



TISSUE BANKING: THE BASICS

*Millions of people receive tissue transplants that improve their lives,
with minimal risk, in a highly regulated system
supported by compassionate professionals and technical experts.*

THE MEDICAL NECESSITY OF TISSUES

- Tissue banks exist to meet critical medical needs. Physicians use tissue allografts to save and improve the lives of more than one million Americans each year.
- Tissue allografts are commonly used to improve medical outcomes across a broad spectrum of clinical specialties.
 - Donated heart valves can replace damaged valves, or correct a baby's congenital defect, allowing the heart to function normally.
 - Special grafts help patients with spinal deformities live normal lives.
 - Musculoskeletal tissue can save limbs from amputation and be used to replace bone, tendons and ligaments lost to cancer, severe trauma, degenerative joint disease, arthritis and other conditions.
 - Donated skin can save the lives of burn victims and improve the lives of patients with significant soft tissue defects.
- Tissue allografts play a key role in restoring function and mobility and, since research shows that physical activity reduces the risk of chronic health conditions, empower patients to live healthier, more active lives.
 - Injured joints or degenerated discs cause pain, hinder mobility and dramatically decrease quality of life.
- As new treatment options are discovered and we live longer, the potential for tissue allografts to improve medical outcomes will increase.

THE AUTHORIZATION PROCESS

- Saving and improving lives through tissue allografts would not be possible without the tens of thousands of donors and their families who authorize the gift of tissues. Health-care professionals should never lose sight of the reality of what an allograft is and where it comes from: a fellow human selflessly provided the donated tissue.
- The authorization process is designed and managed to ensure that donors and their families receive the respect and compassionate care they deserve while their precious gifts are protected and use optimized.
- The authorization of the gift of tissues is governed by state law and the Uniform Anatomical Gift Act.



- There are two ways in which legal authorization can be obtained and documented.
 - Donors provide legal authorization by signing with a state donor registry.
 - After death, there can be the opportunity for a potential donor's legally authorized representative (usually a spouse, or other relative) to authorize the donation as part of a rigorously managed process.

- This process includes the following steps
 - Personnel at a hospital, medical examiner's office, funeral home or law enforcement can notify a representative of the local tissue recovery organization – usually an Organ Procurement Organization (OPO), tissue bank or eye bank – of a death.
 - The tissue recovery organization makes the initial determination of donor eligibility based on medical and social criteria and available information (e.g., age, cause of death, immediate evidence of infection, etc.). If the potential donor is ineligible (i.e., determined to be unacceptable), no contact with a family member is made and the process is terminated.
 - If the person is eligible and registered as a donor, the legal next of kin is informed of that decision and tissue donation can proceed.
 - If the person is eligible and not registered as a donor, a trained requestor contacts the person authorized by law to make an anatomical gift to offer the opportunity to donate. If the legally authorized representative provides authorization, the tissue donation proceeds. If no authorization is provided, the process is terminated.

- AATB-accredited tissue banks must follow exacting policies and procedures to obtain and document authorization. These standards, which are part of AATB's *Standards for Tissue Banking*, are extensive. Any Document of Authorization that does not contain specific core elements will not be acted upon.
 - The core elements include: the name of the donor and the authorizing person, the latter person's contact information and the description of their relationship to the donor; an explanation that no monetary compensation will be provided; a list of general types of tissues authorized to be recovered; and an explanation of actions required to successfully perform recovery.

- Although the pain of loss and grief is overwhelming for many tissue donor families, they often find support by honoring the donation wishes of their loved one or by making a donation decision on his or her behalf.
 - One parent addressed her son directly by saying, "It was a comfort to me that something good came out of your death."
 - A father gave meaning to his child's death by saying, "It only makes sense that such a senseless death benefit someone else."
 - The most common phrase used to describe believing something good had come from donation was that he or she "did not die in vain."



TISSUE PROCESSING AND DISEASE PREVENTION

- Human tissue processed and distributed for transplantation by AATB-accredited tissue banks is subject to Food and Drug Administration regulation and AATB's *Standards*. There are multiple layers of screening, testing, quality assurance and quality control measures in place that help ensure tissue that is safe for transplant.
 - Every medical procedure, including use of tissue for transplant, comes with risks and benefits. The AATB encourages any patient considering a tissue transplant to discuss the risks and benefits of the procedure with his or her physician.

- Organizations involved in tissue transplantation follow a specific process, take precise steps, and adhere to significant safety controls in the interest of providing future recipients with safe tissue for transplantation:
 - **Referral and initial screening** – the tissue recovery organization's initial determination of donor eligibility includes a review of immediate evidence of communicable disease and other health conditions.
 - **Recovery process** – includes obtaining and qualifying donor blood samples that will be used for infectious disease testing, performing a physical assessment of the body, confirmation of adherence to critical time limitations, and recovery of tissue using technical, standard operating procedures like those used in surgery.
 - **Donor eligibility determination** – much like blood donation, the donor's medical history and behavioral risk information is obtained and assessed; all documents, histories, records, cultures and test results are reviewed by the tissue bank's quality assurance program, then the tissue bank's licensed Medical Director will determine the suitability of the donor. This determination can occur after processing if the tissue type requires time sensitive processing to preserve expected function.
 - **Tissue processing** – time-sensitive processing begins within established time limits; tissue is handled in appropriate environmental conditions and by methods validated to prevent contamination and cross-contamination; physical characteristics of the tissue are evaluated and documented; the tissue is cleansed or decontaminated and, if appropriate, it will be sterilized; a tissue preservation method is selected; and tissue is quarantined until final quality control steps are completed, such as cultures and other testing.
 - **Release and distribution** – technical staff perform a thorough review of all records related to tissue processing and quality, which is used in conjunction with the donor suitability determination performed by the Medical Director in making a decision to release tissue for clinical use.

- Tissue transplantation has an impressive safety record, particularly considering that, in the United States, an estimated 10 million transplants have occurred in the past two decades. According to the Centers for Disease Control, the incidence of infections is estimated to be 0.0004% from approximately 900,000 allografts transplanted per year.



- Experience demonstrates that the statistical likelihood of communicable disease infection via human tissue is remarkably low. The risk of contracting a viral infection from an allograft is approximately 1 in 1,600,500.¹
- Human tissue products are inherently biocompatible, meaning they can be incorporated into a human body more easily and with fewer complications than many synthetic products.
- The safety record of tissue transplantation continues to improve with advancements in donor screening and testing procedures, including:
 - Beginning in March 2005, AATB-accredited tissue banks were required to perform more sensitive testing for HIV and hepatitis C virus (HCV) using Nucleic Acid Technology (NAT) which further reduces the “window period” between disease exposure and detection.
 - The sensitivity and specificity of test kits used for detecting infectious diseases have continued to improve over time due to technical and scientific advances.
- Disease transmission to a tissue recipient is extremely rare. The few instances of disease transmission that have occurred in the history of allograft transplantation have largely taken place before advancements in screening and testing methodologies.
 - No case of disease transmission has ever been documented from an allograft that has been subjected to a validated sterilization process.
 - The only reported cases of tuberculosis and Hepatitis B in tissue recipients occurred over 50 years ago. Tissue donor screening, testing, and processing have proven to reduce and/or eliminate the risk associated with these diseases.
 - The only reported transmissions of HIV occurred over 20 years ago, shortly after HIV-antibody testing was introduced in 1985, and the tests were not as sensitive as they are today.
 - HCV transmission from tissue is rare. There are a small number of cases that occurred before HCV NAT was widely used. In 2011, one case occurred due to human error when testing the donor’s blood specimen.
 - There have been no transmissions of LCMV, Chagas’ disease, rabies, malaria, West Nile virus, or malignancy (cancer) from conventional tissue transplants.
 - Transmission of bacteria is extremely rare. When it has occurred, lessons were learned that led to corrective action and process improvements that prevent recurrence.

STANDARDS AND REGULATION

- The tissue profession in the United States is governed by mandatory requirements enforced by federal and state regulatory authorities.
- The Food and Drug Administration can shut down any tissue bank found not to be operating in compliance with regulations.

¹ John J. Klimkiewicz, Brian J. Samsell, Andrew Riff, Thomas M. DeBerardino and Mark A. Moore, Comparison of Human Tendon Allografts and Autografts Used in Knee Reconstruction, 22 Current Orthopaedic Practice 6, 494 – 502 (Nov./Dec. 2011).



- In furtherance of its mission to promote the safety, quality and availability of donated human tissue, the AATB:
 - Publishes standards
 - Accredits tissue banks
 - Certifies individuals working in tissue banking
 - Interacts with regulatory agencies

- The AATB's *Standards for Tissue Banking* are the most comprehensive and detailed tissue-banking standards in the world and have served as the model for federal and state regulations as well as several international requirements. The *Standards for Tissue Banking* include expectations and guidance on:
 - General institutional requirements
 - Functional components
 - Records Management
 - Authorization and consent practices
 - Donor screening and testing, and suitability
 - Parameters surrounding tissue recovery operations
 - Tissue processing, packaging, labeling, storage and distribution
 - Establishment and maintenance of a quality program

- AATB's Accreditation Program checks that tissue-banking activities are performed in a professional manner and in compliance with AATB's *Standards for Tissue Banking*. At least six states and the District of Columbia require tissue recovery organizations to be accredited by the AATB.

- In order to be accredited by the AATB, a tissue bank must meet a rigorous set of criteria, to ensure compliance with the *Standards*.
 - A tissue bank must: perform a self-assessment; complete a detailed application and submit its standard operating procedures; welcome an accreditation inspection performed by an independent third party; be recommended for accreditation by committee; and be approved by a Board of Governors.
 - Accredited members must be re-inspected and be approved for re-accreditation every three years.

- If a tissue bank is found not to be in compliance with AATB's *Standards*, the tissue bank's accreditation can be denied or withdrawn.
 - Since the accreditation program was established in 1986, AATB has exercised the right to deny or withdraw accreditation.

INTERNATIONAL DISTRIBUTION AND TRACING

- The Food and Drug Administration and AATB *Standards* require tracking tissue from the moment of recovery through all handling and distribution to the consignee, the entity that takes the final delivery of the tissue graft.



- The Food and Drug Administration encourages but does not require the consignee to track the tissue to final disposition, such as use in a patient.
 - The Food and Drug Administration does not have jurisdiction over end users and tissue banks do not have enforcement authority to mandate consignees to provide tracking information.
 - AATB *Standards* require that members have a protocol in place that provides recipient follow-up data collection, and support this process by providing an information card that describes use for the consignee to complete and return. However, such participation by end users is voluntary.
- The AATB supports the concept of a uniform, global coding and labeling system to enhance traceability and recipient safety, and is leading a number of efforts to achieve this important goal. In the United States, the AATB formed the North America Tissue Technical Advisory Group in 2005. The group is working together to evaluate the use of ISBT 128, a method for machine-readable universal coding, which would allow easier tracking of tissue through all handling, including use.
- Such a system would provide seamless tracking on a global level. At this time, several AATB-accredited banks distribute tissue allografts internationally and similar efforts to use ISBT 128 are being developed on almost all continents.
- It is important to emphasize that the foreign recovery operations of firms registered with the Food and Drug Administration are regulated and inspected by the Agency. All human tissue distributed in the United States is subject to Food and Drug Administration regulation as well as the laws and regulations for each country of donor origin.

FOR-PROFIT AND NON-PROFIT ORGANIZATIONS

- In tissue banking, both for-profit and not-for-profit organizations operate to make up a network of tissue banks, organ procurement organizations and eye banks that recover and distribute tissue. Regardless of their status, all tissue banks must meet the same regulatory requirements and have the same goal of assisting in the process of making tissue safely available for transplants.
 - The makeup of the tissue bank system, with non-profit and for profit organizations, is common throughout the health care sector in the U.S. (for example non-profit and profit hospitals).
- All organizations – for-profit and not-for-profit alike – need revenues to cover expenses, to be able to provide operating capital for improvements and to support research, to prepare for unexpected expenses such as property damage from a natural disaster (e.g., flood, hurricane) and to provide services in the long-run that assist the community.
- Tissue banks in the United States are governed by the National Organ Transplant Act (NOTA), which dictates that tissues cannot be bought or sold. The law does allow for reimbursement of costs associated with the recovery, processing and storing of tissue and for the development of tissue processing technologies. These activities can include



research, screening and testing, sterilization processes and precision-tooled shaping of allografts for transplantation.

- Costs associated with tissues do not reflect their value, which is priceless, but rather the expenses incurred throughout their recovery, processing and storage.
- The tissue profession, like other professions within the medical field, relies on research and development funding to make possible transplantation innovation and advancements that improve outcomes for tissue recipients.
 - Much of the research and development in the tissue profession is made possible through financial resources available by controlling costs.
 - Pharmaceutical and medical device companies use up to 14 percent of their revenues for research and development.
- Not-for-profit and for-profit tissue banks work together through strategic alliances and partnership for the benefit of all those involved in the tissue transplantation process, including transplant recipients, donors, donor families, physicians and hospitals.
 - Not-for-profit tissue banks have strategic alliances and partnerships with for-profit companies to obtain funding or expertise for research and development, utilize their marketing capabilities and representative forces to increase exposure to the end user (i.e., hospital, physician), and/or to offer some financial stability for the near future over the term of such a contractual relationship.



American Association of Tissue Banks

Vision Statement

Extraordinary people saving and improving lives through the gift of cells and tissues.

Mission Statement

AATB honors donors, saves and improves lives by promoting the safety, quality, and availability of donated cells and tissue.