This Month

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- Developing policies and procedures for autologous tissue banking
  Key words: autologous grafts, tissue banking.

- Labeling autograft storage packages
  Key words: autologous grafts, tissue storage.

- Documentation requirements for autologous tissue
  Key words: documentation for autologous grafts, tissue banking.

Discarding used syringes

QUESTION:
After administering a medication, some of the licensed personnel at my facility are removing the needle from the syringe. They then discard the needle in the biohazard sharps container and discard the syringe in the regular trash. Is this acceptable?

ANSWER:
To lessen the potential for needle-stick injuries, health care personnel should not remove needles from syringes. Percutaneous needle-stick injuries are associated with transmission of hepatitis B virus, hepatitis C virus, and HIV, but they also have been implicated in the transmission of more than 20 other pathogens. The Occupational Safety and Health Administration (OSHA) blood-borne pathogens standard prohibits the bending, recapping, or removal of a contaminated needle or other contaminated sharp.

The OSHA standard provides an exception when an “employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.” In this case, the “bending, recapping or
Needle removal must be accomplished through the use of a mechanical device or a one-handed technique. An explanation for the medical need for needle removal must be documented in the employer’s exposure control plan.

Employers must educate employees on the purpose of the mechanical needle removal device and make certain that it is only available for use in circumstances that meet the OSHA criteria. Employers are responsible for ensuring that employees remove needles appropriately.

Health care organizations and their employees are responsible for actively establishing and participating in strategies to reduce the incidence of percutaneous injuries. Fewer percutaneous injuries are reported in organizations that have a strong culture of safety. A well-developed safety program and support from managers send a clear message about the organization’s commitment to preventing injuries and keeping employees safe. Individual health care workers also have a responsibility to educate themselves about the prevalence and modes of blood-borne pathogen transmission and to use measures to protect themselves.

Needle-stick injuries can be prevented by using, whenever possible, safety-engineered products provided by the employer, such as:

- Needleless systems or sharps with engineered sharp injury protection devices;
- Retractable, protective sheaths or self-resheathing, self-blunting, or hinged recapping needles to administer local anesthetics and other injectable medications; and
- Blunt cannulas to withdraw medications and fluids from vials.

The one-handed recapping technique should be used only when no other alternatives exist. The OSHA bloodborne pathogen standard requires minimal manipulation of needles as a method to limit the practice of removing contaminated needles and protecting health care workers from injury.

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**References**


#### Requirements for storing autologous tissue

**QUESTION:**
The cardiovascular surgeons at our facility often ask us to save and store vein grafts for later use on the same patient. I have been told that storing autologous tissue requires the facility to be registered with the US Food and Drug Administration (FDA) as a tissue bank. Is this true?

**ANSWER:**
A facility that stores autologous tissue for later reimplantation into the same patient is not required to register with the FDA as a tissue establishment (ie, tissue bank). However, FDA’s Good Tissue Practice requirements for preventing the introduction, transmission, or spread of communicable disease as described in the *Federal Register* must be followed.

The Joint Commission also has developed accreditation standards for hospitals, critical access hospitals, ambulatory surgery centers, laboratories, and office-based surgery practices that store or use tissue. Specific requirements apply to autologous tissue use, including the necessity of...
Developing policies and procedures for autologous tissue banking

**QUESTION:**
We do not have a policy and procedure in place for autologous tissue banking and would like to develop one. Are there specific elements that should be included?

**ANSWER:**
Managers in health care organizations should use the standards published by the American Association of Tissue Banks (AATB) to develop policies and procedures for safe storage and transplantation of autologous tissue. These standards reflect the collective expertise and efforts of tissue bank professionals to provide a comprehensive foundation for the guidance of tissue banking activities.

In addition to following the AATB standards, a facility’s policies and procedures must comply with US Food and Drug Administration (FDA) regulations and Joint Commission accreditation standards for tissue transplant safety.

An organization’s policies and procedures should specify that autologous tissue banking is for internal use only and the tissue will not be transferred to another facility. If transfer to another health care facility must occur (eg, patient/donor is transferred to another facility), this is allowed but registration with the FDA as a tissue establishment and adherence to applicable federal regulations is expected. The policies and procedures should include, but not be limited to, the following requirements:

- Aerobic and anaerobic tissue cultures should be collected when tissue is recovered to establish a baseline for later evaluation.
- Tissue should be aseptically recovered and transferred to a sterile storage container.
- The autograft package or storage container selected should be impervious to moisture to provide an adequate barrier to microbial contamination.
- The autograft package or storage container must be labeled in a manner that minimizes the risk of errors.
- Tissue must be transported and stored in a manner that minimizes the risk for compromise or contamination including, but not limited to, the following:
  - Containers for transporting or temporarily storing tissue must protect the tissue from contamination and maintain the tissue at an appropriate temperature during transport.
  - Tissue for transplantation at a later date should be contained and refrigerated or frozen (when indicated) as soon as possible after recovery.

**References**
Tissue must be stored in a secure area, with access restricted to authorized personnel.\(^2\)

Pooling (ie, comingling) of tissue from two or more donors must not occur.\(^2\)

Temperatures selected for storage of autologous tissue should be consistent with AATB standards.\(^1\)

Autografts should be segregated from allografts during storage.\(^1\)

An expiration date that does not exceed AATB recommendations should be assigned to each tissue based on tissue type, processing, preservation, storage, and packaging.\(^3\)

A process should be implemented (eg, periodic communication with surgeons, review of medical records) to minimize the number of autografts in storage and to determine when the tissue is no longer needed.\(^1\)

A process should be outlined for monitoring refrigerator and freezer units used for storing tissue.\(^1,3\) Considerations include, but are not limited to, the following:

- recording daily temperature,\(^3\)
- scheduling annual calibration checks, and
- verifying that the alarm system sounds when the temperature is not in the acceptable range.\(^1\)

A contingency plan should outline actions to be taken in the event of refrigerator or freezer malfunction.\(^1,3\)

A standardized process for verifying release criteria for autografts should be implemented to minimize the potential for errors.\(^1\) This process should include, but not be limited to, the following:

- segregating autografts until all processing (if performed), labeling, and storage criteria have been reviewed and determined to meet the criteria for release;
- releasing autografts only for reimplantation in the autologous donor;
- using two unique identifiers on packaging for verification;
- verifying the contents of the package, expiration date, and other pertinent information by reading back the information before the tissue is dispensed onto the sterile field\(^3\);
- disposal of tissue that does not meet release criteria;
- complying with state and federal regulations when destroying or disposing of tissue\(^4\); and
- autologous bone tissue grafts should not be autoclaved because this is not a compatible process in regard to maintaining the expected biological aspects of bone (Scott Brubaker, CTBS, Chief Policy Officer, AATB, e-mail communication, June 7, 2011).

Health care organizations that store autologous tissue must recover, process, store, and transplant the tissue in a manner that minimizes microbial growth and reduces the risk of errors.\(^2\) Policies and procedures for procuring, storing, distributing, and implanting autologous tissue in the perioperative setting should be developed in accordance with AATB standards,\(^1\) Joint Commission standards,\(^3\) and FDA regulations.\(^2\)

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References
Labeling autograft storage packages

**QUESTION:**
We have been developing a policy and procedure for autologous tissue banking and have been struggling with how autograft storage packages should be labeled. Can you provide guidelines we should follow for labeling autograft packages?

**ANSWER:**
Autograft packages or storage containers should be labeled in a manner that meets American Association of Tissue Banks, standards1 and US Food and Drug Administration (FDA) requirements2 as well as the Joint Commission’s safety goal of patient identification.3,4 To facilitate matching of tissue to the desired recipient and accurate recordkeeping, a bar code label should be applied to the package or container and should be used if the technology is available.1 The FDA requires that a procedure be maintained to verify the accuracy of labels for the labeling of human tissue.2

The autograft package or storage container should be labeled with the following information1:

- warning statements that may include,
  - “For Autologous Use Only”;
  - “Autologous Donation”;
  - “Not Evaluated for Infectious Substances” if infectious disease testing has not been performed; or
  - “Biohazard” if infectious disease tests were performed and found to be positive;
- two unique identifiers of the donor/recipient, including a bar code (if possible)4;
- description of the tissue;
- recovery date and time;
- expiration date, if applicable, including month and year;
- storage conditions, including recommended storage temperature and acceptable storage temperature range;
- method of preservation, if applicable;
- identification of any potential processing agents or solution residues (eg, antibiotics)5;
- method of disinfection or sterilization, if used; and
- whether the tissue was recovered and prepared under aseptic conditions, if it was not sterilized.

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Documentation requirements for autologous tissue

**QUESTION:**
We are in the process of reviewing our documentation for autologous tissue banking and developing a more formal perioperative quality management program. Are there specific documentation requirements for autologous tissue banking? What are the key areas we should include in this quality management program?
Tissue banking poses significant risks to recipients if errors in handling occur, and documentation helps to track problems if they arise. Documentation and records for autologous tissue banking should be developed and maintained in accordance with the recommendations of the American Association of Tissue Banks (AATB)\(^1\) and be in compliance with the US Food and Drug Administration (FDA) regulations.\(^2\) Records should include, but not be limited to,

- the list (eg, log) of all tissue stored and used;
- informed consent documents;
- information on
  - processing,
  - preservation,
  - labeling,
  - storage,
  - quarantine,
  - autologous tissue culture results, and
  - release;
- dates and times of preparation, acceptance, and issuance of tissue;
- quality management records; and
- information about disposal of unused tissue.\(^3\)

The Joint Commission, AATB, and FDA all require that records be maintained for 10 years after the date of distribution, transplantation, other disposition, or expiration, whichever is latest. Records may need to be kept longer if this is required by state or federal statutes.\(^1\)\(^-\)\(^4\)

The FDA requires that any facility banking tissue maintain a quality management program intended to prevent the introduction, transmission, or spread of communicable disease during every step of the tissue banking process, even if only autologous grafts are being banked.\(^2\)

The AATB also recommends that a tissue bank maintain a quality management program intended to prevent contamination, avoid mixups, promote tracking, and develop and maintain an adverse reaction policy.\(^1\) A quality management program should

- establish a multidisciplinary committee to perform a baseline assessment of the process (eg, comparing procedures with regulations and standards);
- provide for at least annual program reviews to monitor ongoing compliance with regulations and safe tissue banking processes;
- identify quality indicators, including but not limited to,
  - tissue processing procedures,
  - labeling procedures,
  - storage requirements,
  - criteria for release of tissue,
  - a verification process that uses two unique donor identifiers for release of autografts, and
  - record maintenance, including documentation and proper reporting of adverse events;
- specify quality indicators to measure compliance; and
- mandate reporting of adverse events, including infections for which there is a reasonable possibility that the transplanted tissue caused the event.\(^1\)\(^,\)\(^3\)

AORN’s “Recommended practices for surgical tissue banking”\(^3\) is a resource that can be used to refine documentation procedures and help develop quality management programs for autologous tissue banking in the perioperative setting.\(^AORN\)

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Clinical Issues

This evaluation is used to determine the extent to which this continuing education program met your learning needs. The evaluation is printed here for your convenience. To receive continuing education credit, you must complete the Learner Evaluation online at http://www.aorn.org/CE. Rate the items as described below.

PURPOSE/GOAL
To educate perioperative nurses about providing safe nursing care throughout the perioperative continuum.

OBJECTIVES
To what extent were the following objectives of this continuing education program achieved?

1. Discuss practices that could jeopardize safety in the perioperative area.
   Low 1. 2. 3. 4. 5. High
2. Discuss common areas of concern that relate to perioperative best practices.
   Low 1. 2. 3. 4. 5. High
3. Describe implementation of evidence-based practice in relation to perioperative nursing care.
   Low 1. 2. 3. 4. 5. High

CONTENT

4. To what extent did this article increase your knowledge of the subject matter?
   Low 1. 2. 3. 4. 5. High
5. To what extent were your individual objectives met? Low 1. 2. 3. 4. 5. High

6. Will you be able to use the information from this article in your work setting? 1. Yes 2. No
7. Will you change your practice as a result of reading this article? (If yes, answer question #7A. If no, answer question #7B.)
   7A. How will you change your practice? (Select all that apply)
       1. I will provide education to my team regarding why change is needed.
       2. I will work with management to change/implement a policy and procedure.
       3. I will plan an informational meeting with physicians to seek their input and acceptance of the need for change.
       4. I will implement change and evaluate the effect of the change at regular intervals until the change is incorporated as best practice.
       5. Other: ______________________

7B. If you will not change your practice as a result of reading this article, why? (Select all that apply)
   1. The content of the article is not relevant to my practice.
   2. I do not have enough time to teach others about the purpose of the needed change.
   3. I do not have management support to make a change.
   4. Other: ______________________

8. Our accrediting body requires that we verify the time you needed to complete the 1.5 continuing education contact hour (90-minute) program:
   ________