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UPDATE: Heparin and Change in USP Monograph – Possible Potency Variation

- The U.S. Food and Drug Administration (FDA) previously issued a Public Health Alert to inform healthcare providers of a change to the United States Pharmacopeia (USP) monograph for heparin, effective October 1, 2009.[1]
- Results of human plasma and animal studies (performed at the request of the FDA) demonstrated:[1]
  - *An approximate 10% decrease in heparin activity of the "new" heparin products compared to "old" heparin products;*
  - *Large individual variations in aPTT responses to a given dose of heparin. Therefore, in a clinical setting, a 10% decrease in heparin dose might not be reflected in the results of an aPTT or ACT (Activated Clotting Time) for an individual patient.*
- Important information and clinical recommendations from the FDA include:[1]
  - *Be aware that there is an approximate 10% decrease in the anticoagulant activity (potency) of the "new heparin" compared with the "old heparin".* The difference in potency is unlikely to be clinically significant in most situations, as individualization of heparin dosing has long been the standard for clinical use due to variability in patient-specific factors that can affect response to the drug.
  - *Continue to exercise clinical judgment in determining the dose of heparin.*
  - *Continue to individualize heparin dosing to the specific patient/patient-specific clinical situation.*
  - *Understand that the labeling for heparin, including the recommended doses for heparin has not changed.*
  - *Consider those clinical circumstances where the potency decrease may require dosage adjustments and more frequent monitoring, such as where aggressive anticoagulation is essential to the treatment of the patient, including:*
    - *pediatric patients undergoing extracorporeal membrane oxygenation ;*
    - *adults and children undergoing cardiopulmonary bypass ;*
    - *the treatment or prevention of life-threatening thromboses.*
  - *Be aware that heparin products, i.e., those made using both the old and the new USP standards may be available for some time.*
  - *Consider not using the products interchangeably.*
  - *Pharmacies and hospitals may wish to consider separating the supplies of old and new heparin and exhausting the supplies of "old" heparin before transitioning to the "new" product (see table below).*

Manufacturer	(Date) Availability of Lots Made to the New USP Standard	How to Identify the New Product	Additional Information/Company Contact
APP	October 2009	**"N"** will appear after the *Expiration Date*	http://www.appdrugs.com
B. Braun	October 2009	**"N"** will appear after the *Lot Number*	http://www.bbraunusa.com
Hospira	October 2009	*Lot Numbers* will begin with the number "82" or higher	http://www.hospira.com/Files/HeparinUSP.pdf
Baxter	October 2009	**"N"** will appear before the *Lot Number*	http://www.baxter.com/index.html

- Providers should enter any adverse events into the VA Adverse Drug Event Reporting System (VA ADERS).

REFERENCES

1. FDA Drug Safety Communiaction. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207506.htm . Accessed April 7, 2010.

ACTIONS

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS).*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe these medications (e.g.,* ***inpatient staff, primary care providers, nurses, cath lab personnel, and pharmacy****, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*