

The background features a dark blue gradient with several colorful, semi-transparent outlines of blood donation bags and their associated tubing. The bags are arranged in a row, with colors transitioning from red on the left to purple on the right. The tubing is depicted as thin, flowing lines in various colors, including red, orange, yellow, green, and blue, extending across the bottom of the frame.

Blood donation restrictions on men who have sex with men (MSM)

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Disclosures & Conflicts of Interest

Disclosures/Conflicts of Interest

I have no conflicts of interest or financial disclosures to disclose.

Policy views/proposals in this presentation/discussed are those of the presenter and are not the official position of nor officially endorsed by Vanderbilt University Medical Center or Vanderbilt University.

Aims & Objectives

- Review current U.S. policy on MSM blood donations & recent policy changes
- Review the history of restrictions on MSM blood donations in the U.S.
- Understand the context for initial restrictions on MSM donating blood & how limitations of initial HIV tests contributed to these restrictions
- Review current procedures for testing the blood supply for HIV and the safety of blood transfusions in the U.S.

Aims & Objectives

- Discuss the current state of MSM blood donation policy globally
- Discuss current positions of different medical & advocacy organizations on MSM blood donation restrictions
- Discuss the evidence for/against MSM blood donation restrictions & ongoing studies
- Discuss possible alternatives to time-based deferrals/restrictions & possible policy-level interventions

Current U.S. policy on MSM donating blood

The FDA guidance: “Defer for 3 months from the most recent sexual contact, a man who has had sex with another man during the past 3 months.”

All U.S. blood collection organizations must follow this federal requirement.



Current U.S. policy on MSM donating blood

These restrictions apply to all gay and bisexual men regardless of HIV risk factors – including:

- MSM in monogamous relationships
- MSM who test negative for HIV
- MSM taking “PrEP” or pre-exposure prophylaxis
- MSM practicing safe sex





The American Red Cross Response

The Red Cross recognizes the hurt this policy has caused to many in the LGBTQ+ community and believes blood donation eligibility should not be determined by methods that are based upon sexual orientation. We are committed to working with partners toward achieving this goal.

We continue to assist in evaluating alternative donor eligibility criteria and the expanded use of new technologies to work toward elimination of donor eligibility questions based on sexual orientation that would no longer be necessary. However, as a regulated organization, we cannot unilaterally enact changes concerning the MSM deferral policy.

In order to gather data related to the possibility of using an individual risk assessment behavior-based health history questionnaire in the U.S., the Red Cross, along with One Blood, Vitalant and partner LGBTQ+ community health centers, are participating in a pilot study funded by the FDA in select cities that could potentially lead to changes for blood donor eligibility criteria for gay and bisexual men. The study is focused on evaluating alternatives to determining donor eligibility.

MSM and the FDA blood donation policies: A Timeline

1981:

The first case of AIDS is discovered in Los Angeles in previously healthy gay men, giving rise to the name GRID (gay-related immunodeficiency disease)

1985:

The FDA issues a warning on men who have had sexual activity with other men, even if just once, since 1977

2015:

After 30 years, the lifetime ban is lifted, but only MSM can donate blood

1983:

The FDA begins selling out recommendations that urge men who have sex with men (MSM) to abstain from donating blood

1997-2010:

Alongside the department of Health and Human services, the FDA holds several meetings and workshops over blood donor deferral policies

2020:

Due to the coronavirus pandemic, the U.S. faces a blood shortage, reducing the 12-month deferral period to only 3 months

Timeline



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1985:

The FDA imposes lifetime ban on men who've engaged in sexual activity with other men, even if just once, since 1977

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After 30 years, the lifetime ban is lifted, but only MSM who remain celibate for one year can donate blood

1983:

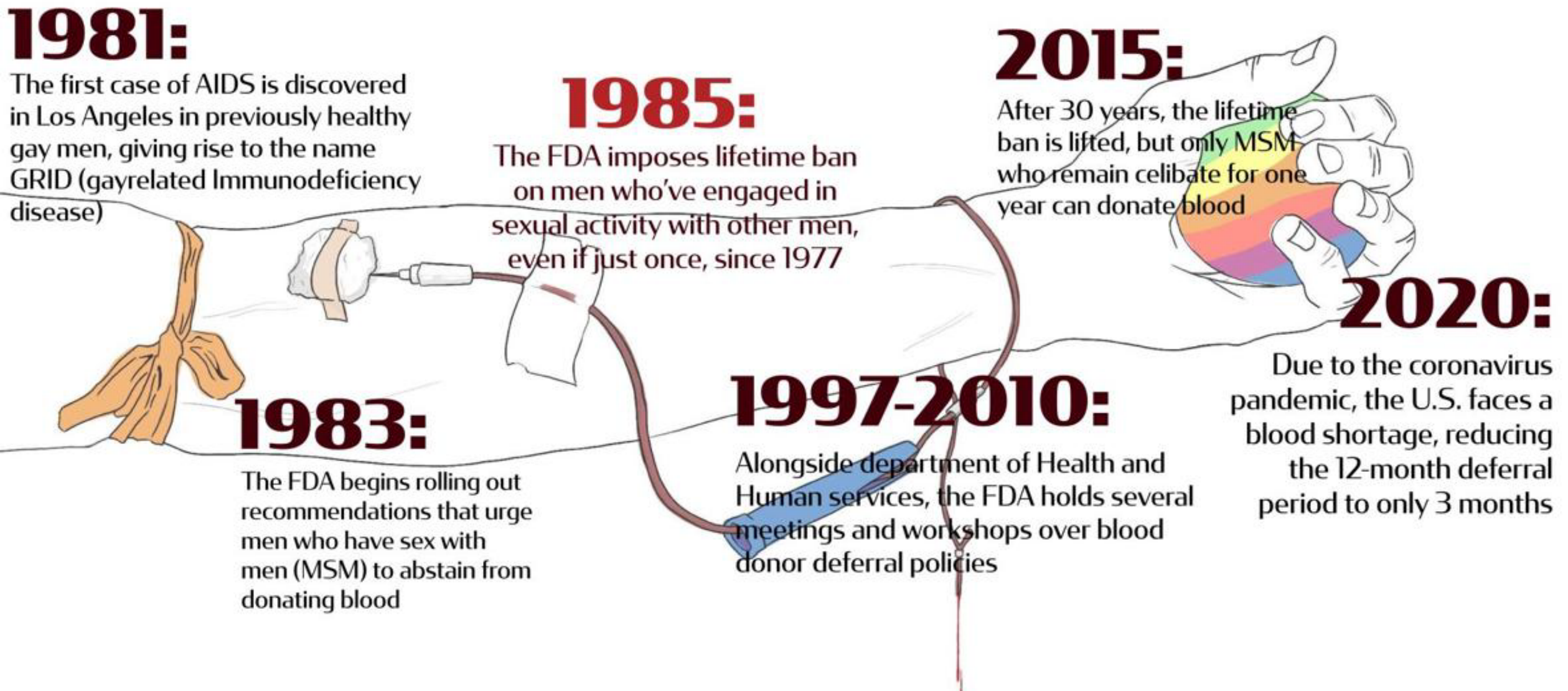
The FDA begins rolling out recommendations that urge men who have sex with men (MSM) to abstain from donating blood

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A Timeline of How We Got Here...

- **1981:** First cases of AIDS reported in the United States
- **1982:** concerns that the cause of AIDS could be transmitted through blood transfusions*
- **1983:**
 - HIV is identified as the cause of AIDS
 - The FDA begins issuing recommendations urging MSM to abstain from donating blood
- **1985:** First HIV tests approved
 - *These tests were designed to screen donated blood for possible infection; the assay had not been FDA approved as a diagnostic test for AIDS*

1985: A Critical Year for HIV & Blood Donation Policy

1985: First HIV tests approved

- *March:* The first 2 tests for HIV are approved– both antibody tests (ELISA tests)
- *April:* Blood centers begin using these tests to screen all blood products
 - At this time 142 Americans had contracted AIDS from blood transfusions (of the 9,600 people who had an AIDS diagnosis in the U.S.)
- *July:* the blood supply was declared free of AIDS.
- *September:* Lifetime ban of blood donations from MSM implemented by the FDA
- *September:* President Reagan addresses HIV/AIDS publicly for the first time

Timeline: From AZT to Treatment as Prevention

- **1987:**
 - AZT introduced as first antiretroviral medication for HIV
 - First Western Blot test for HIV
- **1990:**
 - High school student & AIDS activist Ryan White dies from AIDS-related complications
 - The Ryan White CARE Act passed & signed into law by President Bush creating the largest provider of services for people living with HIV/AIDS in the United States.
- **1995:** June 27, is declared National HIV Testing Day
- **1996:** Protease Inhibitors are introduced, creating the first highly effective “triple therapy” or “combination therapy” treatment options for HIV

Policy Changes

FDA approves Truvada (TDF/FTC) for HIV pre-exposure prophylaxis (PrEP)

2012

Spurred by the COVID-19 pandemic, in April 2020 the FDA reduced the deferral time for MSM from 12 to 3 months.

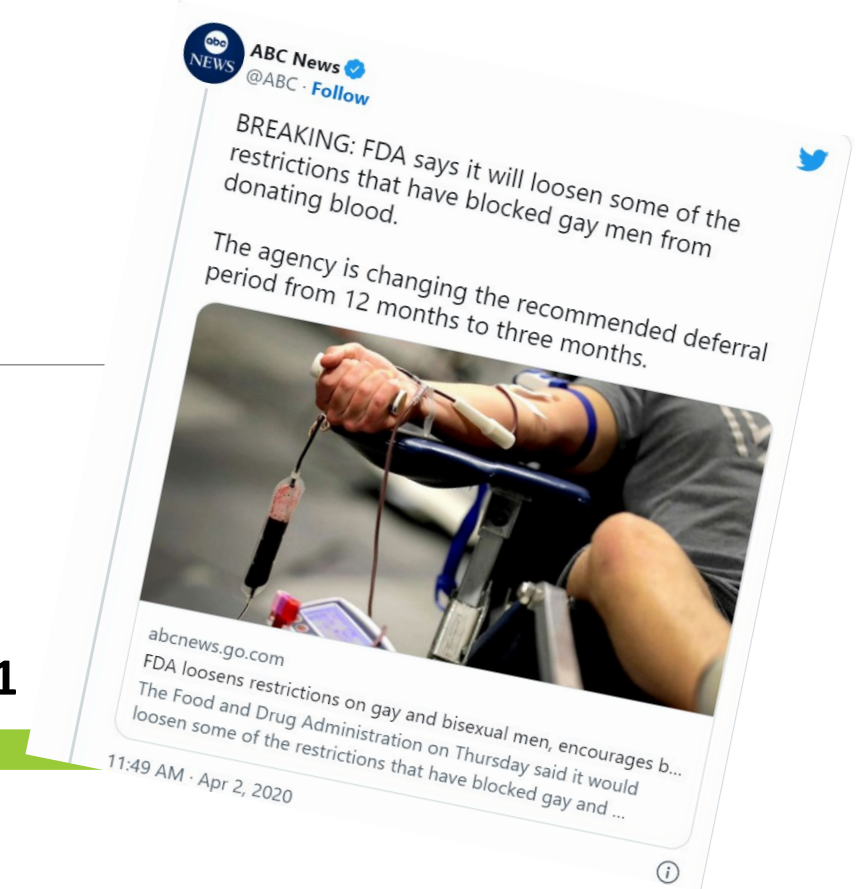
2015

FDA moves from a lifetime ban on MSM donating blood to a deferral of one year for any man who has had sex with another man during the past 12 months

2020

The 3 largest blood suppliers in the U.S. (American Red Cross, Vitalant and OneBlood) launch the ADVANCE study (Assessing Donor Variability And New Concepts in Eligibility)

2021





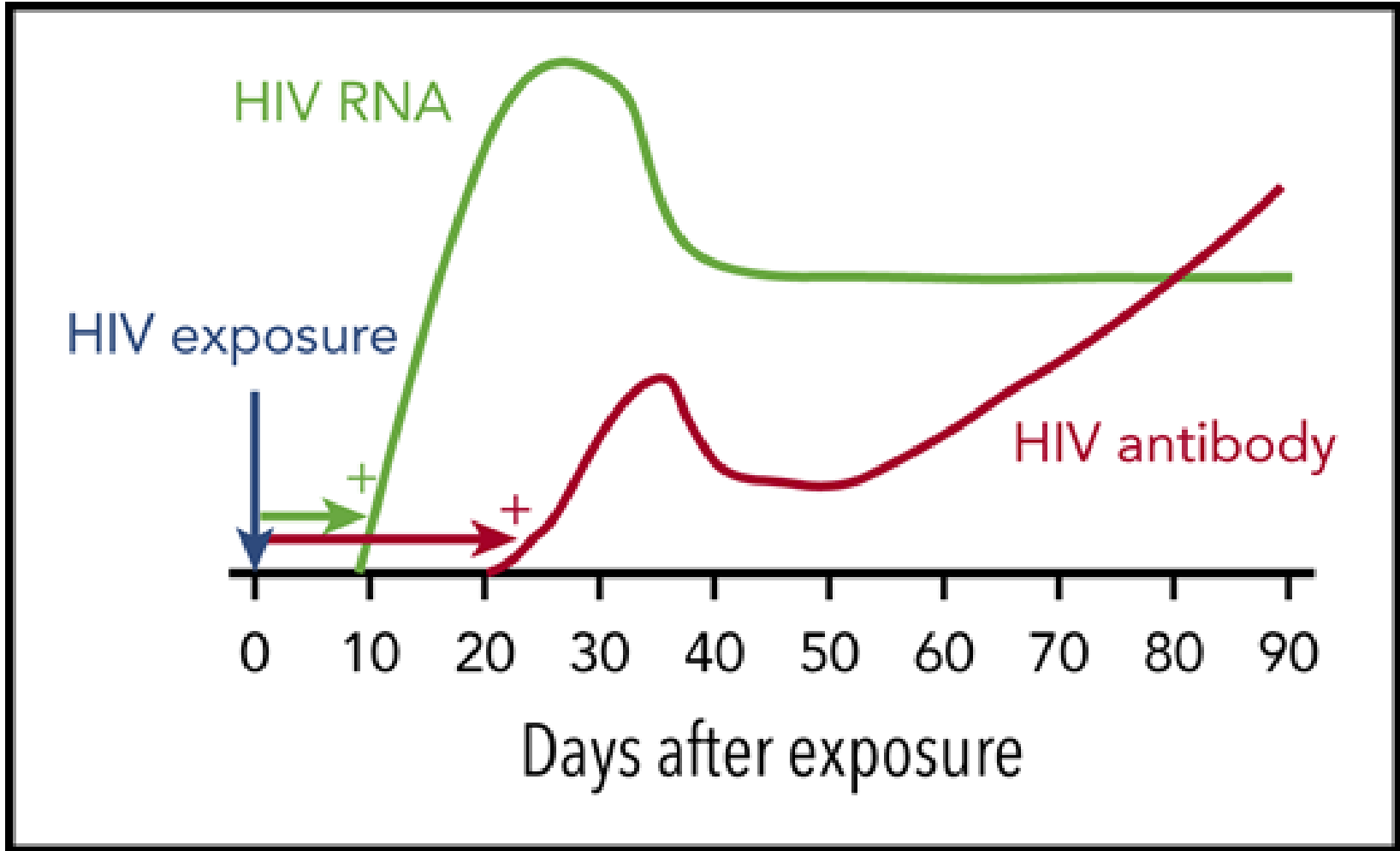
Context of Restrictions/Bans

Understanding the context of early restrictions on MSM blood donations

- Limitations of initial HIV tests
- Limited capacity to perform HIV testing (particularly for diagnostic screening of high-risk groups)
- Lack of ART/effective treatment for HIV
- Stigma/discrimination against MSM

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The Natural History of HIV Infection

Understanding the context:

Limitations of the first HIV tests

- The first tests for HIV was developed in 1985 & were designed to screen blood products (**not to diagnose HIV in people**)
- The first-generation assays detected **IgG antibody to HIV-1 only** & became **positive 6 to 12 weeks post infection**
- False-positive results occurred → two-test algorithm developed using a Western blot (1987) or HTLV III immunofluorescence test as a confirmatory procedure
 - These also detected only IgG & had antibody-negative windows ≥ 6 weeks
- The initial antibody tests for screening often took **1-2 weeks to result**

Limitations of early HIV testing: Understanding the different tests

Nucleic Acid Test (NAT)*
window period

10-33 days



1999*

Antigen/Antibody Lab Test*
window period

18-45 days

Rapid Antigen/Antibody Test†
window period

18-90 days



2010/2013

Antibody Test‡
window period

23-90 days



1985

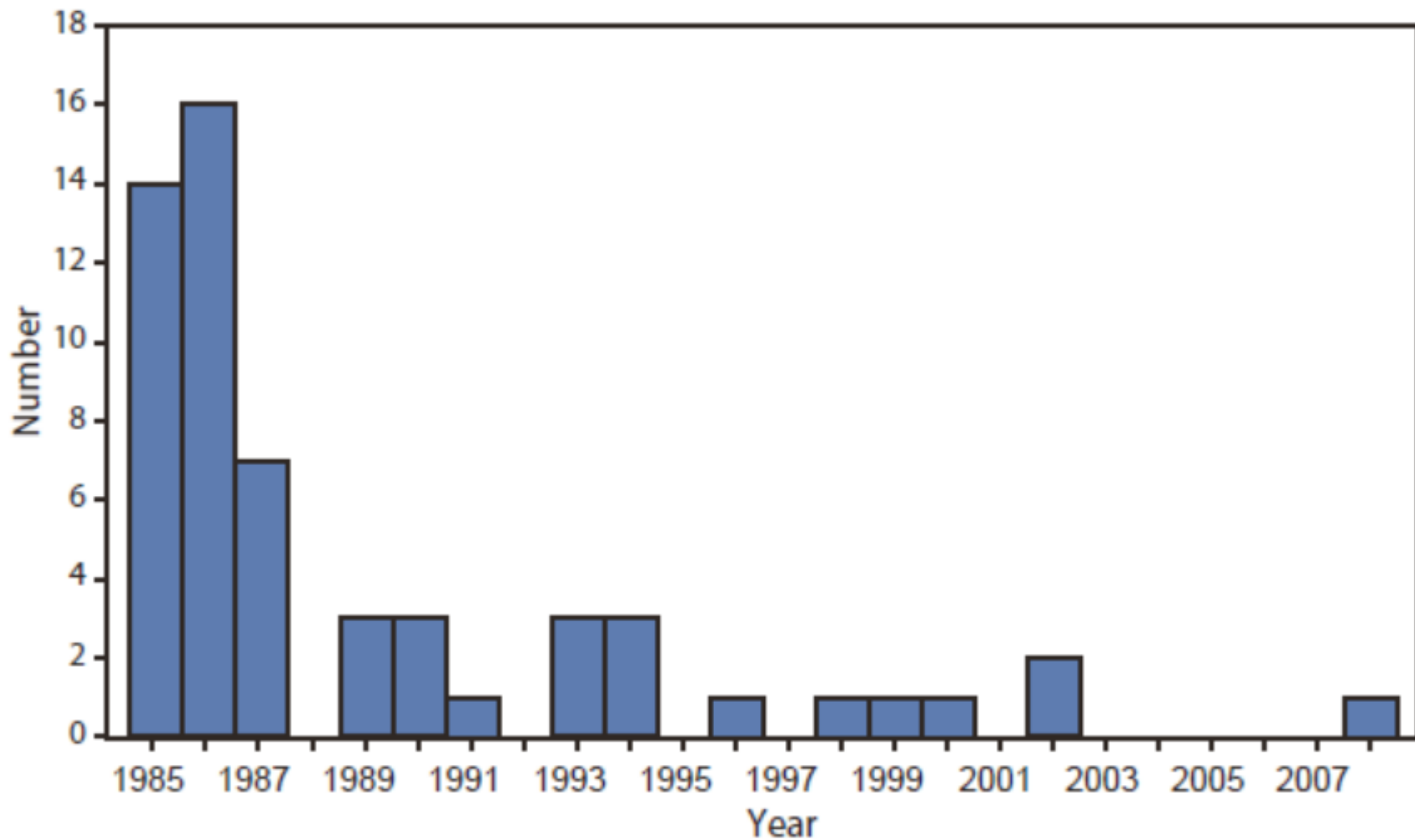
Blood Product Testing for HIV in the U.S. Today

- All blood is screened by **both** an antigen test for HIV antibodies & a highly sensitive nucleic acid test
 - *Test: **GS HIV-1/HIV-2 PLUS O EIA*** for the simultaneous qualitative detection of anti-HIV 1 (groups M and O) and/or HIV-2 in human serum or plasma
- This provides a window of approximately **7 to 10 days of exposure**

More Blood Donation Statistics

- Frequency of detecting HIV-1 in a blood donor is **~1 per 33,000** donations screened
- Frequency of detecting HIV-2 in a blood donor is extremely rare at **~1 per 57 million** donations
 - Only 5 donors identified since HIV-2 screening began in 1992
- **FDA estimates the per-unit risk of HIV infection from a blood transfusion at about 1 in 1.47 million**

FIGURE 2. Number of cases of transfusion-transmitted HIV infection from contaminated blood products, 1985--2008

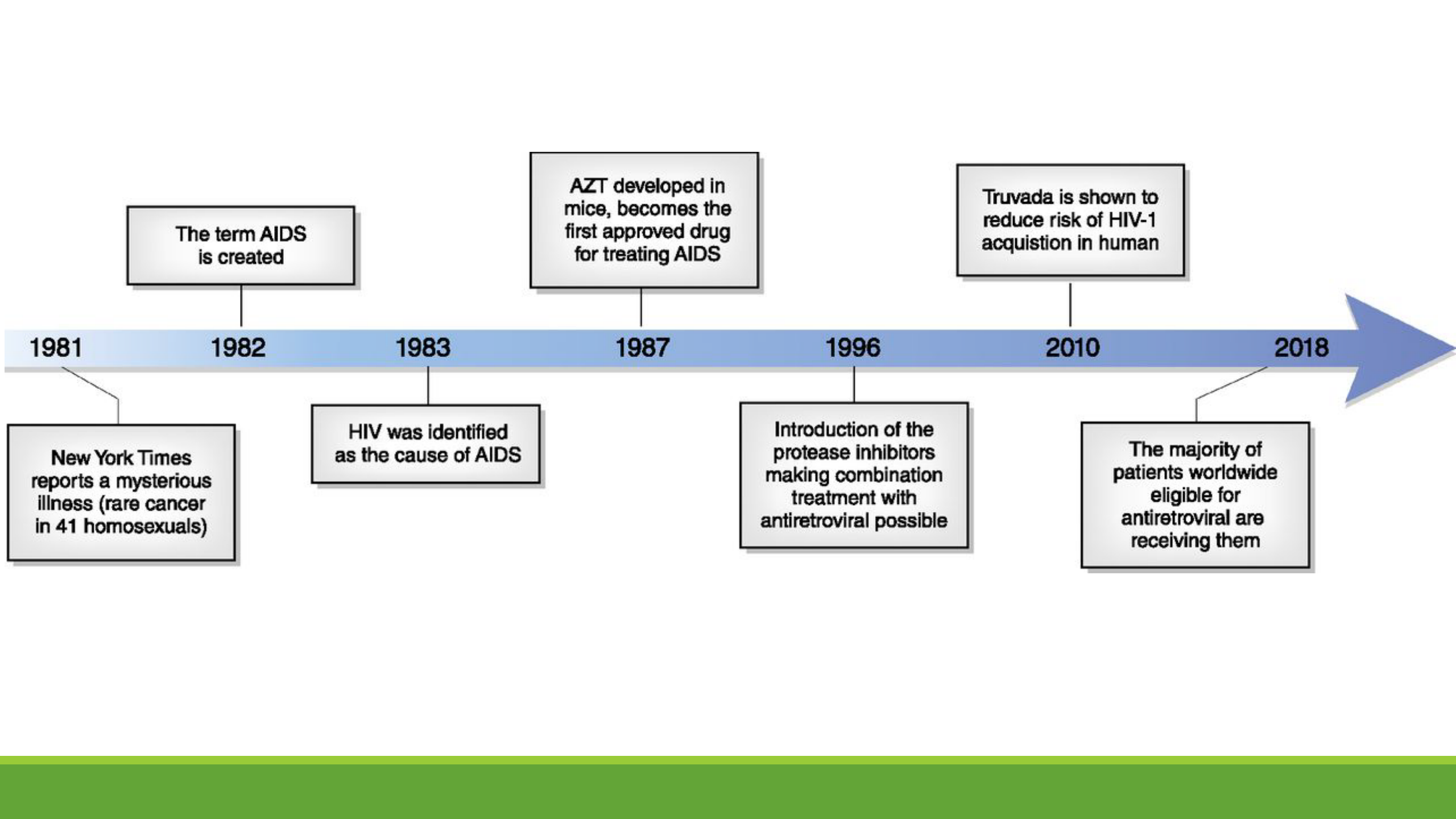


Take Home Message:

The risk of HIV acquisition from blood donation in the United States is incredibly low.

Understanding the context of early restrictions on MSM blood donations

- Limitations of initial HIV tests
- Limited capacity to perform HIV testing (particularly for diagnostic screening of high-risk groups)
- **Lack of ART/effective treatment for HIV**
- Stigma/discrimination against MSM



Understanding the context of early restrictions on MSM blood donations

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A.I.D.S.: WE NEED
RESEARCH,
NOT HYSTERIA!

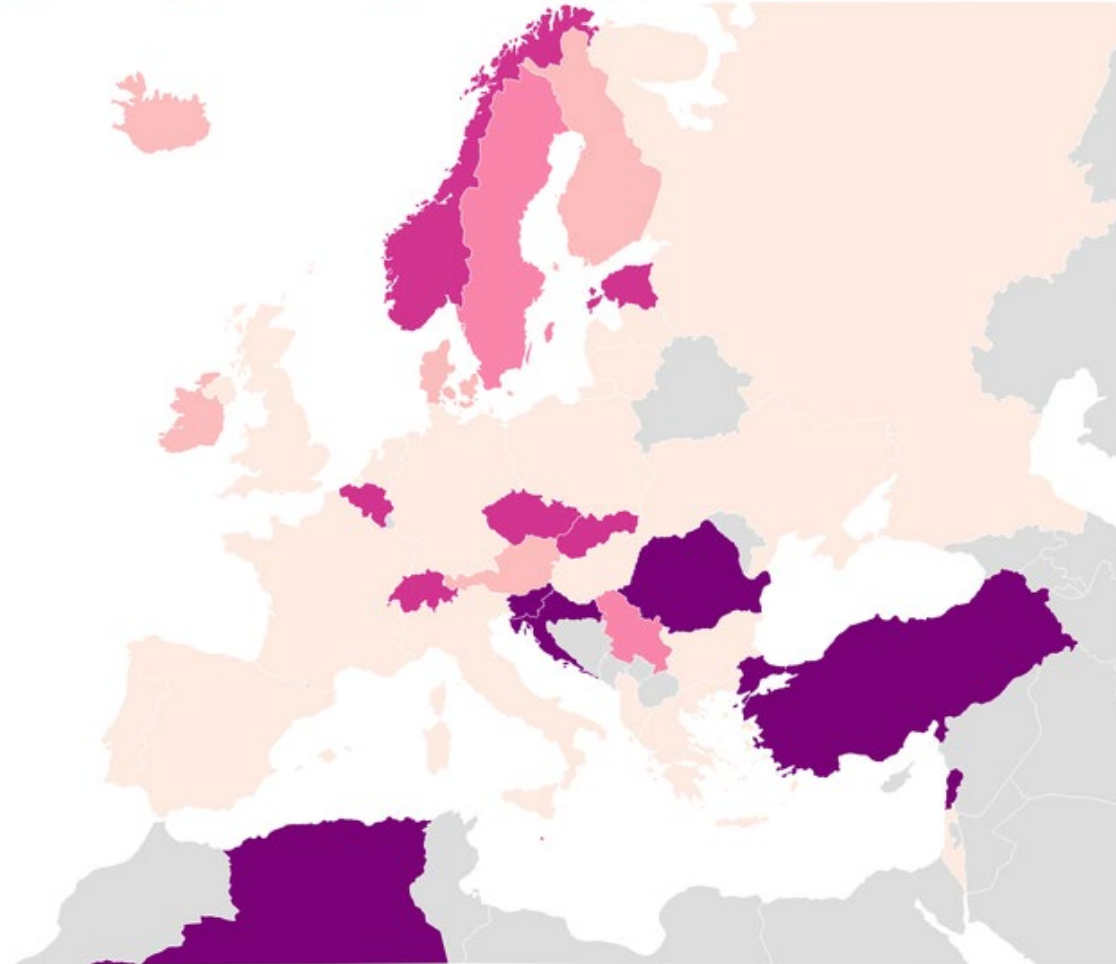
A world map with a dark background, showing various countries color-coded in shades of green, red, and grey. The map is centered on the Atlantic Ocean. The text "Restrictions/Bans Globally" is overlaid in white, with horizontal lines above and below it. A solid green bar is at the bottom of the image.

Restrictions/Bans Globally

Blood donation restrictions on men who have sex with men

As of January 2022 (including laws coming into force)

• No deferral • 4 month deferral • 6 month deferral • 1 year deferral • Indefinite deferral



Source: https://en.wikipedia.org/wiki/Blood_donation_restrictions_on_men_who_have_sex_with_men • Created with Datawrapper

COVID Forcing Change

- United Kingdom: June 2021
 - France: March 2022
- Germany: September 2021*
 - Greece: January 2022
 - Israel: October 2021
 - Lithuania: May 2022
 - Slovenia: July 2022
- Netherlands: September 2021



**Policy
Change**
FOR
DUMMIES

A Time for
Policy
Change?

Again, current official U.S. policy on MSM donating blood

The FDA guidance: “Defer for 3 months from the most recent sexual contact, a man who has had sex with another man during the past 3 months.”

All U.S. blood collection organizations must follow this federal requirement.



Why Should This Policy Change?

- The current three-month deferral period singles out and bans blood donors based on their inherent attributes rather than the risk factors they present.
- This approach not only reinforces stereotypes about the LGBTQ+ community and contributes to stigma, but it also fails to acknowledge HIV-risk factors that people who fall outside of this group may have
- This policy also fails to acknowledge the dramatic improvements in our HIV tests and testing capacity

An Alternative Way Forward?

- Development of a new donor history questionnaire consisting of questions that all potential blood donors answer before donating.
- A new questionnaire should contain questions are written to assess risk factors that could indicate infection with a transfusion transmissible infection, including HIV
- This approach would replace current time-based deferral restrictions/policies

The Data Supporting Policy Change

- The Williams Institute (UCLA) estimates if restrictions were lifted:
 - Blood supply would increase by **2% - 4%**-- average of **345,400 to 615,300** pints of blood annually
 - Given Red Cross data that each blood donation could be used in life-saving procedures on **3 individuals**→ estimates suggest lifting MSM restrictions could help save **up to 1 million** lives
- The American Red Cross estimates if the deferral period were lifted, an additional **360,000** men would donate blood

Who Supports This Policy Change?

- The American Red Cross
- The American Medical Association
- The Human Rights Campaign
- Vitalant
- OneBlood
- GLAAD
- The Biden Administration
- Association for the Advancement of Blood & Biotherpies



JOIN THE ADVANCE STUDY TODAY
ADVANCEstudy.org



ADVANCE Study: Assessing Donor Variability And New Concepts in Eligibility

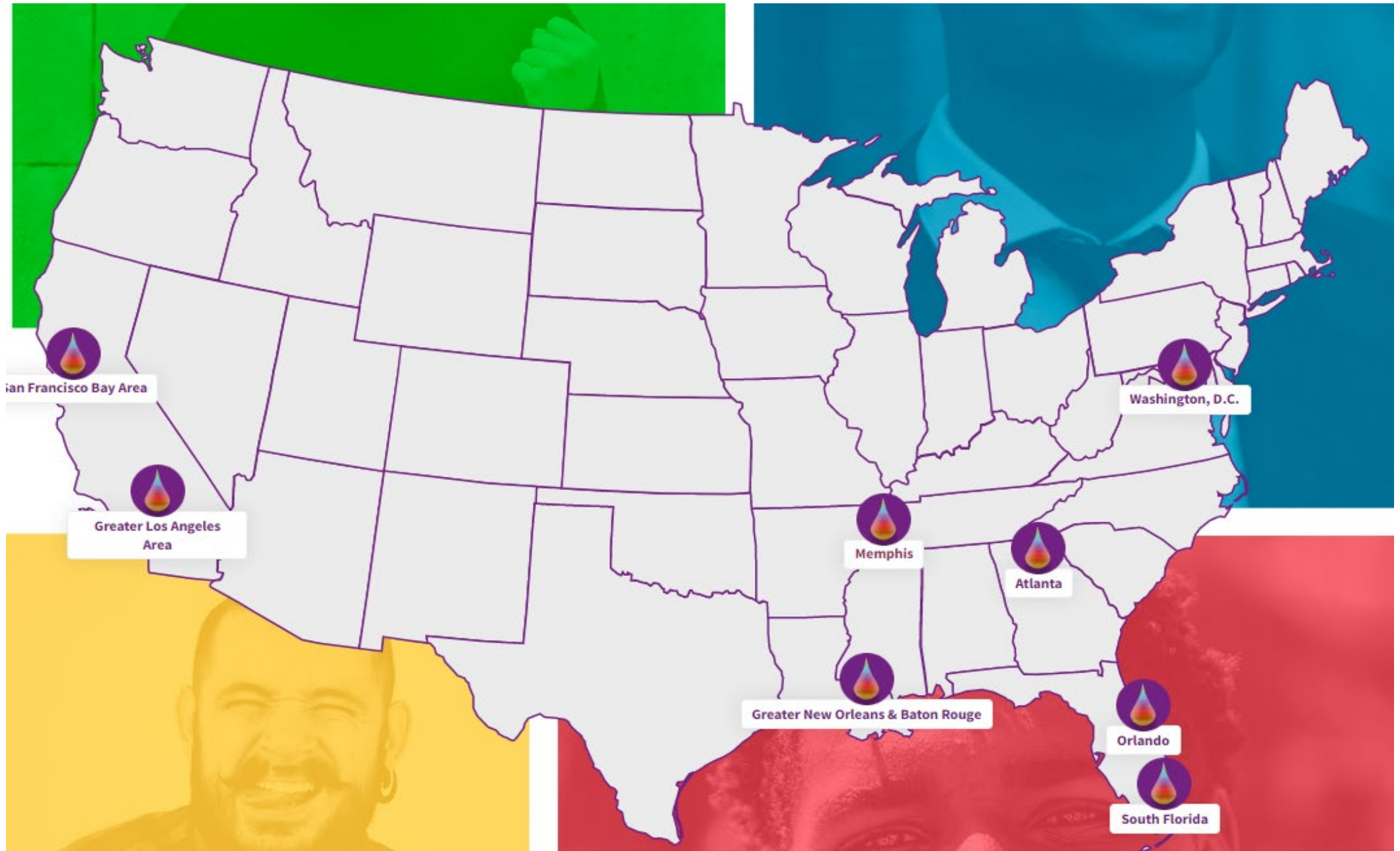
- Pilot study being conducted by the 3 largest blood centers – Vitalant, OneBlood, and the American Red Cross & funded by the U.S. Food and Drug Administration (FDA)
- Focused on evaluating alternatives to blood donor deferral policy known as men who have sex with men for MSM

ADVANCE Study

- The purpose of the study is to determine whether a different donor deferral policy can be used at blood centers nationwide while maintaining the safety of the blood supply.
- For this to be possible, a change would need to be made to the donor history questionnaire
- ADVANCE is the first step in assessing the safety of a change.

ADVANCE Study Continued

- The donor history questionnaire consists of questions that all potential blood donors answer before donating.
 - The questions are written to assess risk factors that could indicate infection with a transfusion transmissible infection, including HIV.
- The ADVANCE study will provide data to help the FDA determine if a **donor history questionnaire based on individual risk** would be as effective as time-based deferral, in reducing the risk of HIV in the blood supply.
- The blood centers will partner with LGBTQ+ Centers in Washington D.C., San Francisco, Orlando, New Orleans/Baton Rouge, Miami, Memphis, Los Angeles, and Atlanta and enroll ~2,000 MSM



Possible Impact of the ADVANCE Study

- If the scientific evidence supports the use of the different questions it could mean MSM who present to donate would be assessed based upon their own individual risk for HIV infection and not according to when their last sexual contact with another man occurred.
- The ADVANCE study is groundbreaking because it's the first time a study is being conducted that could result in individual risk assessment for men who have sex with men to donate blood.
- Results are expected in late-2022 & findings will be submitted to the FDA who will review the data and decide the next steps

“Even with 40 years of technology and advancements, a gay male teen trying to do their civic duty and give blood will still be asked if they’ve had sex with a man—and turned away if the answer is yes”.

“People give blood because they want to help,” he said. “Will they leave crestfallen, feeling there is something inherently wrong and diseased about themselves—o will they be able to carry through and help others?”

- Jason Cianciotto





Questions?

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Thank you!

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