




## Ontario Medication Safety Support Service Anticoagulant Project



Funded by the Ontario  
Ministry of Health and  
Long-Term Care

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## Acknowledgements

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Sunnybrook Health Sciences Centre, Toronto  
Toronto East General Hospital, Toronto  
York Central Hospital, Richmond Hill



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## Expert Panel

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## Medication Safety Support Service (MSSS) Advisory Group

- Canadian Society of Hospital Pharmacists - Ontario Branch
- College of Nurses of Ontario
- College of Physicians and Surgeons of Ontario
- Institute for Safe Medication Practices Canada
- Ontario College of Pharmacists
- Ontario Hospital Association
- Ontario Medical Association
- Ontario Ministry of Health and Long-Term Care
- Ontario Pharmacists' Association
- Registered Nurses Association of Ontario



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## Why Anticoagulant Safety?

The Institute for Safe Medication Practices (ISMP) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Institute for Safe Medication Practices (ISMP) is a member-source expert provider of professional and general health coverage and risk management support.

**ISMP Canada Safety Bulletin**  
Volume 8, Issue 1 February 24, 2008

**Top 10 Drugs Reported as Causing Harm through Medication Error**

ISMP Canada in collaboration with the Canadian Institute for Health Information (CIHI) and Health Canada to establish and implement the Canadian Medication Incident Reporting and Prevention System (CMIRPS). Strategies to prevent harm from medication incidents are based on critical analysis and rely on the collection and sharing of information about medication incidents. The term "medication incident" is widely used to represent the preventable nature of potential and actual adverse drug events. It is also recognized as an alternative term for "medication error". When implemented, CMIRPS will accept incident reports from both individual practitioners (ISMP Canada's lead role) and health service organizations (CIHI's lead role). Of interest are reports of potential and actual incidents, both correct and incorrect, related to any medication, and occurring at any stage of the medication use system.


Although CMIRPS is still in the development stage, individual practitioners are already submitting incident reports through the ISMP Canada voluntary practitioner reporting program (completed). This program allows practitioners to anonymously (if preferred) reporting of incidents and does not collect identifying information about individual patients. Reports are accepted from practice settings within the health care system, including health care professionals, such as physicians, nurses, pharmacists, technicians, and paraprofessionals, as well as risk managers and staff of regulatory colleges, consumer affairs, and insurance providers. A variety of reporting channels is available, including telephone, electronic submissions through a web portal, and mail.

ISMP Canada's reporting program has been in place since 2001. A

Generic Drug Name	Number of Reports
Insulin	54
Morphine	43
Hydrochlorothiazide	32
Warfarin (unfractionated)	19
Fentanyl	11
Valsartan	10
Furosemide	9
Diltiazem	7
Metoprolol	7
Risperidone	7

† These 10 drugs accounted for 10% of 408 harmful medication incidents that were voluntarily reported to ISMP Canada over a 6-year period (2001 to 2006). A total of 10,120 incidents involving near misses were reported, but most did not cause harm to patients.

‡ Similar drugs in these classes (low-molecular-weight heparins, statins, and angiotensin-converting enzyme inhibitors) were also associated with harmful incidents.



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## Anticoagulation Principles

*Need to anticoagulate.....*

*Need to anticoagulate SAFELY.....*



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## Addressing Anticoagulation Safety

Enhance venous thromboembolism (VTE) prophylaxis

- "Errors of omission"

Enhance storage and administration of heparin

- "Errors of commission"

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## Addressing Anticoagulant Safety

Enhance VTE prophylaxis:

- Project underway with Dr. Bill Geerts to improve the use of clinical practice guidelines.

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## Addressing Anticoagulant Safety

Enhance storage and administration of heparin.



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## Heparin Storage – A Patient Safety Priority

Case #1:

- Patient with a triple lumen central venous access device
- Received heparin flush in each lumen 3 times daily
- Post op day 5, aPTT greater than 180 seconds; no other anticoagulant prescribed
- Outcome: intracerebral hemorrhage resulting in death

*ISMP Canada Safety Bulletin, Vol 6, Issue 10,  
December 30, 2006*

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## Heparin Storage – A Patient Safety Priority

Case #2:

- Neonatal ward in US hospital
- Heparin 10,000 units / mL stocked in dispensing cabinet instead of 10 units / mL vial
- Products look similar
- Nurses flushed with incorrect product
- Outcome – 3 premature infants died

*ISMP Safety Alert, September 21, 2006*

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## Heparin Storage – A Patient Safety Priority



Vials similar to those confused.

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## Heparin Storage – A Patient Safety Priority

Questions:

- Is there a problem?
- Why are there so many choices?
- What is the current state of heparin storage in Ontario?
- What is contributing to the current usage patterns?
- How can we improve storage?

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## Heparin Product Concentrations Available in Canada (ampoules and vials only)

Concentration/mL	Concentration/Total Volume	Unit Size
10 Units/mL	10 Units/mL	1 mL
10 Units/mL	100 Units/10 mL	10 mL
100 Units/mL	200 Units/2 mL	2 mL
100 Units/mL	1,000 Units/10 mL	10 mL
1,000 Units/mL	1,000 Units/mL	1 mL
1,000 Units/mL	10,000 Units/10 mL	10 mL
1,000 Units/mL	30,000 Units/30 mL	30 mL
10,000 Units/mL	10,000 Units/mL	1mL
10,000 Units/mL	50,000 Units/5 mL	5mL
25,000 Units/mL*	5,000 Units/0.2 mL	0.2 mL
25,000 Units/mL	50,000 Units/2 mL	2 mL

\* High concentration product, however unit dose ampoule provides only 5,000 units.

ISMP Canada Safety Bulletin, Vol 4, Issue 10, October, 2004

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## Heparin-Related Products

- Low Molecular Weight Heparins (LMWH)
  - Enoxaparin (Lovenox®)
  - Dalteparin (Fragmin®)
  - Tinzaparin (Innohep®)
  - Nadroparin (Fraxiparine®)
- Fondaparinux (Arixtra®)

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## Heparin Uses

Use	Route	Common Dosage
Heparin Flushes	Heparin IV	Heparin 1,000 units in 10 mL
VTE prophylaxis	Heparin SC or LMWH SC (E.g., Dalteparin, Tinzaparin)	Heparin 5,000 units SC or LMWH 2,500 to 5,000 units SC
VTE treatment	Heparin IV bolus plus infusion	Heparin 5,000 units IV followed by 1,000 units per hour (approx)
	LMWH SC (E.g., Dalteparin, Tinzaparin)	LMWH 15,000 units SC (approx)
Acute Coronary Syndromes	Heparin IV bolus plus infusion	Heparin 5,000 units IV followed by 1,000 units per hour (approx)
	LMWH SC	Enoxaparin 1 mg / kg
	Fondaparinux SC	Fondaparinux 2.5 mg SC

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## Heparin Uses

Heparin Flushes


- 100 – 1000 units
- Limited evidence
- Routine use not recommended

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## Heparin Error Potential


Number of products  
 X  
 Number of concentrations  
 X  
 Number of uses / formats / doses

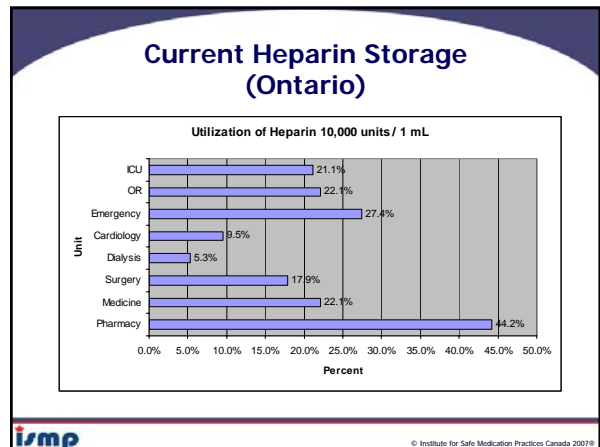
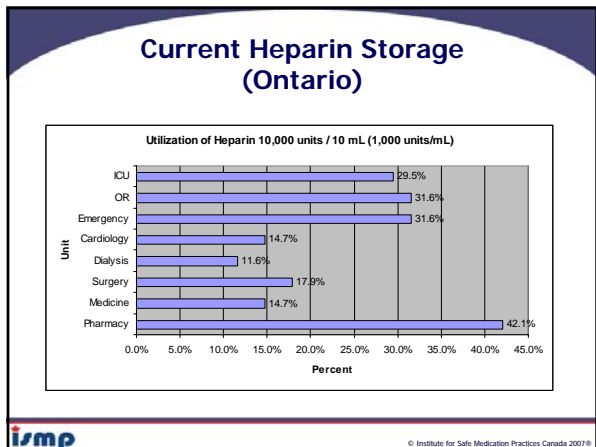
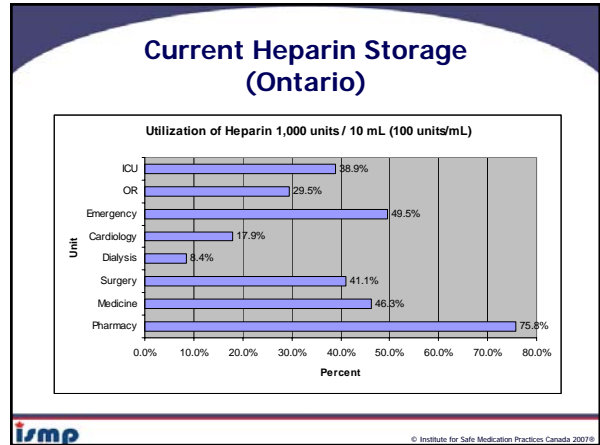
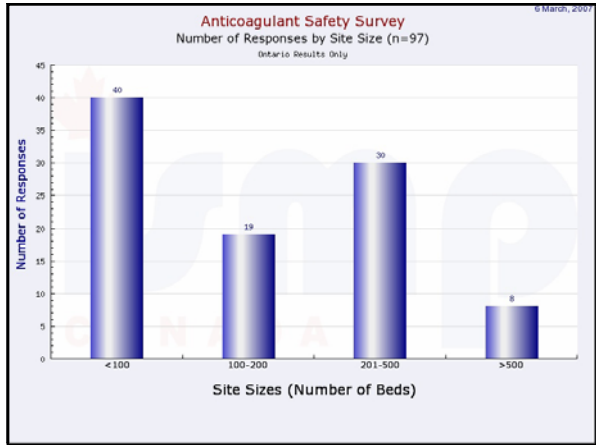

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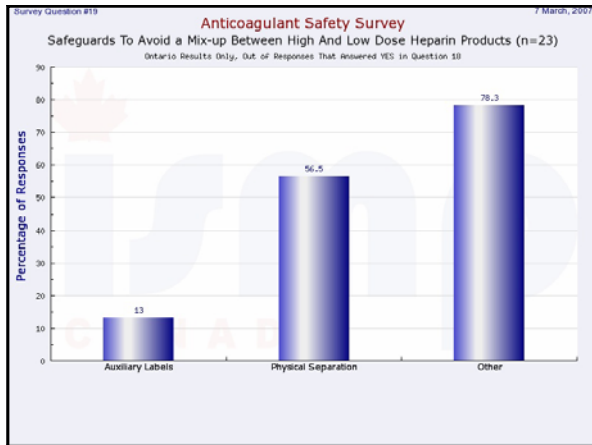
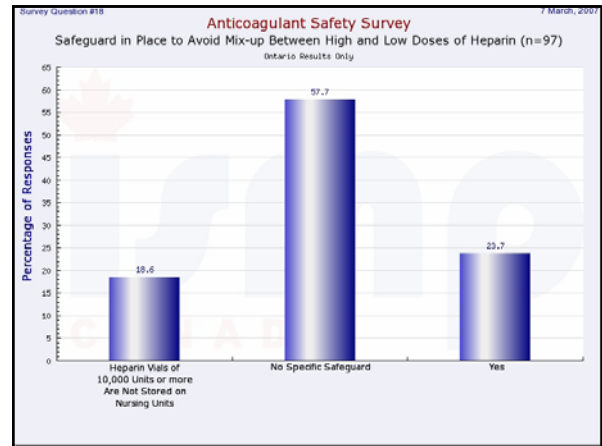
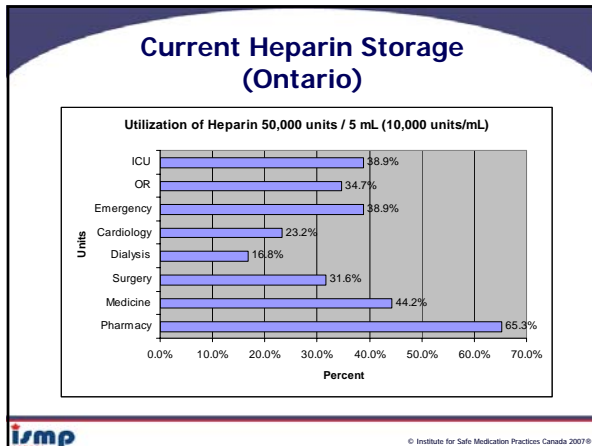
## Current Heparin Storage

Canadian Hospital Survey

- 29 question survey sent to 856 healthcare facilities across Canada
- Addressing a variety of anticoagulant topics including heparin storage
- Response:
  - 195 responses nation-wide
    - Representing 38,350 hospital beds
  - 97 Ontario respondents


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### Current Heparin Storage

Summary:

- High dose / concentration products prevalent
- Stocked with lower dose products (flushes)
- Few interventions made ←

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### Intervention

The Goals:

- Appropriate use of heparin
  - Before addressing heparin storage, must first address usage
- Safety strategies to minimize selection errors

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### Project Development

Coordination by ISMP Canada

- Expert advisory panel formed
  - Process developed to achieve goals
  - Identification / creation of tools to facilitate
    - Analysis
    - Product choices
    - Information sharing
- Resource kit developed

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## Learning from Project Development

- “one size does not fit all”
- Need to use a systematic approach to identify and address areas of risk



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## Recommendations - Overview

1. Assess heparin storage throughout hospital.
2. Address appropriate use of heparin.
3. Reduce the number of potential high-risk situations related to heparin storage.



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## Recommendation 1: Heparin Audit

### Systematic Process for Heparin Review:

- Review products and quantities stored throughout the hospital;
- Assess intended use for each heparin product stored;
- Identify and remove unnecessary products; and
- Identify appropriate quantities to be stored.



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## Audit and Assessment Tool

- Step by step approach
- Documentation (pre and post)
- Impact analysis



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## Cost Analysis

Heparin Format	Cost*
Heparin 5,000 unit pre-filled syringe (Healthmark)	\$2.00
Heparin 5,000 / 0.2 mL amp	\$1.29
Heparin 10,000 units / 1 mL vial	\$1.34
Heparin 50,000 units / 2 mL vial	\$0.92
Heparin 50,000 units / 5 mL vial	\$0.38
Heparin 500 unit pre-filled syringe (Healthmark)	\$0.87
Heparin 1,000 units / 10 mL	\$1.90

\*Based on average contract prices for a single dose



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## Cost Analysis

Estimated annual costs for VTE prophylaxis:

Heparin Format	Cost*
Heparin 5,000 unit pre-filled syringe (Healthmark)	\$93,659
Heparin 5,000 / 0.2 mL amp	\$60,410
Heparin 10,000 units / 1 mL vial	\$62,752
Heparin 50,000 units / 2 mL vial	\$43,083
Heparin 50,000 units / 5 mL vial	\$17,795

\*Assuming average VTE prophylaxis rates in a 400 bed acute care facility



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## LMWH Storage

- Available as both multidose vials and pre-filled syringes
- Multidose vials present a safety hazard
  - May be more concentrated
  - Large quantity of drug per vial
- No cost differential for pre-filled syringes
  - Barrier to use: need for pre-approved dose ranges



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## Recommendation 2: Appropriate Use

Assess current use and compare with best practice:

- Review use of unfractionated heparin to ensure alignment with the evidence based guidelines (e.g., ACCP)
- Considerations:
  - VTE prophylaxis re evidence-based guidelines
    - > Increase use
  - Flushing / locking of access lines
    - > Decrease use of heparin where possible
  - Consider LMWH use



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## Recommendation 3: Reduce Potential High-Risk Situations A/ In patient care areas:

- Remove formats of high dose heparin products from stock in patient care areas:
  - > 50,000 units/5 mL
  - > 50,000 units/2 mL
- Review and reduce, where possible, availability of the following products in patient care areas:
  - > 10,000 units/1 mL
  - > 10,000 units/10 mL



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## Recommendation 3: Reduce Potential High-Risk Situations

- Simplify and standardize heparin product selection:
  - i. Define protocols and standardize products for IV and SC use and for heparin flushes.
  - ii. Select optimal product formats. For example:
    - For continuous IV infusions, select one standardized concentration and purchase pre-mixed solutions.
    - For SC administration, use single dose formats such as 5,000 unit pre-filled syringes or ampoules.
    - If using heparin to flush a central venous access device, use appropriate concentrations (e.g., 10 units/mL, 100 units/mL).
  - iii. When SC, IV and heparin flush doses must be stocked in the same area, maximize differentiation using segregation, labelling, product format and other techniques.



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## Recommendation 3: Reduce Potential High-Risk Situations B/In Pharmacy:

### B/In Pharmacy:

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



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## Heparin Safety Strategies Experience

Pilot Site: York Central Hospital

Ming Lee



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## Implementation

### General Strategies

- Motion was approved by Pharmacy, Nutrition & Therapeutics Committee and Safe Medication Practice Committee to remove high dose heparin products from stock hospital wide
  - Review of products, indications and pre-printed orders
  - Education of all staff and physicians
  - Work with all physician and nursing groups to change stock and pre-printed orders
  - Minimize stock of heparin products with individual patient specific prescriptions where possible



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## Implementation

### York Central Hospital Experience

- Removal of 50,000u/5mL vials hospital wide
- Limited stock in limited areas consolidated to 1000u heparin (i.e. OR, PACU, DI, ICU) and 100u/mL (i.e. ICU, DI, PACU)
- 10,000u/mL provided as patient specific unit dose prescription in acute care areas
- Pre-printed orders reviewed and many revised (e.g. Heparin infusion protocol – use premixed heparin 25,000u/500mL D5W solution)
- Move to use of LMWH for orthopedic DVT prophylaxis and pre-printed orders approved by the Surgical Program
- Use of sodium citrate for renal patients



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## Implementation

### York Central Hospital Experience

#### Successes

- Increased awareness of high dose heparin risks hospital wide
- Collaboration and support of all practitioners – physicians, nurses, pharmacists and pharmacy technicians
- Adoption of revised pre-printed orders with significant practice impact (i.e. use of LMWH and premixed heparin)
- Independent double check for heparin infusions and subcutaneous injections
- Participation in the Canadian Thromboprophylaxis Patient Safety Initiative (CTPSI) helped in providing education to all physician groups, nurses and pharmacists



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## Implementation

### York Central Hospital Experience

#### Challenges

- Time for consultation process (i.e. pre-printed orders, etc)
- Storage space on units
- Decision to use commercially available pre-filled syringe or wait for IV admixture service (redevelopment required)



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## Implementation

### York Central Hospital Experience

#### Next Steps

- Continue to revise pre-printed orders
- Continue to consolidate stock to one of the approved products
- Decision on 5000u heparin format



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Questions?



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Questions?

