U.S. Food and Drug Administration's 5-year MSM Deferral for Tissue Donation

The Basics & Breakdown // Public Brief

Pride & Plasma
@prideandplasma
prideandplasma.com
https://linktr.ee/prideandplasma

Introduction//Purpose

Since 1994, the United States Food and Drug Administration has implemented a 5-year deferral for tissue donations from queer men. The policy was expanded once, in 2005 to include anonymous sperm donation, and upheld again in 2007. The regulation has not been touched since.

This document is here to explain the background and basics of the issue, to make it accessible for those without a healthcare and/or policy background. We'll explain what the policy means, who is in charge, and how it's applied. At the end we'll compare the regulation to other similar policies to recommend potential routes of progress, revision, and implementation.

This is the background of our research, forming a strong foundation for advocacy, but it is not the entirety. To learn more, please read our issue brief once it is released and published, and keep up to date on our website- prideandplasma.com and on Instagram, Twitter, and Facebook @prideandplasma.

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The Basics & Introduction

The Overview

In 1994, the Public Health Service (PHS) implemented a new policy for tissue and tissue donation eligibility[1]. One of the many provisions and criteria included in the policy was a 5-year deferral for any sexually active queer men. A deferral would usually delay eligibility towards a later date, in this case, in 5 years time. However, with tissue donation, there is no opportunity for donation at a later date. If a donor is determined to be ineligible, they lose the one opportunity to donate. This policy was initially put in place to ensure safety in tissue donation, and at-risk populations were identified as ineligible due to inaccurate and ineffective testing methods. The policy was applied to tissues that the Food and Drug Administration (FDA) regulated, including: corneas, sclera, skin, heart valves, dura mater, bone, tendons, ligaments, cartilage, and oocytes. These tissues are broken down in more detail later on in this document.

In 2004, the policy was revised again, instead by the FDA rather than the PHS, covering only tissue donation, and this time, it was expanded. Sperm donation was included for anonymous donations; direct donation (where the donor and recipient know each other and agree to the process) was not included. The 5-year deferment for MSM (men who have sex with men) donors was still in place. In 2007 the policy was upheld, with no revisions, expansions, or removals. That was the last time that the policy was updated, and the queer tissue has not been touched since implementation in 1994.

The tissues that are regulated are grouped into a few categories[2]. The main two (where each tissue falls into one category) are Non-Leukocyte Rich Tissues and Leukocyte-Rich Tissues.

- Non-Leukocyte Rich Tissues include: corneas, sclera, skin, heart valves, dura mater, bone, tendons, ligaments, cartilage, and oocytes.
- Leukocyte Rich Tissues include: sperm and hematopoietic stem/progenitor cells

Additionally, reproductive tissue donations (oocytes and sperm) are also classified. The tissue classifications determine the tests that the donors are subject to.

When an individual registers as an organ donor, they also register simultaneously as a tissue donor- the process and registry are one and the same. However, the federal government's regulation of tissue and organ donation are not universal. The Food and Drug Administration has jurisdiction over tissues (and blood products), while the Department of Health and Human Services handles organs[3].

Tissues are groups of cells that work together to perform a shared function, and tissue donations from queer men [referred to as MSM (men who have sex with men) in the policy)] face a 5-year deferral policy. Organs are groups of tissues and cells that work together to perform larger functions. The Department of Health and Human Services (HHS) does not mandate any *deferrals* for queer men, but they label organs harvested from queer men with "high-risk MSM activity" if the donor had been sexually active with another man in the past 30-days. These organs are still offered to matched recipients and the rationale behind the label is applied. Potential recipients can then decide to accept the organ, or continue to wait. A similar 12-month policy was put in place in 2013 and labeled donations as "increased risk donor", without differentiation between increased risk donor classification (criteria that applied the IRD label were those who had been incarcerated, MSM donors, those who used injection drugs, and sex workers).

Definitions & Terminology

- **Allograft**: A tissue graft harvested from another human.
    - *Allografts are common in tissue donation, and are the term used when describing donations from cadavers.*
- **Anonymous Donation**: Where a donor and a recipient do not know each other prior to the donation process, this is the case for most tissue transplants.
    - *Anonymous tissue donation is subject to the 5-year MSM deferral criteria*
- **Autograft**: A tissue graft harvested from the recipient.
    - *Autografts are where a tissue from one part of a patient's body is relocated to a different location to promote healing, decrease pain, or otherwise improve function.*
- **Deferment**: The action or fact of putting something off to a later time; postponement.
    - *The FDA's policy requires 3 months deferment since a queer man's last sexual contact.*
- **Direct Donation**: Where a donor and a recipient know each other and agree to the donation process.
    - *Direct tissue donation is not subject to the 5-year MSM deferral criteria, like with sperm donation between parties that know each other.*
- **Graft**: A harvested sample of tissue.
    - *Tissue grafts are removed from a donor and transplanted into a recipient.*
- **Guidance**: Current best practices, recommendations, and proposals from a federal agency.
    - *The FDA issues policies and guidances like the tissue donation eligibility criteria.*
- **Matching**: The process of pairing a donation and a recipient.

    - *Matching tissue and organ transplants helps to limit the risk of rejection and ensures that the transplant does its intended job.*
- **MSM**: Men Who Have Sex With Men.
    - *The FDA's blood donation policy prevents sexually active queer men from donating.*
- **Organs**: Groups of tissues and cells that perform larger, shared functions. Organs include your lungs, heart, liver, and more.
    - *Organ donation eligibility criteria is set by the Department of Health and Human Services.*
- **Procuring**: The action of removing a tissue from a donor to prepare it for holding or transplantation.
    - *After a donor is screened and assessed, their tissues are procured.*
- **Queer**: Queer is an umbrella term for people who are not heterosexual or are not cisgender.
    - *Pride and Plasma uses the term "Queer" to remain inclusive of all individuals and sexualities impacted by the FDA's policy, not all of whom identify as Gay or Bisexual.*
- **Screening**: The act of assessing an individual's potential risk of infection prior to tissue donation.
    - *A potential donor's family and close contacts will be screened to learn if a male donor has had any men in the past 5 years.*
- **Tissue**: A group of cells that performs a shared, specific function.
    - *The FDA's tissue donation eligibility policy determines who is allowed to donate tissues to those in need.*
- **Transmission**: The spread of an infection from a donor to a recipient through a tissue transplant.
    - *The 5 year MSM deferral is rationalized due to a risk of HIV and Hepatitis B transmission from queer men.*
- **Xenograft**: A tissue graft taken from an animal (non-human source).
    - *Occasionally, instead of synthetic (lab/factory made) or human tissues, xenografts can be used in treatment.*

The FDA and The Cellular, Tissue & Genetic Therapies Advisory Committee[4]

The USA's federal government is divided into three branches- Executive (Presidency, Departments, & Agencies), Legislative, (Congress) and Judicial branches (Courts). These branches serve specific functions, and while each holds a potential route for advocacy with discriminatory MSM deferment policies, Pride & Plasma brings our argument to the

executive branch- a route that may not be as successful for other endeavors. Here is an overview of routes for advocacy, and why we utilize the executive branch over legislative and judicial efforts:

- **Executive Branch**: The Food and Drug Administration is the creator of these deferment criteria, and the group that can most easily revise the policy. It is the direct route. Further, regulations released by the FDA undergo public comment periods and frequently allow for the public to speak at advisory committee meetings.
- **Legislative Branch**: The US House of Representatives and US Senate form Congress- the branch of government which drafts, passes, and enacts laws. However, congress does not hold authority to legislate or revise executive agency regulations. All that congress would be able to do is vote on a resolution (a formal opinion), which would ask the FDA to revise the policy; or reduce their budget as a tactic to force the FDA to change the policy. The FDA performs vital acts of public service, ensuring the safety of patients, reducing their budget would harm the nation far more than the deferment currently does.
- **Judicial Branch**: A lawsuit against the FDA arguing that citizens are being discriminated against is a tactic we have seen other countries attempt to utilize while fighting MSM deferrals. However, the high costs of legal cases make this route inaccessible for Pride and Plasma at this time. Additionally, there is a high likelihood that a judge would rule in a case saying “we make judicial determinations in this courtroom. Any potential scientific basis for the policy could be legitimate, and that is outside of our jurisdiction”.

The FDA works to ensure the safety, efficacy, and security of drugs, medical devices, cosmetics, food, and biological products[5]. The FDA creates eligibility criteria for donors of blood and human tissue, as well as licenses and approves the tests used to determine if those donors have infections that could be transmitted. The FDA is made up of centers, one of which is the Center for Biologics Evaluation and Research. CBER focuses on biological products for human use and is made up of many advisory committees[6]. One of these, the Cellular, Tissue, and Gene Therapies Advisory Committee reviews data and creates recommendations for policies. They usually meet at least twice a year. They are where we will present our evidence, research, and argument once it is complete.

Every year CBER releases a list of policies that they plan to revise, update, or change for the year. In both 2022[7] and 2023[8], the Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products was included on that list. We did not see a revision in 2022, as the 2007 policy is still the most recent version. The document is 70 pages long, and anything could be added, changed, or removed. However, we hope that the FDA is at least open to revising the MSM deferral. The list of CBER releases does not

mean that the policy is going to be revised, and CBER can choose to leave the current guidance intact.

The 12 Tissues

The 12 tissues explicitly listed in the FDA's eligibility criteria are explained in depth down below, but here is a brief overview of each tissue's location and the reason(s) for implementation.

- **Corneas** are the clear tissues over the front of the eye that allow light to enter[9]. They can restore vision, decrease pain, and improve the external appearance of the eye[9].
- **Sclera**: are the white layer of the eye that supports the shape and protects from injury[10]. Transplants can treat glaucoma, orbit reconstruction, and eyelid reconstruction[10].
- **Skin**: is the body's external covering that protects against infection, injury, water loss, and heat loss[11]. Skin transplants (called "grafts") improve the healing of wounds and burns, improve appearance, and reconstruct damaged skin[12].
- **Heart Valves** lie between the chambers of the heart and ensure that blood flows in the right direction through the heart[13]. Transplants treat valvular stenosis (reduced flow), regurgitation (backwards flow), and infective carditis (bacterial growth)[14].
- **Dura Mater**: the outermost lining of the brain that protects the brain, nerves and neurons. Transplants repair defects, ensure successful surgery, and fix damage[15]. They prevent CSF leakage, protrusion, hemorrhage, and more[16].
- **Bones**: Bones provide structural support and protection for internal organs. Transplants are used to treat fractures or bone loss[17].
- **Tendons**: connect muscles and bones. Tendons ensure movement when muscles contract[18]. Transplants help stabilize anatomy, restore function, and protect against additional injury[19].
- **Ligaments**: connect bones and help keep them stable during movement[20]. Transplants are used to treat ruptures and injuries in order to improve stability, acceleration, strength, and function[21].
- **Cartilage**: Where bones meet, areas that need structural support. Cartilage protects against friction and provides structure[22]. Transplants are used to repair damage and defects in joints[23].
- **Oocytes**: also known as eggs. Oocytes are the female reproductive cell that contains DNA and creates an embryo by combining with a sperm[24]. Donations are used in infertility, queer couples, couples with genetic disorders, surrogates, and other individuals ready to start a family[25].
    - *Although oocytes are not usually typically subject to the 5-year MSM deferral, a female donor who has been sexually active with a queer man in the past*

12-months is determined to be ineligible[2]. Further, we do not yet know how the policy impacts trans men, trans women, & nonbinary donors.

- **Sperm**: the male reproductive component in creating an embryo[26]. Sperm donation is utilized by individuals with infertility, genetic disorders, queer couples, and those who chose to pursue direct or anonymous donation.
    - *Only anonymous sperm donation is impacted by the 5-year deferral for queer men. Direct donation, where the recipient and donor know each other, is not subject to the policy[2].*
- **Hematopoietic Stem Cells/Progenitor Cells**: HSCs are located in bone marrow, circulation, and cord blood and they can form in all forms of blood cells[27]. Transplants are frequently used in the treatment of blood disorders and cancers, where they can elicit remission and prolong life[27].

The Deferral Process

The Screening Questionnaire

Donors are determined to be eligible for tissue donation in two main ways. The first of these is the screening questionnaire. The FDA's tissue donation eligibility criteria determines what makes a potential tissue donor ineligible. The criteria are included due to a potential risk of transmission of infectious agents[2]. If a donor matches with even one criteria, they are determined to be ineligible. The policy determines the criteria, and a screening questionnaire is drafted and approved by the American Association of Tissue Banks (AATB)[28].

The Screening Questionnaire[2]

1. **Men who have had sex with another man in the past 5 years (due to a cited risk of HIV and Hepatitis B)**
2. Non-prescription injection drug use in the past 5 years
3. Individuals with hemophilia/clotting disorders who received human-derived clotting factors in the past 5 years
4. Participated in sex for money or drugs in the past 5 years
5. **Persons who have had sex within the past 12 months with anyone identified in #1-4 or someone HIV/Hep B or C positive**
    a. *This criteria impacts women & nonbinary individuals who have had sex with queer men*
6. Exposure to known/suspected HIV, Hep B/C infected blood in the past 12 months
7. Children born to mothers at risk with/at risk of HIV if <18 months old or breast-fed in the past 12 months
8. Individuals who have been incarcerated for >72hrs in the past 12 months
9. Individuals who have lived with someone who has Hep B/C in the past 12 months.
10. Recent tattoo/piercing in the past 12 months, if the procedures/materials were not sterile
11. Former diagnosis of viral hepatitis after 11th birthday
12. Medical diagnosis of sepsis at time of death
13. Small pox vaccination in the past 8wk (until scab detaches spontaneously or 21 days; whichever is last. 2 months if the scab is removed prior to spontaneous separation).
14. Clinically active vaccinia infection due to contact with a recently vaccinated individual (if a scab is present).

15. Medical diagnosis or suspicion of west nile virus (120 days after diagnosis/onset of illness, whichever is later)
16. Positive test for west nile virus in the past 120 days
17. Treatment for or infection with syphilis in the past 12 months
18. Chlamydia trachomatis or neisseria gonorrhea infection or treatment in the past 12 months.
19. Diagnosis of any form of Creutzfeldt-Jakob Disease
20. Diagnosis of dementia or any demyelinating diseases of the central nervous system.
21. Recipients of non-synthetic dura mater transplants, human pituitary-derived growth hormone
22. Individuals with a blood relative with a history of Creutzfeldt-Jakob Disease
23. - 25. Geographic deferrals for individuals who spent a certain amount of time in Europe from the 1980s-1990s. Vary based on location
26. Recipients of blood products in the UK or France after 1980
27. Individuals (or their sexual partners) born or who lived in certain countries in Africa after 1977
28. Persons who have received a blood transfusion or products in the countries in #27
29. Individuals who received xenotransplants (animal tissue or organs) or their sexual partner/intimate contacts

If an individual answers yes or matches with even one criteria, they are determined to be ineligible. Because it is not possible to ask the donor about their practices, the individual administering the questionnaire has to make assumptions. If a donor is known to be a queer man, the assumption is made that they may have had sex with another man within the past 5 years. It is extremely likely that almost no queer men have had their tissues donated in the past 3 decades.

The questionnaire is asked to individuals close to the donor. This can be their spouse/partner, family members, friends, or others. It is difficult to assess a donor's entire risk, just due to a degree of separation from the individual.

The Physical Assessment[2]

Donors are determined to be eligible for tissue donation in two main ways. The second of these is the physical assessment. This examination is used to look for physical signs of deferment criteria.

1. Physical evidence of risk of STDs (ulcers, herpes, chancre)
2. Physical evidence of syphilis
3. **Physical evidence of anal intercourse (including perianal condyloma)**
4. Physical evidence of non-Rx injection drug use

5. Physical evidence of recent tattoo/piercing
6. Disseminated lymphadenopathy (lymph node swelling)
7. Unexplained oral thrush (fungal infection)
8. Blue/purple spots (Kaposi's sarcoma)
9. 9. unexplained jaundice, hepatomegaly, or icterus
10. Physical evidence of sepsis (unexplained generalized rash/fever)
11. Large scab indicating smallpox immunization
12. Eczema vaccinatum (smallpox symptom)
13. Generalized vesicular rash
14. Severely necrotic lesion consistent with vaccinia necrosum
15. Corneal scarring consistent with vaccinial keratitis

The physical examination is critical to determine certain risk factors for transmissible infections from transplants. However, assessing a donor for “evidence of anal intercourse” is disrespectful and degrading to the donor’s body. Further, it is an ineffective way to determine MSM donors. It does not accurately identify all individuals who are meant to be subject to the policy (leaving out tops, or insertive partners) and also applies the criteria to heterosexual men who participate in receptive sexual intercourse (which likely would not include transmission of fluids).

Additionally, it reinforces the stigmatizing idea that all queer men have hepatitis B or HIV. The application of policies like this former blood donation deferral and the current tissue donation deferral uphold that same stigma.

Individuals Impacted

Liam Dee

Liam Dee was a 26-year old Registered Nurse who lived in rural Nova Scotia, Canada with his husband Jacob. When he was diagnosed with cancer, he held onto hope that his tissues would help to improve the lives of countless others, as his diagnosis prevented his organs from being transplanted to others. However, Liam's tissues were rejected due to "high-risk behavior".

Liam chose to pursue a career in nursing to help people, especially those who were marginalized and overlooked. Although he only worked as a nurse for a few months, we heard from many of his patients that he was knowledgeable, compassionate, kind and dedicated to providing the best care he could.

Organ donation was important to Liam as well as his family. Liam's uncle passed away at 16 in a hockey accident and his organs and tissues were donated. Liam grew up hearing of how his uncle's gift helped so many. Liam was a blood donor until he came out at the age of 20, after which he was rendered ineligible due to the Canadian Blood Services policy that turned away queer men.

Liam and Jacob were in a monogamous relationship for 4 years after meeting at a Forestry College in New Brunswick, and neither of them had HIV. *So, why was he considered to be a high-risk donor?* The FDA mandates a 5-year deferment policy for tissue donations from queer men. However, Liam did not live in the USA. This is where the issue lies.

When Liam passed, his family let the nurse know so that she could contact the tissue bank (which is a member of the American Association of Tissue Banks) to let them know there was a potential donor at the hospice facility. The nurse began to answer the donor screening questions, and the tissue bank explained that they would not take Liam's tissue because he was gay and married, and therefore the 5-year deferral would be applied. The nurse was visibly upset, and Liam's family was first in disbelief, followed by anger.

Canadian citizens shouldn't be subject to policies from a different country. Further, the 5-year policy is outdated, discriminatory, and unnecessary. It is a slap in the face to those who make the lifesaving decision to register as an organ and tissue donor, and it causes further hurt to the families grieving the loss of their loved one.

Liam was angered by the CBS policy that prevented him from donating blood and followed the fight led by Christopher Karas. When Liam's mother Cindy learned that his

tissues weren't donated due to a similar policy, she reached out to Christopher. The two of them, along with Liam's husband Jacob filed a complaint with the Canadian Human Rights Commission to hopefully bring an end to the policy.

We still do not fully understand why the American Policy was applied at a Canadian Tissue Bank, with multiple parties diverting blame to other members. We are working to determine the root cause. Regardless, a removal of discriminatory policies will result in improved access to tissues for all potential recipients, and will ensure that the dying wishes of people like Liam will be fulfilled.

AJ Betts

AJ Betts was a 16-year old rising junior at Southeast Polk High School in suburban Des Moines, Iowa. He was active in his school's performing arts programs, through marching band, plays, and show choir. Those who knew AJ described him as a light, someone who always had a smile and a laugh. On July 27th, 2013, AJ took his own life.

Six months prior, when he was filling out his driver's license application, AJ asked what the checkbox for organ donation meant. His mom, Sheryl Moore explained that it was a way to help others who might need them to live in the case of a car accident or other situation. He responded with "Oh. Of course!" and signed up.

AJ was subject to the FDA's 5-year tissue ban and his tissues were not donated to any individuals, despite him wanting those to go to others in need. Queer men, like AJ, register as organ donors so that they can give the gift of life to those in need. AJ and hundreds of thousands of other queer men have been denied their wish of helping others.

The testing licensed and utilized for screening of tissue donors have seen incredible progress in accuracy and efficiency during the past three decades. The science of the 1990s is no longer the same science of today.

AJ's mom did not learn of the policy until a year after AJ's passing, when she was asked if she wanted to write letters to the recipients of AJ's organs. When she found out that his tissues had been rejected, she was furious. He was excluded because he was gay, even though he was a virgin. AJ's status compounded the anger she already felt about the policy. What upset Sheryl even more was when one of AJ's organ recipients reached out to her through social media and told her that she was asked if she wanted the kidneys, knowing that AJ was gay.

After learning of the policy and the loss of her son, Sheryl began to advocate for multiple issues, including equality in blood and tissue donation. She has given dozens of keynote speeches discussing bullying and the impact that it had on AJ's life. She utilizes social media, grassroots lobbying, and partnerships with researchers who want to enact a change to the current regime.

She worked with members of congress, which resulted in a letter being sent to the FDA signed by 17 senators and 52 representatives. The letter was sent on 9/8/2014 and was a critical step in pressuring the FDA to revise the blood donation eligibility criteria, which was reduced from a lifetime ban to a 12-month deferral in 2015. She has continued to raise awareness of the discriminatory policies as well as the tragic impact of bullying.

Trevaughn Roach-Carter

TreVaughn Roach-Carter is a Black YA author in New York City. In 2018, while he was living in San Francisco, TreVaughn tried to donate at a sperm bank, but was denied until he had obtained his bachelor's degree. He returned in 2019 after graduation and was accepted and invited to begin the process- then, he was told that he could not continue with the donation process, because he was gay.

TreVaughn wanted to donate because he understood the importance of accessibility for those pursuing donor derived children. As a gay man, he would likely have to go through a donor-assisted process to have children of his own.

Additionally, there is a critical shortage of Black sperm donors. In October of 2022, only 2% of all sperm donors were Black[72]. This made it even more important for TreVaughn to help those seeking services. The FDA wouldn't let him. There is little research on national numbers, but a recent (April, 2023) from CBS News report found that less than 4% of available sperm donations at the big 4 sperm banks (Xytex, Seattle Sperm Bank, Fairfax Cryobank, and California Cryobank) were from black donors[73]. Black women pursuing donor assisted pregnancy are forced to choose between a child who doesn't look like them, or not having a child at all.

Anonymous sperm donation is one of the 12 tissues explicitly listed in the FDA's tissue donation eligibility, and therefore is subject to the 5-year MSM deferral. Although direct donation (where the donor and recipient know each other and agree to the procedure) is not subject to the deferral, anonymous donation (through sperm banks) are.

Countless queer men like TreVaughn are being treated differently due to the FDA's outdated policy. Sperm donation is significantly different from tissue donation, for the simple reason that the donors are able to undergo increased screening and questionnaire due to their status as living donors. It is much easier to get a comprehensive assessment of a donor's risk of transmissible infections. It is easier to ensure accuracy of testing by screening donors over a period of time. Living donors should not be treated identically to cadaveric donors, as they can be assessed themselves.

The 5-year deferral is not only unnecessary, but discriminatory. The policy enforces and holds the stigma that queer men and HIV are synonymous. It limits diversity in donation. Queer families are more likely to utilize donor derived reproduction, and may

wish to choose a queer donor to match their own family. This denies the chance of donors to give and recipients to pursue individuals who represent their own relationships.

The 12 Tissues

Corneas

- **Location**: the clear tissue over the front of the eye covering the iris and pupil[9].
- **Function**: they allow light to enter the eye[9].
- **Transplant Conditions**:
    - **Keratoconus**: altered shape of the cornea that changes the location that light is focused and prevents clear vision[29].
    - **Fuchs' dystrophy**: inner cells of the cornea begin to die. This leads to pain, light sensitivity, blurred vision, and worsening vision[30].
    - **Thinning/tearing/swelling of the cornea**: altered histology of the cornea changes where light focuses on the retina and impacts vision[31].
    - **Corneal ulcers**: defect in the surface of a cornea that results in pain, blurred vision, and sensitivity to light[32].
- **Impact:** cornea transplants can return sight to a transplant recipient, improve appearance, and prevent further pain[9].
- **Testing**: corneals are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance[33]**: 66,278 corneal transplants in the USA in 2020 (performed by members of Eye Bank Association of America). Currently 12 million corneal blind individuals globally.

Sclera[10]

- **Location**: the white layer of the eye that covers most of the eyeball.
- **Function**: the sclera supports the shape and structure of the eyeball and protects from injury.
- **Transplant Conditions**:
    - **Glaucoma Surgery**: sclera is used over the tip of a pressure release valve during glaucoma surgery.
    - **Orbit Reconstruction**: Sclera grafts can be wrapped around prosthetic (artificial) eyes, along with muscles to move in unison with the recipient's natural eye.

    - **Eyelid Reconstruction**: sclera can be used to ensure function and appearance of eyelid repair[34].
- **Testing**: sclera transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: there can be up to 8 sclera grafts (transplantable portions) from one eye donation.

Skin

- **Location**: covering the body:
    - **Layers[11]**:
        - **Epidermis**: the top layer, 5 types of cells. Also contains keratinocytes, melanocytes, langerhans' cells, and merkel's cells.
        - **Dermis**: connective tissue and papillary/reticular layers. Beneath the epidermis.
        - **Hypodermis/Subcutaneous tissue**: fat tissue, blood vessels, sensory neurons, vasculature.
- **Function:** temperature regulation, serves as a barrier for infection and injury, water retention[12].
- **Transplant Types[12]**:
    - **Autologous (from the recipient, moving location on the body)**: *these are not impacted by the queer tissue ban.*
    - **Allograft (usually from a cadaver)**: *usually used over autografts when there is not enough healthy tissue on the recipient.*
- **Transplant Conditions**: Skin grafts are used to treat burns, injuries, wounds, disease, infection, cancer removal[12]. These can be temporary, to cover and assist with skin growth. Pressure injuries, slow healing or large wounds. cosmetic and reconstruction, ulcers[35].
- **Testing**: skin transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis. The donors are also assessed for signs of non-prescription injection drug use, smallpox vaccination, recent tattoos or piercings, signs of STIs, kaposi's sarcoma, jaundice, and other infections[2].
- **Importance**: although synthetic and xenograft alternatives are used over autografts and allografts, allografts may be cheaper. Additionally, they may require less maintenance, and provide a basement membrane and scaffold. In first-degree relatives of allografts, the tissue would have a lower risk of rejection. An estimated 100,000 skin grafts will be completed this year, a number that could increase with availability of tissues, and one donor can provide grafts for many individuals[36].

Heart Valves

- **Location**: Like the name implies, heart valves are inside of your heart. They reside between the atria and ventricles, as well as between the ventricles and existing arteries (pulmonary artery and aorta)[13].
- **Function:** heart valves are flaps of tissue and open and close to either allow or prevent blood flow. This ensures that blood doesn't flow too fast, adequate pressure is maintained, and that blood only moves in the correct direction. These are the sounds that you hear in a heartbeat[13].
- **Valve types[13]**: There are 4 valves in the heart,
    - **Tricuspid**: 3 flaps, between right atrium and right ventricle.
    - **Pulmonary**: 3 flaps, between right ventricle and pulmonary artery.
    - **Mitral/Bicuspid**: 2 flaps, from left atrium to left ventricle.
    - **Aortic**: 3 flaps, from left ventricle to aorta and the body.
- **Transplant Types**:
    - **Human Grafts/"Homografts"**:
        - **Autograft**: uses Ross procedure that moves the pulmonary valve to the aortic position, allografts/xenografts are used for pulmonary valve. Utilized mostly for pediatric patients[37].
        - **Allograft**: from a cadaveric, human donor[2].
    - **Mechanical**: longest-lasting, likely will last entire lifetime. Require life-long blood thinner medication to prevent clots[38].
    - **Animal Transplants/"Xenografts"**: 0-20 years, don't usually require medication long-term. Will likely require another replacement/surgery later in life for younger patients[38].
- **Transplant Conditions[14]**:
    - **Aortic/Mitral Stenosis**: narrowed valve, reduced blood flow.
    - **Regurgitation or Insufficiency**: Backwards blood flow.
    - **Infective Endocarditis**: bacterial growth enters the bloodstream and grows on the heart's lining and valves. If infection has progressed beyond medications for treatment, surgery is often indicated.
- **Testing**: allografts are disinfected, sometimes decellularized, and frozen at 4*C/39.2*F until implantation[37]. Heart valve transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: can last 10-20 years. 200,000 HV replacement surgeries occur globally each year (2017), up to 850,000/year 2050[37]. Not all are human donors, but

regardless, when there are hundreds of thousands being performed, options are a good thing.

Dura Mater

- **Location**: The brain and spinal cord is covered by a set of tissues called meninges (dura mater, arachnoid mater, pia mater) The dura is the furthest outside and closest to the skull. It is made up of fibroblasts and collagen[15].
- **Function:** Dura mater covers the cranial nerves, protects the brain and spinal cord, limits movement of the brain, assists with glial cell proliferation (non-nerve cells), regulates axon (nerve) behavior at the central/peripheral nervous system connection[15].
- **Transplant Types**: Synthetic (made in a lab, facility, or factory. Not from a human or living organism), human ("allograft"), animal ("xenograft")[39].
- **Transplant Conditions**: dural defects (congenital, trauma, iatrogenic injuries, inflammatory/tumor invasion). Synthetic grafts can be used to treat fistulae[39]. Xenografts of other (non-dura) tissues can be used, although some options have a risk of post-operative complications.
- **Testing**: Donors of dura mater transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2]. Additionally, the brain of a donor is assessed for degenerative disorders by a pathologist, who will take cross-slices of the brain and look for damage.
- **Importance**: Dura repair occurs in up to 30% of cranial operations[39]. May not be fully utilized, due to risks of prion and viral disease. However, autologous (human) grafts may have lower rates of some complications like CSF leaks[16].

Bones

- **Location**: all over the body.
- **Function**: The skeleton provides structural support and protection to the body and organs.
- **Transplant Types**: Allografts (other human donor), autografts (from the recipient's body), and synthetic (made in a lab, factory, or facility)[40]. Frequently, transplants are used in the knees, hips, and spine[14].
- **Transplant Conditions**: Bone transplants are used to treat fractures and loss of bone. New piece of bone is placed at the area that needs to heal, bones then seal to each other. Osteonecrosis/cancer, spinal fusion surgery, dental implant surgery, surgically implanted devices (total knee replacement- promotes bone growth)[40].

Transplants promote the healing of bones when healing would not occur/complete without a graft[40]. Serves as a framework for new bone growth[14].

- **Risks**: infection, bleeding, blood clots, nerve damage, and anesthetic complications[40].
- **Testing**: Bone transplant donors transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: 2.2 million orthopedic procedures utilize bone grafting globally each year and this is expected to rise (by up to 13%) each year[41]. Not all of these are from deceased donors, but a large portion are.

Tendons

- **Location**: Tendons are all over your body, they connect muscles to bones, so that when you flex a muscle, the part of your body moves[18].
- **Function**: Tendons allow for movement and prevent injury by absorbing impact[18].
- **Transplant Types**: Allografts (other human donor), autografts (from the recipient's body), and synthetic (made in a lab, factory, or facility)[19].
- **Transplant Conditions**: Tendon grafts are most commonly used for repair or replacement of tendon rupture[19]. They may also be used for the treatment of genitourinary prolapse to restore form and assist with support[42].
- **Testing**: Donors of tendon transplants are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: Transplants can result in stable anatomy, restoration of function, protection against further injury. Transplants serve as substitution for improperly functioning tissue and can replace absent tissue.

Ligaments

- **Location**: Ligaments can be found all over the body, with over 900 connecting bones together[20].
- **Function**: connect bones together to ensure that stability is maintained during movement[20].
- **Transplant Types**: Allografts (other human donor), autografts (from the recipient's body), and synthetic (made in a lab, factory, or facility)[21].
- **Transplant Conditions**: Transplants are used in the repair and replacement of damaged or ruptured ligaments[21].

- **Testing**: Ligament donors are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: There are between 100,000 and 300,000 ACL reconstructions are performed a year, which is one of the most common indications for graft surgery[21]. Autografts may result in a decrease in function from the removal site in exchange for improved function at the insertion site.

Cartilage

- **Location**: Cartilage can be found all over your body, cartilage covers the end of your bones and forms other structures within your body (ears, nose, trachea), between discs in your spinal cord, inner ear, larynx, and more[22].
- **Function**: Cartilage protects bones and joints by absorbing shock and limiting the impact of friction[22].
- **Transplant Types**: allograft (from a human donor), autograft (from a separate location in the recipient's body).
- **Transplant Conditions**: Grafts can be used in the treatment of osteochondral defects in joints (bone and cartilage). Cartilage allografts can be used in the femur, tibia, patella, and ankle, as well as other joints[23]. Septorhinoplasty (surgery to improve both function and appearance of the nose)[43]. They also can be used to replace damaged or deficient cartilage in the knee, which may result in decreased pain.
- **Testing**: Cartilage donors are tested for the same infections as all other tissues; HIV, hepatitis B & C, human transmissible spongiform encephalopathies (TSEs), and syphilis[2].
- **Importance**: Although not every case of osteoarthritis, joint pain, or decreased cartilage can be treated via transplant, a viable supply of allografts is critical in ensuring that those who wish to pursue surgical treatment are able to. There were 54.4 million adults in the United States with a form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia (2015)[44].

Oocytes (aka "eggs")

- **Location**: Oocytes can be found in the ovaries.
- **Function**: An oocyte contains DNA that is combined with a sperm to form an embryo[44].
- **Transplant Types[2]**:

    - **Anonymous**: Where the donor and the recipient do not know each other, ex. egg bank.
        - *A 12-month deferral, for any women who have had sex with a queer man, is applicable.*
        - ***At this time**, we are not sure how or if the 5-year deferral is applied to trans men and nonbinary donors who pursue oocyte donation. It may be similar to the experience of cis men who attempt to donate sperm anonymously through a sperm bank.*
    - **Direct**: Where the donor and the recipient know each other, and agree to donation and receipt of the oocyte.
        - *Cases of direct donation are not impacted by the 12-month deferral or the 5-year deferral.*
- **Transplant Conditions**: Individuals may pursue egg donation for pregnancy for a variety of reasons. Some of these may include, but are not limited to, female infertility, queer couples, single individuals who want to start families, surrogacy, individuals with genetic conditions, and more.
- **Testing[2]**: Oocyte donors are tested for the same base infections as all tissue donors, which are- HIV, Hepatitis B & C, Transmissible Spongiform Encephalopathies (TSEs), and syphilis. Since oocytes are reproductive cells, they are also tested for Chlamydia trachomatis and Neisseria gonnorhea.
- **Importance**: Cisgender women are not subject to the 5-year MSM deferral, but are given a 1-year deferral if they have had sex with a queer man. **We don't know how this policy impacts trans men and nonbinary individuals who were assigned female at birth.** The policy is discriminatory for all tissue donations, but with oocytes, the opportunity to discuss and question the donor's history is available. The same screening procedures should not be used since the subject answering questions is not the same.

Sperm

- **Location**: Sperm can be found in the testes and are formed in the seminiferous tubules[26].
- **Function**: A sperm contains DNA that is combined with an oocyte (egg) to form an embryo[26].
- **Transplant Types[2]**:
    - **Anonymous**: Where the donor and the recipient do not know each other, ex. A sperm bank.
        - *The 5-year deferral, for any man who has had sex with another man, is applicable.*

        - ***At this time, we are not sure how or if the 5-year deferral is applied to trans women and nonbinary donors who pursue sperm donation. It may be similar to the experience of cis men who attempt to donate.***
    - **Direct**: Where the donor and the recipient know each other, and agree to donation and receipt of the sperm.
        - *Cases of direct donation are not impacted by the 12-month deferral or the 5-year deferral.*
- **Transplant Conditions**: Individuals may pursue egg donation for pregnancy for a variety of reasons. Some of these may include, but are not limited to, male infertility, queer couples, single individuals who want to start families, individuals with genetic conditions.
- **Testing[2]**: Sperm donors are tested for the same base infections as all tissue donors, which are- HIV, Hepatitis B & C, Transmissible Spongiform Encephalopathies (TSEs), and syphilis. Since sperm are reproductive cells, they are also tested for Chlamydia trachomatis and Neisseria gonnorhea. Since sperm is also a leukocyte-rich tissue, donors are tested for Human T-Lymphotropic virus and cytomegalovirus.
- **Importance**: Queer families may want queer sperm donors, but they are unable to. A greater variety in available donors is beneficial to those seeking to start a family, and newly eligible donors may have traits that are important to recipients. **We don't know how this policy impacts trans women and nonbinary individuals who were assigned male at birth.** The policy is discriminatory for all tissue donations, but with sperm, the opportunity to discuss and question the donor's history is available. The same screening procedures should not be used since the subject answering questions is not the same.

Hematopoietic Stem/Progenitor Cells

- **Location**: HSCs can be found in a donor's peripheral blood (circulation), bone marrow, and umbilical cord blood[27].
- **Function**: HSCs have the potential to develop into all types of blood cells. They are also known as "progenitor cells", descendents of stem cells that develop into specialized cells[27].
- **Transplant Types**:
    - **Donor[27]**:
        - **Autologous**: from the recipient.
        - **Allogeneic**: from a human donor.
    - **Location[45]**:
        - **Peripheral Circulation (Blood Stream)**: quicker engraftment.

    - **Bone Marrow (In the Center of Long Bones, ex. femur)**: longer engraftment.
    - **Cord Blood**: Rapid collection and administration.
- **Transplant Conditions**: HSC transplants are used in the treatment of blood disorders (Acute myeloid leukemia, acute lymphoblastic leukemia, non-Hodgkin lymphoma, Hodgkin disease)[27]. They also can be used to treat myelodysplastic syndrome, myelofibrosis, solid tumors (medulloblastoma, metastatic breast cancer), aplastic anemia, sickle cell disease, and more[45].
- **Testing[2]**: HSC donors are tested for the same base infections as all tissue donors, which are- HIV, Hepatitis B & C, Transmissible Spongiform Encephalopathies (TSEs), and syphilis. Since HSCs are also a leukocyte-rich tissue, donors are tested for Human T-Lymphotropic virus and cytomegalovirus.
- **Importance**: In 2010, over 25,000 HSC transplants were completed annually[46]. That number rises at incredible levels when considering global need and advances in scientific and clinical procedures[46].

These twelve tissues are the donations explicitly listed in the 2007 update to the FDA's tissue donation eligibility policy. However, they are not the only tissues, amniotic tissue, pancreatic tissue, and more have the potential to be subject to the 5-year ban on donations from queer men. Not every tissue bank handles all twelve of these, but they likely will handle more than one (outside of sperm, oocytes, and HSCs). The policy impacts hundreds of thousands of potential tissue donations, and with implementation lasting almost three decades, millions of patients and researchers have dealt with a less than maximum supply of tissues for transplantation and research.

The Infections

All tissue donors are screened for the same infections, but certain tissue donations require additional testing. The FDA mandates which infections donors are tested for in their Tissue Donation Eligibility Policy, and they also license and approve the same tests as an agency.

All Tissue donors are tested for HIV (types 1 & 2), Hepatitis B, Hepatitis C, Human Transmissible Spongiform Encephalopathy, and Syphilis[2]. Donors of reproductive tissues are also tested for Chlamydia and Gonorrhea[2]. Leukocyte-rich cells are tested for Human T-Lymphotropic virus and cytomegalovirus[2]. The policy includes relevant infections- West Nile Virus, Sepsis, and Vaccinia[2]. Tests for these are not explicitly required, but are recommended, and additional deferrals may be related to risk of infection.

The 5-year MSM deferral is rationalized due to a risk of HIV and Hepatitis B from queer men[2]. We go more in depth into these two infections, but include an overview for the other infections as well.

Human Immunodeficiency Virus

- **Definition**: HIV is a virus that attacks an infected individual's immune system. This impacts their ability to fight infections[47]. There are two main variants of HIV, types 1 & 2. Type 2 is less transmissible and less likely to progress into AIDS.
- **Transmission**: HIV can be spread in multiple ways. These include sexual activity, sharing needles, pregnancy & birth, breastfeeding, and contact with the blood of an infected individual[47].
    - *HIV cannot be spread through saliva, sweat, air, or sharing foods or drinks with a positive individual.*
- **Stages of Infection[1]**:
    - **Stage 1/Acute Infection**: Individuals may present with flu-like symptoms. They are highly contagious 2-4 weeks after infection, which spreads rapidly.
    - **Stage 2/Chronic Infection**: Individuals may be asymptomatic. The virus is active at this time and replicating within the body. At this time, individuals can transmit the virus. The second stage can last up to or beyond a decade in length.
    - **Stage 3/AIDS**: AIDS stands for Acquired Immunodeficiency Syndrome. An HIV positive individual is diagnosed with AIDS once their CD4 (an immune system cell) falls below 200 cells/mm^3.
        - *A healthy CD4 count range is between 500-1,600 cells/mm^3.*[48]

        - *Without treatment, the prognosis for AIDS is about 3 years[48].*
- **Prevention[47]**: The best way to prevent HIV infection is to get tested, know your status, and expect the same of your partners. For those at a higher risk, talk to your primary care provider about PrEP (pre-exposure prophylaxis) medications. Don't share needles. In the case of potential exposure or transmission, talk to your primary care provider about PEP (post-exposure prophylaxis) as soon as possible.
- **Testing[49]**:
    - **Types**
        - **Antibody**: looks for HIV antibodies (the immune system's response). This takes 23-90 days to detect. Often used for self testing.
        - **Antigen/antibody**: looks for HIV antibodies and antigens (HIV markers. Performed in a lab and takes between 18-45/90 days depending on the location of the blood draw.
        - **Nucleic Acid Testing**: Looks for the HIV virus itself in the blood. Can detect HIV's presence within 10-33 days.
    - **For Donors[2]**: tissue donors must be tested for HIV-1 (antibody AND nucleic acid), and HIV-2 (antibody or nucleic acid).
- **Treatment[50]**: Although there is no cure for HIV, treatment can prevent the progression of disease and enable individuals to live long, healthy lives. Current treatment regimens include antiretroviral therapies (or ART). These medications work to lower the amount of the HIV virus to levels that are undetectable by lab tests. When an individual is undetectable, their viral load is so low that they cannot transmit HIV through sex.

Hepatitis B

- **Definition**: Hep B is a virus that causes inflammation and damage to the liver[51].
- **Transmission**: Hep B can be spread through a variety of ways. Some of these include birth (mother to child), sexual activity, sharing needles, sharing toothbrushes/razors/medical equipment, direct contact with blood/open sores, exposure through sharps, and poor infection control in medical facilities[51].
    - Hep B cannot be spread through kissing, sharing utensils, sneezing, coughing, hugging, breastfeeding, or sharing food or water[51].
- **Stages of Infection[51]**:
    - **Acute/Short-Term Infection**: this is during the first 6 months after exposure to the virus. The acute period has a range of severity, from asymptomatic to mild illness to hospitalization.
        - *Signs and symptoms of the acute infection include fever, fatigue, lack of appetite, nausea, vomiting, abdominal pain, dark urine, clay-colored*

stool, joint pain, jaundice. Usually begin 3 months after exposure, and last for several weeks (up to 6 months).

- **Chronic/Long-Term Infection**: this is a life-long infection that can lead to heart problems, liver damage (cirrhosis, cancer), and possibly death.
  - *Although individuals with a chronic Hep B infection can be asymptomatic, other signs and symptoms can include signs of liver failure, or those similar to the acute infection.*

- **Prevention**[51]: There is a vaccination for Hepatitis B, talk to your primary care provider to see if you pursue vaccination. It is recommended for everyone under the age of 60, and individuals older than 60 with increased risk factors.
- **Testing**[2]: Tissue donors are tested for Hepatitis B Surface antigen, total antibody to the core antigen (IgG and IgM), and Nucleic Acid Testing.
- **Treatment**[52]:
  - **Acute Infection**: There are no medications indicated for treatment of acute Hep B infections. Most treatment is supportive, with rest, fluids, and nutrition. Some individuals may need hospitalization.
  - **Chronic Infection**: There are some medications that are approved for treatment of chronic infections.
- **Incidence**: There are an estimated between 880,000-1.89 million individuals who have chronic infections in the USA. The number of new cases has been decreasing every year since 2012, with around 3,000 new cases a year[52].

Testing of All Donors

All tissue donors are tested for HIV, Hepatitis B & C, Human Transmissible Spongiform Encephalopathies, and Treponema Pallidum (syphilis). We won't go as in depth for the other infections as we did for HIV and Hepatitis B, but we do find it important to provide a background on what infections the FDA deemed important when considering potential transmission through tissue transplants and donations.

Hepatitis C[53]

- **Definition**: Hepatitis C is a viral infection that causes inflammation and damage to the liver. The infection leads to liver damage and cirrhosis (scarring). Hep C can progress to liver cancer and death.
- **Stages of Infection**:
  - **Acute Stage/Short Term**: The first 6 months of an infection is often asymptomatic, and can progress to a chronic illness.
  - **Chronic Infection**: If the virus progresses beyond the acute infection, the life-long, chronic stage begins.

- **Transmission**: Hep C can be spread in many ways. These include contact with infected blood (sharing needles), pregnancy/birth, tattoos/piercings, sex, and transfusions & transplants.
- **Treatment**: Treatment for Hepatitis C is usually oral prescription medications. In earlier treatment, the post-intervention outcomes improve.
- **Testing**: Testing is recommended for everyone 18 years of age and older, pregnant individuals, individuals who use non-prescription injection drugs, anyone with HIV, patients with abnormal liver tests, and those undergoing hemodialysis.
    - **Antibody Tests**: these look for the immune system's response to the virus and take between 8-11 weeks to be able to determine a positive or negative result.
    - **Nucleic Acid Tests**: These look for the virus itself and take 1-2 weeks for an accurate result.

Human Transmissible Spongiform Encephalopathies (TSEs)[54]

- **Definition**: Also known as "prion" diseases. TSES are degenerative brain disorders that cause microscopic holes in the brain and a "spongy" appearance. Specific diseases are "Creutzfeldt-Jakob disease", "Kuru", and more.
- **Infection**: Symptoms vary from person to person but can include personality changes, psychiatric problems (depression), lack of coordination, unsteady gait, and more.
- **Spread**: TSEs can develop in a few ways, including sporadic (a person's prions spontaneously change), hereditary diseases, and transmission (contact with infected tissue, body fluids, contaminated instruments).
- **Treatment**: There is no cure for TSEs, all treatment is symptomatic, and likely cannot prevent progression. Death commonly occurs within months to years.
- **Testing**: multiple cross sections of the brain are examined by a professional for structural changes. There are no licensed or approved tests (as of 2007)[2].

Treponema Pallidum (Syphilis)[55]

- **Definition**: Syphilis is a bacterial sexually transmitted infection caused by Treponema pallidum.
- **Stages of Infection**:
    - **Primary Stage**: A chancre sore appears. The primary stage occurs 3-6 weeks after the bacteria enters the body. The sore will heal regardless of treatment.
    - **Secondary Stage**: Skin rashes, mucous membrane lesions will begin to appear. Other symptoms include large raised, gray/white lesions, fever,

swollen lymph nodes, sore throat, hair loss, headaches, weight loss, muscle aches, and fatigue. These symptoms will also resolve without treatment and occur several weeks after the end of the primary stage.
    - **Latent Stage**: No signs or symptoms for years after the secondary stage.
    - **Tertiary Stage**: This stage is rare and will occur if the primary and secondary stages go without treatment. This occurs 10-30 years after the initial infection. It is fatal and the infection targets the brain, nerves, eyes, heart, vasculature, liver, bones, and joints.
- **Transmission**: Spread occurs through direct contact with a sore, which frequently present around the genitals and/or mouth.
- **Treatment**: Treatment is commonly penicillin during the primary, secondary, and early latent periods. Treatment will prevent progression but may not undo previous impacts of the infection.
- **Testing**: It is recommended that all pregnant individuals, sexually active queer men, individuals with HIV, and those on PrEP medications be tested. Prevention occurs through use of condoms, knowing your status and the status of your partners.

Testing of Leukocyte-Rich Tissue Donors

Leukocytes are cells within the immune system that can be found in the blood and in the lymphatic system[56]. Also known as white blood cells, they fight infection and other diseases. There are two leukocyte-rich tissues classified in the FDA's tissue donation eligibility policy, Hematopoietic Stem Cells/Progenitor Cells, and Sperm. Donors of these tissues are additionally tested for Human T-Lymphotropic Virus (types 1 & 2) and cytomegalovirus[2].

Human T-Lymphotropic Virus (types 1 & 2)[57]

- **Definition**: Human T-Lymphotropic Virus (HTLV) is a group of at least 4 viruses (HTLV-1, HTLV-2, 3, 4) that cause immunosuppression and inflammation. They may be tumor-causing or asymptomatic.
- **Infection**: HTLV presents as lymphadenopathy, hepatosplenomegaly, lesions, immunosuppression, and opportunistic infections.
- **Transmission**: HTLV can be spread through breastfeeding (most common), sexual contact, and blood transfusions or transplants.
- **Treatment**: Common treatment for HTLV is chemotherapy or HAART (highly active antiretroviral therapy) medications.
- **Testing**: Donors can be tested through serum testing.

Cytomegalovirus[58]

- **Definition**: Cytomegalovirus (CMV) is a common virus. 1/3 children have CMV by the age of 5, and >50% adults the age of 40 have CMV. It stays in the body for life and can be reactivated between periods of latency.
- **Stages of Infection**: CMV presents as mild illness during reactivation- fever, sore throat, fatigue, swollen glands. Can further progress to mononucleosis or hepatitis in severe infections. Individuals with weakened or compromised immune systems may see more critical symptoms related to the eyes, lungs, liver, esophagus, stomach, and/or intestines.
- **Transmission**: CMV can be spread through bodily fluids (saliva, urine, blood, tears, breast milk), sexual contact, transplants and transfusion.
- **Treatment**: Most individuals do not need medical treatment. For infants or individuals with weakened immune systems, antivirals may be prescribed.
- **Testing[2]**: Tissue donors are tested for antibodies (IgG and IgM).

Testing of Reproductive Tissue Donors

Two of the twelve tissues explicitly included in the FDA's Tissue Donation Eligibility Criteria are classified as reproductive tissues- sperm and oocytes. These two tissues are also donated by living donors, unlike most others. The donors of reproductive tissues are tested for the standard infections, as well as being tested for Chlamydia trachomatis and Neisseria gonorrhea, two common sexually transmitted infections (STIs).

Chlamydia trachomatis[59]

- **Definition**: Chlamydia trachomatis (chlamydia) is a common bacterial STI.
- **Stages of Infection**: Symptoms of Chlamydia include cervicitis, urethritis, proctitis; pelvic inflammatory disease, tubal factor infertility, ectopic pregnancy, and chronic pelvic pain (in patients with uteruses). Discharge is common, but some patients are asymptomatic.
- **Transmission**: Chlamydia can be spread through sexual activity and childbirth.
- **Treatment**: Prevention includes use of condoms and getting tested before having sex with a partner. Antibiotics are used to clear the infection.
- **Testing**: Cell cultures can be obtained through swabs or urine testing.

Neisseria gonorrhea[60]

- **Definition**: Neisseria gonorrhea (frequently referred to as "gonorrhea") is a common bacterial STI.
- **Stages of Infection**: Gonorrhea is frequently asymptomatic. Patients with symptoms may present with dysuria, discharge, and groin pain. A lack of treatment

can lead to pelvic inflammatory disease, ectopic pregnancy, epididymitis, and infertility.
- **Transmission**: Gonorrhea can be spread through sexual activity and childbirth.
- **Treatment**: Prevention includes use of condoms and getting tested before having sex with a partner. Antibiotics are used to clear the infection.
- **Testing**: Cell cultures can be obtained through swabs or urine testing.

Other Relevant Infections for Tissue Donors

Along with the required tests for all tissue donors, and those for donors of specific classes of tissues, the FDA's Tissue Donation Eligibility Policy designates relevant infections. The policy doesn't state specific tests for these infections, but supports assessment and testing based on a facility's capabilities. Suspicion, risk, and/or diagnosis of West Nile Virus, Sepsis, or Vaccinia may result in ineligibility for tissue donation.

West Nile Virus

- **Definition**: West Nile Virus is a virus that is commonly spread through mosquitoes.
- **Stages of Infection**: WNV is frequently asymptomatic. Individuals with serious symptoms may present with fever, headache, stiffness, and/or encephalitis[61].
- **Transmission**: WNV can also be spread through exposure to positive blood, breastmilk, and transfusion or transplants[62].
- **Prevention**: There is not a vaccine for WNV. Prevention methods can include the use of insect repellants, covering your skin, and using a mosquito net for sleeping[63].
- **Treatment**: Treatment methods are usually supportive, including rest, fluids, and nutrition[61].
- **Testing**: Individuals can be tested for WNV through blood draws and spinal fluid taps[61].

Sepsis[64]

- **Definition**: Sepsis is an extreme response to infection, progressing to tissue damage, organ failure, and potentially death.
- **Infection**: Symptoms of sepsis can include high heart rate, weak pulse, confusion, pain, fever, shortness of breath, and profuse sweating. At-risk groups include older adults, individuals with weakened immune systems, individuals with chronic conditions (diabetes, lung disease, cancer, kidney disease), present illness, infants (<12 months).
- **Transmission**: Sepsis itself does not spread, but the causative infection can.

- **Treatment**: Treatment for sepsis includes monitoring the patient, administration of antibiotics, and possible admittance to an intensive care unit or facility.
- **Testing**: Sepsis is tested for by screening and assessing for the causative infection.

Vaccinia[65]

- **Definition**: Vaccinia is the virus that is used in the smallpox vaccination. The virus can be transmitted to other individuals for some time after someone has received the vaccination.
- **Stages of Infection[66]**: Symptoms or adverse reactions can include fever, headache, fatigue, myalgia, chills, and a rash.
- **Transmission[66]**: Vaccinia can be transmitted through close contact with the unhealed vaccination site.
- **Treatment[66]**: The infection should be self-limiting and resolve on its own. If treatment is needed, antivirals may be prescribed for adverse reactions.
- **Testing**: Determinations of a donor's vaccinia infection are made based on history and physical evidence.

Safety

Types of Testing

Not every test works in the same way, and some of the easiest ways to categorize testing of donors is by what the test detects. **Antigen tests** look for the part of the infectious agent that elicits an immune response. These are specific to the infectious agent. **Antibody tests** look for the immune system's response to an infectious agent. **Nucleic acid tests** work by detecting the genetic material (RNA or DNA) that makes up an infectious agent.

Other classifications of testing methods are based on the machinery, process, or testing medium that are used. These include:

- **ChLIA/ChemiLuminescent ImmunoAssay**: Detects antibodies through looking for a luminescence (light) triggered by contact between an antibody and a reactive antigen[67].
- **CMIA/Chemiluminescent Microparticle ImmunoAssay[67]**: Detects antibodies through looking for a luminescence (light) triggered by contact between an antibody and a reactive antigen.
- **EIA/ELISA/Enzyme-Linked Immunosorbent Assay[68]**: Antigens line the bottom of testing wells where a serum is filled. Antigen-specific antibodies are then added and the serum is removed. An indicator changes colors in the presence of antibodies to determine reactive status.
- **PCR/Polymerase Chain Reaction[69]**: A sample from a donor is replicated in a machine multiple times using a polymerase enzyme. If the virus is present, it will replicate enough time to reach a detectable level.

Approved Methods

There are 17 tests approved for the testing of HIV (types 1 and/or 2) and/or Hepatitis B. Some of these tests screen for one type of a virus (ex. HIV 1), and others test for multiple (ex. HIV-1, Hepatitis B, and Hepatitis C). We included information for HIV and Hepatitis, since those infections are the rationale for the 5-year MSM deferral.

The 17 Approved Tests[70]

Test	Donor Approval		Infectious Agent	Classification	Initial Approval Date
	Tissue	Blood			
Abbott PRISM HBCore	x	x	Hepatitis B	ChLIA	10/13/05
Abbott PRISM HBsAG; Abbott PRISM HBsAG confirmatory	x	x	Hepatitis B	ChLIA, ChLIA specific antibody neutralization	7/18/06
Abbott Alinity S anti-HBC	x	x	Hepatitis B	CMIA	8/2/19
Abbott Alinity s HBsAG; and Alinity s HBSAg Confirmatory	x	x	Hepatitis B	CIMA	6/14/19
Genetic Systems HBsAg confirmatory assay 3.0	x	x	Hepatitis B	EIA	1/23/03
ORTHO HBc ELISA test system	x	x	Hepatitis B	ELISA	4/23/1998
COBAS AmpliScreen HBV	x	x	Hepatitis B	PCR	4/21/05
COBAS Ampliscreen HIV-1 test, ver. 1.5	x	x	HIV-1	Qualitative PCR	12/20/02
Abbott Prism HIV O plus assay	x	x	HIV-1 & 2	ChLIA	9/18/09
Alinity s HIV Ag/AB Combo Reagent Kit	x	x	HIV-1, HIV-2	CIMA	7/23/19
Genetic Systems HIV-1/ HIV-2 Plus O	x	x	HIV-1 & 2	EIA	8/5/03
Procleix ultrio assay	x	x	Hepatitis B & C, HIV-1	Nucleic Acid Test (TMA)	10/3/06
Procleix ultrio plus assay	x	x	Hepatitis B & C, HIV-1	Nucleic Acid Test (TMA)	5/25/12
Procleix ultrio elite assay	x	x	Hepatitis B & C, HIV-1 & 2	Nucleic Acid Test (TMA)	5/3/18
COBAS MPX test	x	x	Hepatitis B & C, HIV-1 & 2	PCR	10/26/16
COBAS TaqScreen	x	x	Hepatitis B & C,	PCR	12/30/08

MPX Test			HIV-1 & 2		
COBAS TaqScreen MPX Test 2.0	x	x	Hepatitis B & C, HIV-1 & 2	PCR	12/19/14

All 17 of the tests approved for testing donors of HIV and Hepatitis B are dually licensed for testing blood donors for the same infections. They have been deemed effective enough to decrease the blood donation deferment for queer men from a lifetime policy, to a 12-month policy, to 3-month, and now an individual risk assessment. If the same tests are used, the policies should follow each other in suit.

Of the 17 tests, all 17 were first approved after the policy was initially implemented in 1994. The length of the MSM deferral has not changed since implementation in 1994. The policy was expanded to include anonymous sperm donation in 2005. 13 of the 17 tests were approved after that expansion. The policy was last revised in 2007, with no significant changes and no alterations to the MSM criteria. 9 of the 17, over half of the approved tests were approved after the last action.

The FDA is the organization that approves and licenses these tests. They know that they are effective at determining a donor's infectious status.

If they are effective enough to earn the Administration's approval, why are they not effective enough to update the policy?

Related Policies

Blood Donation[71]

In 1985, the FDA implemented a retroactive (impacting any queer man who had been sexually active, even once, since 1977) lifetime ban on blood donation. The policy remained in place until 2015- 30 years later, a reduction which was made thanks in part to the efforts of the National Gay Blood Drive. The new policy applied a deferment to any queer man who had been sexually active in the past 12 months.

In 2020, another reduction was put in place, this time reducing the length of the deferment from 12-months to 3-months. This policy revision was due in part due to national blood products shortages due to the Covid-19 pandemic.

2 years later, Pride and Plasma formed and began researching, advocating, and raising awareness of the policy. After our argument and evidence was presented to the FDA's Blood Products Advisory Committee on 12/8/2022, a draft update to the blood donation eligibility policy was released to the public for public comment on 1/27/2023.

The updated policy was a transition to an individual risk assessment, something that the ADVANCE Study looked into and researched. This is different from the previous blanket deferment policy (any type of sexual activity rendered a potential donor as ineligible). The new policy was finalized on 5/11/2023 (although blood centers needed up to six months to implement the updated policy). Now, all donors are asked the same questions, regardless of sexual orientation and gender.

Donors are asked about their number of partners, and the methods of sexual activity that they practice. This determines an individual's risk more effectively. For example, A cis man and a cis woman practicing vaginal sex have a higher risk than two cis men who only practice oral sex. The previous policy didn't account for this. Currently (as of July, 2023), if a potential donor practices anal sex with new (<3 months)/multiple partners(>1), they would be ineligible.

Additionally, non-cis donors are assessed better. Trans men who practice receptive vaginal sex have lower risk than a cis man who practices receptive anal sex. They were previously subject to the MSM policy at gender affirming centers, despite having a lower risk. The new policy removed all gendered language.

Organ Donation[3]

Unlike blood and tissue regulations, organ donations are not subject to Food and Drug Administration rulings and guidances. Instead, organ donation policies are drafted and introduced by the Department of Health and Human Services. First introduced in 1985, updates were released in 1994, 2013, and lastly in 2020.

On May 24th, 1985, the Public Health Service released recommendations that all blood and plasma be tested for HTLV-Type III (now currently known as HIV), which had begun to be linked to AIDS a few years prior. Organs, tissues, and sperm donations from HTLV-3 positive individuals were considered particularly infectious by the policy. The recommendations also included following the same policy as the blood donation criteria. *The 1983 blood donation criteria recommended "temporarily" deferring increased risk donors, which included "sexually active homosexual or bisexual men with multiple partners"*.

Three and a half months later on 9/6/85, the blood donation policy revised the temporary restrictions and put in place the lifetime deferral that remained until 2015. *We are not sure if this simultaneously updated the organ donation criteria as well, but queer male organ donors likely were rendered ineligible regardless.*

The next change came on May 20th, 1994. This new policy was for organ **and** tissue donors and implemented a five-year deferral for "men who have had sex with another man", as well as a 12-month deferral for any women who had been sexually active with a queer man. That policy remained in place until 2013, which saw significant changes compared to previous iterations, as well as when compared to blood and tissue donation policies.

In 2013, the 5-year deferral for organ donations was reduced to 12-months, while the deferment for any women who had sex with queer men remained the same length, also 12 months. The policy also gave a definition of what "had sex" meant:

"any method of sexual contact, including vaginal, anal, and oral contact"

Previously, the definition of sexual activity was not clearly defined. The report also began the discussion of utilization of donations from "increased risk donors". This procedure would allow for high risk donors (Men who have sex with men, commercial sex workers, those incarcerated, and those who use injection drugs), who would be ineligible due to deferment screening criteria, but who tested negative from infectious agent testing, to potentially transplant their donations into recipients who consented to the increased risk. This was due in part to the systemic shortage in organ donations compared to those eligible, waiting, and in need for transplant(s).

The last, and most recent, policy was introduced in 2020. This update removed the 12-month deferral for women who had sex with MSM in entirety. The policy initially recommended a reduction from the 12-month MSM time frame to 3-months. **However, at the advice of the CDC, which stated that a 30-day period would be effective with the utilization of Nucleic Acid Testing**, a 30-day policy was implemented. Additionally, the practice of labeling "increased risk donors" as "IRD" donations was recommended to be revised. Previously the IRD label was applied uniformly, regardless of the criteria that caused an individual to be identified as high-risk.

The HHS practice for IRD labeling was revised to remove the language of "increased risk donor". The UNOS implementation then began the practice of explaining the specific criteria that a donor matched with, explaining why a donation would potentially be considered to be high-risk. These donors still must test with a non-reactive/negative result in order for the organs to be transplanted/offered to a recipient (with the exception of HIV+ donors to HIV+ recipients, as legislated by the HOPE Act).

Tissue Donation Around the World

Although we prefer to analyze a nation's tissue donation and eligibility policies ourselves, some are difficult to obtain, and others are in languages other than those our team is fluent in. Because of this, we break down global policies into those that we identified and those that we are relying on alternative sources. There is a chance that those from other sources have been updated since the time of publication, but any changes would likely be more progressive, decreasing deferrals for queer men.

Countries We Identified as Having Tissue Policies More Progressive than The USA & FDA

United Kingdom[74]

The UK recommended a 3-month policy for MSM donors in 2017, to replace a 12-month deferment for tissue donors.

Chile[75]

"Risky sexual behavior" is defined as more than one sexual partner in a period of 12 months and is applicable to all donors, regardless of gender or sexual orientation. This policy was put in place in 2018.

Countries Identified by Other Published Sources

Puente et al. 2020[76]

"Association of Federal Regulations in the United States and Canada With Potential Corneal Donation by Men Who Have Sex With Men" lists the following countries as having less than a 5 year deferment policy for queer men. The study focused on cornea donation, which may be applicable to general tissue donation.

- No Additional MSM Deferral: Spain, Italy, Mexico, Chile, Argentina
- France, Netherlands: 4 month deferral for MSM

Synthesis & Evidence

In this section, we'll provide a brief overview of why the policy is unnecessary, outdated, and discriminatory. Although synthesis and evidence will compose a large section of our brief, research, and argument presented to the FDA, this is a small sample to provide a foundation on the issue. To learn more about our research and findings, please read our FDA brief when it is published.

Cornea Donation Research[76]

Detecting HIV at the time of the tissue ban's introduction (1994) took close to 6 months for an effective result. Today, with Nucleic Acid Testing, an accurate test can be determined in just 4-8 days after an exposure. Hepatitis B screening takes a little bit longer, with accurate results available in 20-22 days. Whether a test takes 4 days or 22 days for an accurate result, the 5-year deferral is excessively long and turns away healthy donors.

The researchers determined that 3.9% of men in the US had had sexual contact with another man in the past 5 years, and also found that there were 720 MSM deferrals (46.2% response rate from eye banks across the USA and Canada). This gave them a range of between 1,558 to 3,217 corneas rejected each year due to the MSM deferral between the two countries.

Using the USA vs Canada population (331.9 million vs 38.25 million), we can apply the same difference to the range of corneas turned away to determine how many might have been from the USA. This gives us a range of 1,378-2,846 US corneas rejected. If we divide it by two (2 corneas per donor), we get between 689-1,423 donors rejected every year due to the MSM deferral. The number of impacted individuals is likely higher when considering transgender women and nonbinary donors who were subject to its application.

Psychological Impact[77]

The PRIDE Study found no benefits for sexual orientation and gender identity diverse individuals from the implementation of these deferment policies. However, they did find multiple forms of harm. These included stigmatization and devaluation- the idea that all queer people have infections or are "dirty". The deferment rejects not only the donations, but the dying wishes of potential donors who took the time to register their wishes. The policy has remained untouched for 16 years and unchanged for 29- this shows how discrimination is not a priority for the government.

Other forms of harm include bodily disrespect through rectal examinations and disposal of life-saving and life-changing donations. The rejection of tissues is even more disrespectful when you consider and recognize the critical shortage of tissues on a global scale. The policies can increase the grieving process for a potential donor's loved ones due to disempowerment and disregard for the individual's dying wishes. There are societal impacts due to the patients who have to wait longer for donations when health donors are rejected.

The policies loop queer men into the same category as IV drug use, contact with HIV+ fluids and infection, which the study identifies as problematic. The differences between organ and tissue donation do not instill a strong sense of support. For trans and nonbinary donors- there is a complete lack of guidance or affirming practices, with many donors qualified by the sex assigned to them at birth. The "MSM" label does not go far enough as to who should be subject to the deferral, cis-men, trans-men, etc.

2007 Sources[2]

All 30 were published before 2001. 3 (10%) of the sources were presentations at conferences, which may not have been peer reviewed. 4 (13%) of the studies focused on branches of the US armed forces. A demographic of mostly male individuals is not necessarily applicable to the general public, but additionally, the "Don't ask, don't tell" policy was in place from 1994-2011. Queer men in the military risked discharge if they were actively having sex with other men. Another source focused on child-bearing women, but was used as rationale for the Men who have Sex with Men deferral.

Despite revising the policy between 2004 and 2007 (when the last update was released), no new publications were used to guide the policy. Currently every policy is at least 21 years old, 90% were published 24 years ago, and more than half are older than a quarter century. The science of the 1990s is not the same as the best practices of today. The FDA has an obligation to follow new data and use it to influence policy, to create and publish evidence-based guidelines. For the past 16 years, for tissue donation eligibility, they have not.

Recommendations

Route 1: Our Recommendation

Our Recommendation (1/5): We recommend the removal of the 5-year deferral period for men who have sex with men. Five years is significantly longer than the necessary time period to ensure accurate testing of tissue donors, and the repeated deferral of MSM donors upholds the stigma that queer men are synonymous with HIV, infection, and illness.

Recommendation Cont. (2/5): We recommend a definition as to what "had sex" refers to. The varying routes of sexual contact (oral, vaginal, and anal intercourse) have different risks of all STI transmission, and should not be treated the same.

- We Recommend Specifying sexual activity to include vaginal and/or oral sexual activity.

Our Recommendation Cont. (3/5): We also recommend that the FDA include a line of recommendation to tissue banks to implement gender affirming practices. The 2020 blood donation guidance included:

> "*In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported*".

This isn't perfect language, we would prefer to see inclusion for nonbinary and gender nonconforming donors, but it is a step in the right direction. The 2023 updated blood donation eligibility criteria removed this line. And while it was removed along with all gendered language, not every blood center (and tissue bank) is gender affirming. Federal policies that consider this and push to ensure equality and accessibility in a time where we frequently see shortages is critical. **We recommend including the following**:

- **"In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly"**

Recommendation Cont. (4/5): We recommend that along with the revision of the MSM criteria, the deferral criteria for any women who have had sexual contact with a MSM donor be removed.

Recommendation Cont. (5/5): Implement separate screening criteria and support a separate screening questionnaire for deceased and living donors. The ability for living donors (ex. sperm, oocyte) to speak with an employee greatly improves the accuracy of a screening questionnaire and allows for an individual risk assessment. Further, with sperm

and oocyte donation, living donors have the ability to go through repeat rounds of testing to ensure that a potential testing window does not lead to false negatives for infectious agents.

Route 2: Blood Donation

Our Recommendation (1/3): Follow the blood donation guidance. The FDA's Center for Biologics Evaluation and Research handles both blood donation and tissue donation policies. Rather than a 5-year deferment policy (and a 12-month deferment policy for women who have had sex with queer men) **we recommend replacing the text with the reciprocal text as the blood donation policy**:

- "from the most recent sexual contact, an individual who has had a new sexual partner in the past 3 months **and** who has had anal sex in the past 3 months."
- "from the most recent sexual contact, an individual who has had more than one sexual partner in the past 3 months **and** who has had anal sex in the past 3 months"

Recommendation Cont. (2/3): We also recommend that the FDA include a line of recommendation to tissue banks to implement gender affirming practices. The 2020 blood donation guidance included:

> "*In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported*".

This isn't perfect language, we would prefer to see inclusion for nonbinary and gender nonconforming donors, but it is a step in the right direction. The 2023 updated blood donation eligibility criteria removed this line. And while it was removed along with all gendered language, not every blood center (and tissue bank) is gender affirming. Federal policies that consider this and push to ensure equality and accessibility in a time where we frequently see shortages is critical. **We recommend including the following**:

- **"In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly"**

Recommendation Cont. (3/3): We recommend that along with the revision of the MSM criteria, the deferral criteria for any women who have had sexual contact with a MSM donor be removed as well.

Route 3: Organ Donation

Our Recommendation (1/5): Follow the Department of Health and Human Services' and Public Health Services' *Assessing Solid Organ Donors and Monitoring Transplant Recipients for*

Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection"[1]. In 2020, a revision to the MSM organ donor eligibility was released. This policy reduced the former time frame from 12-months to 30-days, under the recommendation of the HHS Advisory Committee for Blood and Tissue Safety (a reduction to 3-months), followed by evidence from the CDC (30 days). The 2020 update included:

> *"Risk criteria (during the 30 days before organ procurement):"*
>
> > *"2. Man who has had sex with another man"*

We recommend usage of reciprocal language:

- **"Men who have had sex with another man in the preceding 30 days"**

Recommendation Cont. (2/5): We recommend that along with the reduction of the MSM time frame, the deferral criteria be replaced with a labeling system to replace a deferral questionnaire. Of "Increased risk donor", "high-risk donor", or "MSM donor." Although tissue donations are not frequently life-saving at the rate of which organ donations are, tissue donations have a potential to significantly alter a recipient's quality of life. Donors should have the opportunity to accept or decline an organ transplant, knowing the potential risks. This will ensure greater access to care and treatment, as well as faster treatment which will prevent the development and severity of complications and negative health outcomes.

Recommendation Cont. (3/5): We recommend that along with the revision of the MSM criteria, the 12-month deferral criteria for any women who have had sexual contact with a MSM donor be removed as well.

Recommendation Cont. (4/5): We recommend a definition as to what "had sex" refers to. The varying routes of sexual contact (oral, vaginal, and anal intercourse) have different risks of all STI transmission, and should not be treated the same.

- We Recommend Specifying sexual activity to include vaginal and/or oral sexual activity.

Recommendation Cont. (5/5): We include a statement to support gender-affirming practices for transgender and nonbinary donors. Similar to the 2020 Blood Donation Eligibility Criteria, we recommend including:

- **“In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly”**

Next Steps & How You Can Help

Stay Up to Date with Pride & Plasma

Follow us on instagram, twitter, facebook, linkedin, and tiktok. Our social media pages are the quickest way to hear about our research updates, new partnerships, current initiatives, and progress on the front for equality for the LGBTQ+ community in transplant and transfusion healthcare.

We'll have lots of new projects and efforts coming soon- we're not limiting ourselves to blood, tissue, and organ donation. You won't want to miss what we announce next.

You can also review and check out all of our former and current work on our website- prideandplasma.com . We frequently update the website before social media announcements and posts go live, so you might even get a sneak peek compared to our other followers.

Sign Our Petition

Just like with blood donation, we have a petition for the 5-year queer tissue ban. This is the easiest and most effective way to show the FDA that there is not only public awareness, but public support for a change in policy. **We do ask that only American residents sign the petition**. We know that individuals outside of the USA are subject and care about this issue, but the FDA prioritizes listening to their own constituents. We know that the impacts of this policy are far wider than the USA's borders, and that is all the more reason to ensure that our argument is comprehensive and accurate.

You can access this petition, and other links at https://linktr.ee/prideandplasma

Register to be a Tissue & Organ Donor

For our US-based friends and followers- you can register to be an organ and tissue donor at https://www.organdonor.gov/sign-up , which will direct you to your state's

registration process. When you register to be an organ donor, you simultaneously register to be a tissue donor- the process is one and the same for registration.

Citations & Further Resources

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Further Resources

Pride and Plasma's Website: www.prideandplasma.com

Sign Our Petition: https://linktr.ee/prideandplasma

Food and Drug Administration Tissue Guidances: https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/tissue-guidances

Register to Be An Organ & Tissue Donor: https://www.organdonor.gov/sign-up

Find a Blood Center Near You: https://www.aabb.org/for-donors-patients/give-blood

Find a Plasma Center Near You: https://www.donatingplasma.org/donation/find-a-donor-center

Planned Parenthood Trans & Nonbinary Glossary & Support: https://www.plannedparenthood.org/learn/gender-identity/transgender

Find a LGBTQ+ Affirming Primary Care Provider w/GLMA's Directory: https://www.glma.org/find_a_provider.php

Find a LGBTQ+ Community Center Near You w/CenterLink: https://www.lgbtqcenters.org/LGBTCenters

PrEP Resources & Assistance: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program/

Blood Donor Diversity Resources w/University Blood Initiative: https://www.universitybloodinitiative.org/general-9