

# Update on Blood Donor Deferral Recommendations to Reduce the Risk of the Transmission of Human Immunodeficiency Virus (HIV)

AABB Briefing

February 2, 2023

# Blood Guidance for HIV Risk

- 1985 to 2015: indefinite deferral in place for men having sex with another man
- 2015 to 2020: revised to 12 months for men having sex with another man
- 2020 to present: revised to 3 months for men having sex with another man
- Current guidance includes other time-based deferral recommendations
  - Women who have sex with men who have sex with men (3 months)
  - Those who have exchanged sex for money or drugs (3 months)
  - Those who have engaged in non-prescription injection drug use (3 months)
  - Those with history of receiving an allogeneic blood transfusion (3 months)
  - Those with tattooing or piercing at unlicensed establishment (3 months)
- FDA committed to investigating individual risk assessment as an alternative to time-based deferrals in the current guidance

# Examples of Individual Risk Assessments

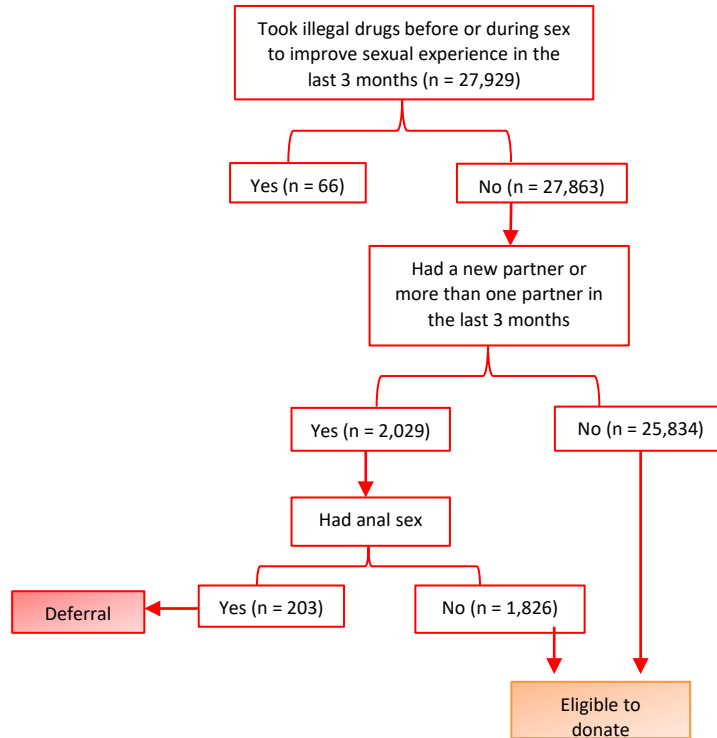
## United Kingdom

- Taken PrEP in last 3 months
  - If Yes, Defer
- Been treated for syphilis or gonorrhea in the last year?
  - If Yes, Defer
- Chemsex in last 3 months?
  - If Yes, Defer
- Had more than 1 sexual partner in last 3 months?
  - If Yes, Defer
- Had a new sexual partner in the last 3 months
  - If Yes, Defer
- Had anal sex in the last 3 months
  - If Yes, Defer

## Canada (Canadian Blood Services)

- PrEP use in the last 4 months
  - If Yes, Defer
- New sex partner in the last 3 months
  - If Yes, had anal sex in the last 3 months?
    - If Yes, Defer
- More than 1 sex partner in last 3 months?
  - If Yes, had anal sex in the last 3 months?
    - If Yes, Defer

# Canadian Donor Study\*



- % new/multiple partner(s):  
 $2029/27,863 = 7.3\%$
- % Anal sex:  
 $203/2,029 = 10.0\%$
- % Donor loss:  
 $203/27,863 = 0.73\%$
- Calculation independently done by FDA using US data estimates donor loss of 0.37 to 1.07%

\*Caffrey N et al. Transfusion Med. 2022;32:422–427.

# Pre-Exposure Prophylaxis (PrEP)

- PrEP is relevant for change to an individual risk assessment strategy
- Public messaging: PrEP use highly encouraged in men having sex with another man (MSM) to prevent HIV transmission
- Non-compliant PrEP use can lead to HIV infection, but the continued use of PrEP may result in undetectable levels of HIV in the blood
- Volume administered is relevant as transfusion involves volumes 100 to 1000 times greater than previously associated with HIV transmission
- Current blood donor deferral for PrEP use:
  - 3 to 4-month deferral in most countries for oral PrEP
  - AABB standard is 2 years for injectable PrEP

# Proposed Deferral Algorithm



- Defer permanently an individual who has ever had a confirmed positive test result for HIV infection.
- Defer permanently an individual who has ever taken any medication to treat HIV infection (i.e., ART).

# Proposed Deferral Algorithm



- Defer for 3 months from the most recent dose, an individual who has taken any medication by mouth (oral) to prevent HIV infection (i.e., short-acting antiviral PrEP or PEP).
- Defer for two years from the most recent injection, an individual who has received any medication by injection to prevent HIV infection (i.e., long-acting antiviral PrEP).

# Proposed Deferral Algorithm

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



# Next Steps

- Draft guidance open for comment
  - <https://www.regulations.gov/docket/FDA-2015-D-1211>
- Comment period on guidance ends at the end of March
- Goal is to issue final version of guidance prior to the end of the public health emergency



**U.S. FOOD & DRUG**  
ADMINISTRATION