

# HIV Incidence in US First-Time Blood Donors During the Entire 12-Month MSM Deferral Period

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## Background

In 2015 the FDA revised guidance from indefinite deferral of male donors who reported sex with another man (MSM) to 12 months, and in 2020 to 3 months. We previously reported an assessment of HIV incidence in first-time donors (FTD) during the fifteen months before and ~2 years after implementation of the 12-month MSM deferral [1]. We evaluated incidence over the full period (>3½ yrs) during which the 12-month MSM deferral (MSM12) was in place at 4 large blood collection organizations compared to the indefinite deferral period, using data on 7.1 million donations, and assessed correlates of incident infection.

## Methods

We applied a recent infection testing algorithm (RITA) to HIV-positive donations:

- NAT+/Ab- donations were considered recent;
- NAT-/Ab+ donations were classified as long-term (virally suppressed through elite control or antiretroviral treatment);
- Concordant NAT+/Ab+ donations were classified as recent or long-term using the Sedia LAg Avidity assay (OD<sub>n</sub>≤2.0) and viral load (>75).

A previously-described Bayesian analysis of repeat donor data provided a locally-appropriate mean duration of recent infection (MDRI) estimate, and analysis of non-blood donor data a subtype B-specific false-recent rate estimate [1].

We estimated incidence rates and incidence rate differences in FTD during 15 months before implementation of MSM12 and during the MSM12 period (>3½ yrs). Confidence intervals (CI) on incidence differences for subgroups were adjusted for multiple comparisons.

We used multivariable Poisson regression models to identify demographic correlates of incident infection. In Poisson regression we treated donor-specific time-at-risk, derived from the MDRI, as an ‘offset’ and used a log link function, allowing regression coefficients to be transformed into adjusted incidence rate ratios. These models allow assessment of predictors of incidence, including MSM12 period and demographic and geographic factors.

## Results

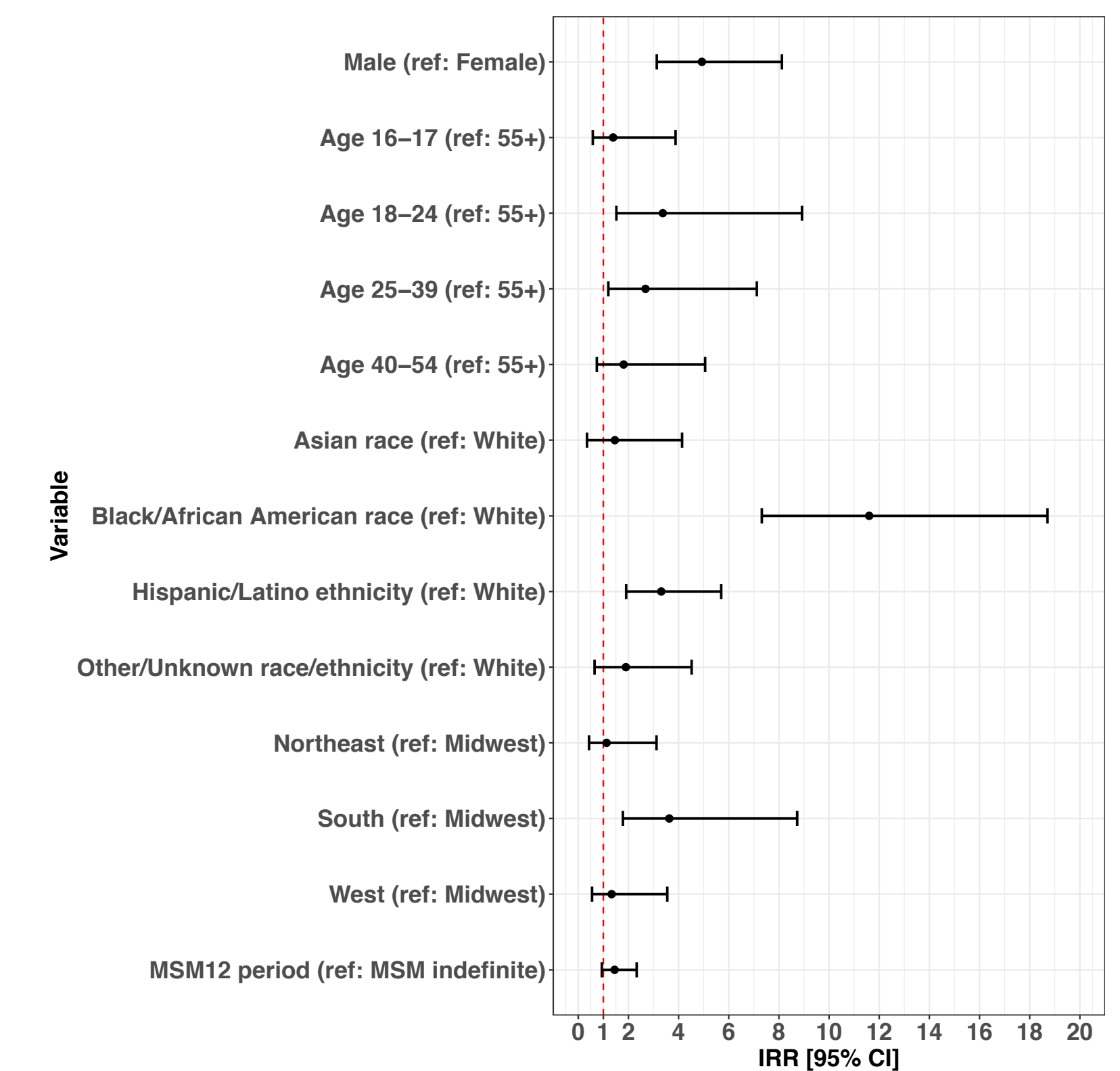
**Table 1: Incidence rate differences between periods with indefinite and 12-month MSM deferral**

Group	Incidence difference cases/10 <sup>5</sup> person-years (CI)
Males	1.24 (-2.51,4.89)
Females	-0.11 (-2.02,1.35)
Age 16–17	0.44 (-3.16,3.48)
Age 18–24	0.09 (-6.69,5.80)
Age 25–39	0.39 (-4.24,4.39)
Age 40–54	1.25 (-2.51,4.17)
Age 55+	1.21 (-2.53,2.88)
White race	-1.10 (-3.26,0.48)
Black or African American race	9.54 (-7.72,26.76)
Asian race	-0.63 (-6.87,5.90)
Hispanic ethnicity	3.71 (-1.43,8.48)
Other/unknown race/ethnicity	2.27 (-3.71,8.82)
Midwest region	-0.75 (-4.43,1.57)
Northeast region	0.52 (-2.47,2.82)
South region	0.28 (-4.52,4.68)
West region	1.98 (-1.87,3.72)
<b>Overall*</b>	<b>0.48 (-0.80,1.73)</b>

\*For the overall comparison, the 95% confidence interval is reported without adjustment for multiple comparisons.

- No statistically significant incidence differences between the two time periods were observed, overall or in any subgroup.

**Figure 1: Incidence rate ratios from multivariable Poisson regression**



- Male sex, age 18–24, age 25–39, Black or African American race, Hispanic ethnicity and residence in the South were statistically significant predictors (CI lower bound > 1), but donating during the MSM12 period was not.
- In additional statistical models (not shown), interactions between the MSM deferral policy period and race/ethnicity were significant. These results require further evaluation.

## References

1. Grebe E, Busch MP, Notari EP, Bruhn R, Quiner C, et al. HIV incidence in US first-time blood donors and transfusion risk with a 12-month deferral for men who have sex with men. *Blood*. 2020;136(11):1359-1367.

## Disclosures

EG and CDG have received research funding or reagents, and EG has received consulting income from Sedia Biosciences Corporation.

## Disclaimer

These statements are an informal communication and represent the authors' own best judgment. These comments do not bind or obligate FDA.



## Conclusions

- An analysis of the entire MSM12 period confirms previous findings that HIV incidence did not increase significantly in US FTD [1]. No statistically significant incidence differences were observed in demographic or geographic subgroups.
- In multivariable regression, male sex, younger ages, Black or African American race, Hispanic ethnicity and residing in the South were significant predictors of incidence. MSM deferral policy period was not significant.
- The adoption of the 3-month deferral in 2020 will necessitate similar analyses to understand if new changes have occurred.