Recommended Practices for Autologous Tissue Management

The following Recommended Practices for Autologous Tissue Management have been approved by the AORN Recommended Practices Advisory Board. They were presented as proposed recommendations for comments by members and others. They are effective November 15, 2014. These recommended practices are intended to be achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice, and as such, these recommended practices are guidelines adaptable to all areas where operative and other invasive procedures may be performed.

Purpose

These recommended practices provide guidance to perioperative personnel for managing autologous tissue in the perioperative setting, including avulsed teeth, cranial bone flaps, parathyroid glands, skin, veins, and dropped autografts. Guidelines are provided for transferring tissue from the sterile field, packaging and labeling, transporting and storing, and handling autologous tissue for delayed replantation or autotransplantation within the same facility. Guidelines for managing autologous adipose tissue are not provided. Currently, adipose aspirates can only be used for immediate autologous fat grafting at the time of recovery, and there is no reliable method for preserving and storing adipose tissue for delayed autotransplantation.[1,2] Recommendations related to processes for intraoperative storage and cryopreservation of autologous tissue are outside the scope of this document.

A facility that handles autologous tissue for delayed replantation or autotransplantation into the same patient and within the same facility is not required to register with the US Food and Drug Administration (FDA) as a tissue establishment (ie, tissue bank) that manufactures human cells, tissues, and cellular and tissue-based products, nor to follow requirements of 21 CFR Part 1271 (ie, the FDA regulations for these products).[3,4] Facilities or health care organizations that handle autologous tissue are required to recover, process, package, label, store, track, and replant or autotransplant the tissue in a manner that minimizes microbial growth, prevents mix-ups, and reduces the risk for errors.[3] Although the regulation defines manufacturing to include recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue,[3,5] the FDA considers most procedures related to autologous tissue to be a single procedure encompassed within the element of storage. The reader can refer to section 1271.15(b), in which storage of autologous tissue is exempt if replantation or autotransplantation will occur in the facility where the recovery took place.[4] Similarly, packaging and labeling of autologous tissue can be encompassed within the exception for storage.[4] Freezing autologous tissue as a method of storage does not, in itself, require registration and listing with the FDA as a tissue establishment.[4]

In addition, the FDA has interpreted the "same surgical procedure" language in its final rule to include recovery and storage before replantation or autotransplantation.[3] Retaining autologous tissue to be used in a subsequent application for the same patient is exempt from registration because the two applications are essentially a single, continuous procedure.[4]

The facility is required to register with the FDA if autologous tissue handling includes steps to process the autograft when any step requires specific manufacturing controls to decontaminate the tissue (ie, subjecting the autograft to a steam sterilization process).[4] If autologous tissue-handling functions are expanded to include distribution of the autograft to another facility located at a different address, registration and listing with the FDA using Form FDA 3356 is required.[3]

Whether or not facility registration is required, the federal regulations described in 21 CFR Part 1271 provide good practices for preventing the introduction, transmission, or spread of communicable disease and enhancing patient safety related to autologous tissue management.[3,5]

The reader can also refer to the standards of the American Association of Tissue Banks (AATB), which reflect the collective expertise and efforts of tissue bank professionals to provide a comprehensive foundation to support tissue banking activities, including practices for managing autologous tissue.[6]

Evidence Review

On January 24 and January 27, 2014, a medical librarian conducted a systematic search of the databases MEDLINE®, CINAHL®, and the Cochrane Database of Systematic Reviews for meta-analyses, systematic reviews, randomized controlled and non-randomized trials and studies, case reports, letters, reviews, and guidelines. The librarian also searched Scopus®, although not systematically. Search terms included *autologous transplantation, tissue preservation, organ transplantation, preservation, storage, storage solution, saline solution, isotonic saline, potassium chloride, N-acetylhistidine, ice, cold temperature, bone flap, bone transplantation, skull, bone and bones, surgical flap, saphenous vein, radial artery, renal artery, mammary artery,* and