

ALERT: Errors with Prefilled Saline Syringes When Used to Reconstitute or Dilute Medications

This alert shares concerns about the use of prefilled saline (0.9% sodium chloride) syringes for reconstitution or dilution of injectable medications. The purpose of this bulletin is to heighten awareness among Canadian practitioners about the medication errors that can occur with this practice and to provide recommendations to prevent such errors.

Background

Prefilled saline syringes are indicated for flushing vascular access devices, a purpose for which syringes may have advantages over vials. For example, they are ready to use, which may reduce the risk of contamination during manipulation, and they are available in several volumes.

In 2006, ISMP (US) reported that prefilled saline syringes were being used for reconstitution or dilution of medications, with the medication being withdrawn from the vial back into the syringe.¹ ISMP alerted practitioners to the increased risk of medication error if syringes used in this way were not appropriately relabelled. This problem can be of particular concern if a high-alert medication is involved. One example provided in the ISMP report was dilution of an opioid in a prefilled saline syringe. Without relabelling, the syringe containing diluted opioid could be mistaken for a syringe containing saline (as labelled), an error that could have potentially fatal consequences if the contents are erroneously administered to a patient.¹

ISMP Canada recently received an incident report describing a newly identified risk for error if prefilled saline syringes are used to reconstitute medications: potential inaccuracy of the resulting dilution and therefore inaccuracy of the intended dose.

Incident Example

Stannous gluceptate, an agent used in diagnostic imaging, is supplied in powdered form. Reconstitution of a single vial of this agent for certain tests requires 3 mL of preservative free saline. The specific dose to be administered is based on the patient's body weight, and after reconstitution, the final volume to be administered is measured to the nearest tenth of a millilitre.² When the diagnostic imaging department of the reporting hospital switched its supply of saline from

vials to prefilled syringes and staff started using the syringes for reconstitution of stannous gluceptate, they noticed a decline in the quality of images produced, with re-imaging required for some patients.

Contributing Factors

When the hospital undertook a review to identify possible reasons for changes in image quality, it noted the following findings:

- The prefilled saline syringes that the hospital was using (BD PosiFlush³) are specifically indicated and intended only for flushing in-situ vascular devices and maintaining catheter patency, consistent with other prefilled saline syringes currently on the market.
- Volumes provided in prefilled saline syringes may be "approximate" and are inappropriate for reconstitution of medications requiring precise dosing, such as stannous gluceptate.
- Staff believed that the volume was accurate for reconstitution.
- The observed changes in image quality coincided with the change to exclusive use of prefilled saline syringes for reconstitution of stannous gluceptate.

The facility implemented several changes to address the situation, including restricting the use of prefilled saline syringes to the flushing of vascular access devices and reinstating the use of saline vials in the diagnostic imaging department. Education was also provided on best practices for reconstituting the diagnostic agent. As a result of these interventions, the number of poor radiographic images was substantially reduced.

ISMP Canada's Recommendations

When contacted by ISMP Canada, several manufacturers of prefilled saline syringes confirmed that their products are indicated specifically for flushing venous access catheters or lines. Although the syringes may be convenient, their use for reconstitution of medications introduces the risk of errors into the medication administration process, particularly when a precise volume is required. ISMP Canada has compiled suggestions shared by the facility that reported this incident, findings provided by other

organizations that have undertaken reviews of the use of prefilled saline syringes, and information from ISMP (US)¹ and presents the following recommendations to enhance the safe use of prefilled saline syringes.

Healthcare Organizations and Practitioners

- Do NOT use prefilled saline syringes for reconstitution or dilution of medications or other injectable agents. Implementing this recommendation may necessitate re-evaluation of various products, to ensure that practitioners have appropriate options for required reconstitution or dilution of medications.
- Keep prefilled saline syringes in their outer packaging until immediately before use, and discard any prefilled saline syringes found open or outside of the manufacturer's outer packaging.
- Alert all practitioners to the potential risks associated with using prefilled saline syringes for reconstitution or dilution of medications (e.g., by sharing this bulletin widely).

Manufacturers

Prefilled saline syringes with gradations may be visually

similar to other parenteral syringes. To promote the safe and appropriate use of prefilled saline syringes, manufacturers are encouraged to consider the following:

- Ensure that the indication for use of prefilled saline syringes is prominently displayed on all labels (including outer package and syringe label).
- Clearly indicate on the label if the volume may not be precisely measured.

Conclusion

Prefilled saline syringes are indicated for flushing lines and should NOT be used for reconstitution or dilution of medications, for the following 2 reasons: (i) such use may lead the practitioner to withdraw the medication into a syringe that is labelled sodium chloride 0.9%, resulting in an incorrectly labelled container once the medication has been added; and (ii) the volume may not be precise.

It is hoped that this bulletin will alert practitioners and organizations about the potential for error when prefilled saline syringes are used for reconstituting or diluting medications.

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References

1. Safety Brief: Is it really saline? ISMP Med Saf Alert 2006 [cited 2012 Sep 7];11(23):1. Available from: http://www.ismp.org/newsletters/acutecare/articles/20061116_2.asp
2. DraxImage® gluceptate kit for the preparation of technetium Tc 99m gluceptate injection (brain and kidney imaging agent) or stannous gluceptate injection (cardiac blood pool imaging agent) [product monograph]. Mississauga (ON): DraxImage; 2010 Oct [cited 2012 Oct 23]. Available from: http://www.draximage.com/Portals/0/Canadian%20catalogue/216112_Gluceptate%20feuillelet_2011AL19%20CLEAN.pdf
3. BD PosiFlush SP syringe [product insert]. Mississauga (ON): BD Medical; [no date].

Education Announcement: Multi-incident (Aggregate) Analysis

ISMP Canada is pleased to offer a 1-day interactive workshop, designed specifically for risk managers, patient safety officers, medication safety officers, and healthcare professionals seeking to enhance their ability to conduct multi-incident (aggregate) analysis and identify potential contributing factors and trends.

During this interactive session, you will learn the stepwise process of conducting a multi-incident analysis and the situations where it is most beneficial. You will also gain hands-on experience under the guidance of ISMP Canada analysts. Take-home materials and tools to facilitate analysis of medication incidents will be provided.

The first workshop will be held on January 16, 2013, at ISMP Canada's Medication Safety Learning Centre in Toronto. Enrolment is limited to 8 attendees. Please send an email message to education@ismp-canada.org if you are interested.

Canadian Incident Analysis Framework (revised version of the Canadian Root Cause Analysis Framework)

ISMP Canada is pleased to announce the release of the Canadian Incident Analysis Framework (previously called the Canadian Root Cause Analysis Framework). This updated framework was collaboratively developed by ISMP Canada, the Canadian Patient Safety Institute (CPSI), Saskatchewan Health, and Patients for Patient Safety Canada (a patient-led program of CPSI), with the assistance of Paula Beard, Carolyn Hoffman, and Micheline Ste-Marie. The framework is a resource to support those responsible for, or involved in, managing, analyzing, and/or learning from patient safety incidents in any healthcare setting, with the goal of increasing the effectiveness of analysis in enhancing the safety and quality of patient care. The framework provides methods and tools to assist in answering the following questions:

- What happened?
- How and why did it happen?
- What can be done to reduce the likelihood of recurrence and thus to make care safer?
- What has been learned?

The current revisions to the framework, which was originally developed in 2006, address the practical realities and the comprehensive needs of Canadian healthcare organizations. The framework includes the following key enhancements, among others:

- Inclusion of the patient and family perspective
- Multiple methods to analyze incidents
- Positioning of analysis in the incident management continuum
- Innovative diagramming to support analysis
- Expanded section on developing and managing recommended actions

ISMP Canada provides customized educational workshops on incident analysis using the Canadian Incident Analysis Framework. For more information about holding or attending a workshop, contact ISMP Canada by email at education@ismp-canada.org, by phone at 416-733-3131, or toll-free at 1-866-544-7672.

ISMP Canada can also provide direct assistance with analysis of critical incidents. For more information about this service, send an e-mail to consults@ismp-canada.org, call 416-733-3131, or call toll-free 1-866-544-7672.

A copy of the Canadian Incident Analysis Framework is available for download: www.ismp-canada.org/rca

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:

(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System