

Introduction to Session 6 MSM and Other Donor Deferral/Recruitment Issues

**28th IPFA PEI Surveillance Workshop
22 September 2022**

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Donor history questions on Anti-Retroviral Therapy (ART) and Prophylaxis to Prevent HIV (PrEP/PEP)

- Published studies in U.S. and South Africa found antiretroviral (ARV) use in donors who tested HIV-positive (1,2) and one study found pre-exposure prophylaxis (PrEP) use in a selected group of infection-negative donors in the U.S. (1).
 1. *Blood*. 2020 Sep 10;136(11):1351-1358.
 2. *J Infect Dis*. 2019 19;220(4):643-647.
- **The AABB donor history questionnaire (DHQ) task force updated the DHQ (v2.0 and v2.1) with more explicit questions intended to improve the disclosure of ARV, and PrEP or post-exposure prophylaxis (PEP) use.**

Impact on US blood donor eligibility

1. Updated AABB DHQ (v2.1) and related materials provided to donors when answering the DHQ
 - Questions and language about medication taken to:
 - Treat HIV infection (Ever)
 - Prevent HIV infection (Last 3 months)
2. Deferral of individuals taking PrEP or PEP (HIV *uninfected*)
 - Until 3 months after the last dose, and after routine lab tests have been completed by prescriber
3. Deferral of individuals taking ART (HIV infected)
 - Indefinite

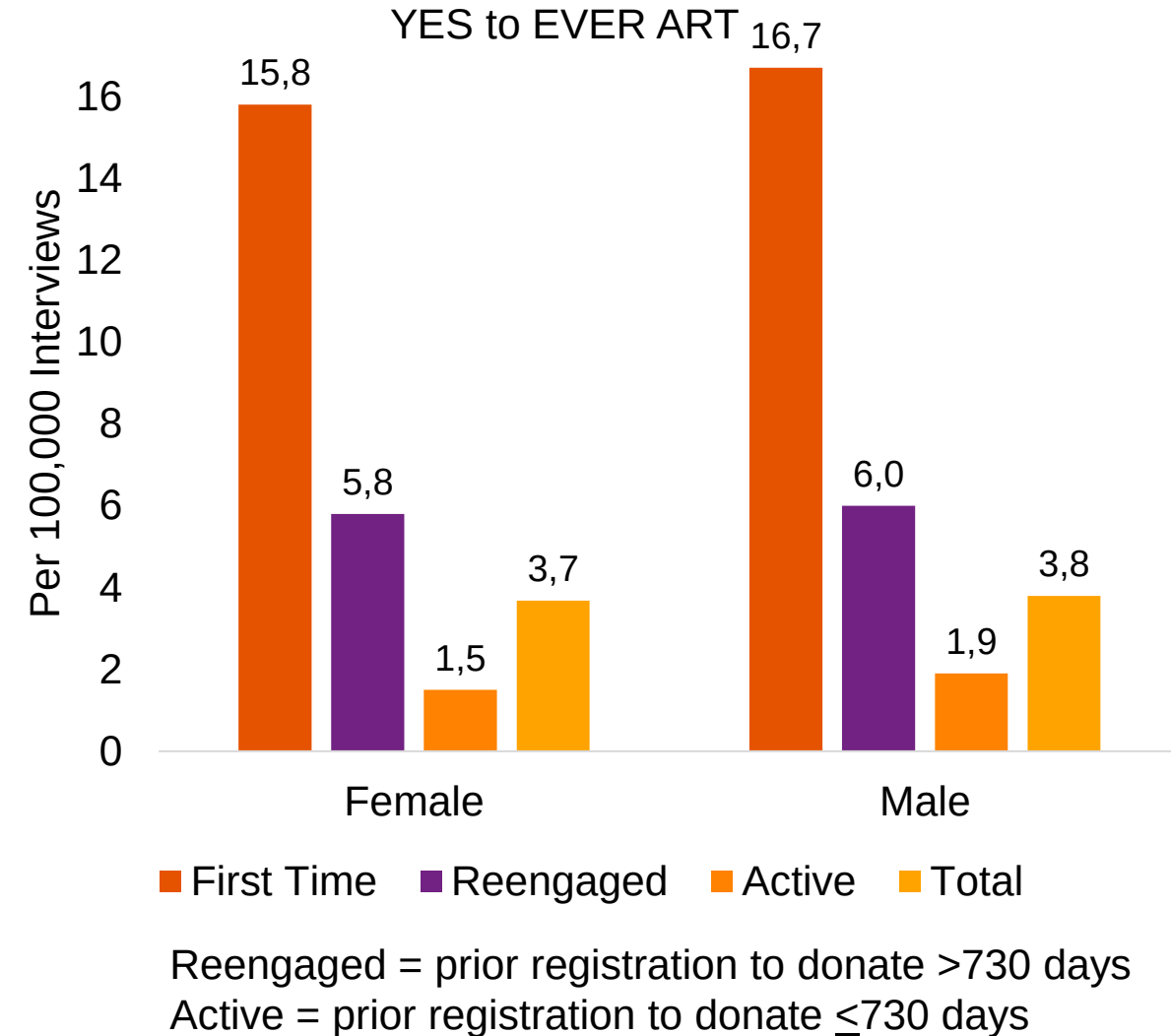
Have you EVER taken any medication to treat an HIV infection?

Responses collected between 8/2020 – 3/2022

	Female	Male	Total
Total Interviews	951,476	922,471	1,873,947
(Total Unique Donors)	395,656	340,746	736,402
NO	951,420	922,428	1,873,878
UNSURE	21	8	29
YES	35	35	70
% YES per 100K interviews*	3.7	3.8	3.7
% YES per 100K donors**	8.8	10.3	9.5

*Proportion not significantly different, $p=0.89$

**Proportion not significantly different, $p=0.53$

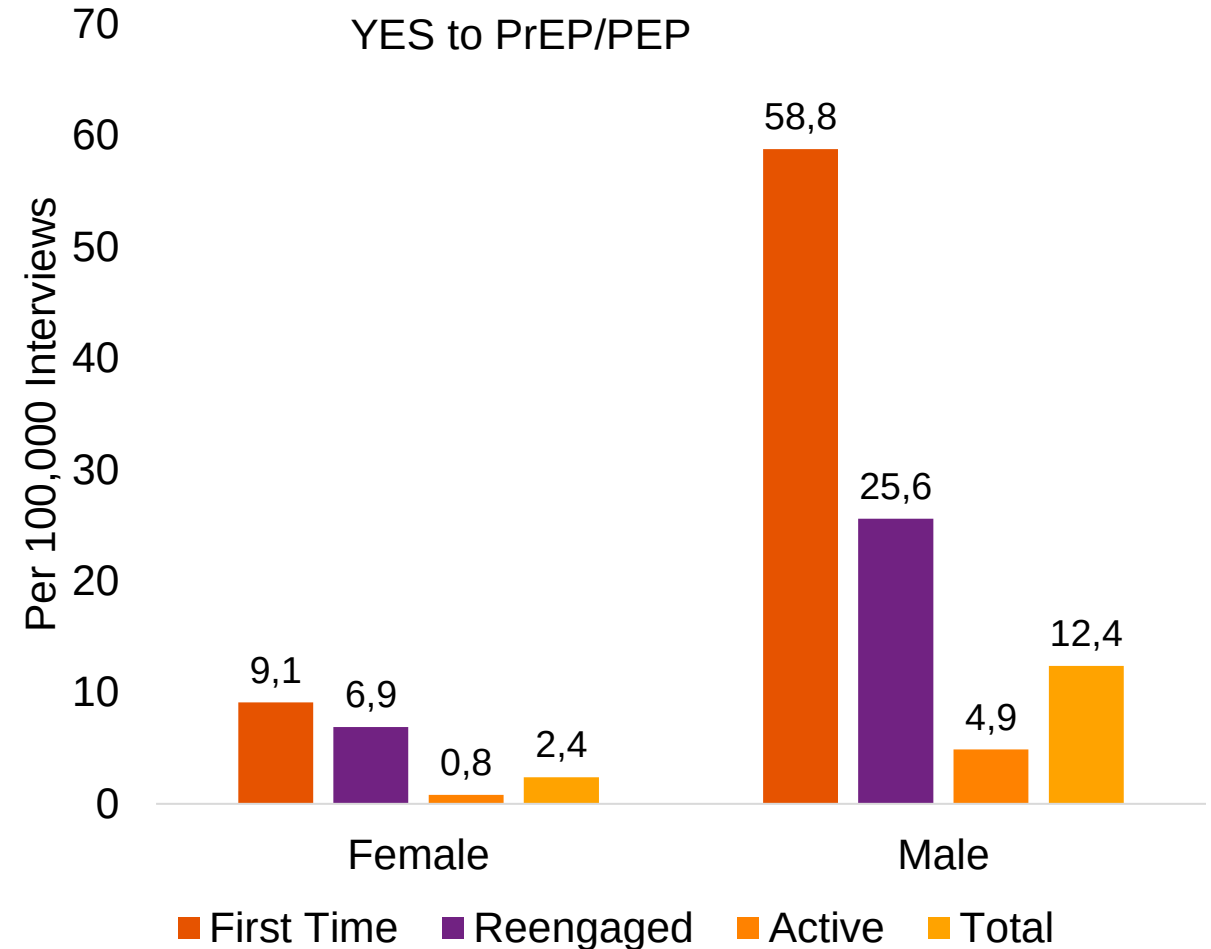


In the past 3 months, have you taken any medication to prevent an HIV infection?

Responses collected between 8/2020 – 3/2022

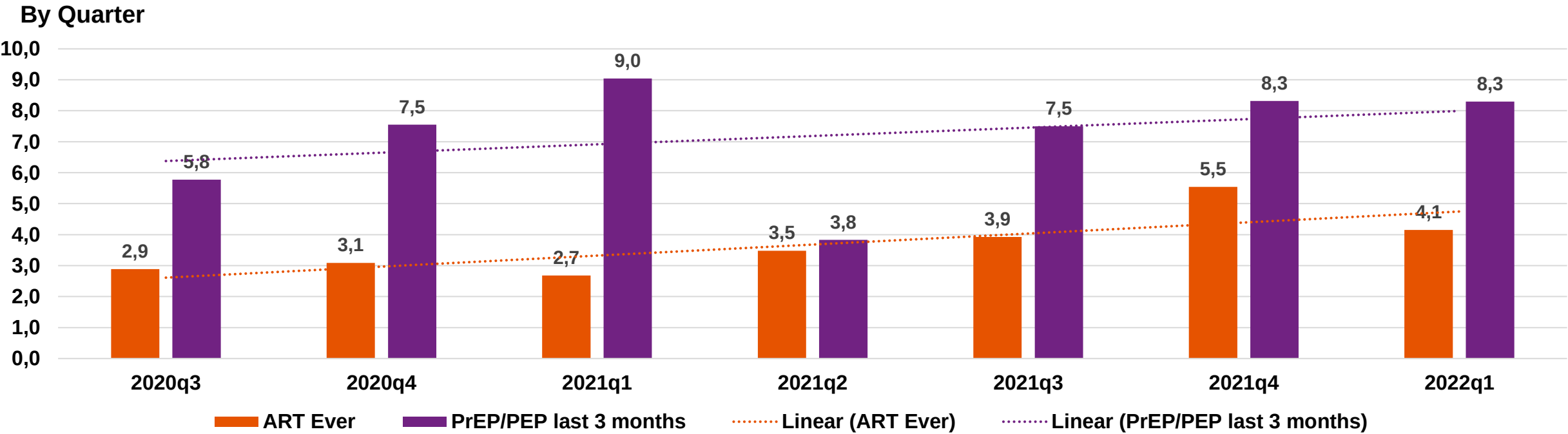
	Female	Male	Total
Total Interviews	951,476	922,459	1,873,935
(Total Unique Donors)	395,665	340,755	736,420
NO	951,435	922,334	1,873,769
UNSURE	18	11	29
YES	23	114	137
% YES per 100K interviews*	2.4	12.4	7.3
% YES per 100K donors	5.8	33.5	18.6

*Proportion significantly different, $p < 0.0001$



Reengaged = prior registration to donate >730 days
Active = prior registration to donate $\leq$ 730 days

Yes Response Proportions (per 100,000 interviews) by Quarter



Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

Guidance for Industry

NOT CHANGED:

- Permanent deferral for ever having tested HIV-positive or taking ART to treat an HIV infection
- Defer for 3 months any individual who has taken Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (PEP)

BUT Many 12-month deferrals were changed to 3-month deferrals from the most recent exposure event:

- A man who has had sex with another man in the past 3 months
- A woman who has had sex in the past 3 months with a man who has had sex with another man in the past 3 months
- An individual who has exchanged sex for money or drugs in the past 3 months
- An individual who has engaged in non-prescription injection drug use or had sex with someone else who has
- An individual who has had sex with a person who has ever had a positive test for HIV
- An individual who has a new tattoo, ear, or body piercing in past 3 months in an unregulated facility
- An individual treated for syphilis or gonorrhea, or an individual with a history of diagnosis or treatment for syphilis or gonorrhea in the past 3 months
- Any individual who has a history of receiving an allogeneic transfusion of whole blood or blood components in the past 3 months
- Accidental blood, open wound, or needlestick exposure in the past 3 months



Methods

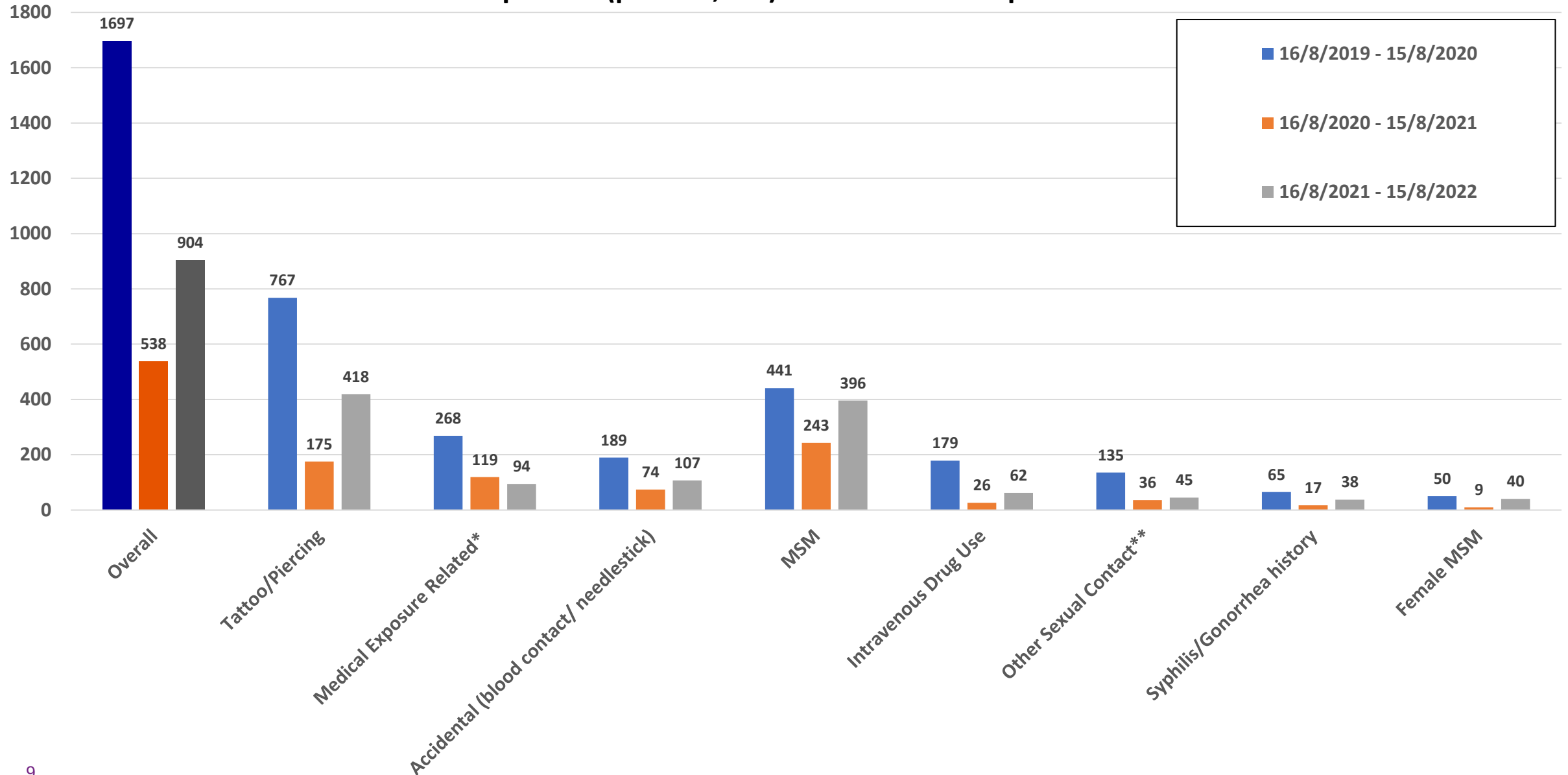
We compared same-center donor disclosed risks for 12-month deferrals in the year before and the two years after the change to 3-month deferrals based on the date of implementation of the 3-month deferrals in our organization.

- 12-month deferrals: Period 1 (P1); 8/16/2019 – 8/15/2020
- 3-month deferrals: Period 2 A (P2A); 8/16/2020 – 8/15/2021
- 3-month deferrals: Period 2 B (P2B); 8/16/2021 – 8/15/2022

Demographic characteristics and deferral rates (per 100,000 DHQ responses/interviews) are stratified by first-time (FT) or repeat donor (RD) status.

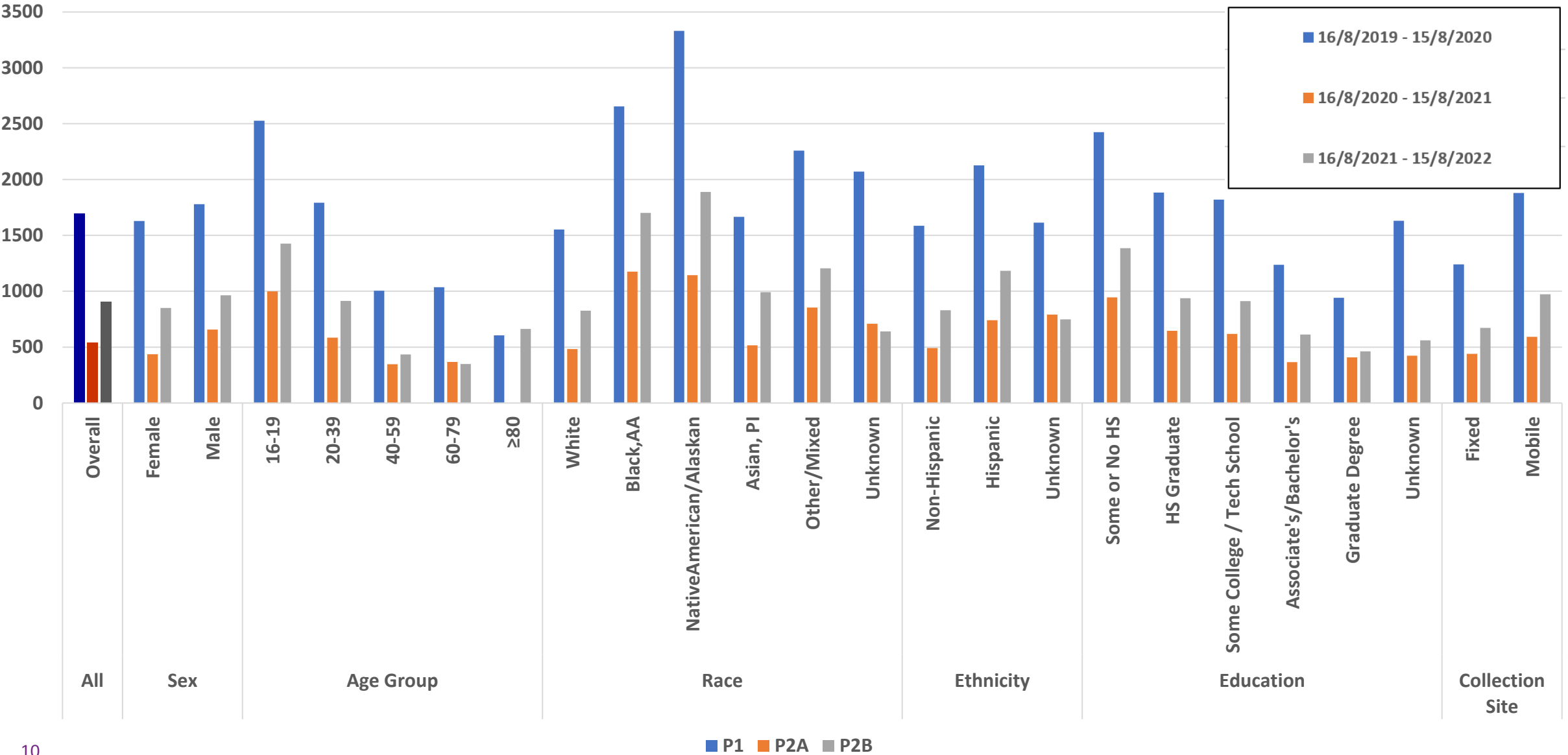
First-Time Donor Deferrals By Risk Category

Proportion (per 100,000) of Deferrable Responses



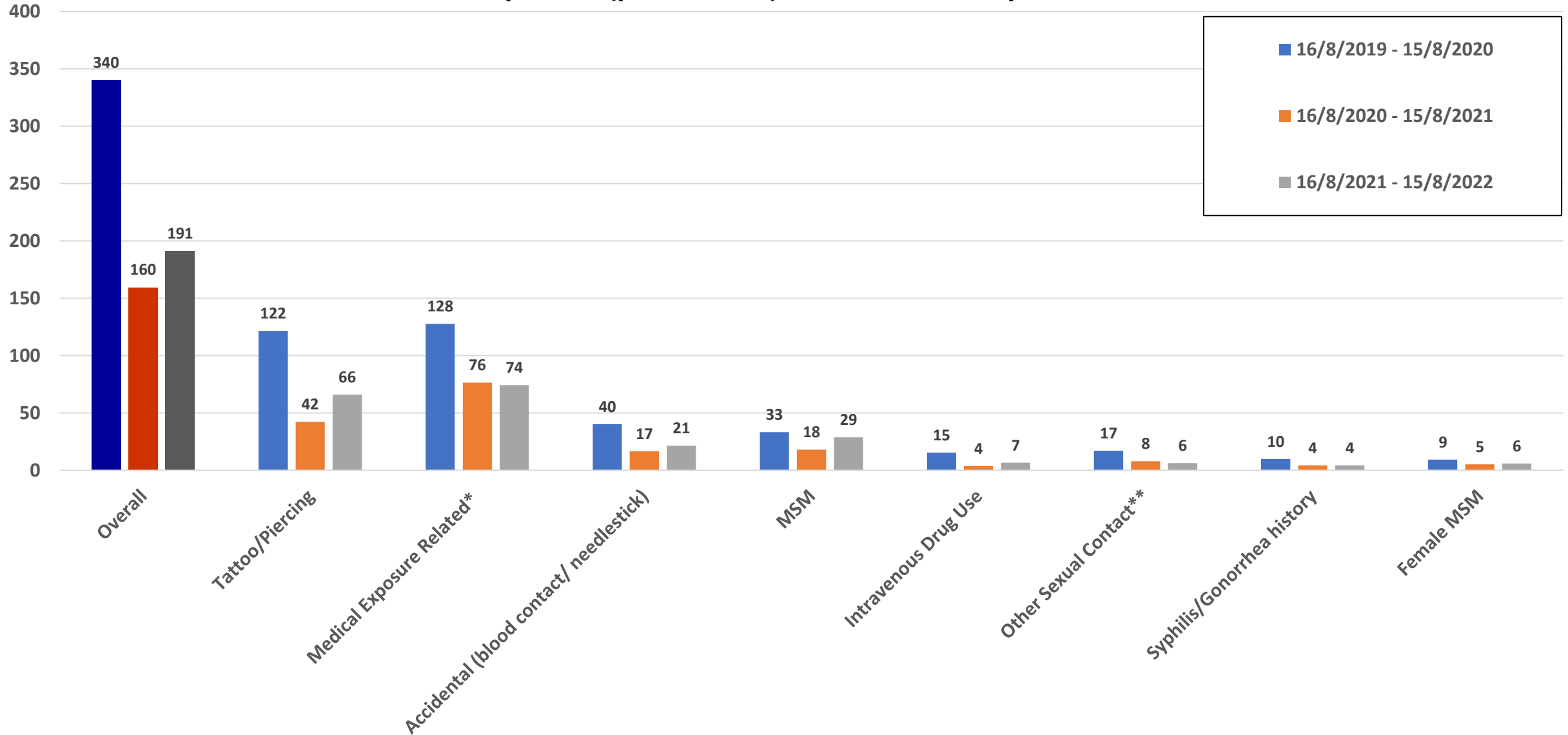
First-Time Donor Deferrals (Proportion per 100,000 Interviews)

Deferrable Response Rates Among First-Time Donors



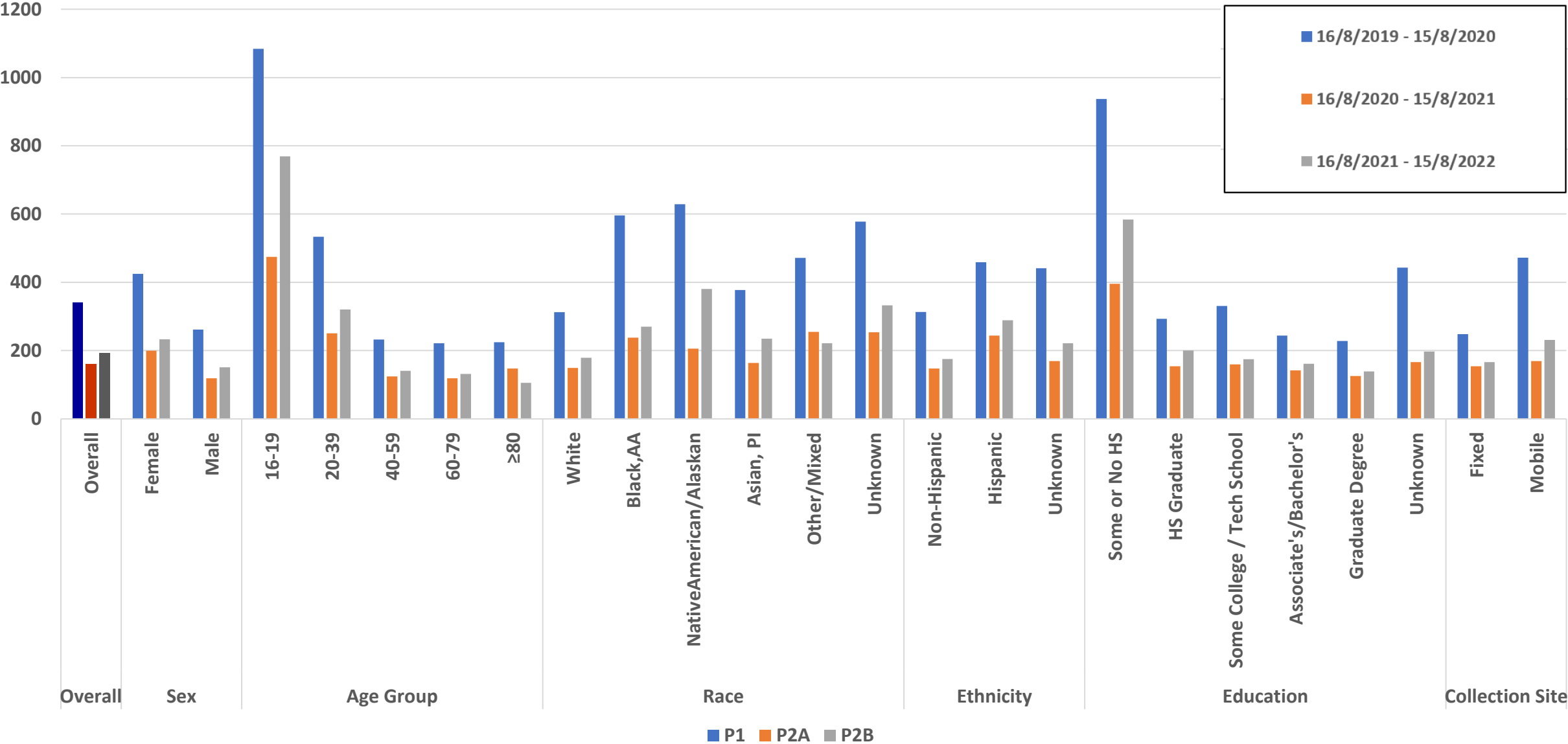
Repeat Donor Deferrals By Risk Category

Proportion (per 100,000) of Deferrable Responses



Repeat Donor Deferrals (Proportions per 100,000 Interviews)

Deferrable Response Rates Among Repeat Donors



Brief history of FDA blood donation policy for men who have sex with men (MSM)

1981 1983 1985 2015 2020 2022



- 1983 to 1985 – MSM were asked not to donate blood along with other groups identified as having higher risk for HIV by FDA at the time
- 1985 to January 2015 – MSM who had any sexual contact with another man after 1977 were indefinitely deferred
- 2015 to April 2020 – MSM were deferred from donation for a 12-month period following last sexual contact with another man
- April 2020 – MSM are deferred from donation for a 3-month period following last sexual contact with another man



Assessing Donor Variability And New Concepts in Eligibility



Protocol Research Questions/Objectives

The purpose of the ADVANCE Study is to provide the FDA with evidence by which to consider changes in policy from the current blood donor deferral interval for MSM.

Primary Objective:

- Conduct an initial assessment of the discriminant function of revised donor history questions for predicting recent infection with HIV in MSM who wish to donate blood.

Secondary Objectives:

- Evaluate the recency of infection in those individuals who test positive for HIV by individual nucleic acid test (NAT) and antibody testing.
- Identify risk factors associated with recent HIV infection.
- The likelihood of identifying individual NAT HIV positive/seronegative study participants (those with an HIV infection acquired within two weeks of study enrollment) or recently infected seropositive participant based on recency testing may be low given the availability of pre-exposure prophylaxis (PrEP).
 - As part of the study, we are assessing PrEP use in the study population to provide currently unknown contextual data.



ADVANCE Study Design

Enrollment Visit

1. All Presenters (all who come for a study visit)
Eligibility Questionnaire (sociodemographic characteristics, other donation deferrable risk behaviors)
2. Consenting Participants
 - a. HIV Risk Questionnaire (HRQ) – test questions for future DHQ
 - b. Blood sample for HIV and tenofovir testing
 - Individual sample NAT for HIV and 4th generation serology using blood (plasma) screening assays (testing conducted at Creative Testing Solutions)
 - Confirmation testing using blood screening assays and algorithms
 - RUO limiting antigen avidity testing if NAT and serology reactive at VRI
 - RUO tenofovir colorimetric ELISA tested using a whole blood sample at VRI

Follow-up Visit (14 -21 days later)

3. All Persons who return for Notification of testing results
Follow-up Questionnaire – Behavioral, HIV prevention, and health status topics
 - From study start in Dec 2020 to Sept 2021: HIV+ or PrEP reactive
 - In Sept 2021: All offered Follow-up Questionnaire



Participation (through 9 September 2022)

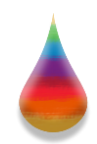
Study Sites
Atlanta
Los Angeles
Memphis
Miami
New Orleans/Baton Rouge
Orlando
San Francisco
Washington, DC

Study Visit	Number
Enrollment visit	1743
Ineligible/not enrolled	212
Enrolled	1531
Follow-up visit	
Notification	1415
Follow-up questionnaire	1129



Study Timeline

- Enrollment started December 2020 at 1 site with 7 other sites coming on board up to August 2021
- Enrollment through September 2022, with field work completion by end of October
- Analysis working group is conducting a preliminary analysis and plans to conduct analysis of final dataset through end of 2022
- Findings submitted to FDA for consideration of next steps and release of results in late 2022/early 2023



ADVANCE Study

