

# *American Association of Tissue Banks*

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## **Safety of Tissue Transplants**

- There are risks and benefits with any medical procedure, and tissue transplants are no different. The AATB has always counseled that patients contemplating transplants should discuss the risks and benefits of any surgery or therapy with their physicians and make the decision that is best for them.
- Given that there have been more than 10 million tissue transplants over the past two decades, the safety record of tissue transplantation is remarkable.
  - The last reported case of disease transmission in a tissue recipient was four years ago in 2002, and the case (HCV) was a classic “window period” case. Beginning in March of 2005, AATB-accredited tissue banks were required to perform more sensitive testing that further reduces this “window period” (i.e., NAT technology).
  - There have been no transmissions of LCMV, Chagas Disease, Rabies or West Nile Virus from tissue transplants. Only organs have transmitted these diseases to recipients.
  - The only reported cases of Tuberculosis and Hepatitis B in tissue recipients occurred over 50 years ago. Tissue donor screening and testing has proven to reduce and/or eliminate the risk associated with these diseases.
  - The only reported transmissions of HIV occurred some 20 years ago, shortly after HIV-antibody testing was introduced in 1985, and the tests were not as sensitive as they are today. This too was a “window-period” case. Beginning in March of 2005, AATB-accredited tissue banks were required to perform more sensitive testing that further reduces this “window period” (i.e., NAT technology).
  - The few cases of Hepatitis C (HCV) transmissions occurred in the early 1990’s, more than 10 years ago.
- The donor associated with the Clostridium transmission in 2001, which resulted in the death of a Minnesota man, was retrieved by a facility that was not accredited by the AATB. In fact, because the donor’s body was not refrigerated for 19 hours, the AATB accredited tissue bank in the same locale refused the donor.

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- Most of the 30-60 bacterial-contaminated transplants mentioned in an AP story published on June 12, 2006, were never confirmed by the CDC. They were merely reports made to the CDC. Most of these post-operative infections were never proven to be associated with the allograft, or if so, it could not be determined how the allograft was contaminated.
- The same AP story cites hundreds of heart valves contaminated with fungus, resulting in more than two hundred deaths annually. To the best of our knowledge, there has been only one published report (1997) of an allograft heart valve contaminated with fungus, and the recipient did not die. Neither we, nor the officials with whom we have spoken at the CDC and FDA, know where the AP got these numbers. The AP may have confused this with the number of infections reported for all heart valve implantation devices, including mechanical devices.
- Tissue donors are screened, the donor's blood is tested for communicable diseases, and the Medical Director of the tissue bank must determine that the donor is suitable before the tissue is released for processing.
- Most tissue is irradiated and highly processed in systems that are validated to destroy or inactivate bacteria and viruses.
- The test kits for HIV and HCV have improved over the years. More importantly, even though it is not yet required by the FDA, the AATB requires the use of the Nucleic Acid Test (NAT) for HIV and HCV, which substantially reduces the "window period."
- There are no reported cases of transmission of a malignancy (cancer) due to tissue transplantation.

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