

Enhancing Safety with Unfractionated Heparin: A National and International Area of Focus

Three serious incidents involving use of an incorrect concentration of heparin to flush intravenous catheters have been reported in the US media over the past 2 years:

- In Indianapolis¹ and in Los Angeles,² the media reported that heparin at a concentration of 10,000 units/mL, instead of the intended 10 units/mL concentration, was inadvertently used for flushing.
- Recently, a mix-up at a facility in Corpus Christi, Texas, has generated media and public attention.³ According to press releases from the hospital, the error occurred during the mixing process in the hospital's pharmacy.⁴ Few details have been made public about the underlying causes, which are still being investigated.

In response to such incidents, ISMP (US) has published recommendations to enhance heparin safety.^{5,6,7,8} In the United Kingdom, similar incidents have led the UK National Patient Safety Agency to release recommendations requiring rapid action.^{9,10} This bulletin provides information about incidents that have been reported in Canada, as well as some details about a current provincial initiative to address this problem.

Two previous articles in the *ISMP Canada Safety Bulletin*^{11,12} described incidents involving confusion among heparin solutions with different concentrations and provided recommendations for system safeguards and strategies to prevent such occurrences. A search of the ISMP Canada Medication Incident Database revealed that more than 1,000 voluntary reports involving heparin were submitted between January 2000 and June 2008, 74 of which resulted in harm or death. A variety of medication-error types have been implicated in heparin-related incidents leading to harm or death, including concentration

mix-ups. Thirteen of the reports in the ISMP Canada database concern intravenous line-flushing incidents, including mix-ups between heparin concentrations; two of these cases resulted in death.

In spring 2006, ISMP Canada conducted a national Anticoagulant Safety Survey. The survey findings, from 195 respondents across Canada, revealed the state of anticoagulant storage and use in Canadian healthcare institutions and the management of patients receiving anticoagulants.¹³ Review of the survey results indicates that hospitals have opportunities to enhance safety strategies for anticoagulant storage, as well as the management of patients receiving anticoagulant therapy.

In response to the survey findings and further to its analysis of reported heparin incidents, ISMP Canada (with support from the Ontario Ministry of Health and Long-Term Care) developed a toolkit entitled "Getting Started with Storage Safeguards to Minimize the Risk of Patient Harm with Unfractionated Heparin".¹⁴ The toolkit is currently being implemented in a collaborative project with Ontario hospitals. In addition, Accreditation Canada (formerly the Canadian Council on Health Services Accreditation), in consultation with ISMP Canada, is introducing a new Required Organizational Practice covering the availability and storage of heparin products in healthcare institutions.¹⁵

A wide variety of unfractionated heparin products are marketed in Canada.¹⁶ When used correctly, heparin is a clinically important and beneficial medication; however, safeguards are needed to protect patients from preventable harm with this high-alert medication. To help healthcare professionals and institutions enhance the safe use of unfractionated heparin, a summary of ISMP Canada's recommendations, taken from the toolkit mentioned above, is included in this bulletin.

References

1. Davies T. Fatal drug mix-up exposes hospital flaws. Boston Globe 2006 Sep 22 [cited 2008 Jul 18]. Available from: http://www.boston.com/news/nation/articles/2006/09/22/drug_mix_up_results_in_3_babies_deaths/
2. Gorman A, Ornstein C. Possible medical mix-up for twins. Los Angeles Times 2007 Nov 21 [cited 2008 Jul 18]. Available from: <http://articles.latimes.com/2007/nov/21/local/me-twins21>
3. Up to 17 babies given overdoses of blood thinner. CNN.com 2008 Jul 9 [cited 2008 Jul 18]. Available from: <http://www.cnn.com/2008/HEALTH/07/09/heparin.babies/index.html>
4. Christus Spohn news. Statement by Dr. Richard David, Chief Medical Officer, Christus Spohn Health System. Heparin update—5:15 PM. Corpus Christi (TX): Christus Spohn Health System; 2008 Jul 10 [cited 2008 Jul 21]. Available from: http://christusspohn.netreturns.biz/NewsReleases/Article_Detail.aspx?id=b8250e15-c437-48f3-8345-edc85a47565a

SUMMARY OF RECOMMENDATIONS TO MINIMIZE RISK OF HARM WITH UNFRACTIONATED HEPARIN*

1. Complete an audit of heparin storage areas throughout the hospital (including the pharmacy department) to identify high-risk situations†

- Review products and quantities stored.
- Assess intended use for each heparin product stored.
- Identify unnecessary products to be removed.
- Identify appropriate quantities to be stored.

2. Assess current utilization of heparin and compare with best practices.

- Review the use of unfractionated heparin to ensure alignment with current evidence-based guidelines, e.g., the latest version of guidelines on antithrombotic and thrombolytic therapy from the American College of Chest Physicians (ACCP).
- Where possible, use alternative products or procedures for flushing and locking of access lines to limit exposure to unfractionated heparin.
- Consider the use of low molecular weight heparin as an alternative to unfractionated heparin where possible.

3. Reduce the number of potentially high-risk situations associated with unfractionated heparin storage.

A) In patient care areas‡

- Remove high-dose formats of unfractionated heparin products (total drug quantity of 50,000 units) from stock in patient care areas:
 - i. 10,000 units/mL in 5 mL vials
 - ii. 25,000 units/mL in 2 mL vials
- Review and reduce, where possible, availability of the following products in patient care areas:
 - i. 10,000 units/mL in 1 mL vials
 - ii. 1,000 units/mL in 10 mL vials
- Simplify and standardize product selection according to use:
 - i. Define protocols and standardize products for unfractionated heparin flushing and for subcutaneous and intravenous use, so as to minimize the number of concentrations stocked in a patient care area.
 - ii. Select the optimal product format appropriate for use:
 - Use premixed solutions of unfractionated heparin for continuous intravenous infusions. Select one concentration for hospital-wide use.
 - Use single-dose formats, such as prefilled syringes or ampoules each containing 5,000 units for subcutaneous administration.
 - If unfractionated heparin is used to flush a central venous access device, use appropriate concentrations (e.g., 10 units/mL or 100 units/mL).
 - iii. When unfractionated heparin flushes and subcutaneous and intravenous doses must be stocked in the same patient care area, maximize differentiation by using physical separation, labelling, product format, and other techniques.

B) In the pharmacy‡

- Review storage areas in the pharmacy to ensure adequate safeguards to prevent selection errors.

* From: "Getting Started with Storage Safeguards to Minimize the Risk of Patient Harm with Unfractionated Heparin", Ontario Medication Safety Support Service - Unfractionated Heparin Safety Initiative 2007-2008.

† High risk situations are defined by the presence of unfractionated heparin products containing 50,000 units (total drug quantity) or 10,000 units (total drug quantity) or by the simultaneous presence in any one patient care area of any flushing product and either intravenous bolus or subcutaneous doses of unfractionated heparin.

‡ In light of recent incidents that have occurred with incorrect stocking of look-alike heparin products in automated dispensing cabinets, an independent verification procedure should be implemented.

5. Heparin errors continue despite prior, high-profile, fatal events. ISMP Med Saf Alert. 2008[cited 2008 Jul 18];13(14):1-2. Available from: <http://www.ismp.org/Newsletters/acute/acute/articles/20080717.asp>
6. Another heparin error: learning from mistakes so we don't repeat them. ISMP Med Saf Alert. 2007[cited 2008 Jul 21];12(24):1-2. Available from: <http://www.ismp.org/Newsletters/acute/acute/articles/20071129.asp>
7. High-alert medication feature: Anticoagulant safety takes center stage in 2007. ISMP Med Saf Alert. 2007[cited 2008 July 24];12(1):1-3. Abridged version available from: <http://www.ismp.org/Newsletters/acute/acute/articles/20070111.asp>
8. Infant heparin flush overdose. ISMP Med Saf Alert. 2006 [cited 2008 Jul 21];11(19):1. Available from: <http://www.ismp.org/Newsletters/acute/acute/articles/20060921a.asp>
9. Rapid response report: risks with intravenous heparin flush solutions. NPSA/2008/RRR002. London (UK): National Patient Safety Agency; 2008 Apr 24 [cited 2008 Jul 18]. Available from: <http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=11433>
10. Additional information. Rapid response report: risks with intravenous heparin flush solutions. London (UK): National Patient Safety Agency; 2008[cited 2008 Jul 18]. Available from: <http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=11434>
11. Appropriate anticoagulant use — a patient safety priority. ISMP Can Saf Bull. 2006 [cited 2008 Jul 18];6(10):1-2. Available from: <http://www.ismp-canada.org/download/ISMPCSB2006-10Anticoagulant.pdf>
12. A need to “flush” out high concentration heparin products. ISMP Can Saf Bull. 2004[cited 2008 Jul 18];4(10):1-2. Available from: <http://www.ismp-canada.org/download/ISMPCSB2004-10.pdf>
13. Geerts W, Stumpo C, U D, Diamantouros A. Report on national anticoagulant safety survey. Manuscript in preparation.
14. Ontario Medication Safety Support Service. Getting started with storage safeguards to minimize the risk of patient harm with unfractionated heparin. A collaborative medication safety initiative of ISMP Canada, the Ontario Hospital Association, and the Ministry of Health and Long-Term Care. Toronto (ON): Institute for Safe Medication Practices Canada; 2007 Dec.
15. New ROPs for 2009. Ottawa (ON): Accreditation Canada; 2008 [cited 2008 Jul 18]. Available from: <http://www.cchsa.ca/default.aspx?page=364>
16. Drug product database (DPD). Ottawa (ON): Health Canada; [search performed 2007 Jun 14; cited 2008 Jul 18]. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index_e.html

Pharmaceutical Bar Coding to Improve Patient Safety

On January 24, 2008, a stakeholder invitational roundtable, co-chaired by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), was convened in Ottawa, Ontario, to discuss and seek consensus on voluntary guidelines for pharmaceutical manufacturers related to the use of bar codes for labelling medications at the unit-of-use packaging level. Before the meeting, ISMP Canada circulated a discussion paper entitled *Canadian Pharmaceutical Bar Coding to Improve Patient Safety: Options for Technical Standards in the Canadian Environment* (available from <http://www.ismp-canada.org/publications.htm>). The 40 participants represented a variety of organizations, professions, and interests. They worked in discussion groups to explore various aspects of bar coding for pharmaceutical labels, including the products to be bar-coded; packaging and placement of bar codes; and the content, format, and symbology of the bar codes themselves. There was overall agreement that a standard is urgently needed for bar coding of pharmaceutical products in Canada. A copy of the proceedings of the stakeholder invitational roundtable is also available from <http://ismp-canada.org/publications.htm>

ISMP Canada and CPSI will work together, in collaboration and consultation with stakeholders, to build on the results of the roundtable and to develop the next steps.

©2008 Institute for Safe Medication Practices Canada. Permission is granted to subscribers to use material from the ISMP Canada Safety Bulletin for in-house newsletters or other internal communications only. Reproduction by any other process is prohibited without permission from ISMP Canada in writing.

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