Never Events in Healthcare

Raising awareness to protect patients from serious harm or death

September 11, 2015

The 4th International Medication Safety Summit Conference
Beijing, China

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Overview

Brief introduction to ISMP Canada

Introduction to Never Events
- Examples, criteria, rationale

Overview of Pharmaceutical Never Events
- Five Canadian Pharmaceutical Never Events

Next Steps

Concluding remarks

About ISMP Canada

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent not-for-profit organization committed to reducing preventable harm from medications, and advancing medication safety in all healthcare settings.

Our aim is to heighten awareness of system vulnerabilities and facilitate system improvements.

www.ismp-canada.org

Medication Incident and Near Miss Reporting Programs

Practitioners

Healthcare Professional - (e.g., nurse, pharmacist, physician)

General Public

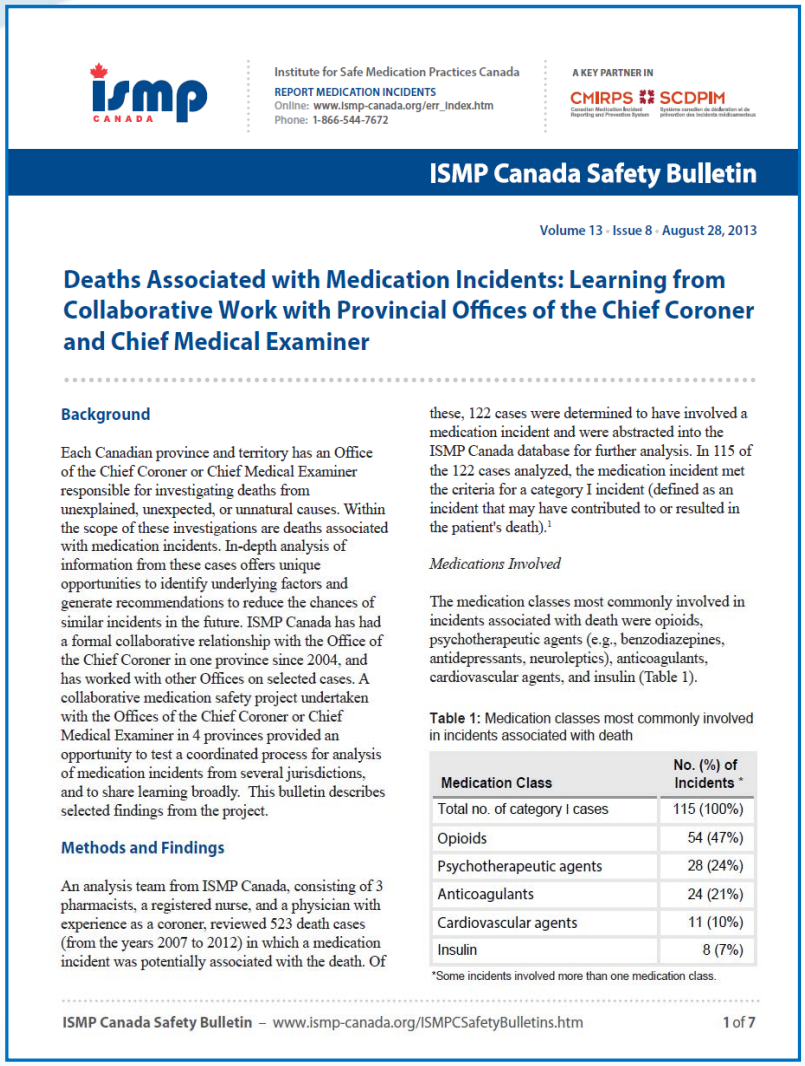
Preventing harm from medication incidents is a responsibility of health professionals. **Consumers like you** can also play a vital role.

CPhIR - Community Pharmacy Incident Reporting Program

For participating community pharmacies.

http://www.ismp-canada.org/err_index.htm

Analysis Outputs: Safety Bulletins



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 13 · Issue 8 · August 28, 2013

Deaths Associated with Medication Incidents: Learning from Collaborative Work with Provincial Offices of the Chief Coroner and Chief Medical Examiner

Background

Each Canadian province and territory has an Office of the Chief Coroner or Chief Medical Examiner responsible for investigating deaths from unexplained, unexpected, or unnatural causes. Within the scope of these investigations are deaths associated with medication incidents. In-depth analysis of information from these cases offers unique opportunities to identify underlying factors and generate recommendations to reduce the chances of similar incidents in the future. ISMP Canada has had a formal collaborative relationship with the Office of the Chief Coroner in one province since 2004, and has worked with other Offices on selected cases. A collaborative medication safety project undertaken with the Offices of the Chief Coroner or Chief Medical Examiner in 4 provinces provided an opportunity to test a coordinated process for analysis of medication incidents from several jurisdictions, and to share learning broadly. This bulletin describes selected findings from the project.

Methods and Findings

An analysis team from ISMP Canada, consisting of 3 pharmacists, a registered nurse, and a physician with experience as a coroner, reviewed 523 death cases (from the years 2007 to 2012) in which a medication incident was potentially associated with the death. Of these, 122 cases were determined to have involved a medication incident and were abstracted into the ISMP Canada database for further analysis. In 115 of the 122 cases analyzed, the medication incident met the criteria for a category I incident (defined as an incident that may have contributed to or resulted in the patient's death).[1]

Medications Involved

The medication classes most commonly involved in incidents associated with death were opioids, psychotherapeutic agents (e.g., benzodiazepines, antidepressants, neuroleptics), anticoagulants, cardiovascular agents, and insulin (Table 1).

Table 1: Medication classes most commonly involved in incidents associated with death

Medication Class	No. (%) of Incidents *
Total no. of category I cases	115 (100%)
Opioids	54 (47%)
Psychotherapeutic agents	28 (24%)
Anticoagulants	24 (21%)
Cardiovascular agents	11 (10%)
Insulin	8 (7%)

*Some incidents involved more than one medication class.

ISMP Canada Safety Bulletin – www.ismp-canada.org/ISMPCSafetyBulletins.htm 1 of 7

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Consumers Can Help Prevent Harmful Medication Incidents

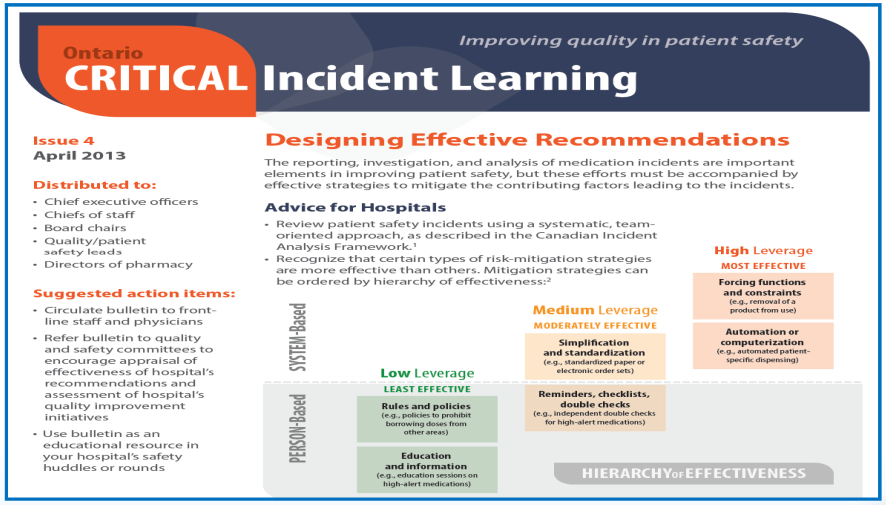
SafeMedicationUse.ca Newsletter

Volume 4 • Issue 6 • September 13, 2013

Reminder - Check Your Prescription!

Has your pharmacy ever made a mistake with your medicine? If so, you're not alone. Mistakes with medicines can happen even when healthcare professionals have tried their best to prevent them. SafeMedicationUse.ca has received many reports from consumers who received the wrong medicine or the wrong dose of a medicine from a pharmacy.

Here is one example: A consumer had been taking trazodone 25 mg (one half of a 50 mg tablet) at bedtime. One day, when the consumer picked up a new supply of trazodone at the pharmacy, she received white tablets with "100" printed on one side and "Novo" on the other. The consumer knew that her tablets were usually peach in colour, but did not notice the difference until after her pharmacy had closed. Thinking that the appearance of the medicine might have changed because she had been given a different brand of trazodone, she decided to take half of one of the new tablets at bedtime. The next day, she called the pharmacist and was told that a mistake had been made. The consumer returned the medicine to the pharmacy and was given the correct strength of trazodone. The person who reported the mistake to SafeMedicationUse.ca stated that the white tablets contained 100 mg of trazodone. Fortunately, the consumer experienced no harm from taking one incorrect dose.



Ontario CRITICAL Incident Learning

Improving quality in patient safety

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]

SYSTEM-Based / PERSON-Based

High Leverage — MOST EFFECTIVE
- Forcing functions and constraints (e.g., removal of a product from use)
- Automation or computerization (e.g., automated patient-specific dispensing)

Medium Leverage — MODERATELY EFFECTIVE
- Simplification and standardization (e.g., standardized paper or electronic order sets)
- Reminders, checklists, double checks (e.g., independent double checks for high-alert medications)

Low Leverage — LEAST EFFECTIVE
- Rules and policies (e.g., policies to prohibit borrowing doses from other areas)
- Education and information (e.g., education sessions on high-alert medications)

HIERARCHY OF EFFECTIVENESS

http://www.ismp-canada.org/ISMPCSafetyBulletins.htm.

Introduction to "Never Events" in Health Care

Incident

*"A young female leukemic patient was erroneously given **intrathecal vincristine** in addition to cytarabine through a **spinal needle**. The vincristine was prepared in a **syringe** (2 mg in 2 mL) by the pharmacy department. The error was not noticed for 3 days and the patient died 22 days after the original incident"*

Gilbar P. J Oncol Pharm Practice; 2011; 18(1): 155 – 157
Hong Kong Hospital Authority. *Online Referencing Special Investigation Panel 2007*

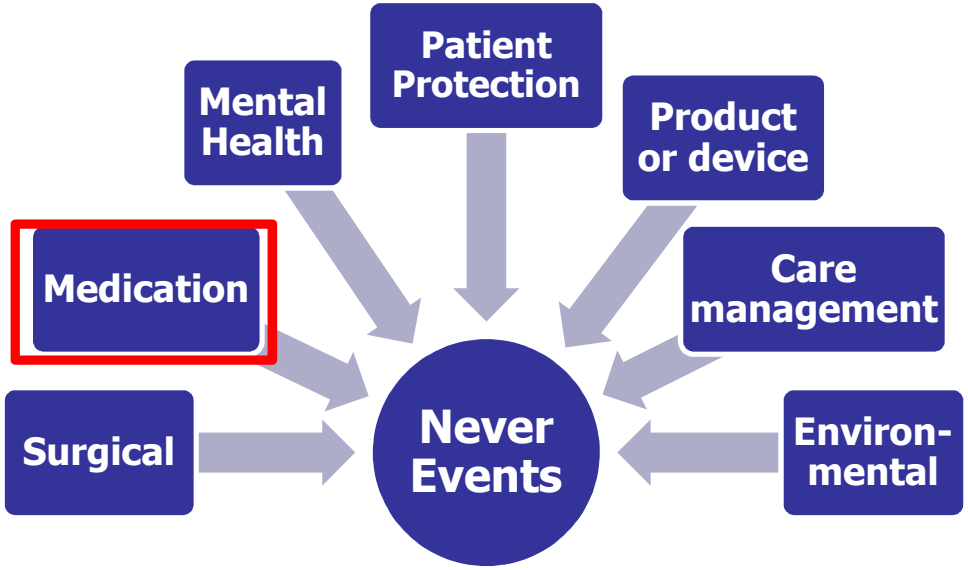
Incident

"*During a day surgery ENT procedure, the surgeon requested* ***local anesthetic for injection*** *(specifically lidocaine 1% with epinephrine 1:100,000) and was handed a pre-drawn syringe. The surgeon injected the medication into the surgical site. Immediately afterward, the patient experienced a cardiac arrest. Despite full resuscitation measures, the patient died.*

Information gathered after the incident indicated that the syringe contained epinephrine 1 mg/mL (1:1000) ***intended for topical use****, rather than the local anesthetic for injection that was requested"*

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
- Various types, e.g.
  - Surgical events
  - Product or Device events
  - Patient Protection events
  - Care management events
  - Environmental events
  - Mental Health
  - Medication



Canadian Patient Safety Institute (2015)
U.S. Centers for Medicare and Medicaid Services (2006)

Never Events

- Usually very rare; account for a small proportion of patient safety issues in health care
  - A 2006 study estimated a typical hospital might experience a case of wrong-site surgery once every 5 – 10 years
- However, when Never Events occur, they are devastating to patients
  - Joint Commission report estimated 71% of events over the past 12 years were fatal

Agency for Healthcare Research and Quality (2014)

Never Event Criteria

- ***Serious***:
  - High risk that the event would cause significant patient harm or death
- ***Recurrence***:
  - Available evidence of a past occurrence (e.g. incident reports)
  - Risk of the event happening to another patient if it is not addressed
- ***Identifiable***:
  - The event is easily recognized, clearly defined, and not attributable to other possible causes
  - Helps minimize disputes around classification, ensures focus on learning and improving safety
- ***Preventable***:
  - Appropriate organizational barriers, (guidance and safety recommendations) when implemented, can prevent the event from occurring

Canadian Patient Safety Institute (2015); NHS England Patient Safety Domain (2015)

Rationale for Never Events

- Never Events Framework identifies high-impact, high-risk areas of improvement that we would like to see change in immediately
  - Provides an opportunity to concentrate on reducing and eliminating preventable incidents with potential for harm or death
- Prioritize and focus on patient safety incidents that can be prevented outright
- Promote a culture of openness and transparency, and continuous quality improvement
  - i.e. Incidents are openly reported, disclosure occurs routinely, open discussion and problem solving encouraged, etc.

Canadian Patient Safety Institute (2015)
NHS England Patient Safety Domain (2015)

Overview of Pharmaceutical Never Events

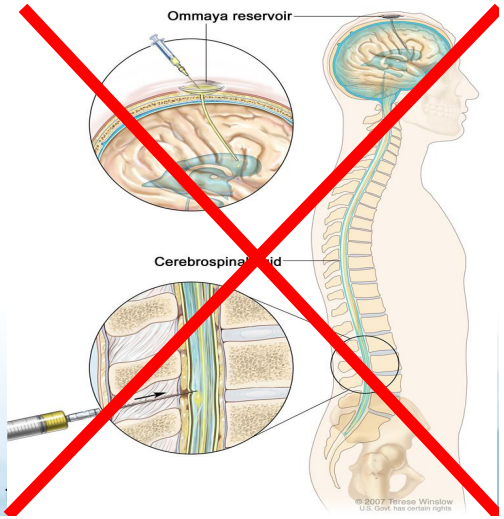
Pharmaceutical Never Events: Canada

1. Wrong route administration of chemotherapy agents (e.g. **vincristine** administered intrathecally)
2. Intravenous administration of undiluted/ concentrated potassium solutions (e.g. **potassium chloride**)
3. Inadvertent injection of **epinephrine** intended for topical use
4. Inadvertent overdose of **hydromorphone** by administering a higher concentration solution than intended
5. **Neuromuscular blockade** without sedation, airway control, and ventilation capability

Pharmaceutical Never Event #1

Wrong route administration of chemotherapy agents (e.g. vincristine administered intrathecally)

- **Issue**:
  - Vincristine (and other vinca alkaloids) are intended for IV (intravenous) administration only
  - Cases of inadvertent administration via the intrathecal route
  - Vincristine is often prepared and drawn up into syringes, which gives the misguided impression that it can be administered intrathecally
  - Inadvertent intrathecal administration can lead to:
    - Spinal cord, cerebellum lesions
    - Myeloencephalopathy causing severe pain
    - Paralysis with motor and sensory dysfunctions
    - Death



Irish Medication Safety Network (2010)
http://www.cancer.gov/images/cdr/live/CDR539773-750.jpg

Pharmaceutical Never Event #1

Wrong route administration of chemotherapy agents (e.g. vincristine administered intrathecally)

- **Prevention Strategies**: Forcing functions and constraints
  - Prepare and dispense vincristine (and other vinca alkaloids) in small-volume IV minibags (not syringes)
    - Larger volume of diluted vincristine is less likely to result in a 'mix-up' in route of administration
    - Stable when diluted to 25 mL of normal saline in minibags
  - Remove vincristine from areas where intrathecal medications are prepared, administered, or stored
  - Employ unique and non-interchangeable connections

ISMP strongly recommends dispensing and administering intravenous Vincristine in a minibag.

ISMP strongly recommends against dispensing and administering intravenous Vincristine in a syringe.

Berwick, D.M., et al. (2001) | ISMP Canada (2001) | Irish Medication Safety Network (2010) | Laws, D. (2001) | Trissel, L.A., et al. (2001) | Davis, N.M. (2001) | ISMP (2006)

Pharmaceutical Never Event #1

Wrong route administration of chemotherapy agents (e.g. vincristine administered intrathecally)

- **Prevention Strategies**: Reminders
  - Auxiliary warning labels when dispensing vincristine
    - "For intravenous use only – Fatal if given by other routes"

ISMP Can Saf Bull (2001)
Irish Medication Safety Network (2010)

Pharmaceutical Never Event #2

Intravenous administration of concentrated potassium chloride (KCl)

- **Issue:**
  - Concentrated potassium (all salts): Concentrations greater than or equal to 2 mmol/mL or 2 mEq/mL (e.g. 20 mEq/10 mL amp, etc.)
  - Concentrated KCl must be diluted in minibag prior to administration and given as an infusion
  - Result of administration of concentrated KCl: Hyperkalemia, cardiac arrest, death

ISMP Canada (2004a); Cornish, P., et al. (2007)

Pharmaceutical Never Event #2

Intravenous administration of concentrated potassium chloride (KCl)

- Issue:

Wrong injection causes

BY GRAEME SMITH

A drug used to execute death-row prisoners was mistakenly injected into an elderly woman, whose death in a Peterborough, Ont., hospital will be examined in a coroner's inquest.

Bonita Porter, Ontario's deputy chief coroner of inquests, announced yesterday that a jury will look at why Frances Marie Tanner, 84, died at the Peterborough Regional Health Centre on Jan. 21.

The cause of Ms. Tanner's death is already known: Somebody injected a dose of potassium chloride into her vein. Small quantities of the drug can cure potassium deficiencies, but larger amounts are poisonous.

At least three other Canadians have died after receiving the same drug, sometimes from nurses who thought it was a different medicine.

Some doctors blame these accidents on manufacturers who sell potassium chloride in plastic ampoules and vials that closely resemble containers of sterile water, administered in the past.

After the latest death, however, the coroner's office decided it was time to emphasize the danger.

"It was felt that an inquest might

were accidentally given potassium chloride; three died, and two were considered "near misses."

More cases could exist, said the institute's president, physicia

Litany of errors

Incidents involving potassium chloride in Canada:

1. Potassium chloride (KCl) was administered via direct IV when the intended action was to flush an intravenous line with diluted sodium chloride. **Result: *Patient died.***
2. KCl concentrate was used to reconstitute a drug for parenteral administration when the intended diluent was sterile water. **Result: *Error was noted before administration.***
3. KCl concentrate was administered as a bolus injection – an injection given in high quantity, all at once – by a health-care professional who was unaware that KCl concentrate cannot be given as a bolus but must be diluted in a minibag and given as an infusion. **Result: *Patient died.***
4. A one-litre IV sol chloride and a very low rate, miss becaus overdose. **Result:**
5. IV solu as a sev
6.

SOURCE: INSTITUTE FOR SAFE MEDICATION PRACTICES REPORT, MAY, 2002 IMAGE: PHOTODISC

Injection death second in 3 y

Ontario hospital's treatment with drug used for executions killed patient in 1999

BY GRAEME SMITH, BRIGHTON, ONT.

Relatives of a hospital patient injected with a drug commonly used to execute death-row prisoners are demanding to know why nothing changed at the Ontario hospital before another woman suffered the same fatal mistake.

They didn't want to publicize the tragic story of why Ruby McConnell's heart stopped.

It has been a family secret since the evening of June 29, 1999, when the 94-year-old woman felt weak, fell hard onto her sofa and was taken to the Peterborough Regional Health Centre with a fractured hip.

But they broke their silence, in an exclusive interview with The Globe and Mail, after hearing a news report last week that sounded tragically familiar to them.

An elderly woman, Frances Marie Tanner, had died at the Peterborough hospital after someone shot potassium chloride into a vein.

A coroner's inquest will investigate.

Few people knew the rest of the story: Ms. Tanner was the second person to die of potassium chloride poisoning at Peterborough's hospital in less than three years.

Only four such cases have been recorded in Canadian hospitals.

"I was just horrified," said Mary Gardner, who had been watching the newscast at home in Brighton,

Earl Gardner, left, listens to his wife, Mary, as she reads from a coroner's report on the death in June, 1999, of Mr. Ga

am I, chopped liver? I'm her nephew.'"

Still, the relatives didn't make a

'You have a busy nurse

The Institute for Safe Medication Practices Canada (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.

Volume 4, Issue 3 **ISMP Canada Safety Bulletin** March, 2004

Concentrated Potassium Chloride: A Recurring Danger

ISMP Canada has worked with hospitals across Ontario and other hospitals in other provinces to identify and implement strategies to promote the safe use of potassium chloride (KCl). A key example safeguard is the removal of concentrated KCl from all patient care areas. Even if hospitals have removed stock of this dangerous drug from their nursing units they must remain vigilant and not let their guard down. We have received reports of sentinel events involving other situations where potassium is used. These include inadvertent injection of other potassium salts (acetate, phosphate); wrong rates of infusion; and the use of potassium chloride as an incorrect additive.

ISMP Canada has recently learned of an adverse drug event resulting from the inadvertent addition of potassium chloride to a renal dialysis fluid for Continuous Renal Replacement Therapy (CRRT). The hospital has shared information about this case recognizing that a similar error could occur in other hospitals:

- A pharmacy technician, in the process of setting up a batch preparation of dialysis solution, picked up a carton of 12 x 250 mL Concentrated Potassium Chloride 2 mmol/mL bottles, instead of a carton of 12 x 250 mL bottles of 23.4 % Sodium Chloride (NaCl) for Injection. Since 85 mL of sodium chloride solution was needed for each 3-litre dialysis solution, and because one batch preparation was 35 bags, an entire carton of 12 bottles of 250 mL of NaCl solution was required. The cartons of stock potassium chloride solutions were located near the sodium chloride solutions.
- The selected items for dialysis preparation were checked against the manufacturing or ingredient worksheet by a second pharmacy technician in the preparation area. The second technician did not notice that the carton was the wrong one.
- During the manufacturing process, 85 mL of potassium chloride 2 mmol/mL were added to the 3-litre bags of dialysis solution.
- A third technician later checked the completed batch of dialysis solutions. Again, the incorrect ingredient went unnoticed.

Each of the 3-litre solutions contained a total of 170 mmol potassium chloride. This amount given over a short period of time, such as 3 hours, is lethal. When one of the renal dialysis patients died suddenly, the physician identified a serum potassium of almost 8 mmol/L. An immediate laboratory test carried out on the dialysis solution revealed the error. The hospital then recalled the remaining bags of dialysis solution. Officials reviewed the charts of all other patients who had received continuous dialysis since the batch had been produced. It was determined that a second patient was probably exposed to this same batch and had died as a result of hyperkalemia. Five of the dialysis bags had been utilized for two patients and the other 30 bags were successfully retrieved from the patient care area.

Figure 1. Cartons containing 250mL size of Sodium Chloride and Potassium Chloride.

This package of lethal potassium chloride is almost identical to vials of harmless saline and water

EDICINE THAT KILLS

potassium chloride that killed Jeffrey happened elsepen again, unless duce the risk. In six ved from 1996 to nt Commission on althcare Organizapotassium chloride e other medication, larities in packgnd labelling. The effective way to preerrors, the commisound, is simply to remove concentrated potassium chloride from patient-care areas.

Like many other institutions, Toronto Western Hospital has done just that. Nursing units now stock only diluted solutions, which are used to treat potassium deficiency. Physicians wanting to have potassium chloride administered to a patient have to write their orders on standardized forms specifying the pre-mixed solutions. Meanwhile, the hospital's frontline medical, nursing and pharmacy staff have been re-educated about the causes of medication mistakes. The hospital made the changes not only to protect patients from risk of error, but to help staff avoid circumstances in which they could commit an error. "Good people can make mistakes," says Sylvia Hyland, the hospital's manager of pharmacy operations. "Words cannot express the devastation they can feel."

Pharmaceutical Never Event #2

Intravenous administration of concentrated potassium chloride (KCl)

- **Incidents associated with administration of Concentrated KCl:**
  - Administered direct IV (intended action was to flush an IV line with 0.9% NaCl)
  - Used to reconstitute a drug for parenteral administration (intended diluent was sterile water)
  - Used as an additive to a renal dialysis fluid for Continuous Renal Replacement Therapy (CRRT) (intended additive was 23.4% NaCl for injection)
  - Administered as a bolus (provider unaware that concentrated KCl should not be given as a bolus)

ISMP Canada (2002a)

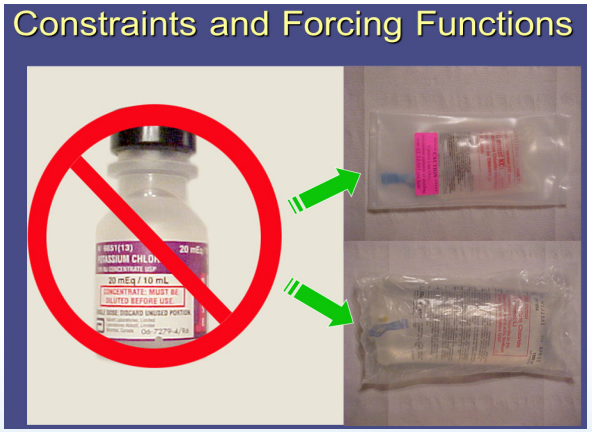
Look-Alike Packaging: Sterile Water, NaCl, and KCl:

Pharmaceutical Never Event #2

Intravenous administration of concentrated potassium chloride (KCl)

- **Prevention strategies:** Forcing functions and constraints
  - Remove all undiluted KCl products from hospital inventory and patient care areas; if needed, stock these items in pharmacy only
  - Concentrated KCl solutions should be stored in a secured area, away from other stock solutions
  - Purchase pre-mixed/commercial IV solutions containing (diluted) KCl; when not available, pharmacy can prepare admixed, diluted KCl solutions

**** CAUTION ****
Concentrated KCl
Fatal if Injected Undiluted
DILUTE before use



ISMP Canada (2002a)

Pharmaceutical Never Event #3

Inadvertent injection of epinephrine intended for topical use

- **Background:**
  - Epinephrine 1:1000 (1000 mcg/mL) – For **Topical Application**
  - Lidocaine 1% with epinephrine 1:100,000 (10 mcg/mL) – For **Infiltration**
    - Lidocaine provides a local anesthetic effect when injected into tissue
    - Dilute epinephrine causes vasoconstriction:
      - Improves surgical field hemostasis and visibility,
      - increases duration of the local anesthetic effect
  - Commonly used during Ear, Nose, and Throat (ENT) procedures

For infiltration/ injection

For topical application

ISMP Canada (2004b)

anada 2015®

Pharmaceutical Never Event #3

Inadvertent injection of epinephrine intended for topical use

- **Issue:**
  - Mix-ups have occurred during ENT procedures due to these two products being placed in the same sterile field:
  - High-dose epinephrine 1:1000 (1000 mcg/mL) intended for **topical use** has been mistakenly injected parenterally during surgical procedures
  - High doses of epinephrine (i.e. > 1 mcg/kg), typically used parenterally in critical care or resuscitation applications, can cause acute tachycardia and hypertension, to more severe complications, e.g. strokes, MI, or death

For infiltration/ injection

For topical application

ISMP Canada (2004b)

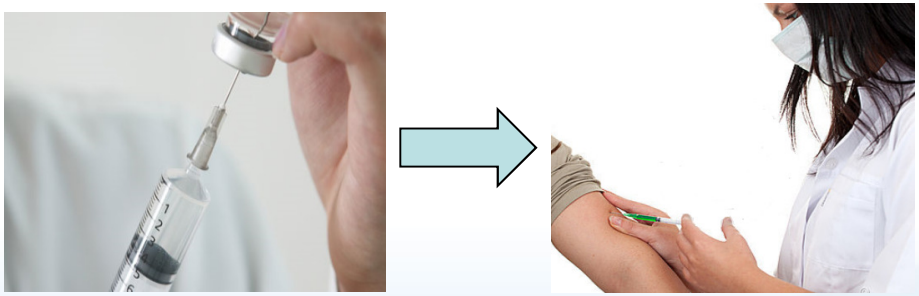
Pharmaceutical Never Event #3

Inadvertent injection of epinephrine intended for topical use

- **Systems-based Contributing factors:**
  - Multiple, similar open basins holding different solutions (topical and injectable) were present in the sterile field
  - Both the local anesthetic and topical epinephrine solutions are clear and colourless
  - The practice of withdrawing a medication intended for topical use into a parenteral syringe poses a risk of substitution error and inadvertent injection

Figure 1a. An example of an open glass container commonly used in sterile fields for holding topical or injectable solutions. The recent error report described using two glass containers, each labelled, one containing a topical solution and the other an injectable solution.

Figure 1b. An example of an open metal container commonly used in sterile fields for holding topical or injectable solutions.



ISMP Canada (2004b)

Pharmaceutical Never Event #3

Inadvertent injection of epinephrine intended for topical use

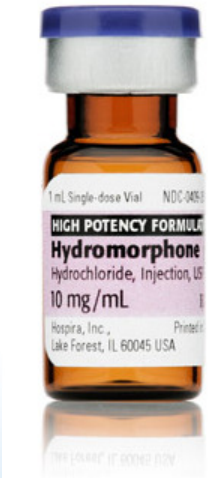
- **Prevention Strategies:** Simplification/Standardization
  - **Topical** (concentrated) epinephrine should be placed in a solution bowl, not a parenteral syringe
    - Label open containers/basins holding a topical solution with "TOPICAL"
  - Lidocaine/Epinephrine for **injection** should be kept in original vial, not in an open solution bowl
    - Only draw the medication into syringe (and label), immediately prior to use
    - Opportunity for independent double check

Pharmaceutical Never Event #4

Overdose of HYDROmorphone by administration of higher-than-intended concentration solution

- **Issues:**
  - Administering an overdose of hydromorphone by withdrawing from a high-concentration solution vial or ampoule (e.g. 10 mg/mL solution) instead of from a lower-concentration solution (e.g. 2 mg/mL solution), or not accounting for needed dilution/dose adjustment

2 mg/mL **10 mg/mL** **20 mg/mL** **50 mg/mL** **100 mg/mL**



Pharmaceutical Never Event #4

Overdose of HYDROmorphone by administration of higher-than-intended concentration solution

- **Contributing factors to harmful "Incorrect dose" incidents involving hydromorphone:**
  - Use of high-concentration and high-potency formats of hydromorphone for administration of small doses
  - Cognitive lapse leading to miscalculation of correct volume to withdraw
  - Misunderstanding of hydromorphone order
    - Lack of "leading 0" (e.g. dose written as ".4" mg interpreted as 4 mg)
    - Verbal or telephone orders

Pharmaceutical Never Event #4

Overdose of HYDROmorphone by administration of higher-than intended concentration solution

- **Prevention strategies:** Forcing functions and constraints
  - Eliminate high-concentration items (e.g. hydromorphone injectable products with concentration over 2 mg/mL) from patient care area stock
  - In circumstances where high-concentration hydromorphone cannot be eliminated (e.g. in palliative care), ensure that it is segregated
    - Implement double-check process or extra step to restrict access
  - Preparation by pharmacy of injectable hydromorphone doses less than 1 mg in prefilled syringes (easier administration of lower doses)

Pharmaceutical Never Event #5

Injection of neuromuscular blocking agents without sedation, airway control, and ventilation capability

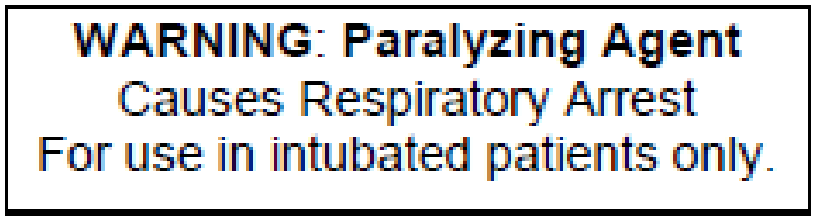
- **Neuromuscular blocking agents (NMBAs):**
  - High-alert medications: Temporarily paralyze essential muscles for breathing in patients who receive them – patients must be immediately ventilated prior to being administered an NMBA
  - Used for indications requiring respiratory and skeletal muscle paralysis in certain circumstances (e.g. to manage increased intracranial pressure)
- **Issue:**
  - NMBAs have been inadvertently administered to non-intubated, non-ventilated patients due to product mix-ups and substitution errors
  - May lead to paralysis of respiratory muscles, respiratory arrest, and acute quadriplegic myopathy syndrome, prolonged recovery

ISMP Canada (2014); ISMP Canada (2002b)

Pharmaceutical Never Event #5

Injection of neuromuscular blocking agents without sedation, airway control, and ventilation capability

- **Prevention strategies:** Forcing functions and constraints
  - NMBAs should not be stored in patient care areas unless absolutely necessary
    - If necessary (e.g. Emergency Dept or critical care areas), place the vials in plastic bags and apply auxiliary warning labels on both sides of the bag
  - Limit the availability of NMBAs on the hospital formulary to a select few to enhance familiarity and expertise with selected products



ISMP Canada (2002b)

Pharmaceutical Never Event #5

Injection of neuromuscular blocking agents without sedation, airway control, and ventilation capability

- **Prevention strategies:** Standardization of labelling and packaging for NMBA vials
  - Warning on a red cap or red ferrule with white lettering: "Paralyzing Agent" or "Warning: Paralyzing Agent"

ISMP Canada (2002b)

Next Steps: Where do we go from here?

- **Encourage reporting of all incident types**
  - Mechanism to drive quality improvement
  - Learn valuable lessons regarding system vulnerabilities, share root causes and information regarding best practices for prevention, and increase awareness of Never Events

Success Story: Minnesota, USA

- Never Events policy first introduced in 2003; later evaluated in 2008…

Incident reporting increased after the introduction of the Never Events policy

Strong majority of respondents believed patient safety was a higher priority in 2008 vs 2003

72% of respondents believed the system was safer overall since the introduction of the Never Events policy

MINNESOTA MDH DEPARTMENT OF HEALTH

Minnesota Department of Health (2009)

Next Steps: Where do we go from here?

- Consider adopting or developing an institution/ organization-specific 'Never Events' policy and framework to implement
- Consider proactively reviewing processes for management of these high-alert medications and potential system vulnerabilities, to mitigate 'Never Events'
  - E.g. Undertaking a Failure Modes and Effects Analysis

Summary

- 'Never events' are serious, largely preventable patient safety incidents that should not occur if relevant preventable measures have been put in place
- Any investigation after a never event should focus on system failures and vulnerabilities rather than assigning blame to individuals

Woodward, H. ,2011

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