Tissue Safety

American Association of Tissue Banks

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.

Oversight. Human tissue processed and distributed for transplantation by AATB-accredited tissue banks is subject to Food and Drug Administration (FDA) regulation and AATB's Standards. There are multiple layers of screening, testing, quality assurance and quality control measures in place to provide tissue that is of high quality and safe for transplant.

Safety Record. The safety record of tissue transplantation is exemplary as it is estimated that **more than 10 million tissues were transplanted in the USA over the past two decades**. 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.
- There have been no transmissions of Lymphocytic Choriomeningitis (LCMV), Chagas Disease, rabies or West Nile Virus from tissue transplants.
- 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.
- Transmission of bacteria is extremely rare. When it has occurred, lessons were learned that led to corrective action and process improvements to prevent recurrence.
- In over a decade, there have only been two cases of viral disease transmission in a tissue recipient, both involved the transmission of hepatitis C (HCV). In 2002, transmission occurred from a patient who was recently infected and whose infection could not be detected by the then-current testing. Beginning in March of 2005, AATB-accredited tissue banks were required to perform more sensitive testing -- nucleic acid technology (NAT) -- that further reduces this potential. ***The FDA did not require NAT, for HIV-1 and HCV, until over 2 years after the AATB required it.*** In 2011, transmission occurred to one recipient and was due to human error when performing the HCV test.
- If a safety issue is identified, AATB quickly establishes new standards to further reduce the risk of harm, well before the FDA can act to impose new requirements.

Ongoing Safety Review. As reported by CDC experts during a meeting in 2005,[1] the estimated incidence, between 1998 and 2003, of infection caused by a tissue graft, was 0.0004% based on distribution estimates of approximately 900,000 allografts per year. This incidence is extremely low and was studied under AATB established tissue banking standards, prior to current FDA regulations.

Additional advantages. 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. In addition, compared to autografts, allografts provide the advantage of no added risk, pain, or scars from the donor site, along with decreased surgical time.

---

[1] Record of the Proceedings, CDC/FDA/HRSA/HHS, the Workshop on Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention, June 2-3, 2005, Atlanta, Georgia