

# **Blood Donation Policies Regarding Men Who Have Sex with Men (MSM)**

120<sup>th</sup> Meeting of the  
Blood Products Advisory Committee  
Silver Spring, MD

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# Overview

## **Topic III A :**

**Update on Donor Deferral Policies and  
HIV Risk Questionnaire (HRQ) Study**

## **Topic III B:**

**Variance Request for Pathogen Reduction of  
Platelet Donations from MSM**

# Overview

## Topic III A :

### **Update on Donor Deferral Policies and HIV Risk Questionnaire (HRQ) Study**

- Brief history
- Background on MSM deferral policies
- Introduce topics and speakers
- Questions for discussion

# Background

- FDA is responsible for protecting the safety of the blood supply, which depends on the implementation of donor screening measures, based on the available evidence
- The AIDS crisis in the 1980s and the recognition that HIV could be transmitted through blood transfusion or plasma derivatives had profound effects on the US blood system

# Brief History, 1980s – 2000s

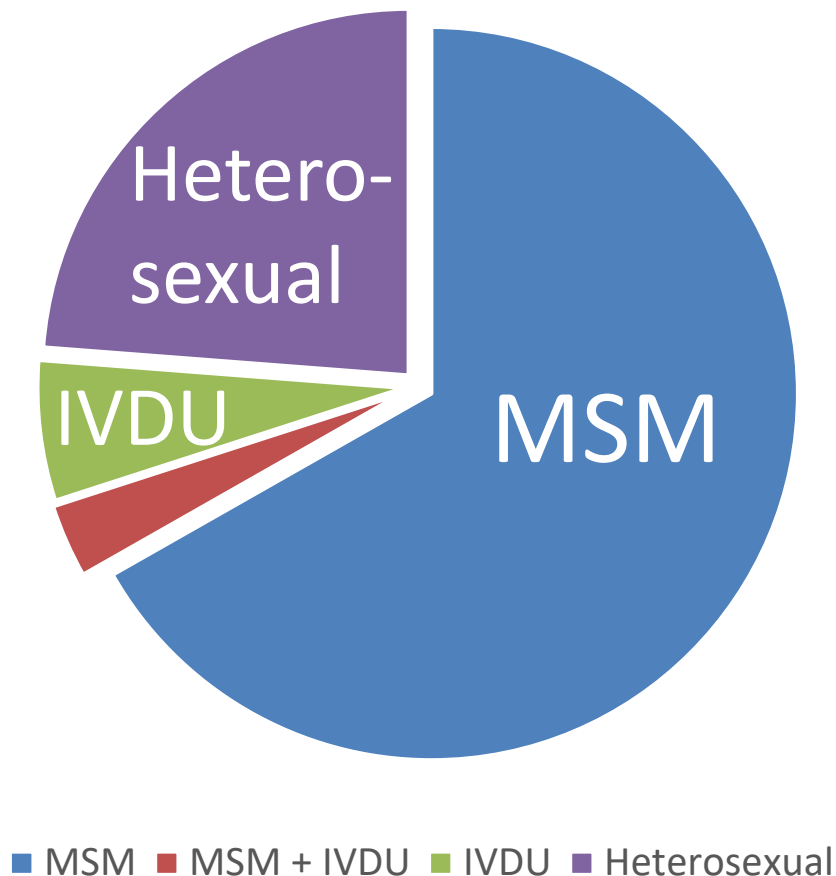


- 1982:** First cases of acquired immunodeficiency syndrome (AIDS) from blood transfusion and plasma derivatives
- 1983-4** **Donor education** about signs and symptoms of AIDS; MSM and other at-risk donors **asked not to donate**
- Mar 1985:** First HTLV-III (HIV) antibody test licensed
- 1992:** Direct questioning and **indefinite deferral** of men who have ever had sex with another man even once since 1977 (**MSM<sub>INDEF</sub>**)
- 1990s:** Subsequent generations of HIV serological (antigen, antibody) tests became increasingly more sensitive
- 2000:** Nucleic acid testing (NAT) introduced

# U.S. HIV Epidemiology, 2017



- About 1,008,929 people are living with HIV
- An estimated 38,739 were infected in 2017 (stable since 2012)
- MSM comprise about 7% of U.S. male population
- MSM account for 66% of new infections overall (82% of infections in men)



CDC (<https://www.cdc.gov/hiv/statistics/overview/atagance.html> )

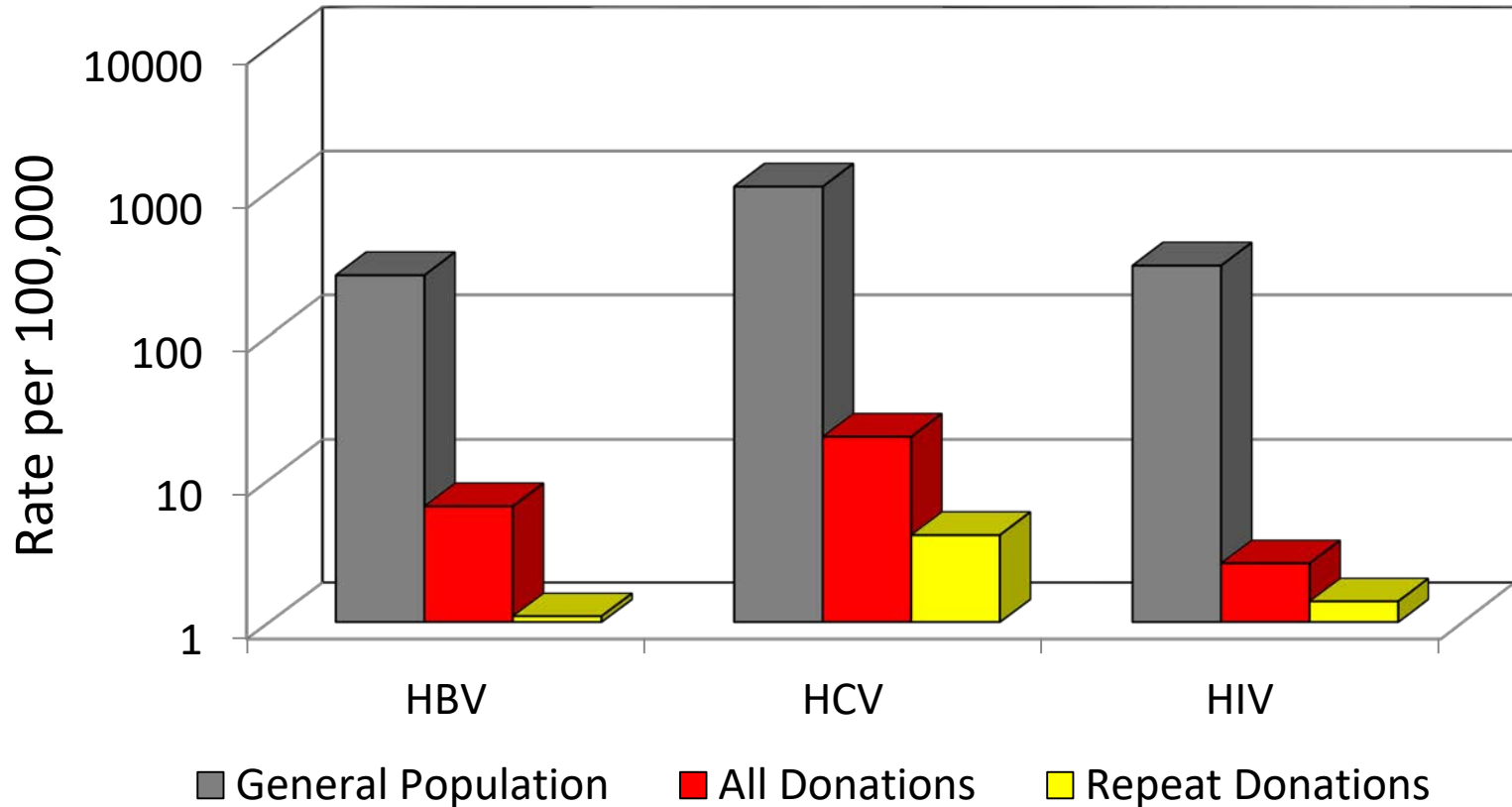
Purcell et al. 2012; Open AIDS J; M6:98-107.

# FDA Regulation of Blood Supply

1. Donor education
  - Provide explanation about readily identified risk factors closely associated with exposure to relevant transfusion-transmitted infections (RTTIs; e.g., HIV)
2. Donor history screening
  - Deferral for behaviors associated with an RTTI
3. Donation testing for RTTIs
4. Donor deferral records
5. Quarantine, investigate problems & deficiencies

1) 21 CFR 630.10(b); 2) 21 CFR 630.10(e); 3) 21 CFR 610.40;  
4) 21CFR 606.160(b)(ii) 5) 21 CFR 606.171, 21 CFR 610.46

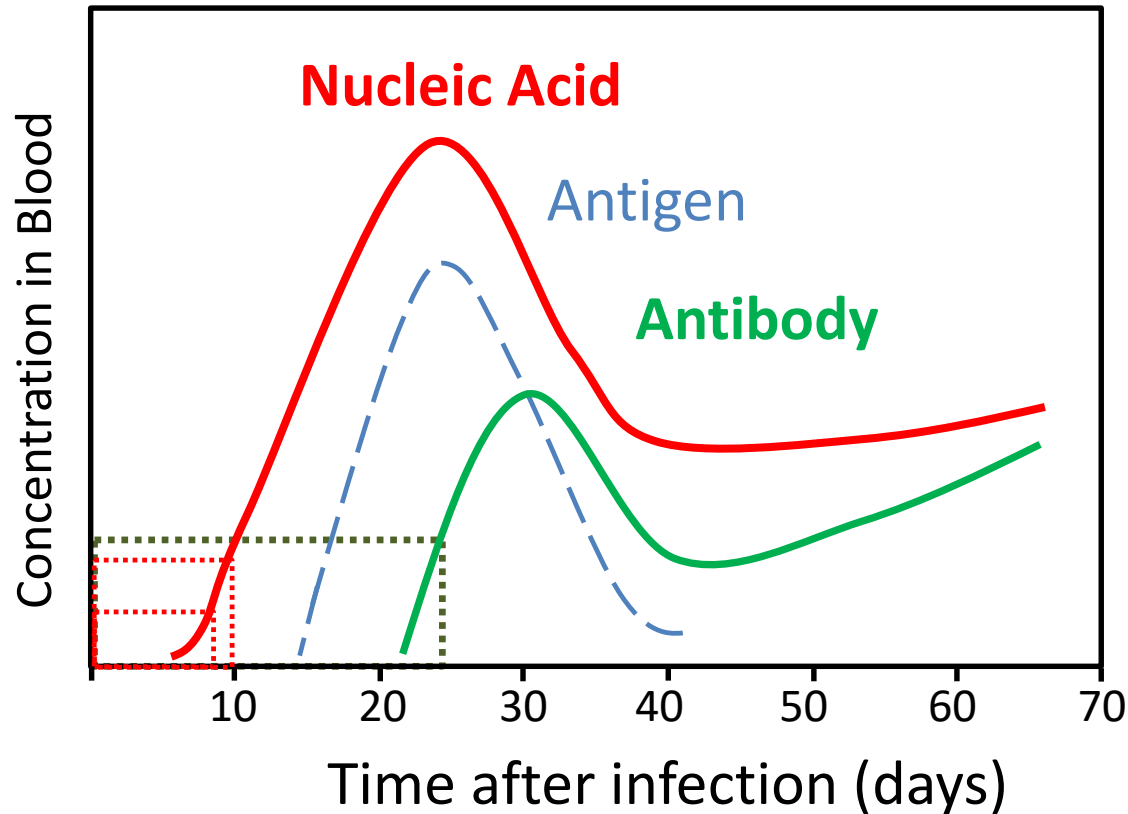
# HIV, Hepatitis in Blood Donors vs. General Population



CDC Viral Hepatitis Surveillance, United States 2015, CDC HIV Surveillance Report, 2016  
Steele WR, et al. Transfusion 2017;57(Suppl. 3):46A (abstract).



# Window-period & Transfusion Risk



NAT	Window (d)	Residual Risk per Unit ; 2014-5
<b>HIV</b>	<b>7-10</b>	<b>1 : 2,430,902</b>

# Revisiting MSM Indefinite Deferral

## 2010 - 2015



- June 2010:** HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommended further study to inform a possible change of the  $MSM_{INDEF}$  policy
- Sep 2010:** HHS Blood, Organ, Tissue Safety (BOTS) Working Group - three research studies and an operational assessment of quarantine release errors
- Nov 2014:** Results of completed studies were presented to ACBTSA
- Alternative deferral policies considered [none, time-based (e.g.,  $MSM_{12m}$ ); individual risk-based; or pretesting]
  - Committee voted **16 to 2** in support of a policy change from  $MSM_{INDEF}$  to  $MSM_{12m}$ , with a system for monitoring transfusion-transmissible infections in blood donors

# Supporting Evidence

1. Study of donors' understanding and adherence to the predonation donor history questionnaire (DHQ)
  - No difference in MSM v. non-MSM patterns of response
2. Retrovirus Epidemiology Donor Study (REDS)-II  
Risk Factors for Retrovirus, Hepatitis Virus Infections
  - MSM (62-fold increased risk) leading independent risk factor for HIV infection in blood donors
  - Multiple sexual partners in last year (2.3-fold increased risk)
3. REDS-III Blood Donation Rules Opinion Study (BloodDROPS)
  - 2.6% of male blood donors report MSM
  - About half of those who were noncompliant indicated they would adhere to MSM<sub>12m</sub> policy

# Supporting Evidence (cont'd)

4. Operational assessment of quarantine release errors
  - Negligible risk with current computer systems
5. Australian Red Cross reported their experience in changing from a 5-year to a 1-year MSM deferral
  - Compared before and after policy change, 5-year time periods (each > 4 million donations)
  - No difference in rate of HIV-positive donations
  - No change in MSM undisclosed risk

# FDA Deferral Policy, 2015



## Indefinite Deferral

- Positive test for HIV/AIDS
- Non-prescription injection drug use (IVDU)
- Exchanges sex for money or drugs

## 12-month Deferral

- **Male donors: MSM**
- **Female donors:** sex with man who has had sex with another man **in the past 12 months**
- **Sexual contact** with a person:
  - Positive test for HIV
  - IVDU
  - Exchanged sex for money or drugs
- Blood contact (e.g., needlestick)
- Treated for syphilis or gonorrhea
- Incarcerated  $\geq$  72 hours
- Transfusion, transplantation

# FDA Commitment to Evaluate Policy and Supporting Evidence



- FDA is committed to ongoing evaluation of the MSM<sub>12m</sub> policy and potentially advancing policy based on the available scientific evidence
- In **July 2016**, Public Docket (FDA-2016-N-1502) requested comments and supporting scientific evidence, regarding potential blood donor deferral policy options
  - Alternatives to time-based deferral policies and feasibility of individual risk assessment strategies
  - Responses were mixed, but a notable cross-section (hospitals, plasma users, blood centers, advocacy groups) commented that data are not yet available to consider further change

# Global MSM Deferral Policies



Deferral	Time or Criteria	Example
Time-based deferral	Indefinite	Several
	12-months	US, Australia, Canada, France
	3 or 4 months	England, Scotland, Wales
Risk-based, sexual activities	New or multiple partners	Spain Italy
Alternative measures	Quarantine and retest	France (plasma)

# Transfusion-Transmissible Infections Monitoring System



- TTIMS, launched 2015
- Sponsored by FDA, NHLBI, HHS
- Collaboration comprises more than 60% of US Blood Supply:
  - American Red Cross, Vitalant, New York Blood Center, OneBlood
- Collects and analyzes data on the incidence and prevalence of HIV, HBV, HCV among blood donors
- Demographic variables, behavioral risk factors, biorepository samples from seropositive donors



# HIV Risk Factor Questionnaire



- Research study to assess MSM risk-based questions as an alternative policy to minimize HIV risk at least as effectively as current deferral policy
- FDA-sponsored research study developed through collaboration with Blood Equality Working Group
  - Advocacy organizations
  - Community health centers
  - Blood collectors
  - Public health agencies



# Speakers and Topics

**Mindy Goldman, MD**

Canadian Blood Services

Global developments  
in MSM Deferral

**John Brooks, MD**

CDC

Epidemiology of HIV  
in the U.S.

**Alan Williams, PhD**

FDA, CBER, OBE

Transfusion-Transmissible  
Infections Monitoring  
System (TTIMS)

**Barbee Whitaker, PhD**

FDA, CBER, OBE

HIV Risk Questionnaire  
(HRQ) Study

# Committee Discussion (1)



- Comment on what has been learned from implementing other MSM policies internationally (such as risk-based deferral methods or quarantine and retest for plasma) and how this information can inform the current U.S. MSM deferral policy.

# Committee Discussion (2)



- Comment on the questions proposed for study in the HIV Risk Questionnaire and whether there are any additions or modifications to this study in order to best identify behavioral risk questions to predict risk of HIV transmission in the MSM population.

