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CMIRPS Canadian Medication Incident Reporting and Prevention System
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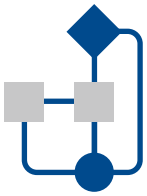
ISMP Canada Safety Bulletin

Volume 21 • Issue 8 • August 26, 2021

Updated Analysis and Shared Learning from COVID-19 Vaccine Errors

Health care providers have been working with the government, public health agencies, and health care and community organizations to provide COVID-19 vaccines to as many Canadians as possible. Earlier this year, an ISMP Canada Safety Bulletin was published to proactively inform stakeholders about risks associated with vaccination processes and safeguards to prevent errors.[1] An updated analysis was informed by the COVID-19 vaccination campaign in Canada, with shared learning from the experiences of health care providers and consumers, including incidents, near misses, and preventive strategies. The key learnings are presented here.

CLINIC/PHARMACY SET-UP AND ORGANIZATION



Vaccine clinics, community pharmacies, and other vaccination settings have been continuously adjusting and improving their workflow processes to reflect experiential learnings and changes in the vaccine environment (e.g., age-groups eligible for vaccination). It has been essential to continually review dose preparation areas and clinic layout, as well as patient flow, to meet evolving needs and to minimize the risk of error.[2,3]

Incident Example

A clinic providing the Pfizer-BioNTech vaccine was set up so that the patients were seated in rows of 10. The team of 2 vaccinators moved (with a cart) along the row, with one person conducting the screening and the second person providing the injection. Staff feedback indicated that the process was cumbersome and error-prone. Through redesign of system flow, the clinic configured the chairs into rows of 12 to match the number of prefilled syringes prepared from 2 vials of vaccine. This utilized all the doses from the 2 vials and allowed for easier checking and auditing.

Shared Learning

- Use continuous improvement processes (e.g., retrospective analysis of reported medication incidents and proactive risk assessments) to optimize workflow design to reduce or eliminate the risk of errors and mitigate potential harm.
- Incorporate frequent audits of the workflow to identify problematic processes and errors.
- For sites that are administering more than one COVID-19 vaccine product, set up separate preparation and administration areas for each vaccine to avoid product or dose mix-ups. Signage to identify the product being prepared/administered in each area should be clearly visible.
- Develop plans to support the patient and family members, and all members of the health care team in the event of a vaccine error.

STORAGE AND TRANSPORT

Each COVID-19 vaccine product has specific, unique storage requirements.[4] Vials and syringes containing vaccine must be labelled before storage or transport,

even within the site's refrigerator, and the integrity of packaging and contents must be maintained.

Incident Example

Syringes were prefilled with vaccine in a clinic, but then were not needed at that site. The prefilled syringes were transported in a small cooler to another vaccination clinic. Upon delivery, staff noted that the plungers had shifted in each syringe, and variable amounts of vaccine had been expelled into the needle caps. All of the doses were wasted.

Shared Learning

- Ensure that containers used to store and transport vaccines are prepared and monitored to maintain the required temperature range.
- Calibrate and monitor thermometers and other cold chain indicators.
- Secure vaccine vials and syringes inside transport containers to limit product movement.
- When vaccine products are received from any source, carefully inspect all vials and syringes, as well as temperature-monitoring devices.
- For sites that are pooling vaccines, segregate storage of partially used vials from other (e.g., full or undiluted) vials.

PATIENT SCREENING

Incidents related to patient screening have been reported. For example, ineligible patients (e.g., ineligible age or incorrect interval between doses) have booked vaccination appointments and/or received COVID-19 vaccines in error. Since the vaccines first became available, eligibility has changed frequently, making it difficult for vaccinators and patients to stay up to date.

Incident Example

An appointment was booked through the provincial booking portal for a 16-year-old to receive their first dose of the COVID-19 vaccine. However, during the screening process at the pharmacy, the teen was not asked their age. The Moderna vaccine (indicated for patients 18 years of age and older) was given instead of the Pfizer-BioNTech vaccine (indicated for patients 12 years of age and older), causing the teen to become anxious about adverse effects.

Shared Learning

- Update booking portals to prevent patients not meeting eligibility criteria from booking appointments. Portals should request screening information (e.g., patient age, product name and date of administration for first dose of COVID-19 vaccine, if applicable), as well as proof of vaccination.
- Ensure that the in-person screening process verifies patient eligibility in the central provincial or territorial COVID-19 vaccine database **before** administration of the vaccine dose, and that it flags any discrepancies.
- Repeat screening questions with the patient and/or family member at multiple checkpoints (e.g., at sign-up, registration, pre-administration) to confirm each patient's eligibility.

PREPARATION

Vaccine preparation may include thawing and dilution before the dose is drawn up into a syringe.[5] Errors reported during the preparation process have included incorrect dilution (e.g., over- or under-dilution), incorrect syringe filling (e.g., air or saline only in syringe), addition of saline to previously diluted vaccine vials, use of an expired product, and misconnections between the needle and syringe, resulting in wastage or needle detachment during administration.

Incident Example

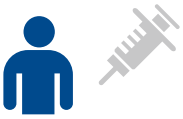
Diluent was administered to a patient, instead of the diluted vaccine. The error was discovered a few hours later when a staff member found a dose left in the diluted vial. The affected patient was later identified.

Shared Learning

- Arrange the work environment to facilitate safe dose preparation and verification (e.g., with

minimal distractions, proper lighting, and a clean, uncluttered work area).
- Segregate work areas by designating different areas for different tasks (e.g., product dilution, dose preparation, and vaccine administration).
- Post specific preparation instructions in each work area.
- Schedule rest periods and task rotation to reduce staff fatigue and optimize alertness.
- Incorporate independent double checks at key points in the preparation process.[3] For example, consider separating syringe prefilling and vaccine administration to allow for 2 individual checks. Include a check to ensure the needle-syringe connection is secure.
- Label diluted vials with the date and time of first puncture. In addition, label these vials and prepared syringes with the beyond-use date and time.

ADMINISTRATION



Safe administration of a COVID-19 vaccine includes a physical check (of the vial and/or syringe) to identify errors missed at the preparation step. Appropriate administration technique, including landmarking of the injection site, is crucial, given that shoulder injuries related to vaccine administration have been reported.

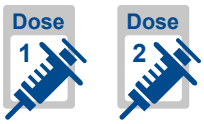
Incident Example

Air, rather than vaccine, was injected because the vaccine was not properly drawn up into the syringe during the preparation step. The lack of vaccine in the syringe was not recognized until the injection was given. A replacement dose was administered to the patient.

Shared Learning

- Before starting each injection, conduct a visual check of the dose, the syringe-needle attachment, and all labelling. Include a check for large air bubbles and particulates.
- Show the prefilled syringe to the patient and verbally confirm the vaccine product and volume being administered. This is a final product check prior to administration.
- Before administering the vaccine, landmark the injection site on each patient.[6]

DOCUMENTATION



Accurate documentation of the first dose supports prevention of errors with the second dose, by helping to ensure administration of the appropriate product after the correct time interval.

Incident Example

A patient presented for their second dose of vaccine but was turned away because the provincial COVID-19 vaccine database indicated that 2 doses had already been administered. Upon review, it was discovered that a "second dose" had been documented in error as having been given on the same day as the first dose.

Shared Learning

- Provide each patient with complete documentation (including personal and vaccine administration information) before they leave the clinic or pharmacy. Ideally, provide such documentation both on paper (during the visit) and in an electronic format (e.g., by email).
- Review and confirm with the patient that the information on the vaccination receipt is accurate.

CONCLUSION

The COVID-19 pandemic has revealed opportunities for safety improvement in health care processes. The learning from reports of vaccine incidents and near misses contributes to the evolution of evidence-based practices and the prevention of similar errors in the future.

ACKNOWLEDGEMENTS

ISMP Canada gratefully acknowledges the Canadian consumers, health care providers, and organizations that provided their vaccine insights and incidents for analysis and learning. We also acknowledge the

expert review of this bulletin by the following individuals (in alphabetical order): Brett Barrett RPh BScH BScPhm, Clinical Lecturer, University of Waterloo School of Pharmacy, Waterloo, ON; Susan Blanchard RPhT, Ottawa, ON; Angela Butuk BSN RN RNFA, Medication Safety Officer, Saskatchewan Health Authority, Saskatoon, SK; Kelly Grindrod BScPharm PharmD; Mary Elizabeth Rowe BN RN, Manager COVID-19 Response Areas, IWK Health Center, Halifax, NS.

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November 2020 - Newsletter:

Calcium and Medications Often Don't Mix

SafeMedicationUse.ca

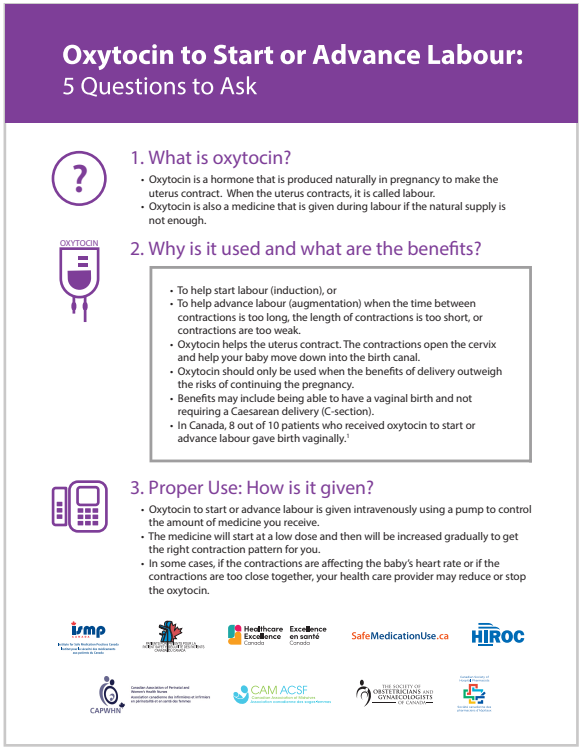
SafeMedicationUse.ca received a report from a consumer describing ineffective treatment of an infection due to a preventable drug interaction involving a calcium supplement. Unfortunately, the consumer was not made aware of the need to separate the timing of administration of one of their antibiotics from the supplement to avoid the interaction.

Tips for Practitioners

- Emphasize to your patients the importance of sharing an up-to-date medication list with all health care providers. The list should include prescription and nonprescription medications, as well as natural health products.
- Before dispensing any medications, screen for potential drug interactions, including interactions with nonprescription medications and natural health products.
- When dispensing multiple medications that require separate timing, work with the patient to customize a medication dosing schedule that is easy for them to follow.

Read the full consumer newsletter here: https://safemedicationuse.ca/newsletter/calcium.html

Oxytocin to Start or Advance Labour: 5 Questions to Ask



World Patient Safety Day will take place on September 17, 2021, with the theme "Safe maternal and newborn care". In support of the World Patient Safety Day theme this year, ISMP Canada is pleased to share a new handout, "Oxytocin to Start or Advance Labour: 5 Questions to Ask", which was developed with funding from the Canadian Medication Safety Coalition.

Oxytocin is a high-alert medication. Its use to start or advance labour has been identified as a high-risk area of practice.[1] The patient handout was developed to provide information about the benefits and risks of oxytocin for these indications. It was designed, in collaboration with patients and providers, to supplement the conversation between health care providers and patients/care partners about oxytocin. The handout aims to increase the role of the patient as a partner in intravenous oxytocin safety.

In a recent Canadian survey ($n = 61$ respondents), 100% of patients and more than 70% of health care providers found this patient handout to be useful.

Download the handout and implementation guide here:
https://www.ismp-canada.org/oxytocinsafety/

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Med Safety Exchange – Webinar Series

Wednesday, September 22, 2021

Join your colleagues across Canada for a complimentary webinar to share, learn and discuss incident reports, trends and emerging issues in medication safety.

For more information, visit
www.ismp-canada.org/MedSafetyExchange/

CMIRPS SCDPIM
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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.

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(Including near misses)

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