Guidelines for the use of blood warming devices（AABB）

Reference: 2002 AABB

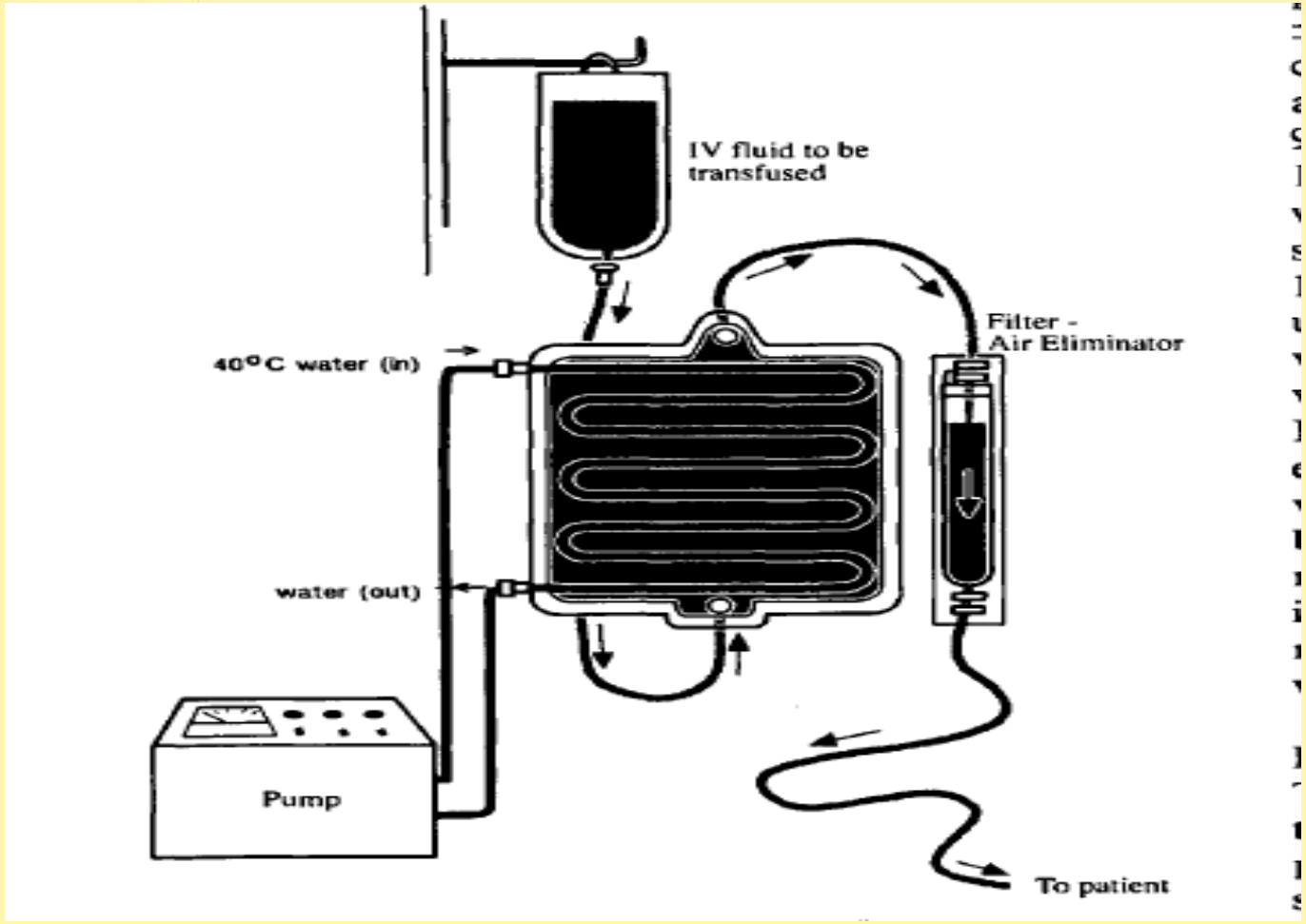
Introduction

- 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

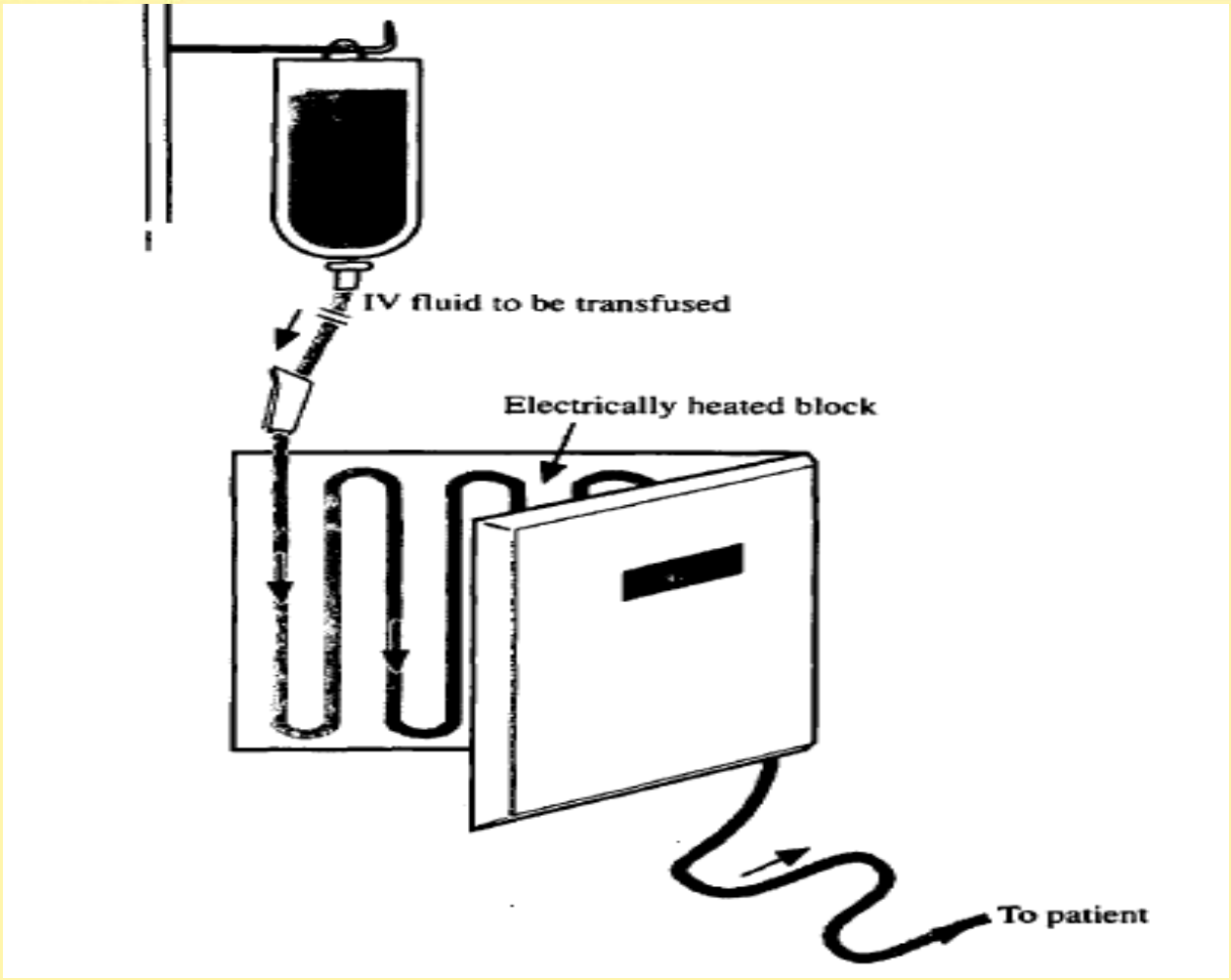
- Countercurrent heat exchange
  - Have a multiple lumen tubing assembly
  - Water circulates the length of the tubing to the patient
  - Preventing conductive heat loss before infusion
  - Have a fluid delivery temperature of 35~41 C with rapid flow rates and low priming volumes



Reference : Canadian journal of anaesthesia, 1995


八光血液加温器 HBW-5
HAKKO BLOOD WARMER MODEL HBW-5
38
38

- 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.



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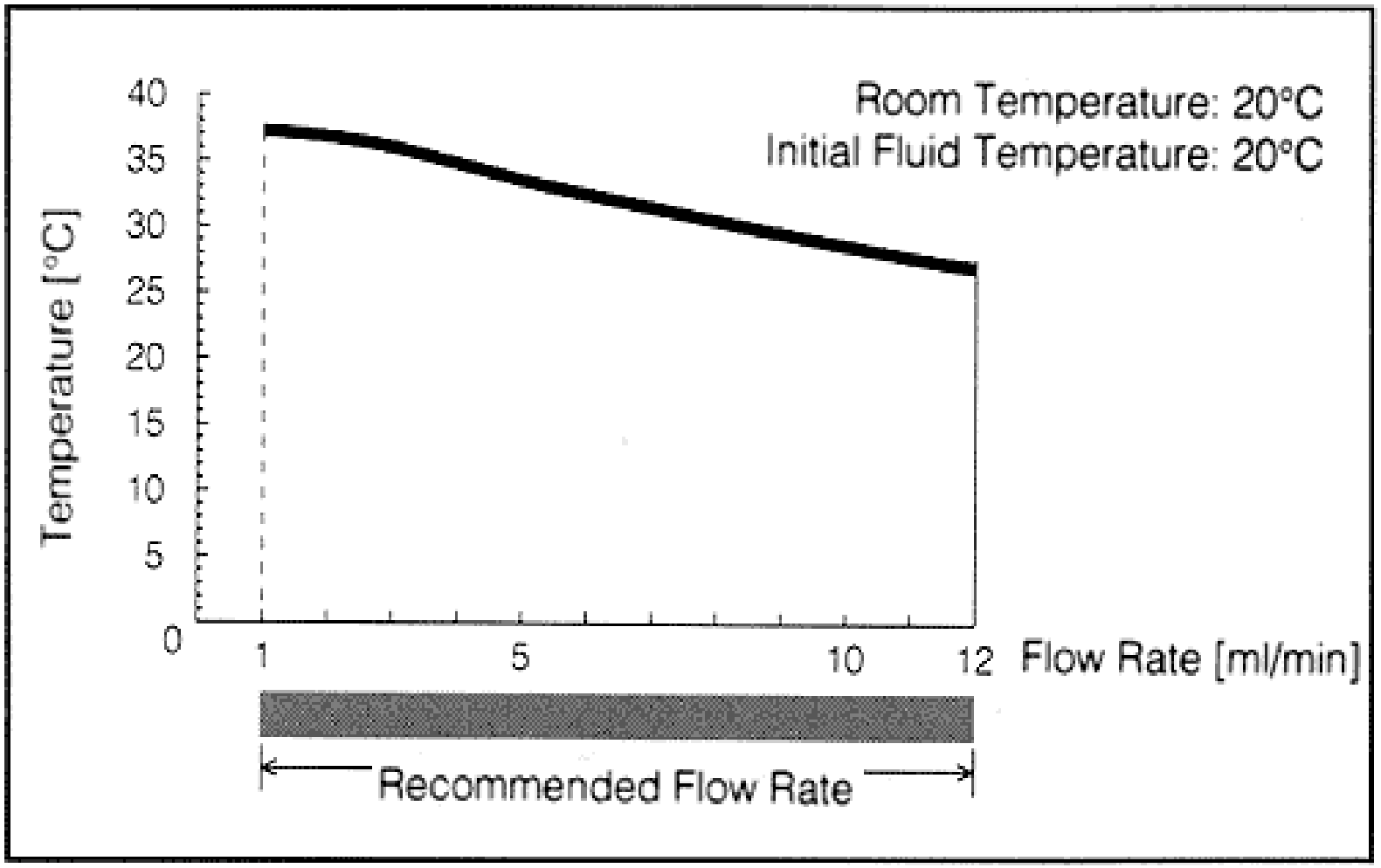
Room Temperature: 20°C
Initial Fluid Temperature: 20°C
Temperature [°C]
40
35
30
25
20
15
10
5
0
1
5
10
12
Flow Rate [ml/min]
Recommended Flow Rate

- 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 35C

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 37C, 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)

Warnings

- There 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

Warnings(3)

  - 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

Administrative aspects

- 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 propertransfusion 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