

Purpose

This position paper describes an approach to stocking & using multi-dose unfractionated heparin in hemodialysis (HD) facilities in British Columbia which meets Accreditation Canada standards and minimizes the risks of infection. While the decision to stock multidose unfractionated heparin in HD facilities resides with each Health Authority (HA), this paper makes recommendations to maximize patient safety in the event a HA/HD unit decides to implement this practice.

Recommendation

Assuming the **suggested safeguards** are in place (refer to "Safeguards" section), Health Authority (HA) Pharmacy & Therapeutics Committees to consider:

- Approving the stocking of heparin 1000 units/mL in vials not exceeding 10,000 units per container in HD units; and
- 2. Approving the preparation of heparin syringes for intradialytic circuit anticoagulation by using a multi-dose vial for more than one patient in HD units.

Background

Unfractionated heparin has been used as the preferred intradialytic anticoagulant in BC since the inception of dialysis. It helps avoid clotting of the line and the dialyzer. Heparin doses used for circuit patency are small compared to other indications.

All patients receive heparin with few exceptions (e.g., patients on therapeutic doses of low-molecular weight heparin, or where significant bleeding risk may be a concern). If a patient is not to receive heparin, it is flagged on the patient's care plan.

The standard concentration of heparin used for intradialytic anticoagulation is heparin 1,000 units/mL. This product is commercially available in 10 mL and 30 mL vials (total of 10,000 and 30,000 units per vial respectively). We propose only 10,000 unit vials be stocked in HD units.

The typical heparin dose is a 500 - 1,000 unit bolus, followed by 500 - 1,000 units per hour given as a continuous infusion during the HD run, amounting to 2,000 - 5,000 units in total for a 4-hour HD run. After accounting for a minimal amount (1 mL) required to prime the hemodialysis circuit, and a small buffer (1 mL) in case more heparin is required during the run (for example, if the dose of heparin is increased, or if the HD run is extended), the average HD patient requires 4 - 7 mL of heparin in the syringe.

Accreditation Canada identifies heparin as a "high alert medication" in the strength and presentation that is currently available as ward stock in many BC HD facilities. Further, the use of multi-dose vials (i.e., single dose vials) is discouraged as a strategy to limit the spread of infection (United States (US) Centers for Disease Control and Prevention (CDC)).

Moving from multi to single dose vials would have significant cost implications (tens to hundreds of thousands of dollars per year in BC).

Relevant Statements from Accreditation Canada and US Centers for Disease Control

- 1. Accreditation Canada (Required Organizational Practices Handbook 2016 Version 2):
 - Heparin has been identified as a high-alert medication that is an area of focus for safety.
 - Unfractionated heparin (high dose, high potency): 50,000 units total per container (e.g. 50,000 units/5 mL; 50,000 units/ 2 mL) should not be stocked in client service areas.
 - Unfractionated heparin (high dose): ≥ 10,000 units total per container (e.g., 10,000 units/1 mL; 10,000 units/10 mL; 30,000 units/30 mL) should be provided on a client-specific basis when required.
 - For specific care circumstances, it may be necessary for heparin products to be available in selected client service areas. In these cases, the organization's interdisciplinary committee for medication management (e.g. Pharmacy and Therapeutics Committee and Medical Advisory Secretariat) reviews and approves the rationale for availability and safeguards put in place to minimize the risk of error.
- US Centers for Disease Control <u>www.cdc.gov/</u> injectionsafety/providers/provider_faqs_multivials. <u>html</u> (accessed Jan 24, 2017):
 - Multi-dose vials should be dedicated to a single patient whenever possible.
 - If multi-dose vials must be used for more than one patient, they should only be kept and accessed in a dedicated medication preparation area (e.g., nurses station¹), away from immediate patient treatment areas.

This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients.

- If a multi-dose vial enters an immediate patient treatment area, it should be dedicated for single-patient use only.
- Medication vials should always be discarded whenever sterility is compromised or questionable.

¹Ideally this would be done in a dedicated medication preparation area designed for such a purpose, rather than just the general nursing station.

Safeguards to Minimize the Risk of Error and Infection in BC

Safeguards suggested for minimizing the risk of error and infections in the use of multi-dose heparin in BC's HD units include:

 Store heparin 1000 units/mL vials in a container/ drawer labelled "High Alert" in the medication storage room/area of the HD unit (away from the patient care area). Keep new syringes, new needles and labels for the heparin syringes in the same area.



2. Utilize the steps below in preparing the heparin syringes for use in the HD machines:



- RN draws up heparin to patient's load and running dose plus 2 mL from vial(s) into 20 mL syringe (or other syringe size suitable for use in the HD machine).
 - A blunt needle is used to draw up the heparin and the cap is replaced.
 - A partial vial is only to be used if a patient's entire dose can be drawn from one vial.
- RN attaches label to heparin syringe and initials run sheet. If consistent with HA practice, 2nd RN performs independent check of heparin and initials run sheet.

Heparin 1000 units/mL Patient:
Date & Time Prepared:
Prepared by:

- 3. Heparin and capped needle is taken to the patient treatment area.
- RN removes the capped needle and places the syringe on the syringe pump in the HD machine. Capped needle is discarded into a sharps container near the HD machine.



 RN programs the load and running dose of heparin on the HD machine as well as the end of the heparin infusion. RN signs run sheet verifying that HD prescription is correct.



- 6. If consistent with HA practice:
 - 2nd RN performs independent check of heparin and initials run sheet; OR
 - 2nd RN checks HD prescription and confirms that programmed heparin load and running dose are accurate and signs run sheet.



- 7. HD machine is checked hourly to confirm that correct amount of heparin is being infused.
- 8. Dialyzer, tubing and heparin syringe are disposed of in the hazardous waste bin at the end of the run.

Additional notes:

- Each nurse is responsible for drawing up heparin into syringes for their own patient(s).
- The heparin doses (both bolus and continuous infusion) are delivered to the patient via the HD machine after settings are programmed by the nurse.
- All nurses receive education specific to heparin.
 Education includes the potential risks of having a high alert medication such as heparin as ward stock and the required safeguards.
- Heparin syringes are prepared from vials in a designated medication preparation area(s). The heparin vials are not brought into the immediate patient treatment area.
- Both the needle or cannula and syringe used to access the multi-dose vial are sterile. Needles/ cannula and syringes are never reused.
- Vials are wiped with 70% alcohol prior to inserting the needle/cannula.
- Heparin vials are discarded if sterility is compromised or questionable.
- If a multi-dose vial enters an immediate patient treatment area, it will be dedicated for single-patient use only or discarded after use.
- Partial heparin multi-dose vials remaining at the end of the day are discarded. Alternatively, they may be kept for 24 hours after opening if the date and time of first entry into the vial is recorded on the vial itself. Either way, HD units need to agree on a process to track the length of time vials have

been open.

 The availability of heparin products in different formats to be stored as ward stock on a unit should be restricted as per Accreditation Canada standards, or as per standards authorized by the HA's Pharmacy and Therapeutics Committee.

Reviewed by:

- BC Renal Pharmacy & Formulary Committee (Feb 23, 2017)
- Renal Educators Group (Apr 5, 2017)
- Hemodialysis/Infection Control Working Group (June 27, 2018)

Approved by:

BC Renal Hemodialysis Committee (September 19, 2018)

References

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