

Directed Donations

HABB Fall Meeting
September 10, 2025

Daniela Hermelin, MD
Chief Medical Officer

Interim Medical Director
SSM Health SLUH and CG

Assistant Professor of Pathology
SLUSOM



Disclosures

Nothing to disclose



Objectives

- Rise of Directed Donations
- Current Safety of the Blood Supply
- Risks of Directed Donations
- Hospital Role



Q&A

Dr. Hermelin, can you speak to her?

29-year-old female with a history of FHTMR

Recent miscarriage, D&C, Hb 16 → 9



"Pure" Unvaccinated Blood

Vaccine opponents advocate for “pure” unvaccinated blood banks

© November 30, 2022

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Several right-wing and anti-vaccine sites are promoting an international movement to open [unvaccinated blood banks](#). Anti-vaccine conspiracists insist that blood from people who have received COVID-19 vaccinations is harmful to unvaccinated people, despite the complete absence of evidence to support their claim. The demand for “clean” or “pure” blood has had [real-world consequences](#), such as the New Zealand parents who are delaying [life-saving heart surgery](#) for their baby until they can guarantee that the infant will not receive blood from vaccinated donors.

December 7, 2022

ASIA

New Zealand takes custody of baby whose parents refused ‘vaccinated blood’

Concerns from donors, patients, and public

Concerns



"Don't want the vaccine"



"Don't want to have side effects and die of the vaccine that's in the blood"
"Blood clots"



"Do not want debris in my body"



Timeline

Acquired Immune
Deficiency Syndrome
(AIDS) epidemic

1981

Covid-19 mRNA vaccine
introduced

2020

2015

HIV 5th generation testing

2022

Interest in blood
segregation, directed
donations in demand

Battle over direct blood donations leaves parents upset

Maria Guerrero • Published June 20, 2023 • Updated on June 20, 2023 at 6:08 pm

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Here's a battle over blood in North Texas and whether patients can choose their own donor. Maria Guerrero explains.

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TEXAS GOVERNOR
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Neighborhoods in Dallas see heavy traffic in grocery stores



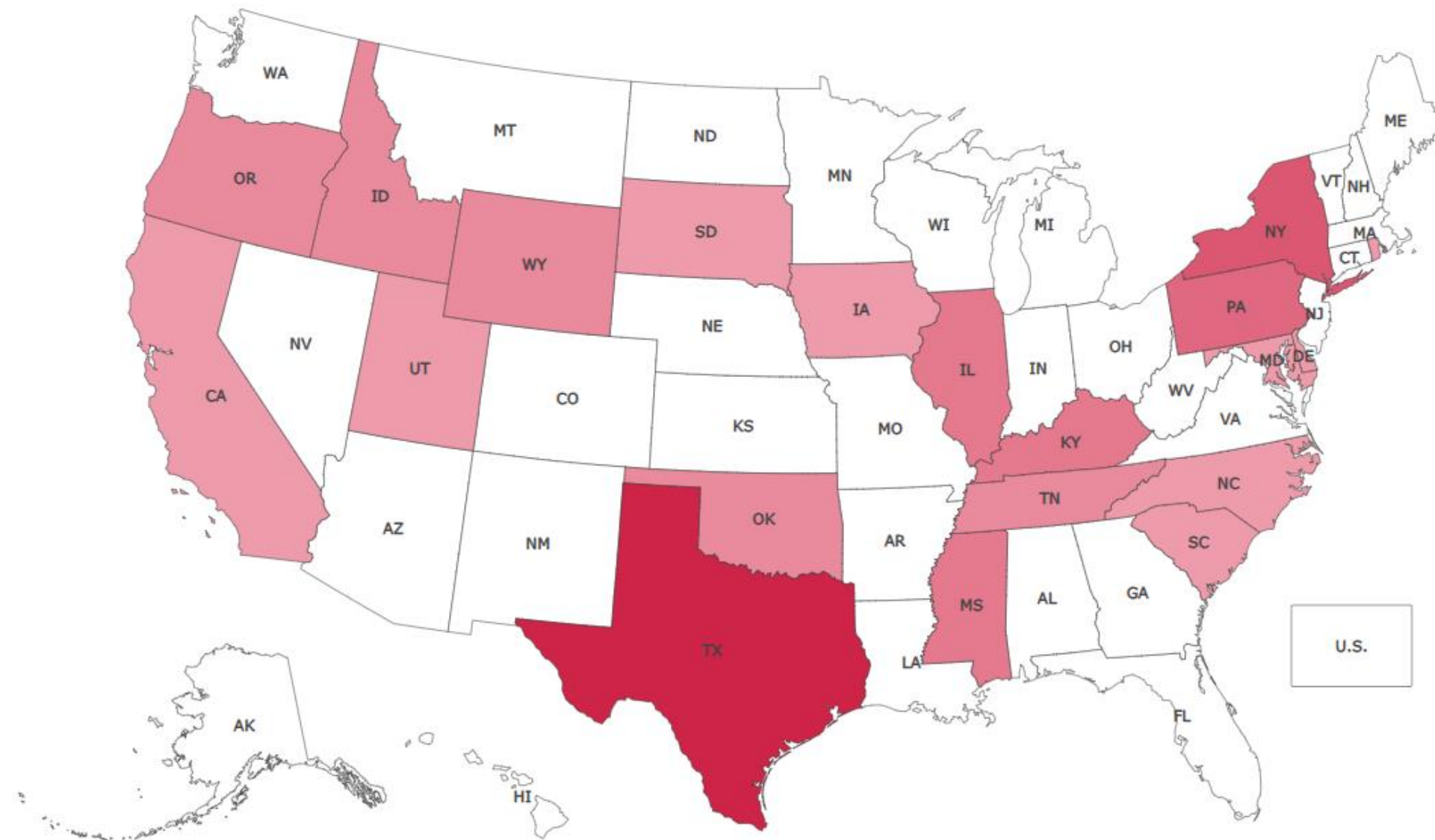
FORT WORTH
Fort Worth area

Legislative activity on directed donations has surged since 2023, with bill language ranging from universal rights to medical-need-only access.

Map of State Based Legislation - America's Blood Centers

Stay Informed About Key Legislation Impacting the Blood Supply.

Explore the latest developments in legislation that's impacting the blood supply across various states. Click on the specific states below to delve into detailed information about the latest introduced legislation at the local level.



Total Bills: 45

Choose a state

Definitions

Directed

request that specific individuals donate blood
for their upcoming transfusion related
procedure or surgery

Designated

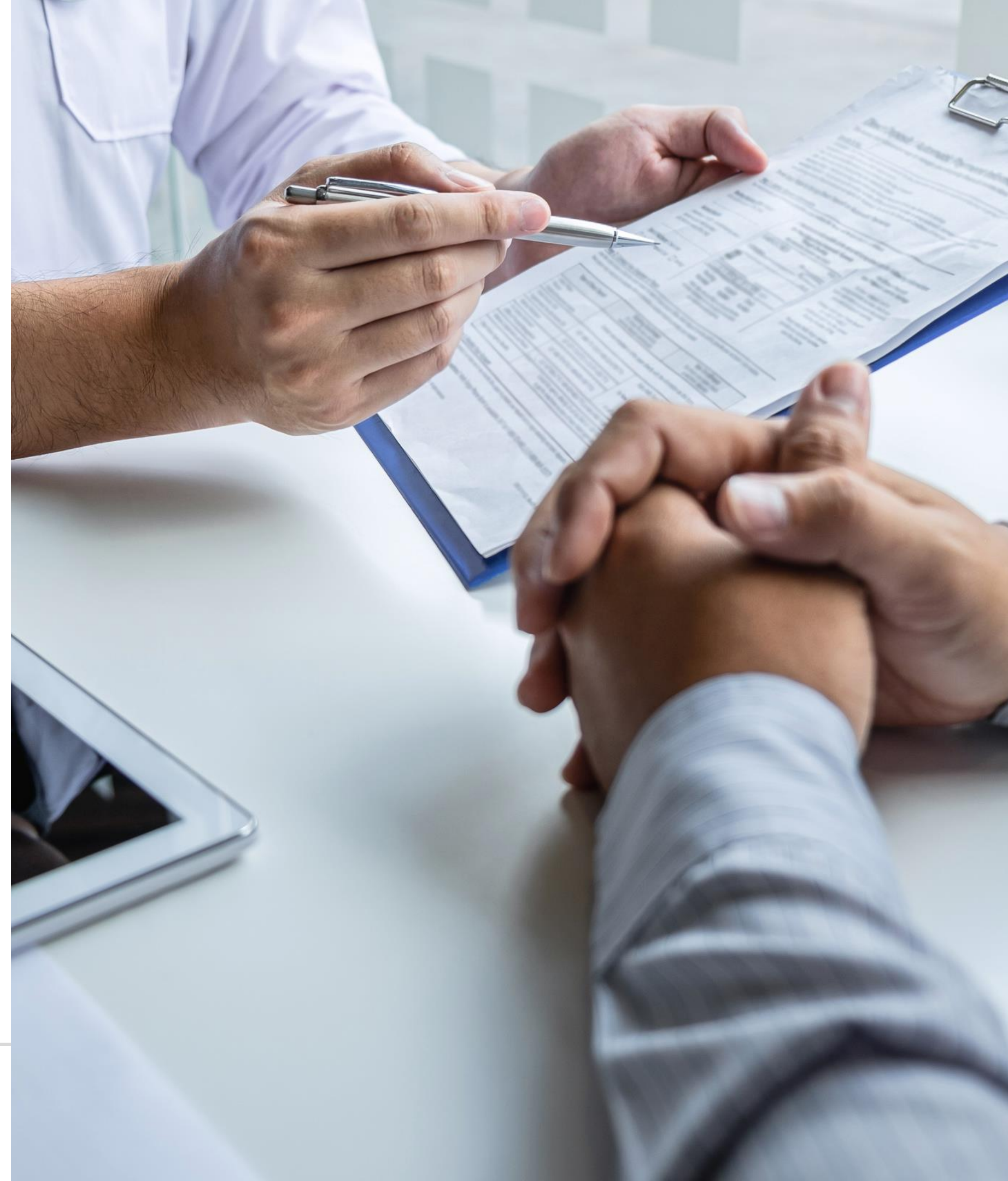
a person who has been deemed the best
candidate to meet a specific medical need, such as
compatible red cells to match a rare blood type



Biologic Drugs

Regulated by the FDA

- Biologic Drugs
- Must be ordered by an appropriately licensed health care provider
- Informed consent of risks



TRANSFUSION RISK

➤ **Infectious**

➤ **Noninfectious**

TACO, TRALI, FNHTR, Immunologic

➤ **Alternatives to transfusion**



HOSPITAL POLICIES FOR DIRECTED DONATIONS

Policy: Directed Blood Donations

Subject: Appropriate indications for directed blood donations

Policy: Directed blood donations

1. Directed blood donations are indicated when a safe, compatible unit is not easily identified in the general donor population. Examples include:
 - Patient is alloimmunized against high frequency antigens
 - Patient is at high risk of alloimmunization due to rare RBC phenotype (e.g. Bombay phenotype, MacLeod's syndrome)
2. Directed donations are not indicated for religious beliefs or concerns regarding the race, vaccination status or ethnicity of donors.

Important Information About Directed Blood Donations that are Not Medically Indicated

October 23, 2023

The Food and Drug Administration (FDA) is advising consumers and health care providers that directed blood donations requested for certain donor characteristics (e.g., vaccination status, sex, sexual orientation, religion) lack scientific support and to be cautious about websites that offer memberships for delivery of blood and blood components from individuals who have not been vaccinated for COVID-19.

01

Most hospitals restrict to rare, medically necessary indicated

02

Patient education is essential to reduce the risk for

03

Role of the ordering provider to communicate the scientific consensus and safety of the blood supply

04

In 2023 , FDA cautioned against the selected of directed donors for indications lacking scientific basis

Important Information About Directed Blood Donations that are
Not Medically Indicated | FDA

Belts & Suspenders

Donor Questionnaire

Set of 40 questions that surveys medical history, travel history and donor behavior

Infectious Disease Testing

Blood tests drawn at the time of donoation:
HIV, HBV, HCV, Syphilis, HTLV
(Malaria, et.)

Safety of Blood

Adverse Event and Approximate Risk Per Unit Transfusion of RBC

**Febrile
Reaction**

1:60

TRALI

1:12,000

Hep C

1:1.5 M

HIV

1:1.47 M

Risk of dying from a lightning strike: 1:161,000

Vaccines + Blood donation



"In the past 8 weeks, have you had any vaccinations or other shots?"

Vaccine Categories

- Live attenuated viral/bacterial
- Toxoids, mRNA synthetic or killed viral/bacterial
- Unlicensed

Deferrals for vaccines (2-4 wks)

- Live attenuated
- False positive testing

Labeling

We do not label our blood products based on vaccine status



ORIGINAL RESEARCH

TRANSFUSION

Clinical outcomes in hospitalized plasma and platelet transfusion recipients prior to and following widespread blood donor SARS-CoV-2 infection and vaccination

Nareg H. Roubinian^{1,2,3} | John Greene¹ | Vincent X. Liu¹ | Catherine Lee¹ | Dustin G. Mark¹ | David R. Vinson¹ | Bryan R. Spencer⁴ | Roberta Bruhn^{2,3} | Marjorie Bravo⁵ | Mars Stone^{2,3} | Brian Custer^{2,3} | Steve Kleinman⁶ | Michael P. Busch^{2,3} | Philip J. Norris^{2,3} | for the NHLBI Recipient Epidemiology and Donor Evaluation Study-IV-P (REDS-IV)

ORIGINAL RESEARCH

Transfusion Complications

Blood donor SARS-CoV-2 infection or vaccination and adverse outcomes in plasma and platelet transfusion recipients

Nareg H. Roubinian^{1,2,3} | John Greene¹ | Bryan R. Spencer⁴ | Marjorie Bravo⁵ | Roberta Bruhn² | Paula Saa⁶ | Mars Stone^{2,3} | Brian Custer^{2,3} | Steve Kleinman⁷ | Vincent X. Liu¹ | Philip J. Norris^{2,3} | Michael P. Busch^{2,3} | for the NHLBI Recipient Epidemiology and Donor Evaluation Study-IV-P (REDS-IV)

1. A multi-hospital study of 21,750 transfusion episodes found no increase in thrombosis, respiratory needs, ICU stay, mortality, or rehospitalization before, during, or after widespread donor COVID-19 infection and vaccination. **These findings confirm that transfusions remained safe across all pandemic phases.**

2. Analysis of over 34,000 transfused units with linked donor infection/vaccination data showed no association between donor COVID-19 history or antibodies and adverse outcomes in recipients. The study reinforces that **blood from vaccinated or previously infected donors poses no added risk.**

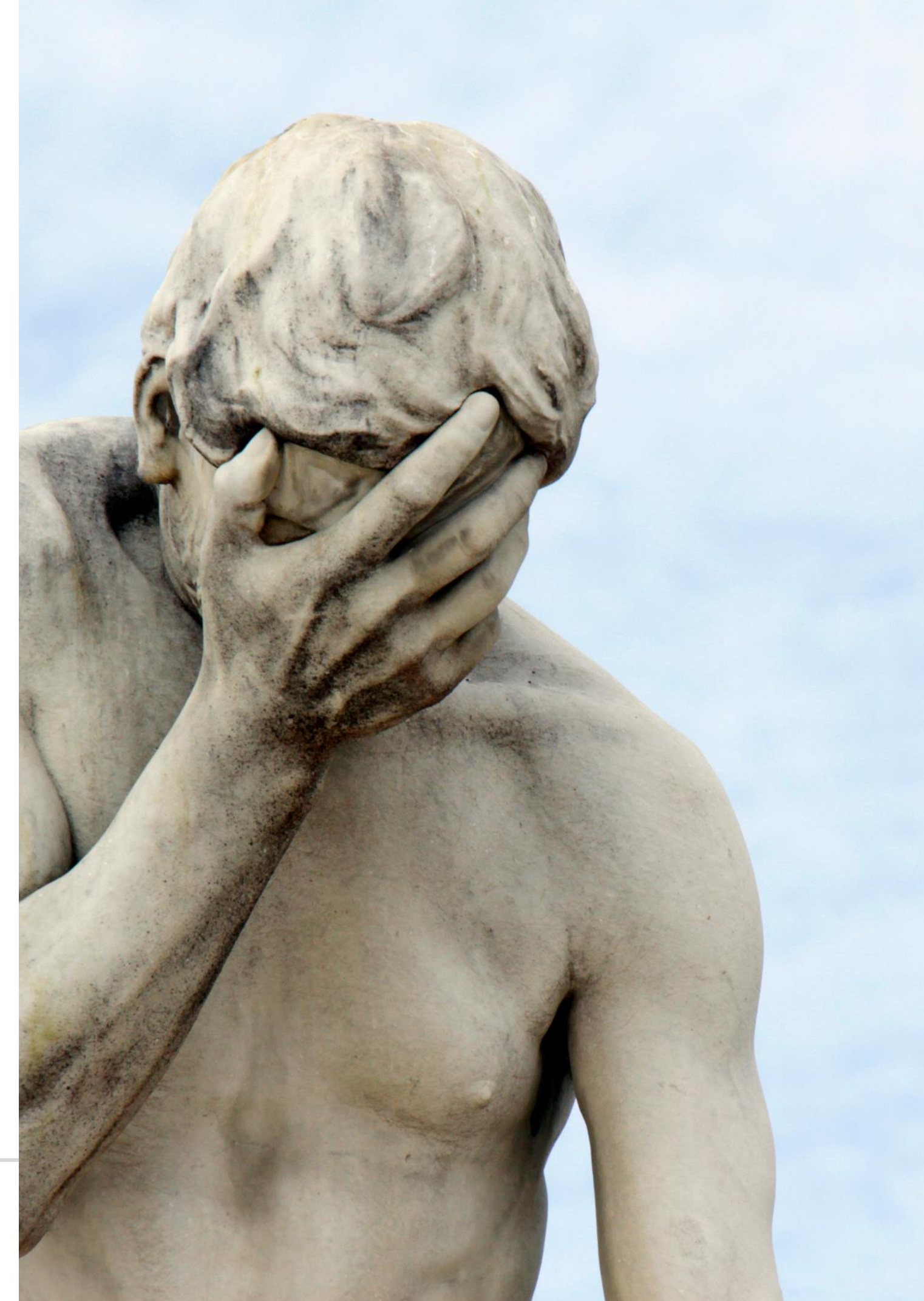
Medical and Logistical Challenges

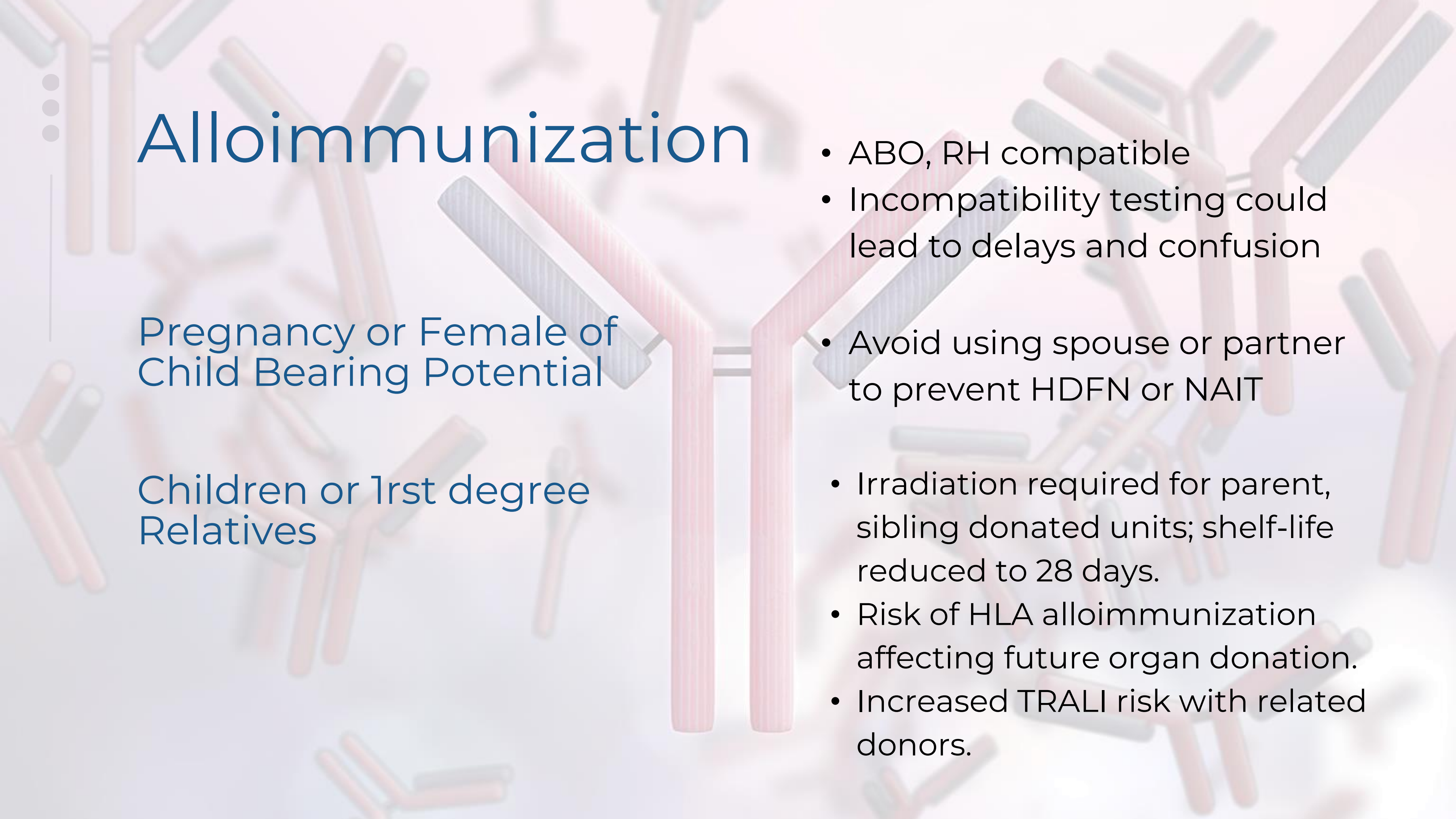
- Infectious disease risk
- Alloimmunization
- Product Handling
- Financial Implications



••• Infectious Disease

- Individual should be selected who have donated blood in the past to decrease ID risk
- Positive ID testing require that blood be discarded
- Notification of both donor and recipient
- Notification to State Public Health Dept





Alloimmunization

Pregnancy or Female of
Child Bearing Potential

Children or 1st degree
Relatives

- ABO, RH compatible
- Incompatibility testing could lead to delays and confusion
- Avoid using spouse or partner to prevent HDFN or NAIT
- Irradiation required for parent, sibling donated units; shelf-life reduced to 28 days.
- Risk of HLA alloimmunization affecting future organ donation.
- Increased TRALI risk with related donors.

Financial and Logistical

- May be a charge for directed donations due to extra resources to collect
- Insurance companies may not reimburse
- Coordination of scheduling and expiration





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FREQUENTLY ASKED QUESTIONS: COVID VACCINES AND BLOOD DONATION

Each year, millions of individuals experience blood transfusion as trauma as well as for ongoing medical care. Maintaining the safety and

Some people have raised concerns about the safety of America's blood supply is safe. Blood transfusion recipient.

How is blood donation regulated?
The Food and Drug Administration regulates blood collectors in the United States for the collection, manufacture,

Are blood donations tested?
Yes. Every blood donation is tested before it is distributed to a hospital or

Can COVID-vaccinated individuals donate blood?
Yes. The FDA explicitly allows COVID vaccines to give blood donors all other eligibility criteria.

Is it safe to receive a blood transfusion?
Yes. A long history of the use of blood recipient and do not increase the risk of infection.

Is it risky to allow COVID-vaccinated individuals to donate blood?
No. Four COVID-19 vaccines including manufactured by Pfizer and Moderna are currently approved vaccines are currently approved through blood.

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BLOOD BULLETIN

Directed Donations and COVID-19 mRNA Vaccinated Blood Donors

Authors: Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife; Nancy Van Buren, MD, Medical Director at Innovative Blood Resources and Community Blood Center of Kansas City, divisions of New York Blood Center; Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center; Richard Gammon, MD, Medical Director at OneBlood; Debra Smith, MD, PhD, Medical Director at Carter BloodCare; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest.

Contributors: Rita Reik, MD, FACP, Chief Medical Officer at OneBlood; Claudia S. Cohn, MD, PhD, Professor of Laboratory Medicine and Pathology at the University of Minnesota; Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest.

The authors disclose no conflicts.



America's Blood Centers
It's About *Life*.

Annals of Internal Medicine

MEDICINE AND PUBLIC ISSUES

Medical, Societal, and Ethical Considerations for Directed Blood Donation in 2025

Jeremy W. Jacobs, MD, MHS¹; Garrett S. Booth, MD, MS²; Mithya Lewis-Newby, MD, MPH; Nabiha H. Saifee, MD, PhD; Eamonn Ferguson, PhD; Claudia S. Cohn, MD; Meghan Delaney, DO, MPH; Sarah Morley, MBBS, PhD; Stephen Thomas, PhD; Rachel Thorpe, PhD; Sheharyar Raza, MD; Meaghann S. Weaver, MD, PhD, MPH; Jennifer S. Woo, MD; Deva Sharma, MD, MS; Cynthia So-Osman, MD, PhD, MSc; Nalan Yurtsever, MD; Christopher A. Tormey, MD; Allison Waters, PhD, MPH; Mindy Goldman, MD; Matthew T.S. Yan, MD, MSc; Ross M. Fasano, MD; Laura D. Stephens, MD; Elizabeth S. Allen, MD; Christian Erikstrup, MD, PhD; Laura Infanti, MD, MSc; Timothy D. Schlafer, JD, MBA, MSc; Matthew A. Warner, MD; Jeffrey L. Winters, MD; Aaron A.R. Tobian, MD, PhD; and Evan M. Bloch, MBChB, MS

In the United States and other high-income countries, blood donation primarily relies on anonymous, voluntary donors. However, directed blood donation—where people donate for a specific recipient—has resurged, particularly due to misinformation surrounding COVID-19 vaccination. Requests for “non-vaccinated” blood, driven by misconceptions about vaccine safety, have led to legislative attempts to mandate compliance. Historically, directed donation was used to mitigate the risk for transfusion-related infections before modern screening techniques rendered it largely unnecessary. Today, it presents important patient safety risks, including increased infectious disease transmission, immunologic complications, and logistic burdens. Directed donations also introduce inefficiencies, diverting resources from the community blood supply and exacerbating shortages. Moreover, directed donation for nonmedical indications lacks scientific justification. Blood safety is ensured through rigorous donor screening, pathogen testing, and processing measures. There is no evidence that blood from vaccinated donors poses risk. Requests for nonvaccinated blood, as well as other directed

donation preferences based on personal beliefs, introduce biases that are not grounded in medical necessity. Accommodating such requests undermines public trust in blood safety protocols and legitimizes unfounded fears. Ethical concerns arise as non-medically justified requests reinforce discriminatory practices, such as selecting donors based on race or gender. Allowing such preferences risks politicizing blood donation, spreading misinformation, and straining health care systems. Although autonomy is a core ethical principle in medicine, it does not justify non-evidence-based interventions. Given the potential harm and societal impact, directed blood donations should be limited to rare, medically necessary cases. Ongoing legislative efforts to mandate these requests require unified opposition from the medical and scientific community to uphold ethical, evidence-based, blood allocation practices.

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For author, article, and disclosure information, see end of text.

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* The first authors—Drs. Jacobs and Booth—contributed equally.

COMMENTARY

TRANSFUSION

Blood Borders: State laws, vaccine misinformation, and the threat to the United States blood supply

Jeremy W. Jacobs¹ | David M. Chooljian^{2,3} | Sheharyar Raza⁴ |
Laura D. Stephens⁵ | Timothy D. Schlafer⁶ | Claudia S. Cohn⁷ |
Aaron A. R. Tobian⁸ | Evan M. Bloch⁸ | Garrett S. Booth¹

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