Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 21 • Issue 11 • December 14, 2021

Sharing Matters!
Sentinel Medication Incident Results in Safer Product Labelling

ISMP Canada received a sentinel event report describing inadvertent bolus administration of a HYDROmorphone product that was intended for continuous infusion. A contributing factor was the misinterpretation of critical information on the label (see Figure 1). The practitioner misunderstood the information provided and believed the bag contained 1 mg of HYDROmorphone. As a result, the entire content of the bag (which contained 50 mg of HYDROmorphone) was administered as a bolus. The error was discovered after the patient was found to have an altered level of consciousness; naloxone was given.

The manufacturer, Baxter Corporation, embarked on a collaborative label enhancement initiative that included consultation with nurses, pharmacy representatives, and ISMP Canada. The following changes (see Figure 2), in line with the Good Label and Package Practices Guide for Prescription Drugs *and within the constraints of labelling software,* were introduced earlier this year:

- The primary label statement (in the red box) now states the following critical information: the drug name, total dose, total volume, and final concentration.
- A new secondary label statement has been added, which reads "SLOW INFUSION ONLY. FATAL if not infused slowly".

Figure 1. Previous Label Format

Figure 2. New Label Format

ISMP Canada is grateful to the reporting organization for sharing this incident and thanks Baxter Corporation for prioritizing patient safety.

Quality Check:
Are There Expired Vaccines in Your Fridge?

Several recent incidents, reported to ISMP Canada and shared in the media, have involved administration of expired vaccines to patients.[1,2] Vaccine effectiveness cannot be guaranteed after the expiry date; therefore, following this type of incident, a replacement dose of the vaccine is often considered, subject to guidance from public health authorities.[3] Analysis findings from incidents reported to ISMP Canada are summarized here to help improve the safe and effective use of vaccines.

Incident Example

A pharmacist realized that expired influenza vaccines from the previous year's supply were being administered at a staff vaccination clinic. The date appearing on the vaccine vials (Figure 1) was the expiry date, but staff members misinterpreted it as the date of manufacture. Documentation completed with each vaccination did not require the vaccine expiry date, and therefore an opportunity to catch the mistake was missed. Follow-up with other clinics revealed that 6 other sites had expired vaccines in their fridges, and expired vaccines had been administered at 3 of these sites.

Figure 1. Influenza vaccine expiry date on vial

Factors that may have contributed to this error include the following:

- ambiguous and inconsistent labelling of the expiry date (e.g., no introductory descriptor such as "EXP" before the date),[4] such that it was not recognized as the expiry date (of note, a vaccine product for pediatric patients prints the date of manufacture,[5] not the expiry date, on the label);
- lack of a systematic approach to vaccine inventory management, leading to storage of unopened, expired vaccines with the vaccine supply;
- inconsistent requirements to check and document the expiry date during preparation and administration of the vaccine; and
- lack of an independent double check in the process from preparation to administration.

RECOMMENDATIONS

The following recommendations are intended for vaccine manufacturers, those managing vaccine administration clinics, and vaccinators.

Vaccine Manufacturers

- Include a descriptor before the expiry date (e.g., "EXP") to improve the clarity of the information presented.[4] This is especially important to distinguish between the expiry date and the date of manufacture.

Pharmacy/Clinic Staff and Management

- Regularly review expiry dates of the vaccine supply, and promptly remove expired vaccines.[6] Schedule a review of inventory before yearly influenza vaccination programs to reduce the risk of administering the previous year's product. Return or discard expired vaccines according to public health guidance.
- Capture the vaccine expiry date in required documentation ***before*** administration of the dose.[7]
- Incorporate independent double checks at key points in the vaccination process.[8] The first check could occur when the vial is punctured. Depending on the process, a second check could occur at the time the syringe is labelled for later administration or just before administration of the vaccine. Some practitioners have the vial and syringe together on a tray at the point of administration, which can allow for a final review with the patient and the opportunity for an extra check.
- Store different vaccines separately and according to their respective cold chain requirements.[6-8] Regularly confirm the storage conditions required to adhere to the labelled expiry date.

Health care practitioners involved in vaccination can help to ensure the safe and effective use of vaccines through appropriate storage and inventory management, including regular monitoring of expiry dates. More information about additional quality checks for vaccines are shared in these safety bulletins:

- Injecting Standardization into Vaccine Clinics
  https://www.ismp-canada.org/download/safetyBulletins/2018/ISMPCSB2018-i7-VaccineClinics.pdf
- Preventing Errors with COVID-19 Vaccines: Learning from Vaccine Incidents
  https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i2-COVID19-Vaccine-Error-Prevention.pdf
- Updated Analysis and Shared Learning from COVID-19 Vaccine Errors
  https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i8-Vaccine-Errors.pdf

REFERENCES

1. Dubinski K. Dozens of members of Saugeen First Nation in Ontario were given expired COVID-19 vaccines for a month. CBC News. 2021 Sep 24 [cited 2021 Nov 12]. Available from: https://www.cbc.ca/news/canada/london/saugeen-first-nation-expired-pfizer-vaccine-doses-1.6188281
2. Lee BY. 899 New Yorkers got expired Pfizer Covid-19 vaccines, must get re-vaccinated. Forbes. 2021 Jun 18 [cited 2021 Nov 12]. Available from: https://www.forbes.com/sites/brucelee/2021/06/18/899-new-yorkers-got-expired-pfizer-covid-19-vaccines-must-get-third-dose/?sh=173735cb4f35
3. Storage and handling of immunizing agents: Canadian Immunization Guide. Ottawa (ON): Government of Canada; 2017 Mar [cited 2021 Nov 17]. Available from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-9-storage-handling-immunizing-agents.html#p1c8a4
4. Expiry date. In: Good label and package practices guide. Ottawa and Toronto (ON): Health Canada and ISMP Canada; 2019 Jun 21 [cited 2021 Nov 12]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs-profile/guidance-document.html#a344
5. National Advisory Committee on Immunization (NACI) statement: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age. Ottawa (ON): Government of Canada; 2021 Nov 19 [cited 2021 Nov 29]. Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age.html
6. Preventing errors with COVID-19 vaccines: learning from vaccine incidents. ISMP Can Saf Bull. 2021 Feb 25 [cited 2021 Nov 15];21(2):1-5. Available from: https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i2-COVID19-Vaccine-Error-Prevention.pdf
7. Injecting standardization into vaccine clinics. ISMP Can Saf Bull. 2018 Sep 24 [cited 2021 Nov 15];18(7):1-4. Available from: https://www.ismp-canada.org/download/safetyBulletins/2018/ISMPCSB2018-i7-VaccineClinics.pdf
8. Updated analysis and shared learning from COVID-19 vaccine errors. ISMP Can Saf Bull. 2021 Aug 26 [cited 2021 Nov 15];21(8):1-4. Available from: https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i8-Vaccine-Errors.pdf

Opportunity for Improvement:
Confusing Labels for Zinc Products

Oral zinc supplements are nonprescription products that are available in several salt forms (e.g., zinc citrate, zinc gluconate). The differences in expression of product strength between the salt entity (e.g., zinc citrate) and the elemental form of the mineral (e.g., zinc) may not be recognized or fully understood. Similar to the situation for iron and calcium products,[1] clear labelling of the elemental and salt doses is critical to prevent dosing errors.

Figure 1. Examples of zinc products and the different ways the elemental zinc strength is expressed on the front and side labels (images obtained from the internet).

ISMP Canada learned of an inadvertent zinc overdose that occurred in a hospital inpatient because of misinterpretation of the strength (elemental vs. salt) expressed on the label. Figure 1 shows examples of 3 zinc products with varying formats to express elemental strength on both the front and side labels. It is not always clear to the user that the strengths expressed represent elemental zinc, rather than the zinc salt. Adding to the confusion, the first 2 examples incorrectly state the elemental strength alongside the salt name (zinc citrate) on the front panel.

RECOMMENDATIONS

ISMP Canada makes the following recommendations to improve the clarity and consistency of strength expression:

- ***Manufacturers:*** Ideally, state both the elemental dose and the dose in salt form.[2] For example, "Zinc 50 mg (as zinc gluconate 350 mg)" is clearer than either "Zinc (gluconate) 50 mg" or "Zinc (zinc citrate) 30 mg".

Also ensure that the product name is associated with the appropriate strength (i.e., if the product name is the salt name, the displayed strength should correspond to the salt strength).

- ***Prescribers:*** Clearly indicate the required dose in elemental form and the name of the preferred salt formulation (if applicable) on prescriptions. Advise patients to seek the advice of a pharmacist when selecting products.

- ***Medication order entry software systems*** *(e.g., computerized prescriber order entry, pharmacy information):* Display both the elemental dose and the dose in salt form in a clear and user-friendly manner. When images are available, it is useful to display an image of the side panel, in addition to the principal display panel that is generally available.

Based on learning from incidents that have been reported, ISMP Canada recently provided feedback to Health Canada on its *Draft Guidance Document: Labelling of Natural Health Products*. Communication of product strengths in a clear and consistent manner, by all stakeholders in the medication-use system (e.g., manufacturers, practitioners, software vendors, regulators, consumers), is critical to preventing medication errors.

REFERENCES

1. Confusing calcium product labels lead to hospitalizations. ISMP Can Saf Bull. 2021 [cited 2021 Nov 15];21)1):1-5. Available from: https://www.ismp-canada.org/download/safetyBulletins/2021/ISMPCSB2021-i1-Calcium.pdf
2. Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products. Toronto (ON): Institute for Safe Medication Practices Canada. 2018 Aug [cited 2021 Nov 29]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-non-prescription-drugs-natural-health-products.html

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 Healthcare Excellence Canada (HEC). 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)

Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

Stay Informed

To receive ISMP Canada Safety Bulletins and Newsletters visit:

www.ismp-canada.org/stayinformed/

This bulletin shares information about safe medication practices, is noncommercial, and is therefore exempt from Canadian anti-spam legislation.

Contact Us

Email: cmirps@ismpcanada.ca
Phone: 1-866-544-7672