Transplant Safety (TS)

Overview

Transplantation of organs and tissues is sometimes the only option for treatment of a wide range of diseases. In the past 10 years, advances in transplantation have led to a greater success rate for transplanted organs and tissues. More and more people receive transplants every year and more people are living longer after transplants.

Organ transplants are often life-saving procedures. They involve replacing an individual's (the recipient) damaged or failing organ, such as a heart, kidney, liver, lung, pancreas, or intestine, with a working organ from another individual (the donor). While tissue transplants are used most often to enhance the lives of recipients, they are also used at times to save lives. Tissues that are transplanted include bones, tendons, corneas, heart valves, veins, and skin. A single donor can save many lives, as well as improve the quality of life for many more.

Transplantation is not free from risk. Transmission of infections from the donor to the recipient is a significant safety concern. With the increased numbers of organ and tissue transplants, the number of opportunities for transmission of infectious pathogens has also increased. Instances of organ- or tissue-borne infection in recipients of donor organs or tissues are well documented. Diseases with documented transmission from infected donors subsequent to transplant include, to name a few, HIV, hepatitis B and C, and Creutzfeldt-Jakob disease (CJD). Recipients may also contract bacterial or fungal infections through contamination during transportation, storage, or handling. The opportunity for transmission of infectious disease will continue to increase as the number of transplants continues to rise.

Effective communication of an adverse event directly related to organ or tissue use is critical to patient safety. The hospital may become aware of an adverse event directly related to organ or tissue use through external notification or internal detection. Prompt investigation of each adverse event provides response and treatment to recipients affected by the infected organ or tissue and could prevent further transplantation from an infected donor.

KEY: **A** indicates scoring category A; **C** indicates scoring category C; Ⓓ indicates that documentation is required; Ⓜ indicates Measure of Success is needed; ⚠ indicates an Immediate Threat to Health or Safety; ⚠ indicates situational decision rules apply; ⚠ indicates direct impact requirements apply; ⚠ indicates an identified risk

About This Chapter

The standards in this chapter focus on the development and implementation of policies and procedures for safe organ and tissue donation, procurement, and transplantation.

Chapter Outline

I. Donating and Procuring Organs and Tissues (TS.01.01.01)

II. Transplanting Organs (TS.02.01.01)

III. Transplanting Tissues
   A. Standardized Procedures to Acquire, Receive, Store, and Issue Tissue (TS.03.01.01)
   B. Bi-directional Tracing of Tissues (TS.03.02.01)
   C. Tissue Adverse Events Investigation (TS.03.03.01)

Standards, Rationales, Elements of Performance, and Scoring

Introduction to Standard TS.01.01.01

Leadership's commitment to creating a culture conducive to organ and tissue donation can have significant impact on the overall success of the hospital's organ and tissue procurement efforts. This standard addresses the hospital's responsibilities for organ and tissue donation and procurement. This includes any individual who has been determined medically suitable for donation by the organ procurement organization (OPO). If the hospital has the necessary resources to support the recovery of organs and tissues after cardiac death, non–heart-beating donors are included in the organ procurement effort.

Standard TS.01.01.01

The hospital, with the medical staff's participation, develops and implements written policies and procedures for donating and procuring organs and tissues.

Elements of Performance for TS.01.01.01

A 1. (D) The hospital has a written agreement with an organ procurement organization (OPO) and follows its rules and regulations. (*See also* PI.02.01.01, EP 7) R

A 2. (D) The hospital's written policies and procedures identify the organ procurement organization (OPO) with which it is affiliated. R

A 3. (D) The hospital has a written agreement with at least one tissue bank and at least one eye bank to cooperate in retrieving, processing, preserving, storing, and distributing tissues and eyes. R

Note 1: *This process should not interfere with organ procurement.*

Note 2: *It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its organ procurement organization (OPO) to provide tissue procurement services, nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement, and is free to have an agreement with the tissue bank or eye bank of its choice.*

A 4. Ⓓ The hospital works with the organ procurement organization (OPO) and tissue and eye banks to do the following: R

- Review death records in order to improve identification of potential donors.
- Maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place in order to maximize the viability of donor organs for transplant.
- Educate staff about issues surrounding donation.
- Develop a written donation policy that addresses opportunities for asystolic recovery that is mutually agreed upon by the hospital, its medical staff, and the designated OPO. When the hospital and its medical staff agree not to provide for asystolic recovery and cannot achieve agreement with the designated OPO, the hospital documents its efforts to reach an agreement with its OPO, and the donation policy addresses the hospital's justification for not providing for asystolic recovery.

A 5. Staff education includes training in the use of discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential organ, tissue, or eye donors. R

A 6. Ⓓ The hospital develops, in collaboration with the designated organ procurement organization, written procedures for notifying the family of each potential donor about the option to donate or decline to donate organs, tissues, or eyes. R

A 7. The individual designated by the hospital to notify the family regarding the option to donate or decline to donate organs, tissues, or eyes is an organ procurement representative, an organizational representative of a tissue or eye bank, or a designated requestor. R

Note: *A designated requestor is an individual who has completed a course offered or approved by the organ procurement organization. This course is designed in conjunction with the tissue and eye bank community to provide a methodology for approaching potential donor families and requesting organ and tissue donation.*

A 8. Ⓓ The individual designated by the hospital documents that the patient or family accepts or declines the opportunity for the patient to become an organ, tissue, or eye donor. R

A 9. The hospital notifies the organ procurement organization (OPO) of patients who have died and of mechanically ventilated patients whose death is imminent, according to the following: R

- Clinical triggers defined jointly with its medical staff and the designated OPO
- Within the time frames (ideally, within one hour of death for patients who have expired) jointly agreed on by the hospital and the designated OPO
- For mechanically ventilated patients, prior to the withdrawal of life-sustaining therapies including medical or pharmacological support

A 10. In Department of Defense hospitals, Veterans Affairs medical centers, and other federally administered health care agencies, notification to the organ procurement organization of patients who have died or whose death is imminent is done according to procedures approved by the respective agency. R

A 11. The organ procurement organization determines medical suitability of organs for organ donation and, in the absence of alternative arrangements by the hospital, it determines the medical suitability of tissue and eyes for donation. R

A 12. Ⓓ The hospital maintains records of potential organ, tissue, or eye donors whose names have been sent to the organ procurement organization and tissue and eye banks. R

Standard TS.02.01.01

The hospital complies with organ transplantation responsibilities.

Elements of Performance for TS.02.01.01

A 1. The hospital performing organ transplants belongs to and abides by the rules of the Organ Procurement and Transplantation Network (OPTN)* established under section 372 of the Public Health Service (PHS) Act. R

A 2. If requested, the hospital provides all data related to organ transplant to the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry, or the hospital's designated organ procurement organization (OPO), and when requested by the Office of the Secretary, directly to the U.S. Department of Health & Human Services. R

* The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

Introduction to Standards TS.03.01.01, TS.03.02.01, and TS.03.03.01

The following standards apply to hospitals that store or issue tissue. This includes any areas outside of the clinical laboratory that store or issue tissue; for example, surgery and outpatient centers or tissue banks. They apply to human and nonhuman cellular-based transplantable and implantable products whether classified by the U.S. Food and Drug Administration (FDA) as a tissue or a medical device. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and are not evaluated under these standards.

Specific tissue transplant requirements apply to autologous tissue. This includes policies and procedures for identifying, tracking, storing, and handling autologous tissue, in addition to investigating tissue adverse events. Also, if the state in which an organization resides classifies something as tissue that falls outside the scope of The Joint Commission definition, the standards would apply.

Examples of Tissue and Cell Products

- Amnion/Amniotic Membrane
- Arteries
- Autologous Cells
- Autologous Tissue
- Bone
- Bone Marrow
- Bone Paste
- Bone Powder
- Bone Putty
- Cancellous Chips
- Cardiac (Heart) Valves (Aortic, Pulmonary)
- Cartilage
- Chondrocytes
- Cornea
- Demineralized Bone Matrix
- Dendritic Cells
- Dermal Matrix
- Dermis
- Dura Mater
- Embryo

- Fascia/Fascia Lata
- Hematopoietic Stem Cells
- Leukocytes
- Ligaments
- Limbal Graft
- Limbal Stem Cells
- Lymphocytes
- Marrow
- Membrane
- Meniscus
- Nerves
- Non-valved Conduits
- Oocyte/Ovarian Cells
- Ovarian Tissue
- Pancreatic Islet Cells
- Parathyroid
- Pericardium
- Peripheral Blood Stem Cells
- Progenitor Cells
- Sclera
- Semen, Sperm
- Skin
- Somatic Cells
- Tendons
- Testicular Tissue
- Therapeutic Cells (T-Cell Pheresis)/T-Cells
- Tissue (also Synthetic Tissue)
- Trachea
- Umbilical Cord Blood Stem Cells
- Vascular Graft
- Veins (Saphenous, Femoral, Iliac)
- Other cellular- and tissue-based transplant or implant products whether classified by the FDA as a tissue or a medical device
- Other tissues that are classified as tissues by state law and regulation

Standard TS.03.01.01

The hospital uses standardized procedures for managing tissues.

Elements of Performance for TS.03.01.01

A 1. The hospital assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuance of tissues throughout the hospital. R

Note: *Responsibility for this oversight involves coordinating efforts to provide standardized practices throughout the hospital. A hospital may have a centralized process (one department responsible for the ordering, receipt, storage, and issuance of tissue throughout the hospital) or a decentralized process (multiple departments responsible for the ordering, receipt, storage, and issuance of tissue throughout the hospital).*

A 2. Ⓓ The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues. (*See also* TS.03.02.01, EP 5) R

A 3. The hospital confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.† R

Note: *This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.*

A 4. The hospital coordinates its acquisition, receipt, storage, and issuance of tissues throughout the hospital. R

A 5. The hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue. △3 R

C 6. Ⓓ The hospital documents the receipt of all tissues. (*See also* TS.03.02.01, EPs 3 and 6) Ⓜ R

C 7. Ⓓ The hospital verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented. (*See also* TS.03.02.01, EP 6) Ⓜ R

† For U.S. Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA's online database: http://www.fda.gov/cber/tissue/tissregdata.htm.

Note 1: *If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.*

Note 2: *Tissues requiring no greater control than "ambient temperature" (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt.*

C 8. Ⓓ The hospital maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. (*See also* TS.03.02.01, EP 5) Ⓜ R

Note 1: *Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.*

Note 2: *Tissues requiring no greater control than "ambient temperature" (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.*

A 9. The hospital continuously monitors the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues. R

Note 1: *Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.*

Note 2: *For tissue stored at room temperature, continuous temperature monitoring is not required.*

A 10. Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency back-up plan. △5 R

Note: *For tissue stored at room temperature, alarm systems are not required.*

A 11. The hospital complies with state and/or federal regulations when it acts as a tissue supplier.‡ R

Note: *The U.S. Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.*

‡ Please refer to the following website: http://www.fda.gov/cber/tissue/tisreg.htm.

Standard TS.03.02.01

The hospital traces all tissues bi-directionally.

Elements of Performance for TS.03.02.01

A 1. Ⓓ The hospital's records allow any tissue to be traced 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. ⚠ R

C 2. Ⓓ The hospital identifies, in writing, the materials and related instructions used to prepare or process tissues. Ⓜ R

C 3. Ⓓ The hospital documents the dates, times, and staff involved when tissue is accepted, prepared, and issued. (*See also* TS.03.01.01, EP 6) Ⓜ R

A 4. The hospital documents in the recipient's medical record the tissue type and its unique identifier. R

A 5. The hospital retains tissue records on storage temperatures, outdated procedures, manuals, and publications for a minimum of 10 years. If required by state and/or federal laws, hospitals may have to retain tissue records longer than 10 years. (*See also* TS.03.01.01, EPs 2 and 8) R

A 6. The hospital retains tissue records for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest). If required by state and/or federal laws, hospitals may have to retain tissue records longer than 10 years. Records are kept on all of the following: R

- The tissue supplier

  Note: *For medical devices, the manufacturer may be the tissue supplier.*
- The original numeric or alphanumeric donor and lot identification
- The name(s) of the recipient(s) or the final disposition of each tissue
- The expiration dates of all tissues

(See also *TS.03.01.01, EPs 6 and 7)*

A 7. The hospital completes and returns tissue usage information cards requested by the tissue supplier.[§] R

Standard TS.03.03.01

The hospital investigates adverse events related to tissue use or donor infections.

Elements of Performance for TS.03.03.01

A 1. (D) The hospital has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. R

A 2. The hospital investigates tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. (*See also* IC.01.03.01, EP 3) R

A 3. As soon as the hospital becomes aware of a post-transplant infection or other adverse event related to the use of tissue, it reports the infection or adverse event to the tissue supplier. ⚠3 R

A 4. The hospital sequesters tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection. ⚠3 R

A 5. The hospital identifies and informs tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus-I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue. ⚠3 R

[§] According to the Health Insurance Portability and Accountability Act (HIPAA) regulations regarding protected health information, "A covered entity may disclose protected health information for public health activities or other purposes to a person subject to the jurisdiction of the Food and Drug Administration (FDA) for the following purposes:

- To track products if the disclosure is made to a person required or directed by the FDA to track the product
- To enable product recalls, repairs or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems" (Refer to 45 CFR 164.512(b)(1)(iii)(B) and (C))