

**ASATT Region 1 & 2 Meeting**  
**March 23, 2024**

# **BEST PRACTICES IN AUTOTRANSFUSION**

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Further, Together

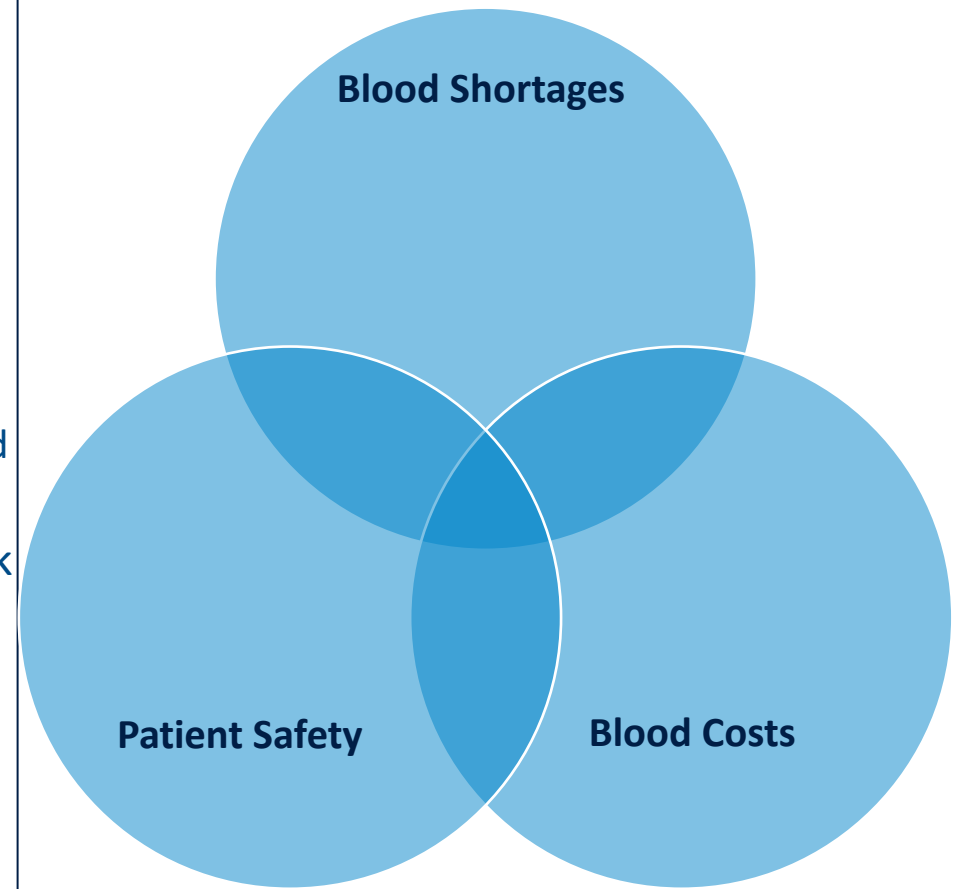
# OBJECTIVES

- Recognize that Perioperative Blood Management is highly indicated due to the ongoing lack of donor blood
- See that Autotransfusion can be implemented in an incremental and cost-effective manner
- Understand that fastidious anticoagulation and quality control testing are key requirements in Autotransfusion
- Realize that Autotransfusion is one of the key modalities in Perioperative Blood Management as stated in the STS/SCA/AmSECT/SABM Blood Conservation Guidelines

# REALITIES OF BLOOD

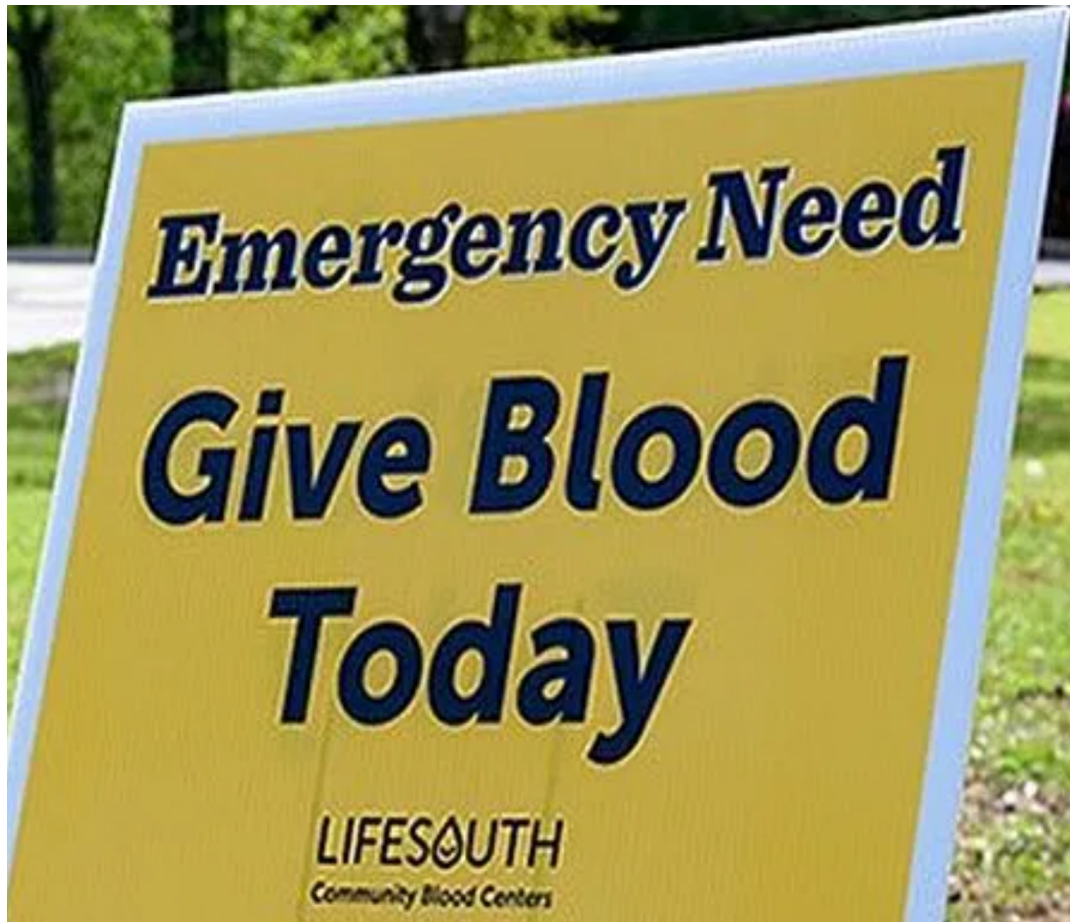
- The need for blood conservation in cardiac surgery is driven by three key factors:
  - **Blood Shortages:** Complex surgeries and low donation rate can cause blood shortages (Blood facts and Statistics, February 15, 2018, [www.redcrossblood.org](http://www.redcrossblood.org))
  - **Blood Cost:** Additional safety measures can add costs to blood products, (Shander, A, et al, Activity-based costs of blood transfusions at four hospitals. Transfusion50(4),753-765)
  - **Patient Safety:** Blood transfusion introduces patient risk
    - Correlated to increased viral and bacterial infections
    - Longer length of stay (LOS)
    - Increased incidence of adverse reactions

AABB Guidelines For Blood Recovery And Reinfusion in Surgery and Trauma, 2010, pg.1



# COVID-19 IMPACTS BLOOD SUPPLY

## AUTOTRANSFUSION NEEDED EVEN MORE!



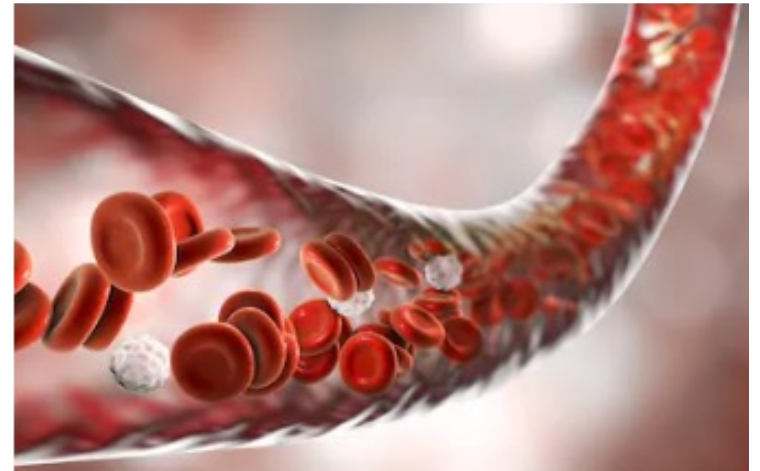
- The American Red Cross stated that as of March 19th:
  - More than 2700 of its blood drives were canceled across the US over coronavirus concerns
  - Approximately 86,000 fewer blood donations
- More than 80% of donated blood collected is from drives at locations closed for social distancing: workplaces, schools, and college campuses
- American Red Cross provides ~40% of blood products to US hospitals
- ARC currently offering incentive-free COVID-19 antibody test with donation



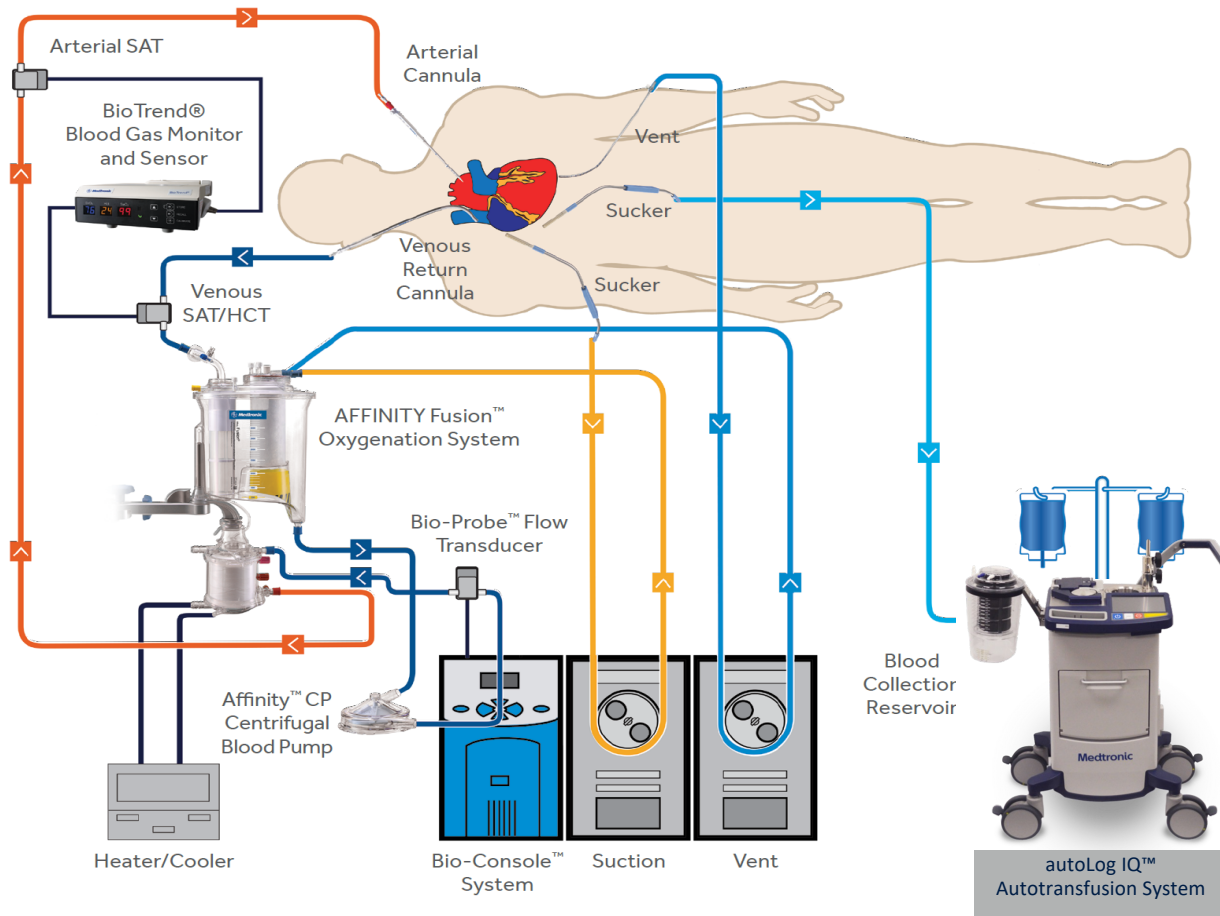
- Hospitals being forced to evaluate elective surgeries to ensure there is enough blood supply in advance of surgery

# WHAT IS AUTOTRANSFUSION?

Autotransfusion is the collection of blood or blood products derived from a patient's own circulation (autologous blood) which is collected or shed from a wound or body cavity prior to, during or following surgery for later reinfusion to the patient.



# WHAT IS AUTOTRANSFUSION?



## Autotransfusion is indicated when:

- Anticipated blood loss  $\geq$  15-20% blood volume
- When 2 units of blood are cross matched
- Average transfusion volume  $>$  2 units
- Patients with rare blood types
- Surgeries where 20% or greater are transfused
- Patients who refuse banked blood due to religious considerations

## Examples of Use areas

- Cardiac Surgery (15-20% of blood transfusions)
- Orthopedic Surgery
- Neurosurgery
- Obstetrics / Gynecology
- Urology
- Vascular
- Spine
- Trauma



## Clinical Benefit

- Reduces transmission of blood borne disease
- Lowers risk of transfusion reaction
- Helps address blood shortages



## Financial Benefit

- Reduces use of costly blood
- Helps reduce costs of transfusion related reactions
- Reduces costs associated with clerical errors (when type and cross matching)



# PATIENT OUTCOMES IN CV SURGERY

## CONCLUSION:

**“PERIOPERATIVE RED BLOOD CELL TRANSFUSION IS THE SINGLE FACTOR MOST RELIABLY ASSOCIATED WITH INCREASED RISK OF POSTOPERATIVE MORBID EVENTS AFTER CABG.”**

## MORBID EVENTS INCLUDE:

- RENAL MORBIDITY
- PROLONGED VENTILATION TIME
- SERIOUS POST-OP INFECTION

**STUDY DESIGN:** MORTALITY AND MEASURES OF MORBIDITY WERE COMPARED BETWEEN PATIENTS TRANSFUSED AND THOSE NOT TRANSFUSED

**PATIENTS:** 11,963 PATIENTS WHO HAD ISOLATED CABG JAN 1995 – JUL 2002

Koch et al. *Critical Care Medicine*. 2006;34(6)

Morbidity and mortality risk associated with red blood cell and blood-component transfusion in isolated coronary artery bypass grafting\*

Colleen Gorman Koch, MD, MS; Liang Li, PhD; Andra I. Duncan, MD; Tomislav Mihaljevic, MD; Delos M. Cosgrove, MD; Floyd D. Loop, MD; Norman J. Starr, MD; Eugene H. Blackstone, MD

**Objective:** Our objective was to quantify incremental risk associated with transfusion of packed red blood cells and other blood components on morbidity after coronary artery bypass grafting.  
**Design:** The study design was an observational cohort study.  
**Setting:** This investigation took place at a large tertiary care referral center.  
**Patients:** A total of 11,963 patients who underwent isolated coronary artery bypass from January 1, 1995, through July 1, 2002.  
**Interventions:** None.  
**Measurements and Main Results:** Among the 11,963 patients who underwent isolated coronary artery bypass grafting, 5,814 (48.6%) were transfused. Risk-adjusted probability of developing in-hospital mortality and morbidity as a function of red blood cell and blood-component transfusion was modeled using logistic regression. Transfusion of red blood cells was associated with a risk-adjusted increased risk for every postoperative morbid event: mortality (odds ratio [OR], 1.77; 95% confidence interval [CI], 1.67-1.87;  $p < .0001$ ), renal failure (OR, 2.06; 95% CI, 1.87-2.27;  $p < .0001$ ), prolonged ventilatory support (OR, 1.79; 95% CI, 1.72-1.86;  $p < .0001$ ), serious infection (OR, 1.76; 95% CI, 1.68-1.84;  $p < .0001$ ), cardiac complications (OR, 1.55; 95% CI, 1.47-1.63;  $p < .0001$ ), and neurologic events (OR, 1.37; 95% CI, 1.30-1.44;  $p < .0001$ ).  
**Conclusions:** Perioperative red blood cell transfusion is the single factor most reliably associated with increased risk of postoperative morbid events after isolated coronary artery bypass grafting. Each unit of red cells transfused is associated with incrementally increased risk for adverse outcome. (Crit Care Med 2006; 34:1608-1616)  
**Key Words:** blood cells; hemoglobin; complications; cardiopulmonary bypass; cardiovascular disease; mortality

**A**dministration of packed red blood cells (PRBCs) has been associated with morbidity and mortality for both medical and surgical patients (1-13). Transfusions are associated with transmission of infectious agents (5), postoperative infectious complications (4, 10, 13), sternal wound infections (1), postoperative pneumonia (11), renal dysfunction (6), impaired postoperative pulmonary function (3), multiple organ failure (7), increased intensive care unit (4, 9, 10) and hospital length of stay (4, 9), and increased short- (2, 8) and long-term mortality (12). Gong et al. (14) recently demonstrated the association between PRBC transfusion and the development and increased mortality from acute respiratory distress syndrome. As little as a 1-unit transfusion of PRBC was associated with increased mortality. Previous investigations have been limited by examining PRBC transfusion as a binary variable (1, 12), thereby limiting examination of a dose-dependent effect, have not included both intraoperative and postoperative PRBC transfusions (1), or have not included the influence of blood components such as platelets, fresh frozen plasma, and cryoprecipitate (4, 7-9, 12). Previous investigators have examined heterogeneous patient populations (2, 4, 7, 9) such as mixed surgical, medical (2, 4), or trauma patients (7, 9). Furthermore, there is heterogeneity within the cardiac surgical literature with the inclusion of mixed valve and coronary artery bypass grafting (CABG) patients who often have different transfusion requirements. Finally, a number of investigators have examined a single morbid outcome and have been limited by sample size.

1608 Crit Care Med 2006 Vol. 34, No. 6



# WHAT ARE THE REAL COSTS OF TRANSFUSION?

- Activity-based costs of blood transfusion in surgical patients at four hospitals, Shander, A. et al, Transfusion 2010;50:753-756
- Englewood Medical Center, Englewood, NJ, Rhode Island Hospital, Providence, RI, University Hospital, Lausanne, Switzerland and General Hospital, Linz, Austria (both have similar costing models to LA)
- COBCON (Costs of Blood Consensus) and ABC (Activity Based-Costing)
- Direct and indirect overhead costs, not just acquisition costs
- \$552-\$1183 with a mean of \$761 +or- \$294
- 3.2 to 4.8 fold higher than initial product costs
- “Blood costs have been underestimated”

# INDICATIONS FOR USE PER AABB

- “Start with a collection system that includes a Collection Reservoir, a suction line and an anticoagulant”
- “The cost for this stand-by setup or collection only system is comparable to the reagent costs for typing and cross-matching two units of allogeneic red blood cells (RBCs).”
- “In cases where the blood loss is certain”... “it is reasonable to immediately begin collecting and processing recovered blood for reinfusion.”
- “Especially useful”... “open-heart surgery, vascular surgery, total joint replacements, spinal surgery, liver transplantation, ruptured ectopic pregnancy, and trauma.”

AABB Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma, 2010, pg. 2

# STANDBY COLLECTION SYSTEM

- Procedures where **two (2) units of blood** are routinely cross-matched (That cost is equivalent to setting up a collection reservoir, suction/anticoagulant line and a bag of anticoagulant)
- Start with a “Stand-by” setup to include a collection reservoir, reservoir connector, suction/anticoagulant line, vacuum line, and anticoagulant
- Anybody in the OR can be trained on how to set this up



# THE GOAL OF PERIOPERATIVE AUTOTRANSFUSION

- Return red blood cells to the patient
  - Highest quantity
  - Highest quality
  - Lowest waste
  - As fast as possible



# AUTOTRANSFUSION DISPOSABLE COMPONENTS

- Suction tip
- Double lumen Suction/Anticoagulant line
- **Anticoagulant solution**
- Filtered collection reservoir
- Centrifuge bowl and disposable tubing set (tubing, bowl, holding bag and waste bag)
- 0.9% Saline wash solution bags
- Blood transfer bags

# FDA WEBSITE APRIL 7, 2010

Data from post market studies reinforce FDA's previous recommendation for healthcare professionals to exercise clinical judgment in determining the dose of heparin for a patient and consider the clinical circumstances where the potency decrease may require dosage adjustments and more frequent monitoring.

- Heparin products made using both the old and the new USP standards may be available for some time (last production lots of old potency expire fall of 2011)
  - do not use the products interchangeably.
  - separate the supplies of old and new heparin and exhausting the supplies of "old" heparin before transitioning to the "new" product
- FDA recommends that healthcare professionals:
  - Be aware that there is an approximate 10% decrease in the anticoagulant activity (potency) of the "new heparin" compared with the "old heparin"
  - 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 but not limited to:**
    - pediatric patients undergoing extracorporeal membrane oxygenation
    - adults and children undergoing cardiopulmonary bypass
    - the treatment or prevention of life-threatening thromboses

# HEPARIN POTENCY NEW USP AFFECTED DOSAGE

- Prospective study period Dec. 2011 – Oct. 2012
- CABG 1<sup>st</sup> time surgery using CPB
- Results: “new” heparin group required 12% increase in dose
- Post heparin ACT in the new group fell by 9.1%
- % of patients achieving an ACT > 480 seconds fell by 12.8%
- % of patients achieving an ACT > 480 seconds in retrospective and prospective study groups was only 61.5%
- Conclusion: An increased loading dose of 12% is required to achieve the results seen before the heparin USP change

Andersen, D. JECT 2013

# EFFECT OF NEW HEPARIN ON ACTIVATED CLOTTING TIME DURING PEDIATRIC CARDIAC SURGERY

- Retrospective review before and after the change in heparin formulation
- 266 pediatric cardiovascular patients receiving heparin doses of 400 IU/kg
- In 17.3% of the cases using the new heparin, the ACT did not reach the critical value of 400 seconds
- Median ACT times for the old heparin were 591 seconds and median ACT times for the new heparin were 484 seconds which was a difference of 18.1%
- This study demonstrated a change in heparin potency was greater than the 10% difference reported by the FDA
- The “new heparin has a trend of lower potency and frequent monitoring is required to maintain a safe level of anticoagulation during CPB”

K Thompson, et al, JECT2014;46:224-228



# AUTOTRANSFUSION ANTICOAGULATION

## Initial Anticoagulation:

- Heparinized saline - 30,000 units of heparin per 1000 mL of 0.9% Normal saline or 15,000 units of heparin per 500 mL of Normal saline (consider a higher dose of 40,000 units due to the change in heparin potency in 2010)
- Heparin complexes with Antithrombin III (ATIII)
- Heparin should NOT be used on ATIII deficient patients or patients prone to Heparin Induced Thrombocytopenia (HIT)
- ACD-A (citrate) inhibits the early steps in the clotting cascade by chelating (binding) Calcium
- Do not use ACD-A on patients with impaired liver function
- ACD-A comes pre-mixed in bags of various volumes
- Do not aspirate blood mixed with Ringers Lactate irrigation solutions as the calcium will reverse the ACD-A anticoagulant

# PRINCIPLES OF AUTOTRANSFUSION

Before commencing blood salvage:

- Prime autotransfusion reservoir with at least 200 mL of anticoagulant solution
  - 30,000 – 40,000 units of heparin per 1000 mL Saline (0.9% Normal)
  - Mix at least 1 mL of anticoagulant per 7 mL of blood which is the same as 15 mL of anticoagulant per 100 mL of blood
  - Agitate the Collection Reservoir frequently and re-prime it when it is emptied
- Suction should be maintained at approximately 80 - 120 mm/Hg under normal circumstances

# HEPARIN

## Advantages of Heparin

- Less expensive than ACD-A
- Larger fluid volume at 1000 mL
- Less potential hold up (retention) in the Collection Reservoir
- Reversal agent (protamine) is not used in irrigation solutions and calcium containing solutions like Lactated Ringers are not an issue

## Disadvantages of Heparin

- Must be pre-mixed by the operator (compounding)
- Requires adequate patient ATIII levels
- Should not be used on patients with Heparin Induced Thrombocytopenia (HIT)
- Derived from porcine sources with decreased potency and high variability issues

# CONTRAINDICATIONS

- Absolute – “inadvertent exposure of the collected red cells to solutions that cause hemolysis” such as sterile water, hydrogen peroxide, alcohol, hypotonic solutions or other solutions that are “incompatible with red cells”
- Relative – “blood aspirated from contaminated or septic wounds or obstetric/surgical fields, and areas of malignancy”
- Use of a double setup consisting of two (2) collection reservoirs and individual suction/anticoagulant lines and minimizing aspiration of frankly contaminated blood
- Transfusion of the recovered, washed autologous red blood cells through a leukocyte reduction filter

AABB Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma, 2010, pp. 6 - 7

# RELATIVE CONTRAINDICATIONS

- Cesarean sections where amniotic fluid is present – “Double suction setup with amniotic fluid minimized” ... “and use of a leukocyte reduction filter”
- Bowel contents – “Double suction setup with bowel contents minimized” ... “and use of a leukocyte reduction filter”
- Malignancies (cancer) – “Avoid blood recovery at tumor site. Medical risks and benefits should be discussed between the surgeon and the medical director of the ATS program. Consider the use of a leukocyte reduction filter or irradiation.”
- Cellulose, collagen or fibrin based hemostatic agents – “avoid aspiration where product is being used” ... “Consider use of a leukocyte reduction filter” ... “after copious irrigation with 0.9% sodium chloride solution”

AABB Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma, 2010, Appendix 1

# TANDEM COLLECTION RESERVOIR USE

- Two (2) collection reservoirs, two (2) suction/anticoagulant lines, and two (2) bags of anticoagulant solution
- Individual vacuum sources for each collection reservoir if possible
- Side by side or “Piggyback” collection reservoir configurations
- Use of a waste suction system as well
- Multiple autotransfusion devices can be used concurrently in Trauma cases

# TANDEM COLLECTION RESERVOIRS

## SIDE BY SIDE



## IN SERIES



# CONTRAINDICATIONS

- The final decision on whether to salvage and process the blood is the autotransfusion team's decision (e.g., Blood Bank, Surgeon, Anesthesiologist and Autotransfusionist)
- See the 2010 AABB Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma, Appendix 1: Complications of and Contraindications to Perioperative Blood Recovery
- Understand that some contraindications are not absolute or may be temporary in nature
- Review the product inserts regarding the approved use of that agent or device during autotransfusion



# TRAUMA OR TRANSPLANT SURGERY

- Critically important to set up the suction/anticoagulant line, anticoagulant solution and collection reservoir for aseptic blood collection as quickly as possible
- Employ liberal dosing of anticoagulant solutions and reprime the Collection Reservoirs with 200 mL of anticoagulant every time they are emptied
- Utilize dedicated vacuum sources for each reservoir
- Consider the use of tandem Collection Reservoirs and multiple autotransfusion devices
- Use the Fast or Emergency wash mode
- Increase vacuum pressure periodically to clear the surgical field

# AUTOTRANSFUSION POST-OPERATIVE BLOOD PROCESSING

- Once the patient arrives in the Recovery Room, connect the reservoir vacuum line to an intermittent Vacuum Regulator, if available
- Vacuum pressure should be set at a maximum of 80 mm/Hg
- Mark the fluid level on the Collection Reservoir if not previously completed and note the patient arrival time in the Recovery Room
- Blood must be processed and transfused within eight (8) hours from the start of blood collection
- If the reservoir is completely emptied during processing, another eight (8) hour time period can be initiated. Maximum time that the same disposable can be used is 24 hours
- Monitor fluid levels in the anticoagulant bag and Collection Reservoir on an hourly basis
- Only use chest drainage systems that are labeled for Autotransfusion use
- Terminate post-operative blood collection if drainage volumes fall under 100 ml per hour or if eight (8) hours has transpired without blood processing

AABB 10<sup>th</sup> Edition of Standards for Perioperative Autologous Blood Collection and Administration, Reference Standard 5.1.8A, pg. 18

# AUTOTRANSFUSION QUALITY CONTROL PER AABB STANDARDS

- AABB 10th Edition of Standards for Perioperative Autologous Blood Collection and Administration January 1, 2023
- AABB Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma, 2010
- Devices, disposables and operators must all be carefully monitored on a frequent basis
- FDA, Joint Commission, CAP, CLIA and State Health Departments should defer to the AABB Standards
- Devices should be validated in vitro prior to placing them into clinical use per AABB Standards if there is expired donor blood available

# AUTOTRANSFUSION QUALITY CONTROL PER AABB STANDARDS

- Adequately trained personnel with annual training, competency evaluation and recertification
- Compliance with hospital QA program and other transfusion practices
- Machine maintenance program every year of operation by trained, qualified biomedical engineering personnel
- Complete written policies and procedures
- Accurate and complete case recording with archiving of records (7 years)
- Review of protocol compliance; morbidity and mortality, and allogeneic blood component usage
- Appropriate labeling to include patient name, patient ID number, date and time of collection, expiration and “for Autologous Use Only”, “Biohazard”, and “Donor Untested”

# AUTOTRANSFUSION QUALITY CONTROL PER AABB STANDARDS

- With the product:
  - Adequate testing of all components
    - RBC: hematocrit, volume processed and returned, residual potassium, or residual plasma protein, or residual anticoagulant or free plasma hemoglobin (if available)
    - The goal is to remove 95% or greater removal of all materials other than red blood cells
    - A clear effluent line is not an adequate indicator of washout
    - Resultant hematocrits should correlate with expected ranges per the device Operator's Manual
    - Periodic quality control testing must be performed
    - Sampling techniques must be atraumatic and appropriate
    - Collection Reservoir **MUST** be sampled for comparison to final washed product in the Holding Bag

Guidance for the AABB 10<sup>th</sup> Edition of Standards for Perioperative

Autologous Blood Collection, 5.1.2, pg. 24

# AUTOTRANSFUSION QUALITY CONTROL PER AABB STANDARDS

- Atraumatic and aseptic, avoid needles and negative pressure
- Personally visit the laboratory to advise them exactly what kind of blood sample is being delivered
- Transfer samples in containers that do NOT already contain anticoagulants or preservatives
- Perform testing in a timely manner, especially if using residual potassium as the measure of washout efficiency
- Use non-serum based Lab testing devices
- Label samples appropriately
- Post wash samples could be maintained for an extended time via transfer bag segments

# AUTOTRANSFUSION FINAL PRODUCT

- Washed red blood cells in a small volume of saline
- 90 to 95% of supernatants and contaminants are removed
- Activated Clotting Time and other coagulation tests will not work because clotting factors and platelets have been removed
- The 24 hour survival rate of washed red cells that have also been irradiated in cancer cases “exceeds the venous control, due to selective loss of aged RBC’s during washing”
- Blood recovered via autotransfusion is of the highest quality available

E Hansen, J Altmeyen, J Marienhagen, K Taeger, Univ Hosp, Regensburg, Germany. Quality of Blood Salvaged and Irradiated During Cancer Surgery. Transfusion 1999-Vol. 39. Supplement, S256P

# 2011 UPDATE TO THE STS/SCA BLOOD CONSERVATION CLINICAL PRACTICE GUIDELINES (FERRARIS,V.A., ET AL, ANN THORAC SURG 2011;91:944-982)

## 2007 – Initial Release

- Evidence based medicine guidelines
- Patients at risk-age; low pre-op Hct; small body size; pre-op drugs; complex cases; emergent; co-morbidities
- TRX triggers: Hgb , 7g/dl
- TRX based indicators: oxygenation/bleeding
- Drug Therapy: amicar; tranexamic acid
- Products and practices:
  - Pump type
  - Heparin management
  - Heparin coated circuits
  - Cell washers
  - Low prime circuits
  - Minimized circuits (RAP prime)
  - Hemofiltration
  - Transfusion algorithms

## 2011 – Update

- Blood Salvage Interventions
  - **Expanded use of blood salvage (using centrifugation) I (A)**
  - Pump salvage of residual blood in CPB circuit IIa (C)
  - Centrifugation of pump blood vs direct reinfusion IIb (B)
- Perfusion Interventions
  - Microplegia to reduce hemodilution IIb (B)
  - Mini-circuits to reduce hemodilution I (A)
  - Biocompatible CPB circuits to limit hemostatic activation and lime inflammatory response IIb(A)
  - Modified ultrafiltration I (A)
  - Conventional or zero-balance ultrafiltration during CPB IIb (A)



# STS/SCA/AMSECT/SABM UPDATE TO CLINICAL PRACTICE GUIDELINES ON PATIENT BLOOD MANAGEMENT

- Tibi P, McClure RS, Huang J, et al., Ann Thorac Surg. 2021
- Routine use of red cell salvage using centrifugation in cardiac operations using CPB
- Class 1, Level A
- Acute Normovolemic Hemodilution is a reasonable method to reduce bleeding and transfusion (Class IIA, Level A)
- All participants in cardiac surgery are included: STS, SCA, AmSECT, and SABM

# PERIOPERATIVE BLOOD MANAGEMENT EXAMINATION

- PBMT - Perioperative Blood Management Technologist and PBMS – Perioperative Blood Management Specialist
- Created and maintained by IBBM (International Board of Blood Management) via American Society of Extracorporeal Technology (AmSECT)
- Available periodically for proctored on-line testing
- Examines operator competencies and they must perform 50 cases per year
- Recognized by AABB
- Recertification is already a regulatory requirement per AABB, CAP, CLIA, FDA, Joint Commission and individual state departments of health
- Covers ALL currently available autotransfusion devices in the perioperative setting
- Includes platelet rich plasma sequestration, platelet gel practices, autologous blood management programs, and anticoagulation testing

[AmSECT.org/IBBM/PBMT/PBMS](http://AmSECT.org/IBBM/PBMT/PBMS)

# CONCLUSION

- Allogeneic blood supplies are still limited and the cost of blood will continue to increase due to new testing
- Autotransfusion is an excellent clinical practice that is also very cost effective
- Autotransfusion devices and disposables can be used in an incremental fashion in the perioperative setting
- Blood collected and processed using autotransfusion devices is of the highest quality
- Autotransfusion is one of the key modalities in Perioperative Blood Management
- Only “Super Users” performing at least 50 cases a year should be operating Autotransfusion devices and they should consider taking the PBMT examination