

Statewide Quality Branch

Quality Use of Medicines Program

Endorsed by the
Victorian Medicines Advisory Committee (VMAC)

Quality use of medicines alert

UNFRACTIONATED HEPARIN

Attention	Chief executive officers, directors of medical services, directors of nursing, doctors, nurses and pharmacists		
Alert	UNFRACTIONATED HEPARIN can cause DEATH or MAJOR BLEEDING EVENTS if administered inappropriately		
Date	March 2009	Issue	Vol.1. No.3
Further information	www.health.vic.gov.au/vmac		

Case studies

How unfractionated heparin (UFH) can cause death or major bleeding events if administered inappropriately

An Australian case example

A patient received a combined lung/kidney transplant. A Hickman's catheter was inserted to facilitate continued antibiotic therapy. The catheter was locked with an inappropriate concentration of heparin solution. Another procedure was performed and the patient was administered IV metaraminol via the Hickman's line. The patient suffered a coughing episode, which precipitated severe bleeding and a cardiac arrest. She was resuscitated and given IV protamine to reverse the effects of heparin, but over the following days she passed away.²

Introduction

Critical incidents have occurred when unfractionated heparin (UFH) has been inappropriately prescribed and administered.

Errors

- Inappropriate dose prescribed for indication or condition.
- Incorrect dose of UFH administered:
 - incorrect formulation of UFH selected
 - miscalculation of infusion concentration
 - incorrect rate of infusion.
- Delayed or inappropriate dose adjustment in response to activated partial thromboplastin time (APTT) results.

Contributing factors

- UFH is prescribed for multiple indications, which increases the risk of dosage errors:
 - prevention of venous thromboembolism (VTE)
 - treatment of VTE
 - prevention and treatment in acute coronary syndrome
 - to maintain catheter patency
 - to maintain extracorporeal circulation.
- UFH has a narrow therapeutic range and can produce unpredictable adverse reactions at therapeutic doses. For example, UFH can cause heparin induced thrombocytopenia syndrome (HITS). Regular monitoring is important. This involves:
 - Baseline and ongoing APTT, haemoglobin, and platelet counts.
 - Being aware of the risks and observing for bleeding.
 - Assessing renal function. UFH excretion is proportional to glomerular filtration rate.
- Increased monitoring is also required when using heparin in combination with interacting drugs (or complementary medicines), or when the patient has certain co-existing medical conditions.
- There are many presentations of UFH available that may look alike and therefore lead to selection error.

UNFRACTIONATED HEPARIN

Case studies

How unfractionated heparin (UFH) can cause death or major bleeding events if administered inappropriately

Overseas case examples

A pharmacy technician with 25 years experience delivered heparin vials for use in adults to the neonatal intensive care unit. The vials looked almost identical to those intended for the neonatal unit. The wrong dose was given to six infants. A two-day-old child and a five-day-old child died from internal bleeding.³

A 19 year old obese woman who had recently undergone C-section presented in the emergency department with dyspnoea. She was prescribed heparin 5,000 units iv bolus followed by 1,000 units/hour infusion. A nurse misprogrammed a pump to run at 1,000 mL/hour, not 1,000 units/hour. The patient did not experience adverse bleeding. The error was found to occur as a result of the dose checking technology of the smart pump being bypassed.⁴

References

¹ Institute of safe Medication Practices, March 6, 2003 'ISMP Safety Alert!- The virtue of independent double check- They really are worth your time!' Available at: www.ismp.org/Newsletters/acutecare/articles/20030306.asp
Accessed on: 29 October 2007'

Recommendations

1. Define heparin as a high risk medicine in your organisation. For definitions and other examples of high risk medicines go to: www.health.vic.gov.au/vmac/projects/hrm.htm
2. Implement antithrombotic guidelines for unfractionated heparin, low molecular weight heparin (LMH) and fondaparinux.
 - Prior to prescribing UFH or a LMW heparin, the patient must specifically be asked if they have a history of heparin induced thrombocytopenia (HIT) or previous allergy to heparin and the response documented in the patient's medical history and where appropriate on the medication chart.
 - An accurate and current medication history must be recorded and the patient asked about over the counter (OTC) medicines and complementary medicines (for example, St John's Wort and Gingko).
 - Recent trauma, surgery and co-existing medical conditions should be noted.
 - Prescribers should document the indication and therapeutic goal for antithrombotic therapy in the patient's medical record and medication chart.
 - Include clearly defined weight-based dosing regimens for prophylaxis and treatment. Identify whether the patient's ideal body weight, actual weight or a medical staff-approved dosing corrected weight is to be used. Include a dosing maximum where appropriate.
 - Define dosage modification required for impaired renal function.
 - Include a dosing table for adjusting infusion rates in response to APTT results and the frequency of ongoing APTT monitoring.
 - Use a standard concentration for infusions; for example, consider a maximum concentration 50 Units/mL for premixed infusions. Adjust the rate of infusion, not the concentration, to achieve dose changes.
 - Consider performing and documenting an independent double check of heparin calculations, preparations, labelling and prescriptions.
 - Include a process for withholding or resuming UFH pre- and post-invasive procedures.
 - Include procedures for managing UFH or LMW heparin overdose with reversal agents.
 - Advise that doses of UFH, low molecular weight heparin products and fondaparinux require dose confirmation if prescribed within 6-12 hours of each other.
3. Develop strict monitoring guidelines for frequent and timely review of the patient's status.
 - Include all blood results and monitoring required (noting frequency of blood tests required) when UFH is prescribed.
 - Results of blood monitoring should be documented in a standardised way.
 - Consider a separate heparin order form that includes APTT monitoring. The form should allow a range of results to be reviewed over a period of time.
 - Develop systems to ensure urgently required laboratory results are available in a timely manner, for example within two hours of a blood test.

UNFRACTIONATED HEPARIN

References

- ² *Fatal facts*. 2007, National Coroners Information System. Edition 13, June 2007
- ³ Methodist rolls out medical safeguards.' 2006 *The Indianapolis star*, Indianapolis USA Sep19, 2006
- ⁴ Institute of Safe Medication Practices, January 2009, 'ISMP' Safety Alert! – Nurse Advise-ERR. Available at: <http://www.ismp.org/Newsletters/acutecare/articles/20070419.asp> Accessed on 13 March 2009.

- Ensure that staff alter infusion rates in a timely manner in accordance with the prescriber's order, APTT results and guidelines.
- 4. Ensure dosing tables are readily accessible to all staff at the point of heparin prescribing and administration.
- 5. Include a process for non-standard or unusual UFH orders:
 - Unusual heparin orders should be questioned with the prescriber.
 - Consider introducing a dose validation system for non-standard orders. For example, a second authorised person to countersign the medical notes.
 - Consider preparing non-standard heparin infusions by pharmacy.
- 6. Rationalise and minimise the concentrations of UFH stocked.
 - Consider removing 25,000 Unit/5 mL ampoules and replacing them with premixed heparin infusion bags. Store heparin infusions, preferably packaged in a contrasting colour, separately from other infusions.
 - Only store 5,000 units/1 mL and 1,000 Units/1 mL ampoules in ward areas if there is a specific requirement for this presentation.
 - Consider not stocking heparinised saline in your organisation. Heparinised saline is no more effective than sodium chloride 0.9% for maintenance of peripheral venous cannulae but may increase the risk of heparin induced thrombocytopenia (HIT). If heparinised saline must be stocked, store separately from other heparin products and sodium chloride 0.9% ampoules to minimise selection error.

Moving from potential harm to safe care

Many organisations have already implemented safety controls for managing unfractionated heparin, however, it is recommended that all organisations evaluate their current procedures against the actions below.

Actions

Successful safety improvements require the development and implementation of sustainable procedures that that are reviewed regularly and have commitment from the range of personnel involved in heparin therapy.

Roles and responsibilities

Chief Executive Officer (CEO)

- Disseminate to relevant committees with responsibility to review and action these recommendations where appropriate. These bodies may include Clinical Governance, Drug and Therapeutics Committee, Quality use of Medicines, Medication Safety committees, directors, doctors, nurses and pharmacists.
- Ensure results of regular reviews from the relevant committees are made available on the progress toward improving and maintaining systems in regard to heparin.

Clinical Governance, Quality Use of Medicines, Medication Safety, Drug and Therapeutics Committees and Directors of Medicine, Pharmacy and Nursing

1. Define and actively increase awareness that heparin is a high risk medicine in your organisation.
2. Assess the benefits and risks of current practices of prescribing, administration and monitoring of heparin within your organisation and review these practices in accordance with the recommendations of this alert.
3. Develop or review guidelines for heparin in accordance with these recommendations.
4. Ensure a formal process exists for approving guidelines, prescription order forms and flow sheets before use in your organisation.
5. Heparin guidelines and procedures should become part of your organisation's training and competency assessment programmes. They should be included in orientation and continuing education sessions for

- relevant clinical staff. Ensure staff initiate appropriate action required for results outside the therapeutic range.
6. Guidelines should include a safe storage policy for heparin that minimises and clearly differentiates the heparin products stocked.
 7. Ensure supplies of the standardised pre-mixed heparin infusion are available on relevant wards and rationalise stocks of formulations of UFH that may be used to prepare a heparin infusion (if 25,000 Units/5 mL ampoules are required, consider segregated storage). Check locations of UFH presentations so that those used for treatment and catheter patency are stored separately.
 8. Communicate any changes to heparin presentations stocked, or to guidelines and processes for documenting orders and blood results, to all relevant staff.
 9. Assess and ensure medical, nursing and pharmacy staff are competent to perform their roles and responsibilities for heparin therapy according to your guidelines.
 10. Use the designated audit tool to evaluate heparin therapy and storage in your organisation. The audit tool encourages a step-by-step approach to the documentation of the actions and improvement towards the safe heparin use in your organisation. The audit tool can be found at: www.health.vic.gov.au/vmac/projects/hrm.htm
 11. Consider broader review of antithrombotic practice using the Medication Safety Self Assessment tool for antithrombotic therapy in Australian Hospitals
 12. Use the findings of the audit for regular review and feedback to those committees with the responsibility for action.
 13. Ensure a reporting process is designed to capture heparin errors and near misses in your organisation. Use reported events to develop error prevention strategies.

Consumers

Inform and involve consumers in discussions around prescribing, administration and dispensing of heparin products including indications for use and possible adverse effects, as appropriate.

Acknowledgements and further information:

- How-to guide: Prevent harm from High-Alert Medications. 5 million lives campaign, Available at: <http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/> (Originally accessed : 23/10/07)
- Medication Safety Self Assessment® for Antithrombotic Therapy in Australia Hospitals (MSSA-AT) developed by the Institute of Safe Medication practices (ISMP) USA, and adapted with permission by NSW TAG for use in the Australian health care environment. Available at: http://mssa.cec.health.nsw.gov.au/at2/MSSAT_introduction.html
- Hadaway, Lynn C 2000 'Managing I.V therapy: 'high alert' drugs keep nurse managers ever watchful.' *Nursing management*. Volume 31, issue 10 Chicago.
- Medication Safety 2007 'High-alert medication 2007- anticoagulation.' *Journal of Pharmacy Practice and Research* Volume 37, No 1.
- National Patient Safety Agency, 2007, Patient Safety Alert 18, UK.
- Medication Safety Committee, Alfred Health, Victoria, Australia.
- The National Working Party on the Management and Prevention of Venous Thromboembolism (2004). *Diagnosis and Treatment of Venous Thromboembolism: Best Practice Guidelines for Australia and New Zealand*. First Edition. Health Education & Management International, Sydney. Available at: [http://stgcs.med.unsw.edu.au/STGCSWeb.nsf/resources/GPInfo/\\$file/VTE_Diagnosis_and_Treatment_Australian_Guidelines-Volume1.pdf](http://stgcs.med.unsw.edu.au/STGCSWeb.nsf/resources/GPInfo/$file/VTE_Diagnosis_and_Treatment_Australian_Guidelines-Volume1.pdf)
- The National Working Party on the Management and Prevention of Venous Thromboembolism (2007). *Prevention of Venous Thromboembolism: Best Practice Guidelines for Australia and New Zealand*. Fourth Edition. Health Education & Management International, Sydney.

Available at:

<http://www.surgeons.org/Content/NavigationMenu/FellowshipandStandards/Resourcesforsurgeons/>