Never Events in Healthcare

Raising awareness to protect patients from serious harm or death

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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

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 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 was the cause or a contributory factor to death (Table 1).

Medications Involved

The medication classes most commonly involved in incidents associated with death were opioids, psychotropic 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

<table>
<thead>
<tr>
<th>Medication Class</th>
<th>No. (%) of Incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>54 (47%)</td>
</tr>
<tr>
<td>Psychotropic agents</td>
<td>28 (24%)</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>24 (21%)</td>
</tr>
<tr>
<td>Cardiovascular agents</td>
<td>11 (10%)</td>
</tr>
<tr>
<td>Insulin</td>
<td>8 (7%)</td>
</tr>
</tbody>
</table>

*Some incidents involved more than one medication class.

Ontario CRITICAL Incident Learning

Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but their 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-based approach, as described in the Canadian Incident Analysis Framework.
- Recognize that certain types of risk-mitigation strategies are more effective than others. Mitigation strategies can be ordered by hierarchy of effectiveness:
  - High leverage
    - Most effective
    - Improve processes and systems
    - Education and awareness
  - Medium leverage
    - Enhancing effectiveness of hospital’s quality improvement initiatives
  - Low leverage
    - Enhancing effectiveness for high-risk populations

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”
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)
**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
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

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.
Overview of Pharmaceutical Never Events
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)
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

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”

FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY OTHER ROUTES.
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)

Wrong injection causes death second in 3 y

Pharmaceutical Never Event #2

Intravenous administration of concentrated potassium chloride (KCl)

Concentrated Potassium Chloride: A Recurring Danger

ISMP Canada Safety Bulletin

Volume 4, Issue 3
March, 2004

INJECTION DEATH SECOND IN 3 YRS

A drug used to execute death-row prisoners was inadvertently injected into an elderly woman whose death is in a Philadelphia, Pa., hospital will be examined in a coroner’s inquest.

The cause of Mr. Turner’s death is already known: somebody injected a dose of potassium chloride into her vein. Small quantities of this drug can cause potassium deficiency, but large amounts are potent poisons. Over 20 Canadians have died after receiving the wrong drug, sometimes from injuries caused by the wrong drug.

Some doctors believe these accidents occur because manufacturers sell potassium chloride in quantities instead of in smaller amounts. A recent study on potassium chloride injections suggests that the drug is being injected without realizing the danger.

A new study has found that potassium chloride injections are only given to patients who are sedated. It is also possible that the drug is being injected into veins without realizing the danger.

The study also found that the drug is being given to patients who are not sedated.

Each of the 1-mL vials contains a total of 170 mEq potassium chloride. This amount given over a short period of time, such as 3 hours, is lethal. When one of the 1-mL vials was injected into the bloodstream, the patient died.

In another study, potassium chloride was given to patients who were not sedated. The drug was injected into the bloodstream, but no harm was observed.

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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)
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
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)
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.
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

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Image</th>
</tr>
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<tbody>
<tr>
<td>2 mg/mL</td>
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</tr>
<tr>
<td>10 mg/mL</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>20 mg/mL</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>50 mg/mL</td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>100 mg/mL</td>
<td><img src="image5.png" alt="Image" /></td>
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</tbody>
</table>
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
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”
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
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
Thank you

Acknowledgements:

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- Roger Cheng, Project Leader, Institute for Safe Medication Practices Canada
References


References


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