all Amphotericin B products to pharmacy (i.e., no night cupboard, ADCs) with pharmacist check



If 2 Formulations Needed

- Create standardized order sets with the descriptor of the formulation (e.g., liposomal) in front of “Amphotericin B”
- Program infusion pump libraries with hard stops for dose limits
- Evaluate ability of order entry systems to
 - incorporate generic names, preceded by descriptors, and trade names
 - Institute hard stops for doses of each formulation

Key Findings



Available at www.ismp-canada.org/ocil

2014 Analysis Report

Overview

Critical Incidents by Degree of Harm		
Year	Deaths	Severe harm
2014	4	23
2013	6	23
2012	8*	21*
	*Proportional contribution from Year 2012	

2014 Analysis Report

Stage

- Administration → 12
- Transcribing → 5 (verification and documentation)
- Prescribing → 3
- Preparation/Dispensing → 3
- Monitoring → 2

2014 Analysis Report

Patient Care Areas

- Emergency department → 9
- Surgical area → 4
- Intensive Care Unit → 3
- Medical/Surgical Ward → 3
- Oncology area → 2
- Mental Health area → 2

2014 Analysis Report

Drug Class

- Opioids → 9
- Anti-neoplastic → 4
- Anti-coagulant → 2
- Thrombolytic → 2
- Insulin → 0

Qualitative Learning from 2014 Analysis Report

Naloxone Rescue

Systematic approaches to monitoring can detect a patient at risk of opioid toxicity and trigger an appropriate response.

Patient Factors

Allergies, weight, co-morbidities, co-prescribed drugs, diet all influence how a drug behaves in a patient. This information needs to influence how we manage drugs in a patient.

Multiple Products

The standardization of medication products to ensure consistency and simplification is supported. The use of independent double checks for high-alert medications is recommended.

Webinars



Advancing Safe Medication Practices




Supporting Medication System Safety
and Preparing for Accreditation

***Applying New Tools for Home and
Community Care and Acute Care***

June 23, 2015


Presented with support from  Ontario



Improving quality in patient safety

**Demystifying the Critical
Incident Reporting Process**

October 21, 2015



© Institute for Safe Medication Practices Canada 2015

Increasing Awareness on Social Media

Follow us on Twitter

- @ismpcanada
- @safemeduse
- @canmedrec

Like our Facebook pages

- Medication Reconciliation Network
- SafeMedicationUse.ca

Like us on Facebook





**You can advance medication
safety in Ontario...**

**by encouraging reporting and
analysis.**