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SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 19 • Issue 1 • January 16, 2019

Preventable Tragedies: Two Pediatric Deaths Due to Intravenous Administration of Concentrated Electrolytes

Take action to check the following:

- *Compliance with current standards for the storage and availability of concentrated injectable electrolytes is mandated.*
- *Robust safeguards are included in procedures for prescribing, dispensing, preparing, and administering IV electrolyte solutions.*
- *The need for calculations and additional manipulations in the patient care area is minimized. Standardized doses of IV electrolytes that align with premixed concentrations of commercially available solutions are prescribed.*
- *Staff and prescribers are educated about strategies to prevent "never events", such as IV administration of a concentrated potassium solution during orientation and continuing education activities.*

Intravenous (IV) administration of a concentrated potassium solution (≥ 2 mmol/mL) is considered to be a pharmaceutical "never event".[1] "Never events" are defined as "patient safety incidents that result in serious patient harm or death, and that can be prevented by using organizational checks and balances."[1] The World Health Organization has focused on high-risk situations, such as these pharmaceutical "never events" and the use of high-alert[2] concentrated electrolytes, as 1 of 3 key areas in its Third Global Patient Safety Challenge, "Medication Without Harm".[3]

ISMP Canada has published information about the dangers of IV administration of concentrated electrolyte solutions, including potassium chloride and potassium phosphates, in safety bulletins dating as far back as 2001.[4-9] Other health quality and patient safety organizations,[10,11] as well as healthcare accreditation bodies,[12,13] have made practice recommendations intended to reduce instances of patient harm caused by inadvertent IV administration of concentrated electrolytes.

Evaluation surveys have shown a decrease in the number of deaths due to inadvertent IV administration of concentrated electrolytes following medication safety improvement efforts.[14]

Despite the recommendations and the trend of decreased deaths, there have been 2 recent fatal incidents involving children and the IV administration of concentrated potassium phosphates or potassium chloride. These cases illustrate the need for sustained, nationwide vigilance to recognize the threat to patient safety when concentrated injectable electrolyte solutions are not appropriately stored, monitored, and administered.

RECENT INCIDENTS

Incident No. 1: Concentrated potassium phosphates solution for injection, available in a patient care area, was mistakenly used to flush a child's IV line; a flush solution of normal saline (0.9% sodium chloride) was intended. The child immediately became pulseless and later died, despite intensive resuscitation efforts. The error was recognized when blood tests revealed severe hyperkalemia and hyperphosphatemia.[15]

Incident No. 2: An infant required IV replacement of potassium during a hospital stay. The medical resident contacted the staff pediatrician by phone for direction. The resident subsequently gave a verbal order to the nurse to administer IV potassium chloride (KCl) to the infant. The prescribed dose was not available in a premixed format, so the nurse used a vial of concentrated KCl solution for injection (stocked on the ward) to prepare the IV infusion for administration. However, the verbal order was misinterpreted, and 10 times the amount of KCl required was added to the IV bag. The IV solution was administered overnight, and the infant went into cardiac arrest and subsequently died.[16]

DISCUSSION

Analysis of these incidents identified several potential contributing factors.

- **Availability of concentrated injectable potassium solution in patient care areas**

  In both incidents, concentrated potassium solutions for injection were available in the patient care area. These 2 fatal incidents occurred despite a long-established high-level Required Organizational Practice in Accreditation Canada standards,[12] developed in consultation with ISMP Canada, warning that concentrated electrolyte solutions should not be stocked in patient care areas.

  Commercially available electrolyte solutions may not be appropriate for neonates, infants, and young children. To meet this clinical need and other exceptional circumstances, storage of a concentrated electrolyte solution in a patient care area may be deemed essential. If so, multiple safety measures **must** be in place to ensure the greatest possible level of patient safety.

- **Nonstandardized processes for the prescription and preparation of IV electrolyte solutions**

  In incident No. 2, the prescriber determined that a nonstandard concentration of KCl solution for IV infusion (not the premixed, commercially available strength) was indicated to treat the infant. Because of the urgency of the clinical situation, the nurse had to perform the calculations and also prepare the nonstandard mixture in the care unit immediately, instead of waiting to have it prepared in the pharmacy the next morning.

  The physician gave a verbal prescription for a specific amount of KCl to be added to 1000 mL of IV solution. The nurse, who was accustomed to receiving orders for doses per 100 mL, mistakenly calculated an amount of KCl to be added to the 1 L bag that was 10 times the dose verbally prescribed. Although a written order was provided to the nurse after the solution was prepared, confirmation bias might have contributed to the mistake being undetected.

- **Lack of independent double checks**

  In both incidents, an independent double check might have detected the error and prevented it from reaching the patient.

  In incident No. 2, an IV solution containing a non-commercially available electrolyte concentration was prescribed. Independent checks of the calculations and preparation steps might have prevented the error from reaching the patient in this case. However, with regard to incident No. 1, it is acknowledged that independent double checks of the solution are not an expectation for routine flushing of an IV line.

- **Similar physical appearance of the electrolyte solutions and vials due to a product shortage**

  The flushing of IV lines to maintain patency is a standard practice, but accidental flushing with unintended medications do occur because of

similarities in product appearance.[12,13] **Clear, colourless injection solutions all look alike.** Notably, in incident No. 1, the shapes and labels of the vials of normal saline and concentrated potassium phosphates were similar. These similarities likely contributed to confirmation bias, resulting in the subsequent selection error. Investigation of this incident also revealed that the concentrated potassium phosphates had been obtained from a different supplier than usual, because of a product shortage at the regular supplier. Procurement from a different supplier resulted in a change in the appearance of the electrolyte vial, which might have caused some confusion and further contributed to the selection error.

RECOMMENDATIONS

Analysis of these incidents led to reminders for system-based improvements.

Healthcare Facilities

- Mandate compliance with current standards for the storage and availability of concentrated injectable electrolytes:
  - Do **not** stock concentrated electrolytes in patient care areas.[12]
  - Store concentrated electrolyte solutions for injection only in the pharmacy, in designated locations, and separate them from other IV solutions. Ensure that product labels are clearly visible.
  - In exceptional circumstances, when there is a request to stock concentrated electrolytes in select patient care areas, an interdisciplinary medication management committee should review and approve the rationale for the request and should also ensure that safeguards are in place to minimize the risk of error.[12] Examples of safeguards may include the use of automated dispensing cabinets with security features, the availability of mixing instructions, independent double checks of calculations, and auxiliary warning labels to identify and distinguish concentrated electrolyte products.
  - Conduct an audit of concentrated injectable electrolytes available in patient care areas at least annually.[12] These audits should help ensure that concentrated injectable electrolytes are not stored in patient care areas or, if such storage is essential, are stored with the appropriate safeguards.

- Ensure that robust safeguards are included in procedures for prescribing, dispensing, preparing, and administering IV electrolyte solutions. Such safeguards may include the following:
  - Prepare all nonstandard dilutions or mixtures containing concentrated electrolytes in the pharmacy only, not in any other area of the facility.
  - Develop preprinted order sets to help standardize the prescribing of electrolyte solutions.
  - Be consistent and use well-understood units of measure (e.g., mg, mmol, mL, L) in preprinted order sets, formulation sheets, and policies and procedures for preparing and administering IV electrolyte solutions.
  - Implement independent double checks during preparation and before administration of IV electrolyte solutions. Integrate the independent double checks into workflow and documentation processes, both paper- and electronic-based.
  - Implement bar coding at the point of administration to reduce the risk of harm from a selection error at the time of dispensing and/or preparation.

- Procure ready-to-use, commercially available products, such as normal saline in prefilled flush syringes (to avoid selection errors), and premixed IV electrolyte solutions (to avoid the risk of calculation or mixing errors).[17,18]
  - Neonates and infants may require IV electrolyte-containing solutions that are not commercially available. Processes should be in place for preparation of these solutions by pharmacy or for use of a mixing sheet including necessary calculations, with a signed, independent double check, to be retained in the medical record.

- During orientation and continuing education activities, educate staff and prescribers about previous deaths involving concentrated electrolytes and the organization's ongoing strategies to prevent similar "never events". Include information about

the safety measures to be used when working with concentrated electrolytes (e.g., electrolyte replacement protocols, independent double checks).

- Develop a contingency plan to be activated in the event of a drug shortage and/or change in supplier. The contingency plan should include a communication process to notify all staff before the "new" product is made available, as well as a prospective consideration of potential errors that could result from the product change. This communication should be printed and kept *with* the stock, in addition to other electronic and printed material.

Healthcare Practitioners

- To minimize the need for calculations and additional manipulations in the patient care area, prescribe standardized doses of IV electrolytes that align with premixed concentrations of commercially available solutions.[5]
- If the patient requires a "custom" or nonstandard IV electrolyte replacement solution, consult a pharmacist for assistance.
- To minimize the risk of misinterpretation, communicate orders in writing. If verbal orders must be given (emergency situations), use a "repeat back" technique to ensure clarity and understanding.

CONCLUSION

In both of the fatal medication incidents described here, the availability of a concentrated potassium solution in the patient care area contributed to the errors and subsequent patient deaths.[15,16] The "never event" of IV administration of concentrated potassium is preventable with appropriate system safeguards. To lessen the risk of patient harm, facilities and practitioners must sustain awareness of and knowledge about the importance of adhering to standards and guidelines for the safe storage, preparation, and administration of high-alert medications, such as concentrated electrolytes.

ACKNOWLEDGEMENTS

ISMP Canada gratefully acknowledges expert review of this bulletin by the following individuals (in alphabetical order): Paul Filiatrault BScPharm RPEBC, Medication Safety Consultant; Anne Matlow MD FRCPC, Faculty of Medicine, University of Toronto; Janice Munroe BScPharm FCSHP, Clinical and Distribution Pharmacy Coordinator, Ridge Meadows Hospital, Maple Ridge, BC; team from Saskatchewan Health Authority, Saskatoon, SK (Angela Butuk BSN RN RNFA, Medication Safety Officer; Terrence Davidson BSP, Medication Safety Resource Pharmacist; Pamela Heinrichs BComm MSc, Patient Safety Specialist, Human Factors and System Safety; Blair Seifert BSP PharmD FCSHP, Clinical Pharmacy Coordinator, Pediatrics).

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New Regulations will Help Protect Canadians from Unsafe Medications and Medical Devices

The Protecting Canadians from Unsafe Drugs Act, also known as Vanessa's Law, strengthens regulations to report Serious Adverse Drug Reactions (ADRs) and Medical Device Incidents (MDIs). The Law improves Health Canada's ability to:

- collect post-market safety information on drugs and medical devices;
- take appropriate action when a serious risk to health is identified; and
- promote greater confidence in the oversight of therapeutic products by increasing transparency.

The Institute for Safe Medication Practices Canada **(ISMP Canada)** in a Joint Venture with Health Standards Organization **(HSO)** and the Canadian Patient Safety Institute **(CPSI)**, were awarded a contract to assist Health Canada with outreach, education and feedback regarding the Law.

The Joint Venture Partners are working with Health Canada to develop and implement an educational approach and content that will help healthcare providers and healthcare leaders identify and report serious ADRs and MDIs. Education will be designed to easily integrate into existing educational activities, courses and programs provided by stakeholders, including the general public, and are anticipated to be available by July 2019.

For more information: http://www.patientsafetyinstitute.ca/en/NewsAlerts/News/newsReleases/Documents/New%20Regulations%20will%20Help%20Protect%20Canadians%20from%20Unsafe%20Medications%20and%20Medical%20Devices.pdf

This segment of the bulletin describes a recent SafeMedicationUse.ca publication from ISMP Canada's Consumer Program.

SafeMedicationUse.ca

November 2018 - Newsletter:

Medication Reviews in Long-Term Care Homes

SafeMedicationUse.ca received a report about a resident in a long-term care home who was mistakenly started on trazodone (commonly prescribed for sleep), which was intended for someone else with a similar name. The mistake was found a year later when a medication review took place. Afterwards, family members commented that their loved one had seemed more tired than usual over the past year, but they did not know to mention it.

Tips for Practitioners to optimize patient safety in LTC:

- Encourage the resident's family members to report any changes they see in their loved one that are new or unexpected, at any time.
- Contact the resident's family members or others designated to act on the resident's behalf (in accordance with privacy legislation) to inform and encourage them to attend, participate in, and request medication review sessions with the pharmacist.
- When initiating new drug treatment for a resident, use at least 2 pieces of documentation to ensure that the correct resident is receiving the medication.
- When initiating new drug treatment for a resident, ensure that the resident's family members are notified, and that they understand the reason for the medication. It is also important to describe potential side effects that they can watch for.
- Upon return of any resident from the hospital to the long-term care home, a medication review, involving the pharmacist and the healthcare team, should be completed as soon as possible. A medication review after hospital discharge is particularly important because drug therapy may have been changed during the hospital stay, and patients at transitions in care are vulnerable to medication errors.
- If the resident's family or designated individuals are unavailable to attend a review in person, ensure that a standardized process is in place to contact them after the medication review to go over the session. Encourage them to ask questions and voice concerns.

For more information, read the full newsletter: https://safemedicationuse.ca/newsletter/medreview-ltc.html

Med Safety Exchange – Webinar Series

Wednesday, January 23, 2019

Join your colleagues across Canada for complimentary bi-monthly 50 minute webinars to share, learn and discuss incident reports, trends and emerging issues in medication safety!

For more information, visit
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CMIRPS SCDPIM
Canadian Medication Incident Reporting and Prevention System
Système canadien de déclaration et de prévention des incidents médicamenteux

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

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

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

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