Hemodilution

EBAA Annual Meeting 2012

Must Qualify Blood Sample

• EBAA Medical Standards
• AATB Medical Standards
• FDA Rules & Guidance Documents
• State Regulations
• FDA reports for 2011 identified 6 deviations for incorrectly evaluating plasma dilution

Why

• Avoidance of false negative serological results in cases where blood or plasma is diluted with intravenous fluids, colloids, or blood products.
Diluted Blood

Pre-infusion Blood

Higher concentration of antibodies and antigens

Lower concentration of antibodies and antigens

POSITIVE Serology Result

FALSE NEGATIVE Serology Result

When

Every time or when “Justified”?

FDA Guidelines

• Under age 12
• <45Kg or >100Kg
• Blood Loss
• Infusion or Transfusion >2000cc

Volume Calculations

• Algorithms should account for both:
  – Blood Volume
    • Mass/0.015
  – Plasma Volume
    • Mass/0.025
  – Mass (Kg)
    • Body weight (lbs)/2.2
Blood & Colloid Products

- **48 Hour Relevancy**
  - **Blood**
    - Account with Blood Volume
      - Packed Cells
      - Whole Blood
      - Leukocyte reduced
        (do not include autologous non banked blood reinfused in same surgical procedure)
  - **Colloids**
    - Account with Plasma Volume
      - FFP
      - FTP
      - Platelets
      - Albumin
      - Others...
        - Dextran, Hespan, Hetastarch

- **Reasoning**
  - Blood (48 hrs)
    - Must allow for life cycle of RBCs and cellular material
  - Colloids (48 hrs)
    - Proteins and extracellular material create osmotic gradient leading to longer lasting fluid imbalance
  - Crystalloids (1 hour)
    - Water moves quickly between intravascular and intracellular spaces
      - Kidney Function

Crystalloids

- **One Hour Relevancy**
  - Account with Plasma Volume
    - NS
    - LR
    - DSW
    - TPN
    - Others

Premortem / Postmortem

- **Premortem** – relevant time frame for product prior to sample draw time.
- **Postmortem** – relevant time for product frame prior to time of death
Exclusion Criteria

• If the total volume infused and transfused is equal to or in excess of the donor’s total blood volume or plasma volume, the sample is not suitable for testing.

Pre-Mortem Testing

• Different qualification
• Tube requirements
• Sample integrity
  – Days
  – Centrifugation
  – Refrigeration
• Volume

Still need to validate sample qualification

Sample Validation

• Sources?
Problem Cases

- Pre-transfusion samples with fluid administration
  - must qualify with algorithm
- Unconfirmed blood loss
  - internal bleeding
- Infusions without evidence of bleeding
  - dilution of blood
- Donors <45Kg or >100Kg in body weight
  - includes pediatric donors and obese donors
- Undocumented volumes of blood products
  - must confirm maximum volume for each product