



Safety of Organs and Tissues for Transplant

Safety and viability of organs and tissues are a foremost priority to ensure that transplant recipients are able to have the best possible quality of life. Federal laws, regulations and guidelines; state laws; and voluntary professional membership organization industry standards that are regularly reviewed address procedures for the safe recovery and transplantation of organs and tissues.

Organ procurement organizations (OPOs), tissue and eye banks conduct extensive medical history and behavioral risk assessment interviews to the greatest extent possible when screening potential organ and tissue donors. Screening assesses the quality of the organs and tissues and identifies risks of transmissible diseases.

OPOs, tissue and eye banks are required to conduct serological testing for communicable diseases on all donors including HIV, Hepatitis B and C, HTLV, and Syphilis. In addition, some OPOs test for specific diseases, such as Chagas' disease, West Nile Virus, Toxoplasmosis or other transmissible diseases based on the population profile of their designated service area (DSA).

Many OPOs, tissue and eye banks impose further safeguards and constantly evaluate best practices within the industry to protect recipients from potential harm. For example, Nucleic Acid Amplification Testing (NAT) for HIV, HCV and HBV are licensed by the Food and Drug Administration. These tests are able to detect antigens and antibodies to determine possible exposure, vaccination, or active infection in the donors. NAT assays are not required to be performed by OPOs for organ donor screening, yet many OPOs choose to utilize them to enhance patient safety. There have been more than 300,000 organ transplants since the Center for Disease Control (CDC) issued its guidelines for preventing the transmission of HIV through organ and tissue transplantation in 1994.

The United Network for Organ Sharing (UNOS) policy regarding organ donor screening and testing sets the minimum standards for OPOs. More information on these policies can be found at <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>.

With regard to tissue donation, the Food and Drug Administration's (FDA) Current Good Tissue Practices (cGTPs) sets forth the regulations that specify the approved test kits and specimen handling requirements for communicable disease testing.

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While standard laboratory serological tests are highly sensitive and specific, there can be the potential for viral and antibody levels to be very low and therefore elude detection. This can occur when a person has recently experienced an exposure episode and these levels are initially low. Transplant centers, OPOs and the CDC recognize that a patient's risk of dying without a transplant is often much higher than the possible risk of acquiring a disease. There are more than 110,000 people on the organ transplant waiting list in the United States. On average, 18 people die each day due to the critical shortage of organs.

Please visit www.unos.org for more information.