Ontario Medication Safety Support Service:

Getting started with system safeguards to minimize the risk of harm with unfractionated heparin

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

Objectives

- Background and overview of initiative.
- Description of recommended strategies for enhancing safe storage and handling of unfractionated heparin.
- Sharing of strategies used by test hospitals to implement the safety recommendations.
- Opportunity for questions and sharing of experiences.

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

Acknowledgements

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Kris Wichman, ISMP Canada
Donna Walsh, ISMP Canada

Test Sites: Royal Victoria Hospital, Barrie
Sunnybrook Health Sciences Centre, Toronto
Toronto East General Hospital, Toronto
York Central Hospital, Richmond Hill

Expert Panel

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Marita Tonkin, Hamilton Health Sciences Centre, Hamilton

Donna Walsh, ISMP Canada

Kris Wichman, ISMP Canada

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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

Why Anticoagulant Safety?

ISMP Canada Safety Bulletin

Volume 6, Issue 1 — February 24, 2006

Top 10 Drugs Reported as Causing Harm through Medication Error

ISMP Canada is collaborating 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 systems analysis and rely on the collection and sharing of information about medication incidents. The term "medication incident" is widely used to represent the preventable subset of potential and actual adverse drug events. It is also recognized as an alternative term for "medication error." [1] 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 critical and noncritical, 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 component. This service offers confidential (or anonymous, if preferred) reporting of incidents and does not collect identifying information about individual patients. Reports are accepted from anyone working within the health care system, including health care professionals, such as physicians, nurses, pharmacists, technicians, and paramedics, as well as risk managers and staff of regulatory colleges, coroners' offices, 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

Table 1. Top 10 drugs most frequently reported as causing harm as a consequence of medication error*

Generic Drug Name	Number of Reports
Insulin	54
Morphine	43
Hydromorphone	32
Heparin (unfractionated)	19
Fentanyl	11
Warfarin	10
Furosemide	9
Dalteparin†	7
Metoprolol†	7
Ramipril†	7

* These 10 drugs accounted for 199 of 468 harmful medication incidents that were voluntarily reported to ISMP Canada over a 5-year period (2001 to 2005). A total of 10,791 incidents, including near misses, were reported, but most did not cause harm to patients.

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

Anticoagulation Principles

Need to anticoagulate…..

Need to anticoagulate SAFELY…..

Addressing Anticoagulation Safety

Enhance venous thromboembolism (VTE) prophylaxis

- "Errors of omission"

Enhance storage and administration of heparin

- "Errors of commission"

Addressing Anticoagulant Safety

Enhance VTE prophylaxis:

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

Addressing Anticoagulant Safety

Enhance storage and administration of heparin.

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

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

Heparin Storage – A Patient Safety Priority

Vials similar to those confused.

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?

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

Heparin-Related Products

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

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**

Heparin Uses

Heparin Flushes

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

Heparin Error Potential

Number of products

X

Number of concentrations

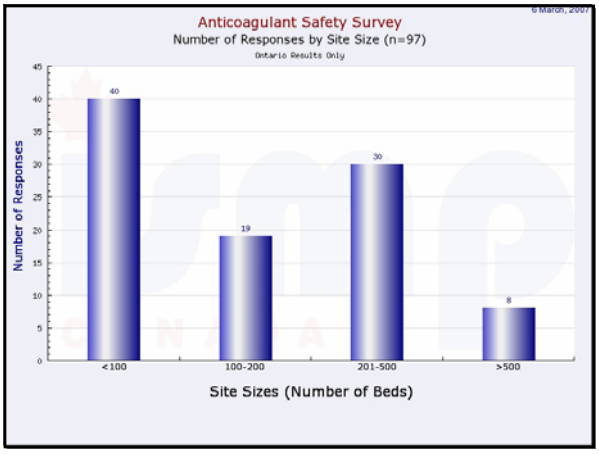
X

Number of uses / formats / doses

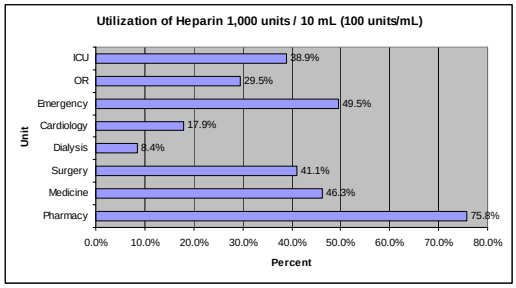
Current Heparin Storage

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



Current Heparin Storage (Ontario)



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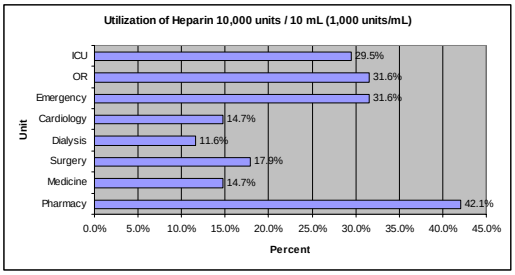

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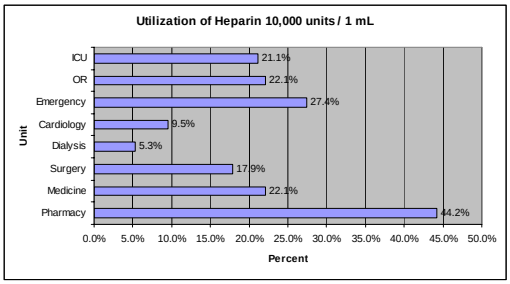

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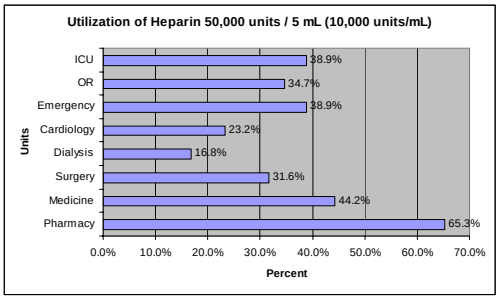

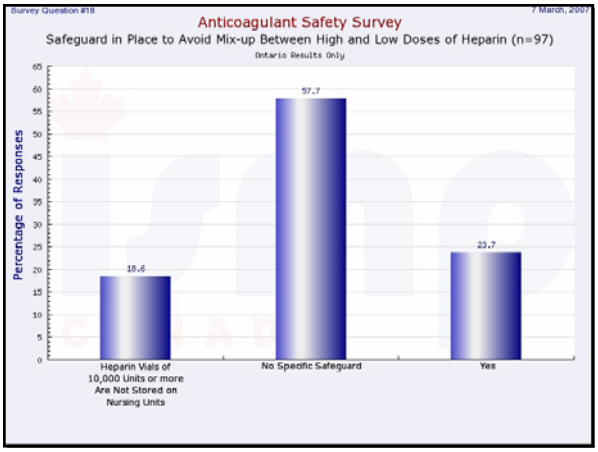

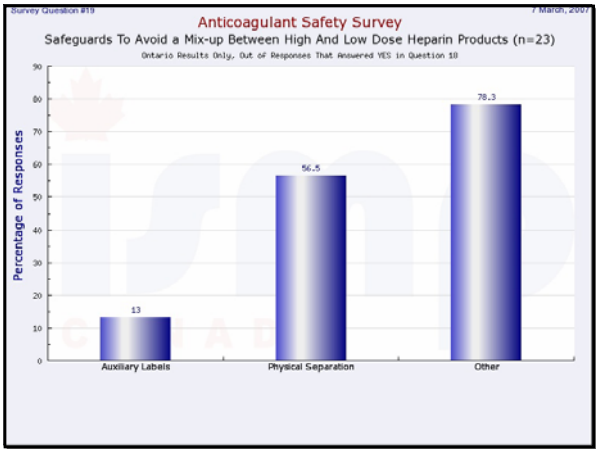

Current Heparin Storage

Summary:

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

Intervention

The Goals:

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

Learning from Project Development

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

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.

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.

Audit and Assessment Tool

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

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

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

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

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

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

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).

Heparin Lock/Flush Products

Recommendation 3 (cont'd): Reduce Potential High-Risk Situations

- Simplify and standardize heparin product selection (cont'd):
  - 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.

B/In Pharmacy:

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

Heparin Safety Strategies Experience

Test Site: Sunnybrook Health Sciences Centre

Toronto, ON

Patti Cornish, RPh, BScPhm, Patient Safety Service,
Sunnybrook Health Sciences Centre

Description of Hospital

- Teaching hospital
- 660 acute care beds on 3 campuses
- 530 long-term care beds
- Strategic programs –
  - cancer, cardiovascular, musculoskeletal, perinatal/gynecology, neurosciences, aging & populations health, trauma, critical care

Prior to Intervention

- Heparin 25,000 Units/mL – 2 mL vial
  - Available on 4 wards, one ICU
- Heparin 10,000 Units/mL – 5 mL vial
  - Available on all patient care areas
- Heparin 1,000 Units/mL – 10 mL vial
  - Available on all ICUs and 3 wards; dialysis; radiology
- Heparin 10 Units/mL (Lock Flush) – 10 mL vial
  - Available on several wards and ICUs

After Intervention

- Heparin 25,000 Units/mL – 2 mL vial
  - Removed from all patient care areas
- Heparin 10,000 Units/mL – 5 mL vial
  - Removed from all patient care areas (except Burn Unit)
- Heparin 1,000 Units/mL – 10 mL vial
  - Availability reduced but remains on several ICUs and 2 wards; dialysis; radiology
- Heparin 10 Units/mL (Lock Flush) – 10 mL vial
  - Availability reduced but remains available on several wards and ICUs

Change Process

- Heparin 25,000 Units/mL – 2 mL vial
  - No problems with removal - ? Why it was ever stock
- Heparin 10,000 Units/mL – 5 mL vial
  - Replaced with pre-filled syringes of 2,500 Units and 5,000 Units and pre-mixed IV bags
- Heparin 1,000 Units/mL – 10 mL vial
  - Used to prepare boluses for ACS heparin nomogram and in flushing protocols in variable volumes – no other options
- Heparin 10 Units/mL (Lock Flush) – 10 mL vial
  - Used to lock Cook PICC, Hickman and Port-A-Cath CVADs

Results

- Main safety improvement
  - Removal of heparin 50,000 Units from wards
  - Availability of pre-filled syringes for IV boluses and SC doses

Barriers

- > 20 patient care areas had to be consulted
- Initially supplied only heparin 5,000 Units pre-filled syringes – 2,500 Units ordered occasionally as IV bolus!
- Nursing concerns regarding use of pre-filled syringe for IV boluses (compatibility with clave, overfill)

Successes

- Increased awareness of safety concerns with heparin
- Reassessment of the need for other heparin formats
  - Elimination of heparinized saline (1,000 units/500 mL) to maintain arterial lines (exception: IABP)
- Elimination of heparin as an option for addition to TPN
- Revision of flushing guidelines for central venous access devices to minimize use of heparin

Successes

- Removal of prescribing restriction for LMWH for thromboprophylaxis
- Complete removal of all heparin stock from cardiovascular surgery areas
  - Pre-printed orders for CV surgery revised – post-op thromboprophylaxis changed from heparin SC to dalteparin SC

Next Steps

- Revision of all pre-printed orders that include heparin SC
- Increase utilization of dalteparin for thrombo-prophylaxis as per ACCP guidelines
  - Development of new pre-printed order sets
- Streamline heparin availability in Cath Lab

Questions?