

Providing Safe Tissue for Transplant



SETA

*Give the gift of
a better tomorrow.*

Southeast Tissue Alliance

Approved for 2 Continuing Education Units (CEUs)

Providing Safe Tissue for Transplant

Purpose

The purpose of this course is to increase awareness and understanding among healthcare professionals of the methods employed by tissue banks to provide safe tissue for transplant.

Course Objectives

Upon completion of this course the participant will be able to:

1. Describe several ways in which transplanted tissue can be used to enhance lives
2. Discuss the five critical steps in providing safe tissue for transplant
3. State the importance of the nurse's role in the initial screening of the potential donor
4. Describe how the Federal Drug Administration (FDA) has regulated the tissue industry

Continuing Education

This course has been approved for two (2) hours of continuing education for RN's, LPN's, ARNP's, and Clinical Nurse Specialists.

Introduction

There are over 1,000,000 tissue transplants performed each year in the United States to save or enhance the quality of life for patients. Tissues that can be transplanted include skin, bone, tendons, arteries, veins, heart valves, nerves, corneas and other supportive and connective tissues. These tissues come from individuals who have unselfishly given consent for donation of organs and tissues upon their death. The bones or tissues that are transplanted from the body of one person to the body of another person are called allografts. Bone allografts can restore function to damaged joints, or they can prevent limb amputation by replacing cancerous bone. Skin allografts may prevent infections in severely burned patients until new skin can regrow and recovered healthy leg veins can replace damaged arteries in people with poor circulation. These are only a few examples of the many ways that tissue transplant can help people regain lost function, relieve debilitating pain or replace diseased or injured tissues. A few of the other indications for allograft transplant include spinal fusions, hip and knee replacement, rotator cuff repair, surgical treatment for incontinence, heart valve replacement and dental procedures.

Imagine that you, or a family member, are one of those one million individuals that will need a tissue transplant this year. It might be for back surgery to relieve pain, corneas to restore eyesight or one of hundreds of other indications for a tissue transplant as the treatment of choice. Do you feel secure in knowing that the tissue your surgeon intends to use for your transplant is safe and free of infection and other dangerous diseases? Are you aware of the risks associated with tissue

transplant and do you know what is being done to help prevent adverse events associated with tissue transplants? Do you know who is involved in monitoring the tissue industry?

The safety record of tissue transplantation is encouraging. "The overall risk of disease transmission through tissue transplantation is believed to be very low," says Jesse Goodman, M.D., M.P.H., director of the FDA's Center for Biologics Evaluation and Research. Tragic results have however resulted from the rare incidents of disease transmission. In 2001, a 23-year-old patient died four days after receiving a transplant of bone and cartilage to reconstruct his knee. He had acquired a deadly infection from toxic bacteria in the tissue. A lengthy delay in refrigerating the donor before the tissue was recovered is believed to have triggered the growth of the bacteria, according to the Centers for Disease Control and Prevention (CDC). In 2002, five tissue recipients in the United States were believed to have been infected by hepatitis C from a single donor's tissues. And in 2003, contaminated corneas resulted in infections and the loss of eyesight in two people.

On the more positive side, transmission of tuberculosis and hepatitis B have not been reported for more than 50 years. There have not been any reported cases of LCMV, Chagas disease, Rabies or West Nile virus from tissue transplants. The only reported case of transmissions of HIV occurred over 20 years ago. A few cases of hepatitis transmissions occurred in the early 1990's. There are no reported cases of transmission of any form of cancer due to tissue transplantation. Tissue transplants are however a medical procedure and still carry a risk of adverse reactions for the recipient.

The process or journey that donated tissue takes from the initial identification of the potential donor to the recipient can be broken down into seven distinct and significant check points. Each one of these critical processes will help to enable the tissue bank to provide tissue that will prevent the introduction, transmission and spread of communicable disease to the recipient.

I. Referrals and Initial Screening

The vast majority of donated tissue comes from patients who expire in a hospital setting. All hospitals must have in place a system for referring every death that occurs in their facility. In order to receive Medicare reimbursement the hospital must follow the Medicare Conditions of Participation which requires that all deaths be reported to an Organ Procurement Organization (OPO), tissue bank and/or eye bank. These referrals are mandatory and are not in violation of HIPAA regulations. When a cardiac death occurs in a hospital, the primary care nurse (or other staff member that has been designated by the hospital) will call the appropriate organ or tissue recovery agency and make the potential donor referral. For potential tissue donors, the call will be answered by a trained and knowledgeable coordinator at the tissue bank who will make the initial determination of donor eligibility based on information that they receive from the nurse. The tissue bank coordinator will ask the nurse the age, weight, cause of death, WBC, results of blood cultures if done, chest x-ray results if one was done and current and past medical history and if there is a diagnosis of cancer, HIV, hepatitis or dementia. The coordinator will then be able to make an initial determination of eligibility based on the answers to these questions. Every question asked and

answered will assist the tissue bank coordinator in completing the initial screening for eligibility and in determining which tissues could potentially be donated.

The tissue bank coordinator will often refer to the Tissue Bank's Uniform Donor Acceptance Criteria Manual (UDAC). The purpose of this manual is to assure that the proper safeguards are implemented when conducting donor screening for determining donor suitability for recovery. The criteria of the UDAC was established to provide a guideline for the inclusion or exclusion for all tissues currently considered for transplant. In addition to an extensive list of diseases and conditions, the UDAC contains algorithms for assisting in the determination of other conditions such as sepsis, abdominal disorders, pneumonia and cancer. Based on the information obtained from the nurse, the tissue bank coordinator may ask for more detailed information, lab results, physician consults or other documentation to assist in making the eligibility determination. If the patient does not meet the initial screening criteria, the tissue bank coordinator will inform the nurse of the ineligibility and no contact will be made with the patient's family. If the potential donor is determined to be eligible for donation, the tissue bank coordinator will request next-of-kin information from the nurse and also inquire if there is a Health Care Surrogate (HCS) for the deceased. The tissue bank coordinator will allow some time to pass before contacting the HCS or next-of-kin to offer the option of tissue donation. The coordinator will also access the online donor registry to determine if the deceased has expressed his/her decision to be a donor by indicating his/her wishes on the driver's license. During this time, the potential donor should be refrigerated in the hospital morgue if one is available.

II. The Informed Consent Process

If the HCS or next-of-kin is in favor of donation, the tissue bank coordinator will document all the necessary information on a consent form. The consent process and documentation must be conducted according to the American Association of Tissue Banks (AATB) *Standards for Tissue Banking*. The AATB's Standards for consent are extensive and the AATB has had requirements for consent since the first edition of its Standards in 1984. If the HCS or immediate next-of-kin is unable to complete the consent process at that time, they may designate another person to speak for them. Generally all consents are done over the phone line and are recorded. The families are informed that the consent process is being recorded. Information regarding the donation and recovery of tissue must be presented in a language that can be understood by the individual giving consent. The consent will be obtained under circumstances that provide the next-of-kin with an opportunity to ask questions and receive adequate information to make an informed decision. In order to have an informed consent the tissue bank coordinator will go through all the tissues that the deceased is able to donate and the family may give consent or decline each tissue. The coordinator will also ask the family if the deceased was ever diagnosed with dementia, or any communicable diseases such as HIV, hepatitis B or hepatitis C. Even though the consent process is recorded, it will be briefly verified by another tissue bank coordinator. The family may request a copy of the consent form if they choose.

III. The Medical Social History

After the completion of the consent process the tissue bank coordinator will obtain a Medical Social History (MSH) from a qualified family member or other person identified as having knowledge of the potential donor's medical and social history. The MSH may also be obtained from the best family historian, close friend, significant other, HCS or Legal Power of Attorney. Some of the questions on the MSH will automatically disqualify the potential donor if they are answered with a yes response. Other questions answered yes will require additional information to enable the tissue bank coordinator to make a determination of eligibility. Affirmative answers may exclude some tissues but not others. The tissue bank coordinator will inform the next-of-kin (or other designee) giving the medical social history of the sensitive nature of many of the questions and emphasize the desired end result which is safe tissue for transplant.

The MSH questionnaire is broken down into five key sections, each with a different focus, to help screen out tissue that may possibly be harmful to the recipients.

A. High Risk Behavior/Conditions

1. Did (donor) ever test positive for viral Hepatitis B or C or HIV? If the answer is yes, the donor is ruled out.
2. Did (donor) have evidence or history of an autoimmune disease? If the answer is yes, the donor is ruled out.
3. Did (donor) ever receive Human-derived clotting factors? If the answer is yes, the donor is ruled out.
4. In the past five years, did (donor) use a needle to inject drugs into his/her body for non-medical use? If the answer is yes, the donor is ruled out.
5. In the past 12 months had (donor)
 - a. been an inmate of a correctional facility for 72 consecutive hours or longer? If the answer is yes, the tissue is ruled out.
 - b. had a tattoo, acupuncture, or ear/body piercing using shared or non-sterile instruments? If the answer is yes, the tissue is ruled out.
 - c. been exposed to known or suspected viral Hepatitis or HIV infected blood? If the answer is yes, the tissue is ruled out.
 - d. lived with persons diagnosed with viral hepatitis? If the answer is yes, the tissue is ruled out.

B. Sexual History Questions

The components of the sexual history questions are to identify high-risk behaviors. If any high-risk areas are identified, then the donor must be ruled out. This is to prevent viral disease transmission, due to associated high risk factors.

1. In the past 5 years did (donor)
 - a. engage in sex in exchange for money or drugs or had sex with anyone who has?
 - b. MALE donors only: did (donor) have sex with another man?
2. In the past 12 months did (donor)
 - a. have sex with someone who had received human-derived clotting factors?

- b. have sex with a person known or suspected to have Hepatitis B or C?
- c. FEMALE donors only: have sex with a male who had sex with another male?
- d. have sex with someone who has been an inmate of a correctional facility (for 72 consecutive hours or longer)?
- e. have sex with anyone who had used a needle to inject drugs into their body for non-medical use?

C. Travel Section

Did (donor) travel to or live anywhere outside the United States (except for Canada) between 1980 and now? An affirmative answer does not automatically rule out the donor. That determination will be based on the answers to subsequent questions regarding the location of the travel or residence. Risk factors also include travel to endemic regions in the last six months. These regions are updated in the Blue Book updated and published regularly by the CDC.

D. Creutzfeldt Jacobs Disease (CJD) and Other General Section

1. Did (donor) receive a dura-mater transplant?
 2. Did (donor) receive a transplant of animal origin (xenograft) or had intimate contact with someone who had?
 3. Has (donor) ever received human derived pituitary growth hormone?
 4. Has (donor) ever received bovine insulin injections between 1980 and now?
 5. Has donor) received any transfusion of blood or blood components from the United Kingdom between 1980 and now?
 6. Did (donor) suffer from CJD or there is a family history of a blood relative with CJD?
 7. Was (donor) diagnosed with active encephalitis or meningitis viral or unknown cause in the last 28 days (including West Nile Virus (last 120 days)?
 8. Was (donor) diagnosed with or suspected to have Severe Acute Respiratory Syndrome (SARS) (last 28 days); or had close contact with anyone that has SARS?
 9. Was (donor) currently suspected to have rabies, or had received a bite from an animal suspected to have rabies within the past six (6) months?
 10. Did (donor) receive a recent small pox vaccination (last 21 days) or exhibit any symptoms of smallpox?
 11. Did (donor) ever have Malaria or be at risk for Malaria?
- Yes answers to any of these questions will rule out the donor.

E. Unexplained Symptoms Section

1. Did (donor) ever have any of the following **UNEXPLAINED** symptoms?
 - a. persistent diarrhea or fever greater than 100.5 for more than 10 days?
 - b. persistent cough, shortness of breath, opportunistic infection, or swollen lymph nodes lasting greater than one month?
 - c. enlarged liver, cirrhosis or yellow jaundice?
 - d. night sweats or weight loss?
 - e. raised blue or purple spots on the skin or mucous membranes?
 - f. persistent white spots in the mouth?

- g. both headache and fever lasting longer than seven days?
- 2. Did (donor) suffer from any type of medically diagnosed or unexplained neurological or brain disease?
- 3. In the past 12 months, has (donor)
 - a. been diagnosed with any significant infectious diseases, including tuberculosis?
 - b. been diagnosed with any sexually diagnosed disease?
 - c. used cocaine?
- 4. Was (donor) ever permanently deferred as a blood donor?
- 5. Did (donor) have any history of cancer?
- 6. Has donor ever been diagnosed with any type of heart disease, hypertension, stroke, poor circulation, muscular dystrophy or Chagas disease?
- 7. Did (donor) have any evidence or history of insulin dependent diabetes?
- 8. Has (donor) ever been exposed to a toxic substance?

F. Additional questions for eye donors and pediatric donors.

IV. Recovery Process

If the MSH is free from any potentially harmful elements, the tissue bank coordinator will call the on-call recovery team for that region and inform them of the donation. The consent and MSH forms will be faxed to the Recovery staff for review prior to going to the hospital. Once the recovery team (which is usually comprised of three technicians) is at the hospital, they will complete a thorough review the patient's chart before examining or preparing the body.

The recovery team will review the chart in its entirety for any documentation that is relevant to the recovery. Certain important details may not have been passed along to the tissue bank coordinator at the time of initial screening. The tissue bank must have complete and accurate records on each donor. The recovery team will review the recent intake and output sheets to determine if the blood sample may be hemodiluted and not adequate for testing. A donor will be considered ineligible if plasma dilution, sufficient to affect the results of communicable disease testing, is suspected. If hemodilution is suspected the team will use an appropriate algorithm designed to evaluate volumes of fluids administered in the 48 hours before specimen collection. If the results indicate that the blood is sufficiently diluted and may affect the outcome of the test results, the recovery team will obtain a pre transfusion blood sample from the hospital lab if one is available.

The recovery team will look to see if a chest x-ray was done prior to death to determine if a lung biopsy will be needed to rule out the possibility of malignancy or infectious diseases. The lungs are prone to pulmonary infection by aspiration and are also directly exposed to ambient air which can lead to infection through inhalation of droplets. If the chest x-ray is negative a lung biopsy will not be required.

The recovery staff will assign a unique donor identification number that will stay with this donor and be the means of identification for tracking purposes. Each piece of tissue that is distributed for

transplant, will carry this unique number to assist in recording where each tissue has been distributed, and for recall purposes should that become necessary.

Once the chart review is completed, the recovery team will confirm the donor's identity and verify the consent and the tissues that are to be recovered. They will obtain the blood sample that will be used for infectious disease testing. They will perform a full-body examination of the deceased and document their findings. Specifically they will look for signs of active infection, evidence of sexually transmitted diseases, needle tracks (non medical), recent tattoos and piercings, lymph node enlargement, jaundice, clinically significant skin lesions or trauma or infection at the recovery site. Times frames will be noted including the date and time of death, the time of refrigeration if applicable, and the time of the start of the recovery process. Tissue is recovered using standard OR aseptic technique procedures and the AATB Standards. The donor skin is surgically prepped, the recovery team is gowned and gloved and the body is draped using surgical methods. Recovered tissue is packaged, labeled with the unique ID number and identified as quarantined. The tissue is transported to the processor and is quarantined until all necessary paperwork and lab results have returned and the tissue is cleared by the Medical Director for processing and distribution.

V. Chart Review

A copy of the donor chart from the hospital is sent to the medical records department of the recovery agency for review and verification of completeness. If any required documents are missing, a request will be sent to the hospital for those documents. If blood cultures were performed during the hospital stay but the final results are not completed at the time of recovery, those reports will be requested. If the donor is going to have an autopsy, those results will be requested. Other examples of necessary paperwork may include the primary care physician's history and physical, the discharge summary, consult reports, lab results, x-rays, intake and output sheets, biopsy results or any other information that may assist the processing agency in making a determination as to the suitability of the tissue for transplantation. Any additional information, that is obtained after the tissues and initial paperwork have been sent to the processors, will also be sent to the processors for their records. The Medical Director of the processing agency will make the final determination as to the suitability of the donor tissue for distribution.

VI. Infectious Disease Blood Testing

The AATB and the FDA have set guidelines as to what tests must be performed on any donated human tissues that will be used for transplant. These include:

- HIV 1/2, Antibody/HIV-1NAT
- HB Core Antibody
- HBsAG
- HCV Antibody/HCV NAT
- Syphilis test
- HTLV-I-II Antibody

The use of Nucleic Acid Testing (NAT) technology for HIV 1 and HCV can substantially reduce the “window period” by identifying an infectious disease earlier than standard testing. The testing must also be performed using an appropriate, approved FDA-licensed, or cleared donor screening test in accordance with the manufacturer’s instructions. In cases in which the donated tissue is recovered from a deceased person, the test kit must specifically state for use with cadaveric specimens.

As newer and more sophisticated tests for infectious diseases are developed, they will be incorporated into the requirements for screening tissue for transplant. Currently there are no tests available to detect CJD, SARS, or West Nile Virus.

VII. Processing Human Tissue for Transplant

Tissue processors are also considered “tissue banks” and should be accredited by the AATB. They should also be following the Current Good Tissue Practices set forth by the FDA. In preparation for release and distribution, tissues undergo some type of “processing” to reduce the potential for disease transmission. Pre processing cultures are either obtained at the time of recovery or by the processing agency before the tissue is sterilized/disinfected. The goal of the processing method is to destroy or inactivate bacteria, viruses, and spores without changing the structural integrity of the tissue. Gamma irradiation has been shown to inactivate most bacteria without affecting the tissue properties. But the low dose needed to ensure the integrity of the tissue may not be enough to kill HIV and other viruses. Irradiation may be used in conjunction with other methods of processing in order to ensure safer tissue. Chemical processing may include a multi-step cleansing that can completely penetrate tissue to remove all blood and bone marrow, then sterilize the tissue. This method can eliminate the most resistant organisms – viruses, fungi, bacteria and spores while preserving the biomechanical integrity and biocompatibility of the tissue.

Role of Voluntary Association and Regulatory Agencies

American Association of Tissue Banks (AATB)

In 1984 the AATB published the only authoritative standards for tissue banks and it is dedicated to ensuring that human tissue intended for transplantation is safe and free of infectious diseases. In order for a tissue bank to become a member of the AATB, they must pass the mandatory accreditation process which includes a rigorous inspection of their operations. Tissue banking activities must be performed in a safe and professional manner and be in compliance with the AATB Standards. All aspects of the tissue banks operations, including record-keeping, quality control, quality assurance, donor screening, testing and suitability determinations are reviewed for compliance with the Association’s Standards.

The FDA

The FDA has regulated the tissue industry since 1993 when it required donor testing and it continues to monitor all aspects of tissue banking. On May 25, 2005 the FDA issued its Current Good Tissue Practice (CGTP) rules for Human Cells, Tissues, and Cellular and Tissue-Based

Products (HCT/Ps). These rules were developed to improve the safety of human cells, tissues, and cellular and tissue-based products by **preventing the introduction, transmission and spread of communicable disease by tissue transplantation**. The requirements aim to ensure that the HCT/Ps do not contain communicable disease agents, they are not contaminated, and they do not become contaminated during processing. The FDA regulates human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient. In addition to cadaveric tissue donation, HCT/Ps include hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, and semen or other reproductive tissue. Current Good Tissue Practice rules are part of 21 Code of Federal Regulations (CFR) 1272 which governs the methods used in the manufacture of HCT/Ps, including but not limited to all steps in the recovery, screening, testing, processing, storage, labeling, packaging and distribution of human cells.

The Joint Commission

Once the tissue has been distributed to the hospital or surgery center it becomes the responsibility of the receiving facility to monitor the tissue to ensure its proper handling, to monitor refrigeration if necessary and to maintain traceability of all tissues. Hospitals, critical access hospitals, ambulatory care settings and office-based surgery programs must all comply with the Joint Commission's tissue storage and issuance standards which became effective on July 1, 2005 and were revised in January 2007. The facility must assign responsibility for oversight of the tissue program throughout the establishment. Standard Operating Procedures must be in place to standardize the process for acquiring, receiving, storing and issuing tissues. The facility must retain records for ten years so that the tissue can be traced both to the recipient and back to the source facility and donor (bi-directional traceability). Records must also indicate the dates and the identities of the staff involved in each significant step of the tissue from receipt of tissue into the facility to transplant. The unique identifying number assigned to the donor tissue must be part of the recipient chart as well as the name of the source facility (distributing organization). There must also be a standardized process for investigating adverse events. Procedures must be in place to investigate any recipient adverse events especially if it is suspected of being directly related to tissue use. Cases of post-transplant infections or adverse events should be promptly reported to the source facility. Serious adverse reactions are defined by the FDA as "fatal, life-threatening, resulting in permanent impairment of a body function or permanent damage to body structure, or necessitating medical or surgical intervention, including hospitalization." (MMWR Weekly May 20,2005 / 54(19);490 FDA Rule for Current Good Tissue Practice for Human Cells, Tissues, and Cellular and Tissue-Based Products)

Conclusion

The demand for allograft tissue continues to rise as new and innovative uses for the tissue becomes available. There will always be a risk associated with tissue transplant and the risk rises with the potential to transmit new strains of viruses and diseases for which there are currently no tests to signify their presence. West Nile Virus, SARS, and CJD fall into this category. Currently, tissue banks rely on screening procedures, interviews with family members, blood testing, and processing procedures to prevent the transmission of diseases through transplant. The standards for tissue

banking will continue to change as new methods for disease identification in donors are developed and new tests are required as part of the screening process.

Mandatory adverse event reporting and tissue tracking will help to increase the data base and further the industry's knowledge of cases of potential disease transmission. Allograft transplant continues to be the best surgical alternative in many situations. Having knowledge of the standards that tissues must pass to be determined suitable and the relative safety of tissue transplants can help to eliminate fears prior to surgery.

Bibliography

"About Tissue Transplants." About Tissue Transplants FAQ. Feb. 06. 23 Jan. 08
<<http://www.cdc.gov/ncidod/dhqp/tissuetransplantsfaq.html>>.

Accreditation, About Us. AATB. Aug. 8th, 2008.
<<http://aatb.org/content.asp?contentid=430>>

Advert Tissue Reaction Policies. Comprehensive Accreditation Manual for Hospitals, The Joint Commission. April 06, 07

"Concerning the Current Good Tissue Practice Final Rule." Questions and Answers. 5 July 07. 17 Feb. 08
<<http://www.fda.gov/cber/rules/gtpq&a.htm>>.

"Concerning the Donor Eligibility Final Rule and Guidance." FDA.CBER- Questions and Answers Concerning the Donor Eligibility Final Rule and Guidance. 5 July 07. 7 July 08
<<http://fda.gov/cber/rules/suitdonorq&a.htm>>.

"Consumer Frequently Asked Questions." FDA/CBER-Consumer FAQs about Tissue. 5 July 07. 17 Feb. 08
<<http://www.fda.gov/cber/faq/tisconsfaq.htm>>.

"FDA Rule for Current Good Tissue Practice..." Notice to Readers:. 20 May 05. 17 Feb. 08
<<http://cdc.gov/mmwr/preveiw/mmwrtml/mm5419a8.htm>>.

Goodman, Jesse L. Tissue Banks: The Dangers of Tainted Tissues and the Need for Federal Regulation. Rep.No. Department of Health and Human Services.

Joyce, Michael J., Seth Greenwald, Scott Boden, Scott Brubaker, and Christine S. Heim. Musculoskeletal Allograft Tissue Safety. Rep.No. American Academy of Orthopaedic Surgeons.

"Keeping Human Tissue Transplants Safe." Keeping Human Tissue Transplants Safe. May 05. 17 Feb. 08
<http://fda.gov/fdac/features/2005/305_tissue.html>.

Official Publication of Revisions to Standard. Joint Commission on Accreditation of Healthcare Organizations, Joint Commission Perspectives.



Providing Safe Tissue for Transplant
Post Test – 2 CE's

- | | | |
|--|---|---|
| 1. Cancer has never been transmitted through tissue transplant. | T | F |
| 2. The current medical history of the patient, which is provided by the nurse at the time of death, is vital in making the initial eligibility determination of the patient for potential tissue donation. | T | F |
| 3. The person giving consent for donation may not always be the same person as the person completing the Medical Social History. | T | F |
| 4. The Medical Social History covers questions regarding the potential donors high risk behaviors, sexual history, travel, CJD exposure and unexplained symptoms. | T | F |
| 5. A lung biopsy may be required in some instances to eliminate the possibility of malignancy or infection. | T | F |
| 6. Hemodilution is considered an issue only if the patient had multiple blood transfusions during surgery. | T | F |
| 7. Every donor will have a unique ID number assigned to it for tracking purposes? | T | F |
| 8. Tissues are recovered using standard OR aseptic technique procedures? | T | F |
| 9. The goal of tissue processing is to destroy or inactivate bacteria, viruses, and spores without changing the structural integrity of the tissue? | T | F |
| 10. The goal of the FDA's current good tissue practices is to prevent the introduction, transmission and spread of communicable diseases by tissue transplant? | T | F |

Name: (please print) _____

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