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Institute for Safe Medication Practices Canada

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

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ALERT: Shortage of Topical Epinephrine 1:1000 Poses Safety Risks

Since early 2015, there has been shortage of epinephrine 1 mg/mL (1:1000) 30 mL vials for topical use and epinephrine 1 mg/mL (1:1000) 30 mL vials for injection. At the time of writing, the only epinephrine 1 mg/mL (1:1000) product is available in 1 mL ampoules for injection, requiring a syringe and needle to withdraw the solution from the ampoule.

As a result of the current shortage of epinephrine for topical use, facilities needing this medication will have to use the injectable product in its place. However, the practice of withdrawing a medication intended for topical use into a parenteral syringe poses a risk of a substitution error and/or inadvertent injection.

In a previous Safety Bulletin, ISMP Canada shared an incident resulting in death that occurred during a shortage of topical epinephrine.[1] In that incident, epinephrine 1:1000 for injection was to be used topically in the operating room and the solution was drawn up into an unlabelled syringe. The epinephrine, instead of the intended local anaesthetic, was accidently administered by injection into the operative site, resulting in cardiac arrest and subsequent death of the patient. Similar incidents related to inadvertent administration of epinephrine by injection have been previously reported by ISMP Canada and by the US Institute for Safe Medication Practices.[2-4]

ISMP Canada would like to remind facilities that perform procedures involving the use of epinephrine 1:1000 for topical application to review their processes and consider the following strategies and safeguards to prevent a tragedy similar to the one described above:[1]

- **Do not place any medication such as concentrated epinephrine intended for topical use in a parenteral syringe to avoid accidental injection. Conversely, do not use open containers to hold medications intended for injection (e.g., local anesthetic with diluted epinephrine combination products).**
- Consider the packaging of epinephrine for topical application by pharmacy in a distinct, ready-to-use pour bottle for the duration of the back order to avoid the need for practitioners to draw up the injectable format into a syringe. Any hospital taking this approach should consider the factors affecting the stability of epinephrine[5] to determine the appropriate packaging and expiry date.
- Develop distinct and separate processes for the storage, preparation, and handling of medications intended for topical application and those intended for injection. Give priority attention to any processes used for epinephrine for topical application, if not already in place.
- Do not add 30 mL multidose vials of injectable epinephrine 1 mg/mL (1:1000) to any operating room stock. This recommendation is particularly relevant if the multidose format of injectable epinephrine becomes available before the 30 mL product intended for topical use.
- Keep local anesthetics (with or without epinephrine) for injection in their original vials, and withdraw such medications into a syringe (and

label the syringe) immediately before use. This procedure will allow the surgeon to participate in a reliable verification process using the manufacturer's product and the syringe label.
- Always label all syringes and containers. Sterile and preprinted labels are available to facilitate labelling in operating room areas. Discard any unlabelled syringes and containers.
- Ensure that the word "TOPICAL" appears on the label of any container used to hold a solution intended for topical application.
- Ensure that point-of-care communication is provided by the pharmacy when a product is changed because of a new supplier or because of a product back order.

A collaborative failure mode and effects analysis on this very topic was conducted by ISMP Canada and an Ontario hospital in 2010, with support from the Ontario Ministry of Health and Long-Term Care. The full report with additional recommendations is available at https://www.ismp-canada.org/operatingroomchecklist/index.php#fmea

Inadvertent injection of epinephrine intended for topical use is a deadly but preventable medication incident. Hospitals and practitioners are encouraged to proactively review their processes for management of this high-alert medication and to take additional precautions as required to ensure safe patient care during this back order situation and at all other times.

References

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4. Case update: epinephrine death in Florida. ISMP Med Saf Alert. 1996 Dec 4 [cited 2015 Mar 17]. Available from: http://www.ismp.org/newsletters/acutecare/articles/19961204.asp
5. Donnelly RF, Yen M. Epinephrine stability in plastic syringes and glass vials. Can J Hosp Pharm. 1996;49(2):62-65.

Announcing the Draft Good Label and Package Practices Guide

Health Canada and ISMP Canada are pleased to announce the release of the draft *Good Label and Package Practices Guide* for stakeholder consultation. The purpose of the guide is to provide direction to manufacturers in designing safe and clear labels and packages.

The information in the guide will assist manufacturers in the organization of health product information that is required by Canadian regulations. It will provide additional recommendations to support the design and development of labels and packages that are clear and effective and that support proper identification of the product to minimize the risk of errors causing harm.

Recommendations presented in the guide are drawn from regulatory documents, professional standards and guidelines, safety literature, documented reports of health product incidents, and experience in Canada and other jurisdictions.

Stakeholders are invited to provide input on the draft *Good Label and Package Practices Guide*. The consultation is open until May 4, 2015. To obtain a copy of the draft guide please go to http://www.ismp-canada.org/labelpackage/

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.

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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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