

Tissue Transplant Safety

Although rare, complications from tissue transplants due to mishandling or improper donor screening can lead to serious health consequences, such as infections, graft failure, and immune response. Quality standards from Joint Commission provide guidelines to minimize the risk of adverse events from tissue transplants and ensure hospitals implement and follow the correct protocols for safe transplant practices.

Background

Since 2005, Joint Commission has elevated the profound consequences of tissue transplant-related adverse events through targeted standards that guide hospital prevention protocols. Complications from tissue transplants can lead to graft failure, immune response, and transmission of infections that affect patient health, such as viruses, bacteria, fungi, and others.¹ While rare, infections due to mishandling of tissues or improper donor screening and testing still occur. Joint Commission's tissue transplant safety standards, elevated to a *National Performance Goal™* in 2025, require hospitals to establish and follow safe tissue transplant procedures to minimize that risk.



Standards

Joint Commission tissue safety standards ensure the hospital develops and implements safe transplant practices.

Hospitals must:

- Implement standardized procedures for managing tissues (acquisition, receipt, storage, and distribution of tissues) and confirm tissue suppliers are U.S. Food and Drug Administration (FDA)-registered with required state licenses
- Trace all tissues bi-directionally from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier
- Using defined protocols, investigate adverse events related to tissue use or donor infections such as disease transmission or other complications suspected of being related to the use of the tissue

Rationale

- The U.S. Food and Drug Administration (FDA) and key stakeholders such as the Centers for Disease Control (CDC), American Association of Peri Operative Nursing (AORN), the Organ Procurement and Transplantation Network (OPTN), and the American Association of Tissue Banks (AATB) require tissue transplant safety measures and reporting of suspected donor-derived disease transmissions.
- Despite this oversight, outbreaks continue to occur. In 2021, there was a tuberculosis (TB) outbreak involving 113 patients across eighteen states after surgical implantation of contaminated bone allografts. In 2023, a second nationwide TB outbreak was narrowly prevented after two patients died from contaminated bone allografts.ⁱⁱ This second outbreak of bone allograft-related TB underscored the urgent need to ensure tissue transplant safety protocols are implemented at hospitals.
- Joint Commission's tissue transplant safety standards are based in laws and regulations such as the FDA regulations for tissue management under 21 CFR Parts 1270 and 1271.ⁱⁱⁱ In 2025, these standards were elevated to *National Performance Goals* to further protect patients and organizations from risk.
- The standards, developed with broad healthcare stakeholder input, align with those of key industry players such as the American Association of Tissue Banks, the premier standard setting body promoting safety and use of human tissue.^{iv}



Related Activities

- Joint Commission continues to collaborate with the CDC to ensure our requirements enable prevention and management of outbreaks.
- Joint Commission sits on the Organ and Transplantation Alliance^v Board of Directors, a national convening platform to identify emerging concepts and innovative practices and deliver relevant, targeted, and scalable learning solutions for the organ donation and transplantation community.

ⁱ CDC Transplant Safety: About transplant safety. February 28, 2024. [About Transplant Safety | Transplant Safety | CDC](#) ⁱⁱ Wortham JM, Haddad MB, Stewart RJ, et al. Second Nationwide Tuberculosis Outbreak Caused by Bone Allografts Containing Live Cells — United States, 2023. *MMWR Morb Mortal Wkly Rep.* 2024; 72:1385–1389. DOI: <http://doi.org/10.15585/mmwr.mm7036a4> ⁱⁱⁱ US Food & Drug Administration (FDA). Tissue and Tissue Products. Accessed 3/13/2025 <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products> ^{iv} American Association of Tissue Banks. Accessed 5/13/2025. <https://www.aatb.org/> ^v The Alliance. Accessed 3/21/2025. <https://www.organdonationalalliance.org/about/>



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