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### **Guidelines for Best Practices in Intraoperative Cell Salvage**

#### Introduction

The following Guidelines for Best Practices were researched and authored by the AST Education and Professional Standards Committee, and are AST approved.

AST developed the Guidelines to support healthcare delivery organization's (HDO) reinforce best practices in performing *intraoperative cell salvage* (ICS) in the operating room (OR) as related to the role and duties of the Certified Surgical Technologist (CST®), the credential conferred by the National Board of Surgical Technology and Surgical Assisting. The purpose of the Guidelines is to provide information OR supervisors, risk management and surgical team members can use in the development and implementation of policies and procedures for ICS in the surgery department. The Guidelines are presented with the understanding that it is the responsibility of the HDO to develop, approve and establish policies and procedures (P&P) for the surgery department regarding ICS practices per HDO protocols.

#### Rationale

The management of blood administration is essential to maintaining *homeostasis* in the surgical patient and requires a team approach if it is to be successful.<sup>1</sup> ICS is defined as collecting shed blood from the patient (*autologous* blood), cleaning the blood of impurities, and reinfusion of the blood.<sup>2</sup> The purpose of ICS is the replacement of lost blood that occurred due to trauma or during the course of surgery to prevent *hypovolemia* and *hypoxia* while maintaining the oxygen transport properties equivalent to that of stored *allogenic* blood, as well as reducing the risk of transfusion reaction, disease transmission and dependence on banked blood.<sup>3</sup> One method of ICS is use of the *cell saver* machine (henceforth referred to as "cell saver") to suction, wash and filter blood for parenteral administration.<sup>4</sup>

The results of research have shown that ICS has lower costs as compared to other methods of transfusion, but its use should be reserved for selected procedures based upon the amount of blood loss that typically occurs.<sup>5-7</sup> Additionally, studies have reported that patients who received ICS required fewer intraoperative units of allogenic packed red blood cells (RBC) as compared to patients who did not undergo ICS and is much safer with fewer complications as compared to allogenic transfusions.<sup>6-9</sup> In 2006, Carless et al. reported that ICS decreased the requirements for allogenic transfusion up to 40% without causing cardiovascular, immunological and neurological complications.<sup>10</sup>

As compared to allogenic transfusion and the number of risks including transmission of viral disease and immunological reactions, ICS has many advantages that promote patient safety<sup>9,11</sup>:

- Does not transmit viral diseases;
- Reduces the risk of *alloimmunization*;
- Maintains normal potassium concentration;
- Eliminates the risk of transfusing the wrong type blood;
- Does not have the risk of side-effects from antifibrinolytic agents or coagulating factors;
- Eliminates the risk of transfusing the wrong unit of blood preoperatively donated by the patient;
- Requires no preoperative preparation of the patient making ICS ideal for unexpected massive transfusion.

The following are web sites to organizations that provide additional resources and information regarding ICS techniques:

- American Association of Blood Banks <u>www.aabb.org</u>
- American Board of Cardiovascular Perfusion <u>www.abcp.org</u>
- American Society of Anesthesia Technologists & Technicians <u>www.asatt.org</u>
- International Board of Blood Management http://intbbm.org

#### **Evidence-based Research and Key Terms**

The research of articles, letters, nonrandomized trials and randomized prospective studies is conducted using the Cochrane Database of Systematic Reviews and MEDLINE®, the U.S. National Library of Medicine® database of indexed citations and abstracts to medical and healthcare journal articles.

The key terms used for the research of the Guidelines include: allogenic; alloimmunization; autologous; cell saver; homeostasis; hypovolemia; hypoxia; leukocyte filter; massive transfusion; skimming. Key terms used in the Guidelines are italicized and included in the glossary.

#### **Guideline I**

#### CSTs should know the precautions to be taken when ICS is used as well as contraindications.

- 1. Reinfusion of blood from the primary reinfusion bag when it is still connected to the cell saver can cause an air embolism. The primary reinfusion bag must be disconnected from the cell saver circuit and air evacuated from the bag prior to reinfusion.<sup>1</sup>
- 2. Several types of antibiotics and hemostatic agents should not be aspirated and re-infused due to the possibility of causing systemic adverse effects.
  - A. Antibiotics, such as bacitracin and polymyxin, should not be aspirated as intravenous (IV) administration may cause neurological and renal toxicity.<sup>12</sup>
  - B. Topical hemostatic agents, including bone wax, fibrin sealants, gelatin, microfibrillar collagen and oxidized cellulose, should not be aspirated as they may cause clotting within the body system when re-infused IV.<sup>12</sup>
  - C. CSTs, particularly in the first scrub role, should assist the surgeon in confirming antibiotics and/or topical hemostatic agents are not aspirated.
- 3. Polymethyl methacrylate (PMMA) should not be aspirated as it will obstruct the suction tubing.
- 4. Gastric or pancreatic secretions should not be aspirated as they may cause enzymatic hemolysis and are not removed during the washing step.

- 5. Controversy surrounds the use of ICS during bowel surgery, penetrating abdominal injury or any procedure where the presence of infection puts into question the possibility of collecting blood that is contaminated by bacteria. Bowley et al. conducted a randomized, controlled study reporting no evidence of an increased risk of contaminated collected blood when compared with allogenic transfusion.<sup>13</sup> Additional studies of autologous transfusion of microbiologically contaminated salvaged blood reported no adverse outcomes or increase in postoperative surgical site infections.<sup>14,15</sup> Therefore, contamination or systemic sepsis should not be considered an absolute contraindication to the use of ICS.<sup>8</sup>
  - A. Prior to aspirating the blood, the CST should assist the surgeon in thoroughly irrigating the infected surgical wound with antibiotic irrigation solution.<sup>1,9</sup>
- 6. Pleural effusions should not be aspirated, and should be suctioned using a separate suction set-up prior ICS.<sup>1</sup> After suctioning the fluid, the blood that subsequently accumulates in the pleural space can be aspirated.
- 7. Amniotic fluid should not be aspirated based on the theoretical risk of causing an amniotic fluid embolus.<sup>1,15</sup>
  - A. Evidence has increased that supports the safety of ICS in obstetrics.<sup>1,16-18</sup> However, the CST in the first scrub role should assist the surgeon in taking several precautions including providing two suction set-ups. One suction is connected to the cell saver and the other connected to regular suction fluid cannister to collect the aspirated amniotic fluid; the CST should use some method of marking the separate suction set-ups so as to eliminate any confusion.<sup>9</sup> It is recommended that a *leukocyte filter* (LCF also called a leukocyte depletion filter or leukodepletion filter) is used to reduce the fetal squamous cell contamination.<sup>1,9,16,19</sup> The amniotic fluid should first be thoroughly aspirated prior to aspirating the blood.
- 8. There are studies of the use of ICS in cancer surgery. However, manufacturers continue to recommend that ICS should not be used during surgical procedures involving a malignant tumor to prevent the metastasis of cancer cells that may have not been removed during the filtering step and are reinfused.<sup>1,9</sup>
  - A. Neider et al. provided evidence from their study that there is no difference in recurrence or long-term survival in patients who underwent a radical prostatectomy and cystectomy who received ICS versus those that received not blood.<sup>20</sup> Muscari et al. completed a prospective study on patients undergoing cancer surgery and reported no difference in the recurrence rate between those who underwent ICS versus those who did not.<sup>21</sup>
  - B. It is a co-decision of the surgeon and anesthesia provider whether ICS should be used based upon the risks versus benefits if hemorrhaging is at a level that justifies the use of ICS.
  - C. It is recommended that a LCF is used in place of the routine filter.<sup>1,9,22-25</sup> Mahmoud et al. completed a five-year retrospective controlled study of all patients undergoing metastatic spine tumor surgery (MSTS) at a single health care facility, reporting that ICS with LCF utilization significantly reduced the need for postoperative allogenic blood transfusion and normal postoperative hemoglobin levels were maintained.<sup>25</sup>
- 9. The indications, contraindications and precautions for ICS should be included in the surgery department P&Ps for ICS.<sup>1</sup>

#### **Guideline II**

Surgical personnel should be cost conscience regarding the expense to the patient for the use of the ICS and only target those procedures where there is enough bloodshed to justify setting up and using the ICS.

- 1. Medical treatment is obviously very expensive and unnecessary waste should be avoided. The demand for blood and blood products has continued to increase as well as the cost. Factors that have contributed to the increased cost of blood transfusion include aging population; increases in the costs of collecting, storing and processing allogenic blood; and the ongoing issues of contamination with human immunodeficiency virus (HIV) and hepatitis that created the need for stringent standards of testing, but increased the costs of testing.<sup>26</sup> In 2011 (most recent data that could be found during the evidence-based research conducted by AST), Toner et al., reported the results of a cross-sectional survey of a randomized sample of hospital-based blood bank and transfusion service directors regarding the costs to HDOs of acquiring and processing blood in the United States; 213 completed surveys were received. The mean cost for one unit of red blood cells (RBC) was \$210.74 and the mean charge to the patient \$343.63.<sup>27</sup> 28% of the respondents to the survey reported that costs for acquisition, screening and transfusion had significantly increased from 2006 – 2011 and 23% reported that blood shortage is a significant problem.<sup>27</sup> Waters et al. completed a review of ICS data from 2,328 patients to estimate the average cost of a packed RBC unit processed by ICS. The analysis showed that ICS can be significantly less expensive as compared to allogenic blood, but the costs of ICS can vary depending on case volume, anticipated levels of blood loss per case and initial investment costs in the equipment and training.<sup>26</sup> Cost containment is the ethical responsibility of surgical personnel to prevent the patient from having to pay for preventable expenses.<sup>28,29</sup>
  - A. Research has shown that there are specific surgical procedures and specialties in which the use of ICS is not warranted. Attaran et al., completed a retrospective and prospective data collection on cardiac surgical procedures; the data revealed that in 93.2% of the routine cardiac procedures there was an insufficient amount of bloodshed to justify the use of ICS.<sup>30</sup> Therefore, in those cases where the cell saver was set up and an insufficient amount of blood was collected, the patient was still responsible for the acquired costs.<sup>30</sup> If blood loss is less than 500 mL, the cost of using the cell saver is not justified.<sup>11</sup>

However, ICS has been proven to be a cost-effective method by reducing spending on allogenic blood transfusion in specific procedures.<sup>11</sup> Odak et al., completed an observational study of 49 patients who had been admitted to the pelvic trauma unit over a period of ten months. They reported that after using ICS, an average of 500 mL of allogenic blood was transfused postoperatively, proving ICS to be clinically effective for pelvic trauma patients as well as economical saving approximately \$118 per patient as compared to using allogenic blood transfusion.<sup>7</sup>

In 2010, Carless et al. completed a systematic review reporting that the use of ICS is justified in elective orthopedic procedures based on the finding of a 55% decrease in the relative risk of postoperative transfusion using ICS.<sup>31</sup> Zarin et al. reported a decrease in perioperative blood loss when performing revision total hip arthroplasties.<sup>32</sup> Savvidou et al. reported that ICS is clinically- and cost-effective in reducing blood loss for posterior lumbar fusion procedures.<sup>33</sup>

#### **Guideline III**

# CSTs in the first scrub role should know the methodology for collecting blood at the sterile field to effectively assist the surgeon.

- 1. The CST should assist the surgeon with examining the wound and blood to determine if the shed blood is appropriate for ICS.
  - A. The surgical site is assessed by the CST and surgeon and the correct suction tubing (waste or cell saver tubing) is used according to the type of shed blood.
  - B. The CST should assist the surgeon in confirming the following:
    - 1) Heparin that has been added to the saline is delivered to the tip of the suction cannula via the smaller bore lumen of the suction assembly at approximately 1-2 drops per second.
    - 2) The heparin is aspirated together with the blood salvaged from the surgical wound through the larger bore lumen of the suction assembly into the reservoir.<sup>9</sup>
    - 3) The flow of heparin into the reservoir is manually controlled and the flow must be adjusted according to the rate of blood collection from the surgical wound. Once collection begins, the circulator must be present to be able to adjust the rate of flow. If it is identified that a clot has formed in the reservoir the blood should be discarded and the flow rate of the heparin increased prior to resuming blood salvage.
    - 4) The anticoagulant blood to be re-infused should be suctioned from the surgical wound at a vacuum level that is less than 150 mm HG to avoid *skimming* of the blood and prevent red blood cell damage.<sup>9</sup>
    - 5) When it has been confirmed with the surgeon that at least 500 mL of blood has been collected, the blood may be processed and re-infused; approximately one-third of the collected amount of blood is lost in the cell saver.<sup>9,11,30</sup>
    - 6) The salvaged RBCs must be transfused within 6 hours.<sup>16,34</sup>
- 2. The CST must keep careful track of the amount of irrigation used to assist the surgeon and anesthesia provider in deciding if ICS is required.

#### **Guideline IV**

CSTs in the assistant circulator role should know how to set-up and operate the cell saver; the three processes for ICS: collection, processing and reinfusion; and protocols for handling processed blood to be an effective member of the surgical team.

- 1. CSTs should complete training related to the specific cell saver that is utilized by the surgery department.
  - A. It is essential that the CST complete cell saver training, even if the CST operated a cell saver at another surgery department.<sup>12</sup> This allows the surgery department to establish and document a baseline of knowledge and training completed by the CST.
  - B. If the surgery department purchases a new cell saver, the surgery department personnel should complete training on the set-up and operation of the machine.<sup>35</sup> The training should be documented that includes date(s) of the training; names and job titles of employees that completed the training; synopsis of the training that was provided; names, credentials and experience of instructors.
- 2. Due to the number of activities that simultaneously take place when ICS is employed, CSTs and other surgical personnel who are not assigned to other procedures should be available to assist the OR team, e.g., transporting cell saver to the OR, transporting blood specimens to the laboratory. If the procedure is taking place during off-hours, e.g., emergency trauma procedure, the OR team can rely on personnel from other departments such as the emergency department for additional assistance.
- 3. CSTs should know the storage location of the cell saver and single-use items to transport to and set-up in the OR. This is particularly important for emergency/trauma procedures that require quickly transporting supplies and equipment to the OR, or if unexpected severe hemorrhaging occurs during a procedure.
  - A. If the surgeon and anesthesia provider have confirmed that the cell saver will be used during a scheduled procedure, it should be transported to and set-up in the OR prior to the patient's arrival.
  - B. The cell saver and single-use items should be stored in a location that meets the manufacturer's recommendations for humidity and temperature.
- 4. The cell saver and single-use items should be set-up by the CST in the assistant circulator role according to manufacturer instructions for use (IFU).
  - A. If the surgeon and anesthesia provider are not certain if enough blood will be recovered for reinfusion, the cell saver can be set-up for standby. The reservoir outlet clamp can be attached to the outlet port of the blood collection reservoir. The clamp must be kept closed until the required amount of blood is collected to justify the cost of processing. Aspiration of blood can begin when the anticoagulant is ready, and the suction assembly can be quickly attached to the top of the reservoir via the outlet clamp and the reservoir is attached to the vacuum source.
  - B. Some types of cell savers can be operated in manual mode; however, that is not advised as it may lead to insufficient washing of the RBCs and reinfusion of contaminants such as heparin.<sup>1</sup> It is recommended that the cell saver should always be operated in automatic mode.
  - C. Sterile normal saline (0.9% NaCl) must be used as the wash solution.<sup>9</sup> Most cell savers have a minimum wash volume recommended by the manufacturer and the volume should not be decreased below this level.<sup>1</sup> However, it may be advisable to

increase the wash volume for procedures where the risk of contamination of the salvaged blood is higher as compared to other procedures, e.g., obstetrics.<sup>1</sup> The end-product of washed, packed RBCs are suspended in the normal saline to be pumped into the reinfusion bag.<sup>1,9</sup> The CST must make sure that over-filling of the bag or reinfusion under pressure does not occur that can cause the bag to rupture, thus wasting the collected blood.

- D. To reduce the risk of air embolus, the CST should evacuate all air from the reinfusion bag prior to reinfusion.<sup>1</sup> The CST should also inspect the reinfusion bag for fat or debris; if identified, the blood should be returned to the cell saver to be re-washed.
- E. The CST must disconnect the reinfusion bag from the cell saver prior to reinfusion. The anesthesia provider is responsible for and supervises the reinfusion.
- 5. CSTs should know how to label the processed blood and complete the perfusion record that will be included in the patient's chart.
  - A. The processed blood must be labelled with the patient's name, HDO identification number, date of birth, date and time of collection, expiration time (6 hours after processing the blood), name of RN circulator or CST in the assistant circulator role that carried out the processing procedure and wording that indicates it is blood that has not been typed and crossmatched such as "ICS blood for autologous use only".
  - B. The perfusion record should contain the identification number assigned by the HDO biomedical or clinical engineering department, type and amount of anticoagulant, volume of blood processed, volume of blood re-infused, cell saver operator's name, name of surgical procedure, date of procedure and any issues or complications that occurred related to the use of the cell saver.
- 6. The anesthesia provider will obtain a blood specimen from the patient when the autologous blood has been re-infused. A CST not assigned to another OR, informally referred to as a "runner", can deliver the blood specimen to the laboratory to perform a full blood count, prothrombin time, activated partial thromboplastin time and heparin concentration. The test results can be communicated from the laboratory to the OR by computer or by the CST runner.
  - A. If the surgeon has activated the *massive transfusion* protocol (refer to *AST Guidelines for Best Practices for Massive Transfusion*), the anesthesia provider may obtain blood samples after the reinfusion of each liter of autologous blood to keep track of the potential for having to treat coagulopathy.
- 7. Near the end of a surgical procedure, or when it may be assumed that no more blood will be collected, the CST must communicate with the surgeon and anesthesia provider to confirm that ICS is no longer required prior to discontinuing use of the cell saver and removing single-use items.<sup>1</sup>
  - A. The CST should confirm with surgeon and anesthesia provider that any remaining collected blood should be processed.
  - B. The CST should verify that the RBC/saline content of the reinfusion bag has been reinfused into the patient and the bag can be detached from the processing set.<sup>1</sup>
  - C. The manufacturer's IFUs should be followed for disconnecting the single-use items.<sup>1</sup>

## **Guideline V**

CSTs should be knowledgeable of the various considerations and issues regarding cultural diversity, and understand that a patient's religious and/or cultural beliefs may not allow the use of certain blood replenishment products and ICS may be a viable option.

- 1. There are specific religions that prohibit the allogenic transfusion of blood and blood products, such as Jehovah's Witness.<sup>36</sup> Additionally, there may be state and federal laws regarding allogenic transfusion of blood and blood products in infants and children (age group 0 12) and minors (age group 13 17). Therefore, ICS may be an option that is acceptable.<sup>8,9</sup>
  - A. The surgeon and/or anesthesia provider have the responsibility for making the sole decisions regarding the various types and methods for transfusing blood and/or blood products based upon consultation with legal counsel and obtaining patient consent, and documenting the decisions.<sup>1,8,9</sup>

# **Guideline VI**

The cell saver should be cleaned in-between uses according to manufacturer IFUs, and single-use items and waste products are properly disposed according to surgery department policies and procedures (P&P) as well as local, state and federal regulations.<sup>12</sup>

- 1. Following the use of the cell saver it should be cleaned and disinfected according to manufacturer's instructions.
- 2. The contaminated single-use items should be disposed of according to surgery department P&Ps as well as in accordance with local, state and federal waste regulations, and OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030.
- 3. The waste products left over from the centrifuge step of ICS including clotting factors, fat, free plasma hemoglobin, heparin, plasma, platelets and white blood cells, are collected in a bag that must be disposed of as medical contaminated waste.<sup>9</sup>

# **Guideline VII**

## The surgery department should review the P&Ps regarding ICS on an annual basis.

- 1. The surgery department should include members of the surgical team and administration when reviewing the P&Ps, including CSTs, surgeons, anesthesia care providers, RNs, lab technicians, blood bank technicians, risk management and infection control officer.
  - A. It is recommended the surgery department establish an ICS Committee that is responsible for development and revision of the P&Ps for use of cell salvage and quality assurance program, and establishing a training program. An anesthesia provider should be charged with the responsibility of leading the committee.
  - B. The surgery department should document when the P&Ps were reviewed, revision completed (if necessary), and who participated in the review process.
  - C. The P&Ps, as well as the manufacturer's instruction manuals, should be kept in a place in the surgery department where they are easily accessible to all surgical personnel for reference at any time.
- 2. CSTs should be familiar with the P&Ps for ICS. The orientation of new employees should include reviewing the P&Ps.

# **Guideline VIII**

## CSTs should complete continuing education to remain current in their knowledge of ICS.<sup>35</sup>

- 1. The continuing education should be based upon the concepts of adult learning, referred to as andragogy. Adults learn best when the information is relevant to their work experience; the information is practical, rather than academic; and the learner is actively involved in the learning process.<sup>37</sup>
- 2. It is recommended surgery departments use various methods of instruction to facilitate the learning process of CSTs.
  - A. If the education is primarily lecture, methods to engage learners include presentation of case studies for discussion, and audience discussion providing suggestions for reinforcing ICS.
  - B. Other proven educational methods include interactive training videos, and computerized training modules and teleconferences.
  - C. The continuing education should be delivered over short periods of time such as in modules, and not in a one-time lengthy educational session.
- 3. Continuing education programs should be periodically evaluated for effectiveness including receiving feedback from surgery department personnel.
- 4. The surgery department should maintain education records for a minimum of three years that include dates of education; names and job titles of employees that completed the continuing education; synopsis of each continuing education session provided; names, credentials, and experience of instructors.

Competency Statements	Measurable Criteria
1. CSTs are knowledgeable of the principles	1. Educational standards as established by the
and practices of ICS.	<i>Core Curriculum for Surgical Technology.</i> <sup>28</sup>
2. CSTs have the knowledge and skills to set- up and operate the cell saver in the first scrub and assistant circulator roles according to surgery department P&Ps and manufacturer IFUs.	2. The didactic subjects of blood and blood products, and principles of ICS are included in a CAAHEP accredited surgical technology program.
	3. Students demonstrate knowledge of ICS
3. CSTs have the expertise and knowledge to	during clinical rotation.
serve on a surgery department committee that	
reviews the policies and procedures for ICS,	4. CSTs complete continuing education to
and develops and establishes a quality	remain current in their knowledge of blood
assurance process.	and blood products, and ICS. <sup>35</sup>

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# Glossary

Allogenic: Belongs to the same species.

Alloimmunization: Immune response to foreign antigens; unanticipated and unwanted outcome of allogenic blood transfusion.

Autologous: Donated previously by the patient and stored or obtained through ICS.

*Cell saver*: A procedure that uses a medical device to recover blood lost during surgery to reinfuse into the patient; it also referred to as intraoperative cell salvage, autologous blood transfusion or cell salvage.

*Homeostasis*: The state of dynamic equilibrium of the internal environment of the body that is maintained by the ever-changing process of feedback and regulation in response to external or internal changes.

*Hypovolemic*: Decreased blood volume that may be caused by external or internal bleeding.

Hypoxia: An oxygen deficiency in the body tissue.

Intraoperative cell salvage (ICS): Use of the patient's own blood, which has been processed for reinfusion.

*Massive transfusion:* Emergency situation in which the surgical patient receives a blood transfusion that is greater than their calculated circulating volume.

*Skimming*: Red blood cell lysis due to excessive vacuum level of suctioning that causes air to mix with the blood during suctioning.

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