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
Co-leads: Carmine Stumpo, Toronto East General Hospital
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
Svasti Bhajan Mathur, Rouge Valley Health System, Ajax/Pickering
Judy Chong, Royal Victoria Hospital, Barrie
Patti Cornish, Sunnybrook Health Sciences Centre, Toronto
Nancy Giovannazzo, Joseph Brant Memorial Hospital, Burlington
James Lam, Providence Health Care, Toronto
Ming Lee, York Central Hospital, Richmond Hill
Michelle Methot, Kingston General Hospital, Kingston

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?

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.

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

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*

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)

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Concentration/mL Volume</th>
<th>Unit Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>2 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>3 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>5 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>10 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>25 mL</td>
</tr>
<tr>
<td>10,000 Units</td>
<td>10,000 Units/mL</td>
<td>50 mL</td>
</tr>
</tbody>
</table>

*High concentration product. Remove one dose ampoule provides only 3,000 units.*

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

<table>
<thead>
<tr>
<th>Use</th>
<th>Route</th>
<th>Common Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin flushes</td>
<td>Heparin IV</td>
<td>Heparin 1,000 units in 10 mL</td>
</tr>
<tr>
<td>VTE prophylaxis</td>
<td>Heparin SC or LMWH SC</td>
<td>Heparin 5,000 units SC or LMWH 2,500 to 5,000 units SC</td>
</tr>
<tr>
<td></td>
<td>(E.g., Dalteparin, Tinzaparin)</td>
<td></td>
</tr>
<tr>
<td>VTE treatment</td>
<td>Heparin IV bolus plus</td>
<td>Heparin 5,000 units IV followed by</td>
</tr>
<tr>
<td></td>
<td>infusion</td>
<td>1,000 units per hour (approx)</td>
</tr>
<tr>
<td>LMWH SC</td>
<td>(E.g., Dalteparin, Tinzaparin)</td>
<td></td>
</tr>
<tr>
<td>Acute coronary syndromes</td>
<td>Heparin IV bolus plus</td>
<td>Heparin 5,000 units IV followed by</td>
</tr>
<tr>
<td></td>
<td>infusion</td>
<td>1,000 units per hour (approx)</td>
</tr>
<tr>
<td>LMWH SC</td>
<td>Enoxaparin 1 mg / kg</td>
<td></td>
</tr>
<tr>
<td>Fondaparinux SC</td>
<td>Fondaparinux 2.5 mg SC</td>
<td></td>
</tr>
</tbody>
</table>

### Heparin Error Potential

- Number of products
- Number of concentrations
- 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

#### Utilization of Heparin 1,000 units / 10 mL (100 units/mL)

- ICU: 50.3%
- OR: 45.2%
- Emergency: 12.5%
- Cardiology: 3.4%
- Dialysis: 2.4%
- Surgery: 41.1%
- Medicine: 14.2%
- Pharmacy: 3.1%

### Anticoagulant Safety Survey

Number of Responses by Site Size (n=97)

- Site Sizes (Number of Beds):
  - <900: 19
  - 100-199: 20
  - 200-399: 30
  - 400-599: 26
  - 600+: 6

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Current Heparin Storage (Ontario)

Utilization of Heparin 10,000 units / 1 mL (1,000 units/mL)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU</td>
<td>31.6%</td>
</tr>
<tr>
<td>OR</td>
<td>31.6%</td>
</tr>
<tr>
<td>Emergency</td>
<td>34.7%</td>
</tr>
<tr>
<td>Dialysis</td>
<td>11.0%</td>
</tr>
<tr>
<td>Surgery</td>
<td>17.3%</td>
</tr>
<tr>
<td>Medicine</td>
<td>16.5%</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>41.7%</td>
</tr>
</tbody>
</table>

Utilization of Heparin 10,000 units / 10 mL (1,000 units/mL)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU</td>
<td>21.1%</td>
</tr>
<tr>
<td>OR</td>
<td>21.1%</td>
</tr>
<tr>
<td>Emergency</td>
<td>17.3%</td>
</tr>
<tr>
<td>Dialysis</td>
<td>17.3%</td>
</tr>
<tr>
<td>Surgery</td>
<td>31.6%</td>
</tr>
<tr>
<td>Medicine</td>
<td>29.5%</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>31.6%</td>
</tr>
</tbody>
</table>

Utilization of Heparin 50,000 units / 5 mL (10,000 units/mL)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU</td>
<td>23.2%</td>
</tr>
<tr>
<td>OR</td>
<td>38.9%</td>
</tr>
<tr>
<td>Emergency</td>
<td>38.9%</td>
</tr>
<tr>
<td>Dialysis</td>
<td>34.7%</td>
</tr>
<tr>
<td>Surgery</td>
<td>31.6%</td>
</tr>
<tr>
<td>Medicine</td>
<td>16.8%</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>18.7%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Heparin Format</th>
<th>Cost*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin 5,000 unit pre-filled syringe (Healthmark)</td>
<td>$2.00</td>
</tr>
<tr>
<td>Heparin 5,000 / 0.2 mL amp</td>
<td>$1.29</td>
</tr>
<tr>
<td>Heparin 10,000 units / 1 mL vial</td>
<td>$1.34</td>
</tr>
<tr>
<td>Heparin 50,000 units / 2 mL vial</td>
<td>$0.92</td>
</tr>
<tr>
<td>Heparin 50,000 units / 5 mL vial</td>
<td>$0.38</td>
</tr>
<tr>
<td>Heparin 500 unit pre-filled syringe (Healthmark)</td>
<td>$0.87</td>
</tr>
<tr>
<td>Heparin 1,000 units / 10 mL</td>
<td>$1.90</td>
</tr>
</tbody>
</table>

*Based on average contract prices for a single dose
Cost Analysis

Estimated annual costs for VTE prophylaxis:

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

*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

Available as both multidose vials and pre-filled syringes.
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

**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?