

The Need for Policies Recognizing and Screening Gender-Diverse Blood Donors

The Basics & Breakdown // Public Brief

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Introduction//Purpose

The FDA provides no guidance for blood banks and facilities to help with screening, testing, and the experience of transgender, nonbinary, and other gender-diverse blood donors. Despite including partially affirming language in 2015 and 2020, this support was not included with the transition to the individual risk assessment in 2023.

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 share our recommendations for improved policy and best practices.

We at Pride and Plasma believe that the public deserves to learn and be informed about policies and issues impacting them, this is why we create “the breakdown”, providing additional background information and making our research bite-sized. We know that not everyone has a background in healthcare or public policy, and our Public Briefs work to provide supplemental information that the FDA might not need, but will help you understand a topic entirely. To learn more, please read our research brief on the topic, and keep up to date on our website- prideandplasma.org and on Instagram, Twitter, TikTok, and Facebook @prideandplasma.

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The Basics & Introduction

The Overview

Across the country, blood banks and donation facilities are facing severe shortages that threaten access to lifesaving whole blood, platelets, and plasma. One of the greatest routes to fighting systemic shortages is to ensure that new donors become repeat donors. If donors understand the importance of their donation and impact, they are more likely to donate multiple times. However, if a donor has an unwelcoming experience, they are less likely to donate again.

Another factor in blood shortages is the transition of population donating, older adults have been giving blood for decades, but as these individuals leave the donor pool, younger donors are less likely to give. Generation z, and also millennials, are increasingly openly queer and gender-diverse. If blood banks want to secure younger donors, they need to create and implement inclusive practices and policies.

Unfortunately, the FDA provides no guidance on how to facilitate inclusive experiences for gender-diverse populations, nor do they have any information regarding the unique needs of these individuals.

We started advocating for gender-diverse blood donors as a means to capture all individuals impacted by the previous queer blood ban, a policy that was routinely centered around cisgender gay men, but also was applied to transgender women, nonbinary donors, and other gender-diverse folks.

As we began to research best practices, science, and sociology, we identified real risk for both donors and recipients if blood banks did not acknowledge the existence of non-cisgender donors giving blood. What began as the ethically and morally right thing to do- advocating for marginalized communities- became a scientific fight to protect blood product donors and recipients.

The needs and support of gender-diverse individuals is a critical component of Pride & Plasma's work, although this is our first initiative for the trans and gender-diverse community, it will not be our last.

Definitions & Terminology

Gender, Sex, and Transitioning

- **Cisgender:** individuals whose gender identity matches their sex assigned at birth¹
 - *A cisgender man is an individual who identifies as a man and was assigned male at birth*
- **Gender:** attitudes, feelings, and behaviors that a given culture associates with a person's biological sex¹
 - *Common gender identities include man, woman, nonbinary, and more*
- **Gender Diversity:** refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex¹
 - *When using "gender-diverse", Pride & Plasma seeks to be inclusive of individuals who are impacted by the issues at hand, but may not identify as transgender, non-binary, or cisgender.*
 - *The inclusion of individuals with different genders in research ensures that the gender-diversity of the research sample matches that of the general population*
- **Gender-fluid:** A person who does not identify with a single fixed gender or has a fluid or unfixed gender identity²
 - *A gender-fluid individual may identify as male or masculine one day, but identify more feminine or as a woman another day*
- **Gender Identity:** one's sense of oneself as male, female, or something else (American Psychological Association, 2006). When one's gender identity and biological sex are not congruent, the individual may identify along the transgender spectrum (cf. Gainor, 2000; APA guidelines)¹
 - *A person's gender identity (man, woman, nonbinary, etc) influences their presentation (how they dress, act, speak with others).*
- **Gender Non-conforming:** individuals whose gender expression, gender identity, or gender role differs from gender norms associated with their assigned birth sex¹
 - *An individual who identifies as gender non-conforming may present outside or beyond typical male/masculine or female/feminine traits and characteristics*
- **Genderqueer:** refers to a person whose gender identity falls outside of the gender binary (i.e. identifies with neither or both genders)¹
 - *Genderqueer individuals might use the label to express that their identity falls outside the genders of man or woman*
- **Intersex:** a range of conditions associated with atypical development of physical sex characteristics (American Psychological Association [APA], 2006). Intersex individuals may be born with chromosomes, genitals, and/or gonads that do not fit typical

female or male presentations (OII-USA, 2013). Some examples of these conditions include ambiguous external genitals, inability of the body to respond typically to sex-related hormones, and inconsistency between external genitals and internal reproductive organs (APA, 2006)¹

- *Individuals who have sex chromosomes other than XX or XY are intersex*
- **Nonbinary:** An adjective describing a person who does not identify exclusively as a man or a woman. Non-binary people may identify as being both a man and a woman, somewhere in between, or as falling completely outside these categories. While many also identify as transgender, not all non-binary people do. Non-binary can also be used as an umbrella term encompassing identities such as agender, bigender, genderqueer or gender-fluid²
 - *Gender can be expressed as a spectrum, with the two ends (or binaries) as male/man/masculine and female/woman/feminine. Non-binary individuals sit somewhere outside of the middle of this spectrum.*
- **Pronouns:** pronouns are words used to refer to an individual or group of people other than their name. These include he/him, she/her, they/them, or others.
 - *Levi Schmitt was unable to donate blood due to being a sexually active gay man. **He** talked to Miranda Bailey and **she** told **him** that **she'd** help **him** "fight this hateful rule".*
- **Sex:** a person's biological status and is typically categorized as male, female, or intersex (i.e., atypical combinations of features that usually distinguish male from female). There are a number of indicators of biological sex, including sex chromosomes, gonads, internal reproductive organs, and external genitalia¹
 - *The common sexual assignments include male (xy chromosomes), female (xx chromosomes), and intersex (other than xx/xy chromosomes).*
- **Transgender:** is an umbrella term that incorporates differences in gender identity wherein one's assigned biological sex doesn't match their felt identity¹
 - *An individual assigned male at birth, but whose gender is female/a woman is transgender woman.*
- **Transitioning:** A series of processes that some transgender people may undergo in order to live more fully as their true gender. This typically includes social transition, such as changing name and pronouns, medical transition, which may include hormone therapy or gender affirming surgeries, and legal transition, which may include changing legal name and sex on government identity documents. Transgender people may choose to undergo some, all or none of these processes²
 - *Once an individual comes to terms with their transgender identity, they may begin the process of moving towards a presentation that aligns with that identity.*
- **Transexual:** refers to an individual who has undergone gender-reassignment surgery. This term has largely been replaced with "Transgender", but some individuals may still hold onto and prefer this term³

Blood Products, Donation, and Transfusion

- **Whole Blood:** this contains red blood cells (erythrocytes), white blood cells (leukocytes), plasma, and platelets (thrombocytes). Although this can be donated, it is often separated into individual components prior to transfusion. Whole blood has a shelf life of up to 35 days.⁴
- **Red Blood Cells/Erythrocytes:** red blood cells or “erythrocytes” are the oxygen carrying components of blood. These are administered when donors have low hemoglobin (the protein in RBC that binds to oxygen). RBC can be stored for up to 42 days.⁴
 - *Some facilities now have the capabilities of donating two units of RBC at once, under the name “PowerRed” or “Double Donation”. A donor’s plasma and platelets will be returned, to ensure adequate circulatory volume. Additional restrictions and eligibility requirements may apply.*
 - **Erythrocytosis:** erythrocytosis is a clinical term for a high level of red blood cells in a person’s bloodstream. This can be due to a variety of causes, including but not limited to, increased circulatory testosterone.⁵
- **Platelets/Thrombocytes:** platelets are fragments of blood cells that assist with clotting (aka coagulation) to prevent excessive bleeding and sealing wounds. Platelets are administered to patients with low counts, including cancer patients, whose treatments may inhibit or limit platelet production. Donated platelets only have a shelf life of 5 days.⁴
- **Plasma:** plasma is the fluid component of blood and also contains white blood cells. Fresh frozen plasma (or FFP) may be administered to trauma patients, burn patients, patients with active bleeding, or in preparation for surgery. Plasma has a shelf life of up to a year when frozen.⁴
- **Cryoprecipitate:** Cryoprecipitate, commonly referred to as cryo is a part of plasma that contains components for clotting- factor VIII and fibrinogen. These assist in stopping bleeds and are frequently used for patients with diagnoses of hemophilia and von willebrand disease. This is derived from plasma and has a shelf life of up to 1 year when frozen.⁴
- **White Blood Cells/Leukocytes:** although not donated or transfused by themselves, white blood cells are a critical component of whole blood. White blood cells are a part of the immune system and help to fight infection.
- **Blood Type:** a person’s blood type is determined by two types of antigens.⁶
 - **Antigen:** an antigen is a protein found on the surface of a blood cell (as well as other cells)
 - **ABO antigens** determine the blood type. A antigens mark a blood type as A, B antigens mark a blood type as B, the presence of both marks a blood type as AB, and the presence of neither marks the blood as type O.

- **Rh antigens** determine if the blood is identified as positive (+) or negative (-). Similar to type O blood, if there is no Rh antigen, the blood is negative, if it is present, the blood is positive.
- **Matching:** when a blood donation is “matched” to a donor, it means that the donor’s blood type is the same as the recipient’s blood type. It is important that a recipient receives the same type of blood as their own to avoid a potential transfusion reaction.
- **Screening:** Screening is asking questions of a potential donor before they donate blood. These questions include certain risk factors that may impact their ability to donate blood on a date or donate certain types of blood products.
- **Testing:** Testing occurs between donation and transfusion (administration) of a blood product. The donated blood will be tested for infections (like HIV and hepatitis), as well as for the blood type. If the donation is determined to be unsafe for administration, the donor may be contacted to assess risk or to be notified of a status.
- **Phlebotomy:** the science/study/practice of vasculature and blood draws. In the case of blood donation, a phlebotomist is a trained individual who inserts an IV to allow the donated blood to leave the body.
 - **Therapeutic Phlebotomy:** in cases of individuals who produce too many red blood cells, they may be prescribed “therapeutic phlebotomy”, or the act of donating blood to return their cell counts to a typical, safe level.⁷
- **Eligibility:** the status of being legally able to donate blood at a certain date based upon federal and facility policies and regulations.
- **Deferment:** to put off until a later date or time. In the case of blood donation, deferment means that an individual is not eligible at a current date due to a risk factor, but may be able to at a later time based upon eligibility criteria.
- **Individual Risk Assessment:** the IRA was a new screening tool utilized by blood centers starting in May of 2023. This tool replaced the previous blanket deferment for MSM (men who have sex with men) donors, informally referred to as the “queer blood ban” that was in place since 1985.
 - *Pride and Plasma researched and compiled a brief for the FDA on the topic and spoke at the FDA’s blood products advisory committee prior to the transition and approval of a new screening process in 2023.*

Organ Systems

- **Respiratory System:** the respiratory system is a system of organs, tissues, and cells that ensures oxygen and nutrients are transported and accessible for your body’s

other organs, tissues, and cells. The respiratory system is composed of the lungs, trachea & bronchi, diaphragm, mouth & nose, and vasculature.⁸

- **Lungs:** the lungs are two large sacks in your chest that fill with oxygen and expel carbon dioxide. Blood enters the lining of alveoli to facilitate the exchange of oxygen for carbon dioxide.⁸
- **Alveoli:** tiny air sacs in the lungs that promote air exchange.⁸
- **Bronchi:** two tubes that branch off of the trachea into each of the lungs.⁸
- **Edema:** fluid retention that results in swelling.⁹
 - **Pulmonary Edema:** fluid accumulation in the lungs that can be caused by a variety of events including trauma, infection, or in the case of transfusion-reactions, an immune system response.⁹
- **Ventilation:** the act of moving air in and out of the lungs. This is achieved through the use of muscles expanding and contracting the lungs.¹⁰
 - **Mechanical Ventilation:** a machine that performs the work of breathing for individuals in intensive care settings who need assistance to maintain oxygen-rich blood to their tissues.¹⁰
- **Circulatory System:** The circulatory system is made of the heart and blood vessels.
- **Arteries:** blood vessels that carry oxygenated blood from the heart to the tissues and capillaries
- **Veins:** blood vessels that carry deoxygenated blood from the capillaries and tissues back to the heart
- **Capillaries:** the smallest blood vessels that link arteries and veins, where oxygen is exchanged for carbon dioxide at the tissues
- **Immune System:** the immune system is a collection of organs, tissues, and cells that work to protect against infection and other threats, along with promoting healing.
- **Antigens:** proteins on the surface of cells that identify a cell as either self (a part of a person's body) or non-self (not originating from a person's body).⁶
 - *Antigens determine a person's blood type*
- **Antibodies:** immune system responses to non-self antigens. Antibodies attach to antigens.⁶
- **Endocrine System:** a group of organs, tissues, and cells that secrete hormones through the body
 - *Testosterone and estrogen are two hormones present in every person, regardless of sex or gender*
- **Testosterone:** a hormone that increases body hair growth, red blood cell production, muscle growth, and altered body composition
 - *Individuals seeking more masculine presentation and attributes may pursue testosterone administration and prescription*

- **Estrogen:** a hormone that decreases body hair production, increases breast growth, and alters body composition.
 - *Individuals seeking a more feminine presentation and attributes may pursue estrogen administration and prescription*
- **Exogenous:** from outside of the body.
 - *Exogenous hormones refer to hormones added to the body via injection,, topical application, or other route of administration*

Who We Direct Our Research Towards:

Unlike with our advocacy related to blood and tissue donation bans, we are advocating for the creation and application of a new policy, which means that we can target organizations at three levels: the federal level (FDA), the professional organization level (AABB), and at the individual blood bank level.

The Federal Government: The FDA // the Center for Biologics Evaluation & Research // the Blood Products Advisory Committee

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 create a policy.
- **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 cost, time commitment, and the

fact that we are not fighting an active policy, we're advocating for the creation of one makes this less than feasible.

The FDA works to ensure the safety, efficacy, and security of drugs, medical devices, cosmetics, food, and biological products.¹¹ 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.¹² One of these, the Blood Products Advisory Committee reviews data and creates recommendations for policies. They usually meet at least three times a year. These meetings are where we previously presented our evidence, research, and argument, and provide the opportunity for future advocacy.

The Association for Advancement of Blood & Biotherapies // Individual Blood Banks

AABB, or the Association for Advancement of Blood and Biotherapies, is a professional organization for individuals and organizations working in the blood donation and transfusion medicine industries.¹³ Individual phlebotomists, nurses, and advanced practice providers (Nurse Practitioners, Physicians, Physician's Associates/Assistants) are eligible for membership in AABB.

AABB plays a critical role in maintaining compliance with FDA regulations. They approve and provide accreditation for blood banks and facilities. They provide continuing education and publish research in the field of blood donation. AABB was one of the top organizations pushing forward the individual risk assessment to replace the blanket queer blood ban. For the topic at hand, AABB translates the FDA eligibility criteria into the donor history questionnaire.

Donor History Questionnaire¹⁴

The DHQ is a tool utilized by blood banks and their employees to determine if a potential donor is currently eligible to donate at a current date. The DHQ is revised when the FDA updates eligibility criteria and was last reviewed in May of 2023, version 4.0. After the FDA releases an eligibility update, AABB will draft a donor history questionnaire, which the FDA will then approve. The approved DHQ is sent to blood banks for implementation.

Sex, Gender, & Gender-Diversity

Definitions

- **Sex:** a person's biological status and is typically categorized as male, female, or intersex (i.e., atypical combinations of features that usually distinguish male from female). There are a number of indicators of biological sex, including sex chromosomes, gonads, internal reproductive organs, and external genitalia
 - Male: individuals with an x/y chromosome set
 - Female: individuals with an x/x chromosome set
 - **Intersex:** a range of conditions associated with atypical development of physical sex characteristics (American Psychological Association [APA], 2006). Intersex individuals may be born with chromosomes, genitals, and/or gonads that do not fit typical female or male presentations (OII-USA, 2013). Some examples of these conditions include ambiguous external genitals, inability of the body to respond typically to sex-related hormones, and inconsistency between external genitals and internal reproductive organs.¹
- **Gender:** attitudes, feelings, and behaviors that a given culture associates with a person's biological sex
 - **Cisgender:** individuals whose gender identity matches their sex assigned at birth.¹
 - **Transgender:** is an umbrella term that incorporates differences in gender identity wherein one's assigned biological sex doesn't match their felt identity.¹
 - **Nonbinary:** An adjective describing a person who does not identify exclusively as a man or a woman. Non-binary people may identify as being both a man and a woman, somewhere in between, or as falling completely outside these categories. While many also identify as transgender, not all non-binary people do. Non-binary can also be used as an umbrella term encompassing identities such as agender, bigender, genderqueer or gender-fluid.²

- **Gender Non-Conforming:** individuals whose gender expression, gender identity, or gender role differs from gender norms associated with their assigned birth sex.¹
- **Gender-fluid:** A person who does not identify with a single fixed gender or has a fluid or unfixed gender identity.²
- **Agender:** a gender identity without a connection to male and or female genders.²
- **Gender-Diversity:** refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex.¹
 - *When using "gender-diverse", Pride & Plasma seeks to be inclusive of individuals who are impacted by the issues at hand, but may not identify as transgender, non-binary, or cisgender.*
- **Transitioning:** A series of processes that some transgender people may undergo in order to live more fully as their true gender. This typically includes social transition, such as changing name and pronouns, medical transition, which may include hormone therapy or gender affirming surgeries, and legal transition, which may include changing legal name and sex on government identity documents. Transgender people may choose to undergo some, all or none of these processes.²

Sex vs Gender

Sex and gender are not the same, but for many cis-gender individuals, they do align. Sex refers to biology, an individual's chromosomes. Sex is assigned at birth based, male or female. For transgender and gender-diverse individuals, their gender might not align with the sex assigned to them at birth.

Gender is a person's internal feelings and external presentation related to their sex. **Gender dysphoria**, or a feeling of pain, distress, or discomfort related to one's biological sex may be experienced by many gender-diverse individuals¹. In contrast, **gender euphoria**, or a feeling of contentment and joy when their external presentation matches their gender identity, is commonly experienced by gender-diverse individuals when they begin and are in the process of transitioning to their true gender.

A person's gender identity may be stagnant, or it may change from day to day, situation to situation, or with other factors. Some gender-diverse individuals pursue transitioning, or assistance with aligning their external presentation with their gender identity, but not all do. An individual's gender and identity is no less valid if they elect to not pursue medical, surgical, or other forms of transitioning.

Transitioning¹⁵

Just as each individual's gender identity and gender-expression are both deeply individualistic, so is an individual's process of transitioning. There is no right or wrong way to "do gender", nor is there one process to reach a point of comfort in one's body. Some transgender, non-binary, and gender-diverse individuals. There are a multitude of assistive treatments, procedures, and processes that can help individuals reach this stage, not all of which are included here.

Internal Transitioning

These are practices and actions that an individual can participate in to begin the process of feeling at ease with their true gender identity. These include dressing differently, calling yourself a different name, using your voice differently all while in private.

Social Transitioning

Social transition begins when an individual is ready to progress from internal to external transition (private to public). These can include actions such as coming out to friends and/or family, changing the pronouns that you use, changing or modifying your name, dressing differently (such as binding or stuffing your chest, or tucking or packing your groin), and using your voice differently. These are methods of adapting your presentation in social settings, attempting to influence the perception of your gender by others, as well as making yourself more comfortable when publicly presenting as your gender.

Medical Transitioning

Medical transition can include prescriptions and medical treatments that alter your presentation. These processes vary based upon the intended presentation (masculine, feminine, androgynous), as well as an individual's intended outcome, or the extent of a change one is seeking to achieve.

Hormone Replacement Therapy (HRT)

Some gender-diverse individuals elect to pursue hormone replacement therapy to assist in their medical transition. This is frequently abbreviated to HRT. Transitioners pursuing a more masculine presentation may use testosterone administration, while individuals pursuing a more feminine presentation may pursue progesterone and estrogen.

Testosterone is initiated with the goal of initiation of secondary sex characteristics; deeper voice, facial hair, muscle growth, redistribution of body fat away from hips/breasts, delay or stop menstrual period. Side effects of testosterone administration include weight gain, sleep apnea, altered cholesterol, increased blood pressure, **increased red blood cell production**.¹⁶

Progesterone and Estrogen are initiated with the goal of initiation of secondary sex characteristics; breast growth, redistribution of fat towards hips, decrease in overall body hair. Effects of these hormones include blood clots, stroke, heart problems, altered cholesterol, increased potassium in the blood, weight gain, higher blood pressure, and diabetes.¹⁷

Surgical Transitioning¹⁵

Gender affirming surgery(ies) are permanent procedures to help align an individual's body with their gender, gender identity, and transition process. Not all gender-diverse individuals pursue surgical assistance in their transition


Masculine surgeries include mastectomy or top surgery (removal of the breasts/breast tissue), laryngoplasty (surgery to alter vocal cords), hysterectomy (removal of internal reproductive organs, the uterus, fallopian tubes, and ovaries), phalloplasty (construction of a penis using skin from other parts of the body), metoidioplasty (surgical creation of a scrotum and testes), vaginectomy/vulvectomy (removal of the vagina and/or vulva, paired with other surgeries), nullification (surgery that removes or hides external genitals).

Feminine surgeries include breast augmentation (creation of breasts, also referred to as "top surgery"), laryngoplasty (surgery to change vocal cords), tracheal shave (decreasing the size of the adam's apple), facial feminization surgery (altering the size/shape of facial structures), orchiectomy (removal of the testes), vaginoplasty (creation of a vagina, inverting the skin of the penis), nullification (surgery that removes or hides external genitals).

Legal Recognition

The difficulty of changing one's gender marker from M to F or F to M, as well as changing one's name through the legal process varies greatly by geography. Additionally, not every state has legal recognition of X gender-markers (an option other than M or F) on birth certificates or drivers licenses

Legal Transitioning



The general process of legal transition from one gender identity to another is as follows, but not all gender-diverse individuals have the ability, resources, or right to do so based upon a state's current laws and regulations.

To change one's name requires a court order and similar documentation. Following a name change, a social security card can be changed along with proof of a gender change (an updated passport, a court order, or a signed letter from a primary care provider documenting gender-affirming treatment). A state ID or driver's license requires a court order for a name change and requirements for gender marker changes vary. Other documents include financial accounts and documents like bank accounts and credit cards, health/care/home insurance, school IDs, and more.

Legal transitioning can help facilitate more inclusive policies for gender-diverse individuals and may allow them to avoid disclosure of their non-cisgender status in unsafe situations, but the process can be lengthy and unclear.

Regardless of an individual's ability or choice to pursue legal recognition of their gender and/or name change, blood banks should allow donors to revise their gender identity, name, and other information with minimal difficulty and without documentation.

Blood Donation

Policy History

Blood donation has been a critical component of health care delivery for decades. One of the most significant updates to donor eligibility came in 1985 during the HIV/AIDS crisis. Without a clear understanding of the HIV virus, and without adequate means of testing for it amongst blood donations, the FDA enacted a lifetime deferral for MSM (men who have sex with men). The policy was retroactive, impacting any queer man who was sexually active with another man, even once, since 1977. The policy was also likely applied to transgender women, nonbinary individuals, and other gender-diverse donors.

The policy remained unchanged for 3 decades, with a revision in 2015, thanks to the efforts of the National Gay Blood Drive. The FDA cut down the lifetime ban to a 12-month deferral, meaning that any queer men (and transgender women, nonbinary, and gender diverse donors) who were sexually active with another man in the past 12-months were eligible to donate.

In 2020 due to national shortages related to the Covid-19 pandemic, as well as no increase in HIV transmission or risk following the 2015 update; the FDA reduced the 12-month deferral to a 3-month policy. Both of these were steps forward, but still discriminatory against the LGBTQ+ community. **Both the 2015 and 2020 updates to blood donor eligibility included the following line:**

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

The language was supportive of transgender donors who identified as male or female, but did not include other gender-diverse blood donors whose identities did not align with the binary genders. The FDA also failed to provide any action plans to support these donors or to implement this recommendation.

In 2023, the FDA replaced the 3-month blanket deferral for MSM donors (any type of sexual activity between two men, regardless of route of activity or risk reduction strategies), with an individual risk assessment. This new policy aims to ask all donors the same questions, regardless of a donor's gender, sexual orientation, or the gender of their partners. This is a significant step forward for gender-diverse blood donors, in theory. The new criteria removed all gendered language, but also removed the supportive language from 2015 and 2020.

Blood Products

There are 4 components of whole blood (the blood currently circulating in a person's blood vessels. These are red blood cells, white blood cells, platelets, and plasma. Blood products can be donated as whole blood, isolated red blood cells, plasma, or isolated platelets. White blood cells are not traditionally donated on their own. Plasma can also be processed into a collection of clotting proteins called cryoprecipitate. Whole blood donations are often separated into individual components prior to transfusion. Whole blood has a shelf life of up to 35 days

Red Blood Cells (AKA “Erythrocytes”)

Red blood cells (aka “erythrocytes”) are the oxygen-carrying components of blood, oxygen molecules bind to hemoglobin, a protein on the blood cell's surface, and travel to the body's tissues where they are exchanged for carbon dioxide. These are administered when donors have low hemoglobin (the protein in RBC that binds to oxygen). RBC can be stored for up to 42 days.

Some facilities now have the capabilities of donating two units of RBC at once, under the name “PowerRed” or “Double Donation”. A donor's plasma and platelets will be returned, to ensure adequate circulatory volume. Additional restrictions and eligibility requirements may apply.

White Blood Cells (AKA “Leukocytes”)

White blood cells (aka “leukocytes”) are a part of the immune system and help to fight infection.

Platelets (AKA “Thrombocytes”)

Platelets (aka “thrombocytes”) are fragments of blood cells and help to clot off bleeds and seal wounds. Platelets are administered to patients with low counts, including cancer patients, whose treatments may inhibit or limit platelet production. Platelets only have a shelf life of 5 days.

Plasma

Plasma is the fluid component of blood and contains proteins and electrolytes, and ensures that your blood cells can move around the body. Plasma donations may also contain white blood cells. Fresh frozen plasma (or FFP) may be administered to trauma

patients, burn patients, patients with active bleeding, or in preparation for surgery. Plasma has a shelf life of up to a year when frozen.

Cryoprecipitate

Cryoprecipitate, commonly referred to as cryo is a part of plasma that contains components for clotting- factor VIII and fibrinogen. These assist in stopping bleeds and are frequently used for patients with diagnoses of hemophilia and von willebrand disease. This is derived from plasma and has a shelf life of up to 1 year when frozen.

Hemoglobin

Hemoglobin is a protein within red blood cells that binds to oxygen allowing red blood cells to transport oxygen to the body's tissues. Hemoglobin is measured in grams per deciliter (1/10 of a liter) g/dL. Hemoglobin ranges are categorized as male or female; as cisgender men and cisgender women have different baselines and ranges, however, varying factors can impact an individual's normal range. Factors impacting an individual's hemoglobin include diet, exercise, medications, menstruation.

Hemoglobin Ranges¹⁸

	Normal Range	Donation Range
Cis-Males	13.5-17.5g/dL	13.0-20.0g/dL
Cis-Females	12.0-15.5g/dL	12.5-20.0g/dL

The current hemoglobin ranges fail to consider individuals who are not cis-gender. If a transgender man has only pursued legal and social transition, his hemoglobin range was 12.8, he might be deemed ineligible to donate, despite being eligible on the cis-female range. There is no guidance from the FDA on how to address the unique needs of gender-diverse blood donors. Additionally, individuals who take testosterone have the potential side effect of increased red blood cell production and therefore increased hemoglobin, but these factors are not considered by having two gender-binary scales.

Current Gendered Criteria

Hemoglobin is one of a few gendered criteria for determining blood donor eligibility. Some blood banks gender a history of pregnancy, which affects if a donor can give plasma or platelets. Additionally, a donor's body mass may fall into a gendered scale, but this can vary from facility to facility.

Computer Systems ^{19.20}

Many blood centers use third-party, or outside organizations, for their computer systems, however, this can result in significant issues with implementing changes for donor eligibility, donor interface, and updating donor information at the facility. These computer systems can be significantly out of date compared to modern technology, which increases the time required for facilities to implement updates. This was seen in 2023 with the transition to the individual risk assessment. The FDA finalized their recommendation for donor eligibility in May of 2023 and AABB's new donor history questionnaire was approved the same day. We saw some blood centers requiring until January of 2024 to implement updated eligibility criteria. Although taking the time to ensure updates are implemented correctly is critical, this saw months of newly eligible donors being unable to give blood in an era of chronic blood products shortages across the country.

Many blood donation facilities only have gender options for male and female, and some do not allow for donors to revise their gender marker at a later date. Although not required by the FDA, some blood banks may require employees to use a donor's legal name and/or gender, even if these do not align with the donor's identity and presentation. Gender-diverse donors want to know why questions about their gender are asked, and if they aren't necessary, they should be avoided. Staff should maintain privacy and confidentiality during the donation process.

With severe shortages of both blood donors and blood products, we need blood banks and facilities to create inclusive environments for all donors, and this starts with donor's creating their accounts and scheduling their appointments. If they have an unwelcoming environment online beforehand, there is a chance that they won't even make it through the doors.

Organ Systems

Respiratory System

The respiratory system is a system of organs, tissues, and cells that ensures oxygen and nutrients are transported and accessible for your body's other organs, tissues, and cells. The pulmonary system is composed of the lungs, trachea & bronchi, diaphragm, mouth & Nose, and vasculature.

Oxygen enters the body through the nose and mouth, travels through the trachea (in the neck), and enters the two bronchi which lead to the lungs. The lungs are composed of small air sacs called alveoli, which have increased surface area. Oxygen is able to travel across the surface of the alveoli to blood vessels, in exchange for carbon dioxide. This newly oxygenated blood returns to the heart, where it is pumped out to the body's tissues. Blood is transported from the heart via arteries, and meets the tissues at capillaries. After exchanging oxygen for carbon dioxide, blood returns to the heart via veins.

Immune System

The immune system is a collection of organs, tissues, and cells that work to protect against infection and other threats, along with promoting healing. The immune system works by detecting self cells (your body) and non-self cells (ex. Bacteria, viruses, or transplant/transfusion). The immune system is composed of lymph nodes, white blood cells (leukocytes), bone marrow, and more.

Antigens are proteins on the surface of cells that identify a cell as originating in your body. Your blood type is an example of antigen markings. Antibodies are the proteins produced by the immune system. They bind to non-self antigens and attack the non-self cells. White blood cells are the immune cells within your bloodstream or circulation. There are multiple types of white blood cells that serve different functions and can identify non-self cells, attack non-self cells, or release chemicals to trigger a response by other immune cells.

One type of antigen, human-leukocyte antigens, are present in your body, but hold a risk in transfusion reactions. When a fetus develops within a pregnant person, the pregnant person's immune system can produce antibodies to these, called human-leukocyte antigen antibodies (abbreviated as HLA Antibodies). These antibodies may be in circulation for years after the end of a pregnancy via miscarriage, abortion, or delivery.

Transfusion Reactions

Transfusion-Related Acute Lung Injuries²¹⁻²⁹

HLA- antibodies are one of the leading causes of transfusion-related acute lung injuries, which are the current second leading cause of transfusion-related mortality.

As with most medical treatments, there is some inherent risk, which in most cases is outweighed by the benefits. Patients in need of a transfusion are at high-risks of adverse effects, whether that is internal bleeding, hypotension, decreased oxygen carrying capacity, or more. Interventions are implemented to prevent the risk of these adverse effects, like testing blood donations for infections, and deferral of high-risk donors. Donors with a history of pregnancy are prevented from donating plasma or platelets because these blood products are more likely to have HLA-antibodies present.

In TRALIs, an existing inflammatory condition leads to increased neutrophil (white blood cell) accumulation within the lungs. These white blood cells are activated by the transfusion of blood products and the HLA antibodies. This is followed by the immune system response and white blood cell infiltration (increased presence within the lungs). This immune response causes increased fluid accumulation in the lungs (called pulmonary edema). This increase in fluid leads to a requirement for supplemental oxygen administration.

TRALIs present in a few ways. Patients may have difficulty breathing and shortness of breath while at rest. They may start to require increased oxygen. Recipients may have a fever, a decreased blood pressure, and a faster heart rate. Nurses stay with a patient during the start of a blood transfusion to monitor a patient and to ensure that any adverse effects are flagged and treated as soon as possible.

If a patient does begin to experience signs and symptoms of a transfusion-reaction (including but not limited to TRALIs), the transfusion will be stopped immediately and then sent back to the blood bank or lab.

Diagnosis for TRALIs include a review of symptoms and a chest x-ray. The x-ray will show increased density on both sides of the lungs (the fluid from the pulmonary edema). Treatment for TRALIs is mostly symptomatic, medications for fevers, oxygen to maintain tissue perfusion (ensuring that tissues are receiving oxygenated blood). If patients require severe treatment they may be transferred to an intensive care unit in a hospital.

Some TRALI patients require mechanical ventilation, the use of a machine to perform the work of breathing to ensure adequate oxygenation to the body and tissues. A ventilator keeps the airways open, applies oxygen, and removes carbon dioxide.

Transfusion Mortality³⁰⁻³⁸

Unfortunately, each year a small number of individuals who receive blood transfusions experience adverse reactions, and despite the best efforts of healthcare workers and clinicians, some of these patients die. The benefits of the blood product transfusion outweigh the potential risks for administration and patients are educated on the benefits and risks before administration. Additionally, investigations are completed by the administration facility, blood bank, and potentially by the regulatory organization. These investigations are completed to prevent future occurrence of all adverse events.

Diagnoses listed in the FDA's reports for cases of transfusion fatalities include anaphylaxis, contamination, hemolytic transfusion reaction, transfusion-associated circulatory overload, transfusion-related acute lung injury, other transfusion reaction, and other. These diagnoses are compiled into the "total" section for each year, but not all diagnoses result in a fatality every year.

Cases are defined based upon probability, as the FDA Definitions are as follows:

- **Definite:** Conclusive evidence beyond reasonable doubt for attributing the fatality to the transfusion/donation
- **Probable:** Evidence clearly in favor of the transfusion/donation as the cause of the fatality
- **Possible:** Evidence is indeterminate for attributing the fatality to the transfusion/donation or alternative cause
- **Doubtful:** Evidence in favor of attributing the fatality to an alternative cause, but transfusion/donation cannot be excluded
- **Ruled Out:** Conclusive evidence beyond reasonable doubt for attributing the fatality to cause other than transfusion/donation

For the research we conducted, we focused solely on cases defined as "definite", "probable", or "possible".

National incidence of possible transfusion-related acute lung injury (pTRALI) and transfusion-related acute lung injury (TRALI) from 2009-2021

Year	pTRALI			TRALI			Total TRALI	%	Rank	Total Cases
	Definite	Probable	Possible	Definite	Probable	Possible				
'09 ²⁷							<u>13</u>	<u>30%</u>	<u>1st</u>	44
'10 ²⁷							<u>18</u>	<u>45%</u>	<u>1st</u>	40
'11 ²⁷							<u>10</u>	<u>33%</u>	<u>1st</u>	30
'12 ²⁷							<u>17</u>	<u>45%</u>	<u>1st</u>	38
'13 ²⁷							<u>14</u>	<u>37%</u>	<u>1st</u>	38
'14 ²⁸							<u>13</u>	<u>43%</u>	<u>1st</u>	30
'15 ²⁹	0	0	0	5	0	7	<u>12</u>	<u>32%</u>	<u>1st</u>	37
'16 ³⁰	0	0	5	2	0	1	<u>8</u>	<u>19%</u>	<u>2nd</u>	35
'17 ³¹	0	0	4	0	2	3	<u>9</u>	<u>24%</u>	<u>2nd (tie)</u>	37
'18 ³²	0	2	2	0	0	0	<u>4</u>	<u>13%</u>	<u>4th (tie)</u>	31
'19 ³³	1	2	4	2	2	1	<u>12</u>	<u>27%</u>	<u>1st (tie)</u>	44
'20 ³⁴	0	1	1	2	2	0	<u>6</u>	<u>21%</u>	<u>2nd (tie)</u>	29
'21 ³⁵	0	1	4	1	1	0	<u>7</u>	<u>16%</u>	<u>2nd</u>	42
<i>17-21³</i> <i>5</i>								<u>21%</u>	<u>2nd</u>	

Although less than 50 blood transfusions per year have resulted in fatalities over the past years, this is due to critical research and prevention work. If these reactions are preventable through screening, testing, and matching, interventions should be put in place.

Through all diagnoses and causes of transfusion-mortality, TRALIs are routinely in the top two spots, and comprehensive prevention, inclusive of all donors (including gender-diverse donors) is necessary to ensure that no high-risk donors slip through the cracks.

Gender-Diverse Issues in Blood Donation

Screening and Gender

Current screening questions, as well as some previous questions were based on gender, with some questions being asked of male-identified donors, some of female-identified donors, and some of both. Until 2023, male-identified blood donors were asked about their sexual history with other men. Additionally, some transgender women and other gender-diverse donors who were assigned male at birth were subject to policies intended to impact MSM (men who have sex with men) donors. Some blood centers may only ask female-identified donors about a history of pregnancy.

Another gender-based eligibility criteria is a donor's hemoglobin level. The two ranges of eligible results are based upon typical cisgender male or female ranges. There is no guidance on how to screen donors who are not cisgender- and zero recommendation on how to screen gender-diverse donors who are undergoing hormone replacement therapy. Some blood donation facilities may calculate a donor's body mass index or body composition, which may result in differing eligibility determinations on if a donor is screened as male or female. Transgender men and other gender-diverse donors who have been pregnant might not be screened for a history of pregnancy, and therefore might be able to donate plasma or platelets with increased concentrations of HLA antibodies.

Beyond screening criteria, the screening process as a whole is not inclusive of gender-diverse blood donors. Blood establishment computer systems (abbreviated BCESs) are incredibly rigid in user interface and adaptability. This means that most blood centers are limited to the original settings that were in place when the computer systems were started. Although this is easy to see when implementing updated FDA regulations (some blood banks required 9 months to implement the update from May of 2023), it also has been evident with gender-diverse blood donors.

Trans and gender-diverse people have always existed, but consideration and public acceptance for these members of the LGBTQ+ community has seen significant progress in the past 2 decades. In the 1990s and 2000s, support was not as high, and most blood centers only introduced options for "male" or "female" donors. Today, when some blood centers are interested in introducing a third gender option they are unable to, although

they purchase or license these computer systems and programs, they don't have the capability to introduce new gender-markers. ***Although this is not a pass for blood banks to ignore gender-diverse blood donors indefinitely, it is a small explanation for why progress has taken this long.***

Some blood centers elect to implement screening and eligibility criteria more restrictive than the FDA's recommendations and regulations, which they are fully able to do. The FDA sets minimum standards for safety, blood banks can absolutely be more restrictive in their donors if they feel the need. If blood banks want to decrease the risk of TRALIs and HLA antibodies, they might prevent all female-identified donors from giving plasma or platelets. However, this might also prevent transgender women and some other gender-diverse donors from donating these blood products, even if they cannot become pregnant themselves. The failure to consider gender-diverse blood donors may inadvertently limit the number of blood products donated and processed by facilities.

Therapeutic Phlebotomy

Therapeutic phlebotomy is the process of being prescribed to donate blood by a primary care provider. Individuals who undergo therapeutic phlebotomy have a condition that results in increased red blood cell production, termed "erythrocytosis". One frequent cause of this is exogenous testosterone administration, with most cases documented for cisgender men undergoing testosterone replacement therapy. As a hormone, testosterone impacts red blood cell production, which occurs as an unintended side effect among patients receiving the medication for other treatments.

Most cases of therapeutic phlebotomy focus on cisgender men, and most therapeutic phlebotomy programs amongst blood centers target cisgender men undergoing TRT for participants. However, the testosterone administered to cisgender men and the testosterone prescribed to transgender men and other gender-diverse donors is the exact same medication. The dosing is calculated in the same way; with a goal of returning to a typical cis-male baseline. If an individual's serum testosterone level is too high, you decrease the dose. If the level is too low, a prescriber might increase the dose.

Because of this, both cisgender men and gender-diverse patients may see the same side effects, including increased red blood cell production.

Therapeutic phlebotomy programs may benefit their blood bank supplies if they recruit gender-diverse blood donors currently undergoing testosterone administration. However, more research needs to be conducted on the subject area and community. Current therapeutic phlebotomy programs are few and far between. With chronic ongoing shortages of all blood products, this is one way to ensure that donors are able to safely donate and for blood banks to ensure donors return for future appointments.

Synthesis & Evidence

In this section, we'll provide a brief overview of why the policy is unnecessary, outdated, and discriminatory. It will be a small section of our research and argument that will be presented to the Blood Products Advisory Committee; Cellular, Tissue, and Gene Therapies Advisory Committee; and Advisory Committee on Blood and Tissue Safety and Availability.

Blood donation has not always been an accessible nor equitable process for members of the LGBTQ+ community. With the revisions to the previous blanket MSM (men who have sex with men) deferment criteria, strides have been made by the FDA, CBER, and BPAC to reconcile past actions. However, transgender, nonbinary, and other gender-diverse individuals have been left to the side of this progress. These individuals not only serve the potential to contribute safely to the nation's blood supply, but have been subject to deferment criteria in opposition to their gender identity(ies) (e.g. transgender women and non-binary individuals subject to deferment criteria intended for men and male donors).

Attempts to create affirming environments for gender-diverse blood donors have been introduced, namely the language "In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported", which was present in the 2015 and 2020 iterations of eligibility criteria. However, the preceding language does not consider individuals outside of the two poles of the gender binary. Additionally, there were no best practices, guidelines, or instructions provided for blood banks and donation facilities in regards to the screening and treatment of these donors prior to the language's disappearance in 2023 with the transition to the individual risk assessment.

Although not every individual trans+ individual chooses to pursue legal, medical, or surgical assistance with their transition, many do. The treatments, prescriptions, and procedures that these individuals undergo result in a diverse pool of donors, whose needs and safety must be considered. Individuals undergoing testosterone administration may find themselves with higher concentrations of erythrocytes. While some cisgender men undergoing TRT (testosterone replacement therapy) are prescribed therapeutic phlebotomy to prevent the risk of clots and other adverse effects, transgender individuals prescribed the same medications have not been identified in the same risk.

For transgender women or nonbinary/gender-diverse individuals taking HRT estrogen, the hemoglobin and hematocrit levels were found to be within the standard female range following therapeutic administration. One research publication stated "blood cell findings revealed a different time course of change. After 3–4 months on GAHT, the

HCT or Hgb levels of transwomen matched those of cisgender women, with levels remaining stable within the 'normal' female range for studies lasting up to 36 months".³⁹

Erythrocytosis, or an increased concentration of red blood cells, can occur with testosterone administration, for both transgender and cisgender patients. This occurrence is significant enough that the FDA enacted mandatory warning labels for a risk of thromboembolism for all testosterone prescriptions in 2015.⁵ "Secondary erythrocytosis, a potentially serious adverse effect of testosterone therapy as it is associated with an increased risk of thromboembolic events by an increase in blood viscosity".⁴¹ As with many other aspects of this issue, research on the topic is limited to cisgender individuals, or has not been pursued related to gender-diverse groups. The exact incidence and prevalence of erythrocytosis related to HRT rather than testosterone replacement therapy (TRT), is not available.⁴⁰

HRT and TRT are the same practice of administering exogenous testosterone for patients seeking to increase serum concentrations and systemic effects, with HRT indicating transgender, nonbinary, and other gender-diverse patients; whereas TRT designates cisgender male patients. Although the points and evidence in this brief is meant to be applied to HRT patients, the lack of data on transgender individuals limits our ability to include sources that solely included gender-diverse participants. As the goal of HRT is to reach testosterone levels equal to cisgender men, data is supplemented with samples and studies on TRT.

To prevent thrombotic events, or hypercoagulation in the result of increased viscosity and erythrocytosis, some providers prescribe therapeutic phlebotomy for patients undergoing TRT⁷. This order requires individuals undergoing TRT to donate blood to decrease their red blood cell counts⁴². These individuals may be prescribed therapeutic phlebotomy at intervals more frequently than the typical minimum of 8 weeks between whole blood donations. This process is approved by the FDA, as evidenced by variances submitted by facilities to allow the practice^{43, 44}. Although many of these programs are created and maintained through cisgender men who are undergoing TRT, the applications or benefits may be also achieved through transgender men and nonbinary or gender diverse persons undergoing HRT. If both demographics of donors are seeking to maintain testosterone levels within a defined threshold, they may see similar, if not the same side effects. These donors, who currently are not acknowledged by federal regulations or policies, may be some of the safest repeat donors from a donor-risk standpoint.

Transfusion related acute lung injuries are the second leading cause of transfusion-related mortality. An issue prevalent enough to recommend deferral for previously pregnant women from donating plasma and/or platelets. These deferrals are a method of preventing patients from dying, from requiring mechanical ventilation, from requiring prolonged hospitalization, amongst other adverse effects. But the application of

these deferral criteria related to platelets and plasma donations are not inclusive of all those who are high-risk.

Factors that affect the incidence of TRALLs include patient populations, such as those with existing hematologic issues, pediatric patients, or trauma patients; donor factors, such as previous pregnancies, miscarriages, or abortions; the type of blood product administered, the quantity and volume of blood products administered, and definition and diagnosable criteria used to identify cases, and the methods of symptom surveillance and reporting²⁸. Other conditions that have been tied to TRALI and acute respiratory distress syndrome include sepsis and non-cardiogenic shock²¹.

Prevention is implemented through the use of donor deferral through the history questionnaire, HLA screening, and increasing the percentage of plasma and/or platelet donations from male donors^{22, 29}. Deferral criteria include a lifetime deferral for plasma and/or platelet donation for individuals with a history of pregnancy or a history of transfusion¹⁹. Some facilities may defer all women from donating plasma or platelets, as not all individuals are aware that they were pregnant if the pregnancy ended in the first weeks following conception^{22, 29}. Previously pregnant donors may be permitted to donate if testing for HLA antibodies is negative²⁸. These methods have been effective, with an 80% decrease in TRALLs when the American Red Cross implemented a male-predominant plasma donor program in 2007²⁷.

Research on transgender, nonbinary, and gender-diverse persons as individuals and as a whole has been significantly lacking when related to blood, tissue, and biologics. While identification of areas of growth for the screening, treatment, and testing of these donors has been published, solutions that address the needs and concerns of this community have not been uniformly shared nor implemented in the nation's blood centers. These donors can not only help ease shortages and decreased donations but must be acknowledged in an era of low donor turnout. Besides the necessity of ensuring welcoming environments for all donors, the failure to consider the differences of this sample when compared to the general population of blood donors has resulted in potential risk for individuals receiving transfusions due to a lack of preventative measures applied to those at higher risk.

Current practices by many blood centers fail to consider these individuals while drafting, implementing, and reviewing donor screening mechanisms. Part of the issue is the outdated and limited capacity of blood establishment computer systems (BECSs)¹⁹. These programs and systems may only have two binary gender markers for selection by donors or staff. They may not have the capability to change a gender marker in the future if a previous donor has begun social and legal transition. Unfortunately, in a 2017 survey of US and Canadian blood centers, most American facilities did not allow the use of gender designations other than male or female (97%)¹⁹. However, a growing number of states and municipalities are transitioning towards gender markers beyond the gender binary, with X serving as an option for non-binary, gender non-conforming, and other gender-diverse.

Even ignoring the ethical justification of acknowledging the existence of gender-diverse donors, the computer systems are not equipped or up to date with the necessary categories from a legal standpoint.

Further, this lapse in capability of categorizing gender-diverse donors has a critical implication on recipient outcomes. “In the United States and Canada, most questions on the questionnaires are identical; however, several questions differ according to female or male designation in the BECS. The “female” questionnaire will contain an additional question about recent pregnancy; there may also be a question about ever being pregnant, including miscarriages and abortions, to reduce recipient transfusion-related acute lung injury (TRALI) risk”.¹⁹ Donors on TRT may be limited to donating RBC or whole blood rather than plasma or platelets⁴⁴. Transgender men and some gender-diverse individuals should be subject to the same donation eligibility as previously pregnant donors due to TRALI risk if undergoing HRT criteria.

The experience of gender-diverse blood donors is greater than just the questions asked of them. The environment, the attitudes of staff, and acceptance of their gender identity encourage or discourage initial and repeat donations. AABB publications include sharing pronouns and removal of gendered language, but these interventions do not solve the issue of outdated and limiting BCEs²⁰. Other recommendations include using a donor’s preferred or chosen name and gender, which may not be the same as the information on their legal documents⁴⁵. Gender-diverse donors want to know why questions about their gender are asked, and if they aren’t necessary, they should be avoided. Staff should maintain privacy and confidentiality during the donation process.

Under the language proposed in 2015 and 2020, transgender men, as well as nonbinary individuals who selected the male gender in the screening process may have been assigned the female sex at birth. These individuals, if screened as male, may not have, or may not currently be asked if they have ever been pregnant. If these individuals have previously been pregnant, they may have higher rates of HLA-antibodies in their bloodstream, which could be transfused to an individual, and result in a Transfusion-Related Acute Lung Injury, and possibly death.

The issue in the current screening and recommendation is not that transgender and gender-diverse donors exist, it is that the guidance (or lack of guidance(s)) ignores their unique needs and traits, and therefore allows them to fall through the cracks in risk-related deferrals. In order to ensure that all individuals are accounted for their individual risk, an individual risk assessment should be applied to all individuals, not just those with a certain gender.

As done with the previous MSM (men who have sex with men) deferment criteria, all donors should be asked if they were ever pregnant, including cisgender men and transgender women. In order to ensure that no further individuals are at a risk of a

preventable risk, the FDA should recommend screening all donors with all questions. Gender-diverse donors exist everywhere. They may be more likely to be first time donors compared to cisgender donors, are more likely to be younger than the existing donor population, and may donate more frequently. In a study of 282 transgender/non-cisgender donors at Memorial Blood Centers found that only 14.07% of donors who selected male/female (cis-gender) returned for a second donation, whereas 23.76% of donors who selected transgender or “other” as their gender returned for a second donation⁴⁶.

National shortages in blood donations have impacted the ability to provide care to patients in need. This issue was exacerbated with the Covid-19 pandemic, and supply has yet to return to pre-pandemic levels. While looking at shortages at a systemic level, or a national level, revising eligibility for MSM donors, or creating policies inclusive of gender-diverse donors will not alleviate and solve all supply issues. But looking at the issue from a donor and recipient perspective, benefits will be felt. If donors are welcomed into inclusive environments they may be more likely to donate, and donate more frequently. One donation can be the difference between a life saved and a life lost. Enlisting new donors will save more than just one life, especially when considering the unique benefits that this demographic brings.

Transgender men and other gender-diverse donors undergoing testosterone administration may be some of the safest donors to give red blood cells due to the effects of HRT. Transgender women and other gender-diverse donors may currently be deferred from donating plasma or platelets if a blood center is affirming and following the previous language introduced in 2015 and 2020. However, these individuals would be able to donate platelets without an increased risk in HLA antibodies. With such a short shelf-life of platelets, enlisting donors is a critical practice in transfusion medicine.

In an era of chronic shortages of all blood products, blood donation facilities cannot afford to turn away donors, or to create unwelcoming or unaffirming environments for any donors. However, they do not know how to create settings that promote return donations. The FDA must step in to create guidelines and recommendations for national implementation.

Recommendations & Rationale

Issue 1- TRALIs, HLA Antibodies, and History of Pregnancy

Our Recommendation (1/2): We recommend asking all donors, regardless of sex, gender, or presentation about a history of pregnancy. Donors should not have to publicly identify their gender, nor their alignment of gender and sex to staff unless necessary. By asking all donors, including those who staff, facilities, and systems assume to be cisgender men about pregnancy history, donors with increased risk of HLA antibodies will be deferred from donating platelets and plasma.

Our Recommendation (2/2): Promote the reporting and public dissemination of data and information related to diagnosed TRALI cases that do not result in patient mortality.

Issue 2- Inclusive Environments, Screening, and Gender Options

Step 1: Promote Research on the Experience of Gender-Diverse Individuals:

Our Recommendation (1/2): In order to fully understand the current typical practice of screening and managing gender-diverse blood donors, research should be conducted with blood donation facilities. This research should be conducted with the goals of identifying current shortfalls, patient responses to current practices, and current affirming practices that can be utilized in other facilities. Other topics of concern include the relation between legal status of third gender markers as related to BCEs, donors who have transitioned after an initial appointment, and donor outlooks following the transition to an individual risk assessment.

Our Recommendation (2/2): It is possible that a review of current practices may not be sufficient to create new policies, even when paired with the existing literature on the topic. New research studies should be created, conducted, and disseminated similar to the ADVANCE Study.

Step 2: Draft Federal Recommendations and Guidelines for the Screening, Treating, and Interacting with Gender-Diverse Donors:

Our Recommendation (1/3): The usage and degree of medical and surgical assistance for gender transition varies greatly from individual to individual. Individuals who undergo surgical transition but not HRT would have hemoglobin and hematocrit concentrations greatly different than individuals who pursue only HRT. Because of this, two gendered, binary scales for vitals and laboratory results are not comprehensive to meet the needs for gender-diverse donors. A universal scale for hemoglobin, hematocrit, as well as body composition should be created to ensure that all donors can give blood safely.

Additionally, if donors are able to donate safely, they may experience fewer adverse effects and be more incentivized to make a repeat donation in the future.

Our Recommendation (2/3): As with the language in 2015 and 2020, donors should be able to both self-identify and self-select their gender. However, there should be additional options besides the binary “male/man” and “female/female”. Additional options should be available for gender-diverse donors, and donors should be able to easily alter their gender-selection if needed. Gender should be prioritized rather than biological sex or sex assigned at birth; this should also be clearly communicated to donors, facilities, and staff. This should be affirmed through language in FDA documentation, which was removed in the 2023 update for the Individual Risk Assessment.

Any new practices should not be limited to donors who have pursued, begun, or completed medical and/or surgical assistance with gender transition, as was the case by Canadian Blood Services (only permitting gender marker changes following a 3-month period post-op.). This would likely be alienating to individuals who do not wish to, or cannot pursue such treatments, as well as the significance that one’s gender is not more or less valid following medical treatment.

Our Recommendation (3/3): One of the largest hurdles for implementation of inclusive practices and environments is the lack of facility control of BCEs. This has resulted in significant delays in implementation of FDA regulation changes, as was seen by prolonged application of the individual risk assessment. The FDA should advocate for improved access at the facility level of these systems, including the ability to add additional gender markers.

Step 3: Continual Monitoring and Solicitation of Feedback with the Transgender, Nonbinary, and Gender-Diverse Community:

Our Recommendation (1/3): Those impacted by these policies should be consulted during the drafting, public comment, and finalization of updates.

Our Recommendation (2/3): Response and adherence to guidelines impacting transgender, nonbinary, and gender-diverse donors should be collected following

implementation of changes. These should be compiled by blood donation facilities nationally, and used to draft future improvements and changes by both FDA and AABB.

Our Recommendation (3/3): Intentional action should be made to explain why new policies are inclusive, improved, and more accessible to transgender, nonbinary, and gender-diverse donors. These donors may have poor relationships with blood donation facilities and the blood donation process due to unwelcoming environments and unaffirming practices in the past. The same should be done with MSM donors who were previously deferred, as there is likely significant overlap between both demographics.

Issue 3- Testosterone, Erythrocytosis, & Therapeutic Phlebotomy; Transgender Women & Platelet Donation

Our Recommendation (1/2): The incidence of erythrocytosis amongst individuals prescribed and taking hormone replacement therapy w/testosterone should be better measured. On part of the FDA, variances for erythrocytosis should be promoted to blood donation facilities in an era of systemic shortages. Transgender men, nonbinary individuals, and other individuals who have secondary erythrocytosis following HRT should be considered in these programs.

Our Recommendation (2/2): Without the increased risk of HLA antibodies, transgender women, nonbinary individuals, and other gender-diverse individuals assigned male at birth, should be prioritized for platelet and/or plasma donation. Any blanket deferrals for all women donating plasma and/or platelets should be revised to not include transgender women as they do not hold the same risk as cisgender women for pregnancy attributed increases in HLA antibodies.

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.org . 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.

Make an Appointment to Donate Blood

If you're eligible, you can make an appointment to save lives in your community by donating blood, plasma, and/or platelets. AABB can help you find a blood donation facility near you at <https://www.aabb.org/for-donors-patients/give-blood>. If you aren't eligible at this point, ask your friends, families, coworkers, and neighbors to donate on your behalf. There is no alternative to human blood donations, and patients, providers, and facilities in need can't do their lifesaving work without donors like you.

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

Citations

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Further Resources

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

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>