

Quality Assurance and Quality Control in Autotransfusion: The Basics of Compliance, Safety and Practicality



**SUSAN D.
WICKERSHAM,
MLT, PBMS**

PROFESSIONAL BACKGROUND & EXPERIENCE

Susan holds an Associate Degree in Medical Technology and has expanded her expertise and passion for blood banking and patient outcomes outside the laboratory for over nearly 30 years. She began her career at the bench and followed a diverse path to a specialty in perioperative blood management and autotransfusion. She has experience in blood collections, testing and distribution, apheresis, dialysis and perioperative blood management techniques with expertise in autotransfusion and sequestration applications in cardiovascular, ortho/neuro/spine and OB. She has dedicated the last 25 years providing clinical support and educational programs to the surgical & laboratory community.

ABSTRACT

Autotransfusion is the long-established practice of collecting, processing and reinfusing the patient's own blood during surgery. The blood is collected, anticoagulated and filtered in a sterile reservoir from the sterile field. That blood is then processed through an autotransfusion device.

The device simultaneously concentrates the red blood cells while removing the plasma and most other cells to a waste bag. The concentrated red blood cells are then "washed" and transferred to a bag so they can be reinfused to the patient. This practice can significantly decrease the need for allogeneic red cell transfusions.

Quality assurance of the product obtained for transfusion is crucial to determine both safety and efficacy.

Although there are a myriad of interpretations and opinions on achieving this; the best practice is one which is evidence based, and follows the Standards and Guidance set forth by the AABB and clinical experts in the field.

AUTOTRANSFUSION DEFINED: FDA PERSPECTIVE

§ 868.5830 Autotransfusion apparatus.

(a) Identification. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due

to surgery or trauma. (b) Classification. Class II (performance standards). Title 21 Chapter I Subchapter H Part 868 Subpart F.

What is the practice of autotransfusion by FDA terms?

"The practice of autotransfusion, as a method of blood donation and transfusion, is regulated by the FDA under the guidelines for blood/ blood components intended for transfusion or further manufacturing use. The regulations ensure that blood donations are tested ... and that the blood components are suitable for transfusion."

In other words, the FDA defines autotransfusion to be manufacturing blood products and that those products intended for transfusion are tested and meet established criteria for transfusion. To adhere to this regulation, the AABB has established Standards and Guidance to ensure safety and efficacy. Both quality assurance and quality control are important aspects in this endeavor.

QUALITY ASSURANCE VS QUALITY CONTROL

Quality Assurance is: A proactive process focused on prevention by improving production processes and standards and maintaining them.

- Primary Goal: Prevent defects from happening.
- Implemented before and monitors during production.
- Long-term and system wide, covering the entire cycle.
- Includes design, training, audits, risk assessments and management.
- Is the responsibility of ALL team members.
Example: Validation of equipment for its intended use.

Quality Control is: A reactive process that occurs after production to detect and correct defects by inspecting and testing the final product.

- Testing final products to ensure maintenance of desirable quality through every stage of the process.
- Identifies "gaps" that lead to less than desirable results.
- Equipment, people, policies, processes.
Example: Periodic quality testing.

AABB PERSPECTIVE ON QUALITY IN AUTOTRANSFUSION

Quality Control- AABB Guidance for Standards for Perioperative Autologous Blood Collection and Administration 11th edition states:

"The organization must have in place a program of quality control to ensure that reagents, personnel, equipment and processes function as expected" The purpose of a quality control program for perioperative collection activities is to ensure that a component of consistent quality is made."

The program should specify the type and frequency of testing. Any failures should have a documented investigation and the recipient's chart reviewed for any adverse events.

Quality Control Measurements that may be done:

Hematocrit: Hematocrit values can be tracked over time to demonstrate continuous process control to identify trends and failures. A root cause analysis may reveal

- A partially filled bowl or premature wash (excess hemolysis)
- Inadequate pump speeds (Fill too fast)
- Dirty optics (red cell or buffy coat detector) or calibration need
- Unexpected events during the case, operator error.

Hematocrit determines concentration of red cells -"40% to 60%. Acceptable range should be determined by the institution based on manufacturer's specifications.

Color of the waste line

- Clear suggests little pfHgb - does not reflect actual amounts (of pfHgb or K+) in final product or overall efficiency of supernatant removal nor heparin concentration
- If heparin is used as the anticoagulant the measurement should be very low to undetectable. The assay that is used is critical. Only tests that do not rely on normal plasma in the sample are acceptable.

Albumin removal: Samples need to be taken from both the collection reservoir and the final product. Concentration of albumin in the final product depends on the initial concentration in the recovered blood; therefore percent removal should be calculated "(typically, it is greater than 95%)" Free hemoglobin – Recommended parameter is also percent removal. "Residual free hemoglobin may be quite

high (500-1000mg/dL) despite greater than 90% removal; particularly in orthopedic cases.

Potassium: recommended indicator is also percent removal

Note: Substances that may be harmful if transfused in sufficient quantity. If accurately sampled and tested, it is a direct reflection of patient safety of the component. Most frequently chosen: Potassium and pFgHb. These do not reflect efficiency of the process, device or operator.

A surrogate marker is defined as a measurable factor that is a substitute that reflects changes or deviations. These changes will reflect changes in clinical outcomes. It is an indirect measurement of quality, not a direct measurement of patient benefit or harm. A surrogate marker is an excellent measurement of processing efficiency because it is neither generated nor consumed during the process. Albumin has been shown to be a good surrogate for other substances soluble in plasma that may be harmful.

In order to establish how much of a given substance has been removed, draw both a pre and a post sample. Mix the sampling source well prior to sampling. Do NOT use a needle to draw samples or to fill vacutainer tubes. Sample both pre and post using a sampling apparatus such as a spike with a stopcock.

Draw pre samples mid-fill. Draw post samples after completely emptying the bowl contents. Deliver samples to lab for testing as quickly as possible.

Record both the hematocrit from the reservoir and the hematocrit of the final product. Record the volume of the final product. Record the bowl size.

To accurately calculate the percent mass of the substance:

$$\text{MASS} = \text{CONCENTRATION} \times \text{VOLUME (1-HCT)}$$

$$\text{MASS IN} - \text{MASS OUT} / \text{MASS IN} = \% \text{ REDUCTION (PE*)}$$

*Processing Efficiency Examples:

Albumin Concentration = 0.4 u/ml Volume = 225 ml
Hematocrit (1) = 45% Hematocrit (2) = 55%

$$(1) M = C \times V (1-HCT) 0.4 \times 225 (1-.45) = 55 \text{ U}$$

$$(2) M = C \times V (1-HCT) 0.4 \times 225 (1-.55) = 45 \text{ U}$$

"A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended." 5.1.2.1 – Quality control results shall be reviewed and evaluated against acceptable criteria. 5.1.2.2 – Quality control failures shall be investigated before release of test results, products, or services.

Standard 5.1.2 Quality Control

5.1.2.3 – The validity of test results and methods and the acceptability of products or services provided shall be evaluated when QC failures occur.

SUMMARY

The practice and processes of autotransfusion are more complex than they may appear. Adherence to FDA regulations and AABB Standards and Guidance are crucial to establishing and maintaining a robust and patient-focused program. 

REFERENCES

AABB Standards for Perioperative Autologous Blood Collection and Administration 11th edition and Guidance to Standards for Perioperative Autologous Blood Collection and Administration 11th edition Effective date January 1, 2025

Educational Guide to Autologous Blood Recovery Sorin Group USA, Inc.

Take the
QUIZ
on the
next page

Continuing Education Quiz

PAGE 1 of 2

To test your knowledge on this issue's article, provide correct answers to the following questions on the form below. Follow the instructions carefully.

1. What is the primary purpose of autotransfusion?

- A) To transfuse donor blood during surgery
- B) To collect, process, and reinfuse a patient's own blood
- C) To store blood for future elective procedures
- D) To increase plasma volume during trauma

2. According to the FDA, an autotransfusion apparatus is classified as which type of medical device?

- A) Class I (general controls)
- B) Class II (performance standards)
- C) Class III (premarket approval)
- D) Unclassified investigational device

3. Why does the FDA consider autotransfusion to be "manufacturing" blood products?

- A) Because blood is collected outside the body
- B) Because blood is filtered but not tested
- C) Because blood products intended for transfusion must meet established criteria
- D) Because only donor blood is regulated

4. What is the primary goal of Quality Assurance (QA) in autotransfusion?

- A) Detecting defects after production
- B) Preventing defects by improving processes and standards
- C) Inspecting final blood products only
- D) Correcting operator errors after reinfusion

5. Which of the following is an example of Quality Control (QC)?

- A) Training staff on equipment use
- B) Validation of equipment before use
- C) Periodic quality testing of final products
- D) Risk assessment and audits

6. According to AABB guidance, the purpose of a quality control program in perioperative autologous blood collection is to:

- A) Reduce documentation requirements
- B) Ensure a component of consistent quality is made
- C) Eliminate the need for QA activities
- D) Focus only on equipment maintenance

7. What is the generally acceptable hematocrit range for concentrated red blood cells after processing?

- A) 20%–40%
- B) 30%–50%
- C) 40%–60%
- D) 60%–80%

8. Which substance is identified as a good surrogate marker for processing efficiency?

- A) Potassium
- B) Free hemoglobin (pfHgb)
- C) Heparin
- D) Albumin

9. Why are potassium and free hemoglobin commonly monitored in quality control?

- A) They measure operator skill directly
- B) They indicate the efficiency of the device
- C) They directly reflect patient safety if transfused in excess
- D) They are generated during processing

10. When should post-processing samples be drawn for accurate quality measurements?

- A) Before the wash cycle begins
- B) During mid-fill of the bowl
- C) After completely emptying the bowl contents
- D) At any convenient time during surgery

Continuing Education Quiz

PAGE 2 of 2

To apply for Continuing Education/ Contact Hours:

- 1) Provide all the information requested on this form.
- 2) Provide correct answers to this issue's quiz in the box to the right
- 3) Mail this form along with \$10 Member or \$20 Non-Member (check or money order, payable to ASATT) to:

ASATT

**6737 W Washington St, Ste 4270
Milwaukee, WI 53211**

The answers to the Fall 2026 "Quality Assurance and Quality Control in Autotransfusion: The Basics of Compliance, Safety and Practicality" Quiz 1 are: (circle answers)

- | | |
|------------|-------------|
| 1. A B C D | 6. A B C D |
| 2. A B C D | 7. A B C D |
| 3. A B C D | 8. A B C D |
| 4. A B C D | 9. A B C D |
| 5. A B C D | 10. A B C D |

Quiz 1

Name: _____

ASATT Number: _____

Street Address: _____

Phone Number: _____

City: _____ State: _____ Zip: _____

Signature: _____ Date: _____

ACHIEVE 80% IN THIS QUIZ TO EARN ONE (1) CONTINUING EDUCATION CREDIT.