Guidelines for the use of blood warming devices (AABB)

Reference: 2002 AABB
Introduction

• Hypothermia
  – Induced by rapid, large-volume transfusion of refrigerated blood components
  – A potential source of serious complications
  – Especially in pediatric and elderly

• Prevent systemic hypothermia
  – Warming of blood component and other IV fluids during massive transfusion
Blood warming technologies

- Countercurrent heat exchange
- Dry heat
- Thermostatically controlled waterbath
- In-line microwave
• Countercurrent heat exchange
  – Have a multiple lumen tubing assembly
  – Water circulates the length of the tubing to the patient
  – Preventing conductive heat loss before infusion
  – Have a fluid delivery temperature of 35~41°C with rapid flow rates and low priming volumes
Reference: Canadian journal of anaesthesia, 1995
• Dry heat
  – Previous comparative studies indicated less efficiency
  – Recent improvements and design changes
  – More convenient to use
    • No water chambers are required
    • Some do not require special transfusion sets.
Reference: Canadian journal of anaesthesia, 1995
Comparison of fluid warmer performance during simulated clinical conditions.

- Room Temperature: 20°C
- Initial Fluid Temperature: 20°C

The graph shows the temperature change over different flow rates. The recommended flow rate is indicated within the shaded area.
• Thermostatically controlled waterbath
  – Immersing the entire unit of blood into the heated water
  – This is older technology and has several safety concerns
  – To ensure even warming, blood must be agitated during the warming process
  – The unit is hung for transfusion it begin to cool rapidly
  – It is possible to inadvertently return the unit to general inventory should the unit not be needed.
• In-line microwave
  – Single-patient, disposable-tubing assemblies that fit into the warming chamber (where the blood passes through, is heated to approximately 37 C)
  – Affects the warming efficiency
    • The initial temperature of the blood component
    • The flow rate through the heating chamber
– The blood is heated while passing through a small disposable cartridge inserted into the microwave cavity.
– The microwave energy emitted in the cavity is strictly controlled
– The temperature of the fluid is measured and displayed throughout the heating process
• Blood warmers
  – Must have an exact temperature control to prevent hemolysis caused by excessive heat
  – An alarm system and a visible temperature display are required
  – In order to comply with AABB, CAP, FDA regulation, a blood warmer must be properly maintained and either be FDA-approved
As with all equipment used in the blood bank and transfusion process

- Must be procedures for equipment operation
- Validation
- Routine preventive maintenance
- Quality control (training and competency of staff)
- Properly documented installation, validation, and maintenance records
- The blood bank medical director should be actively involved in establishing these procedures
Advantages of blood warming devices

• To prevent the complication caused by hypothermia
  – Improving survival rate and patient outcomes (including decreased length of hospitalization)

• Hypothermia
  – Defined
    • Reduction in core body temperature below 35°C
Hypothermia

• Side effects
  – Cardiac arrhythmia
  – Hemostasis abnormalities from impaired platelet function and slowed enzymatic reactions in the coagulation cascade
  – Vasoconstriction
  – Dehydration
  – Lack of oxygen to tissue
  – Increased red cell release of potassium
  – Citrate toxicity(with blood component transfusion)
• Side effects
  – The metabolism of drugs is also impaired (prolong)
  – Immune function impaired (reduced oxygen in tissue impairs oxidative killing of bacteria by neutrophils)
  – May promote surgical-wound infection (reduces the deposition of collagen during wound healing)
• If the core body temperature reaches 25~30 C
  – Cardiac output decreases
  – Ventricular irritability increase
  – Possibly leading to ventricular fibrillation
  – Cardiac arrest
Disadvantages and complications

- Risk of hemolysis
- Risk of sepsis
- Decreased Infusion Rate
- Inefficient Heat Transfer
- Expense
• Risk of hemolysis
  – The red cell membrane become less pliable at higher temperature and is more susceptible to the effects during rapid transfusion
  – Thermal injury to red cells may occur if is not used according to the manufacturer’s directions
  – If the flow within the warmer is stopped temporarily, the temperature may rise above 37°C, resulting in slight hemolysis
  – Out of order
• Risk of sepsis
  – Due to bacterial growth at warmed temperature is increased (especially if the blood is kept warm for a prolonged period of time)
  – All disposables should be inspected before use and installed according to the manufacturer’s directions (damage disposables could leak contaminated water)
• Risk of sepsis(2)
  – Warm waterbaths
    • Have the potential risk of harboring pathogens that could contaminate the ports or injection sites of the blood bags
    • Water may be splashed into the sterile field during insertion of the transfusion disposables
    • Water-tank decontamination procedure is essential
• Decreased Infusion Rate
  – The long, narrow tubing increases the resistance to flow and reduces flow rate.
  – In trauma situation, this decrease in infusion time may be detrimental.
  – The selection of equipment designed for rapid infusions will offset this drawback.
• Inefficient Heat Transfer
  – Limited by the flow rate of the infusion
  – Limited by the heating technology of the device in use
  – Most do not deliver normothermic (37C) fluids at very rapid flow rate (only 33~36C)
• Expense
  – The cost of the equipment
  – The disposables
  – Staff training
  – Quality control
  – Preventive maintenance
Indication for use

- Massive transfusion
- Trauma situations in which core-rewarming measures are indicated
- Administration rate > 50mL/min for 30 minutes or more (Adult)
- Administration rate > 15mL/kg/hour (Children)
- Exchange transfusion of a newborn
- Patient re-warming phase during cardiopulmonary bypass surgical procedures
• Using blood warmer should be based on
  – The size and clinical status of the patient
  – Blood loss
  – Replacement needs
  – Rate of transfusion
  – Available warming systems
• Other clinical situations where blood warming may be considered
  – Potent, high-titered, cold autoantibodies, reactive at body temperature and capable of binding complement, thus causing hemolytic anemia
  – Raynaud’s syndrome or other cold-induced vasoactive effects
  – Neonatal and pediatric transfusions
  – Therapeutic plasma apheresis or red cell exchange procedures
Contraindications

- Blood warmers are not usually needed or provide no clinical advantage in situations such as:
  - Elective transfusions at conventional (slow) infusion rate
  - Most cold agglutinins encountered in pretransfusion testing
  - Patient experiencing shivering and discomfort due to the cold (Method to warm the patient, not the blood)
  - Administration of Platelets, Cryoprecipitate, or Granulocyte suspensions (Warming may render these products less effective)
There are many warnings to consider when using blood warming equipment:

- Do not use fluid warming equipment that is not FDA-approved for use with blood components, or is not internally validated
- Do not use faulty blood warming equipment
- Do not use transfusion sets not approved for use with the blood warming device
- Do not warm blood components by placing on or near a radiator, heater, stove, patient-warming blanket, or in a conventional microwave oven or plasma thawer
Warnings(2)

- Do not allow the unit to sit at room temperature for prolonged periods to warm up
- Do not place blood components under running hot tap water or in an unmonitored or improvised warm waterbath
- Do not place pediatric syringe aliquots or transfusion tubing under warming lamps. Validated shielding should be used to prevent inadvertent and uncontrolled (over) warming when tubing has to pass through a warmed field
– Do not return blood components that have been warmed to inventory

• Even warming is imperative, the addition of heated saline as a diluent/admixture to red cell is difficult to standardize or control

• However, it does have the advantages of rapid heating, not requiring expensive equipment, and the rapid infusion of diluted blood
Choosing an appropriate blood warming device should be based on:

- Equipment cost
- The cost of disposables
- The ease of use (Training concerns)
- The disposables used should be latex-free
- Noted in the transfusion record
Compliance Issues (AABB)

• Blood warming devices must have
  – A visible thermometer
  – A warning system to detect malfunction
  – The warming method should not cause hemolysis

• The standards regarding critical equipment and process control include:
- Defined processes for installation, calibration, validation, and documentation of problems encountered
- Equipment management
- Development of procedures and schedules for calibration and maintenance
- Documentation of period calibration and maintenance, timeliness of repairs, and post-repair calibration
Compliance Issues (CAP)

- TRM41500
  - An FDA-cleared blood warming system must be equipped with special feature to alert the user to proper transfusion conditions
  - The blood-warming system must be
    - FDA-cleared
    - Properly maintained
    - Special features (a visible thermometer and a audible alarm)
    - Does not damage to the blood component being warmed
• TRM41000
  – Transfusion service must have a written policy and procedure for blood administration
  – Transfusion personnel have been trained and are competent in the procedure
Quality Assurance

- Ownership
  - The primary difficult encountered by transfusion services
- Several different brands or types of blood warmers may be in use within the hospital
- Distributed through several departments such as surgery, emergency……
- The users may include nurses, anesthesiologists, technicians.
• The transfusion service medical director responsibility
  – Ensuring the proper function of blood warmers
    • Determining procedures
    • Frequency of testing
    • Review and retention of records
• If the biomed department routinely performs only electrical safety checks:
  – Alarm activation
  – Effluent temperature/thermometer calibration
  – Cleaning and disinfecting of the water tank (If applicable)
• Quality control procedures and routine maintenance must be performed, documented and reviewed
• Any devices found to be out of control or faulty must be sequestered and promptly followed by corrective action
• Staff training and continued competency assessments must be performed and documented
Thank you for your attention