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Recently Acquired Infection Among HIV Seropositive Donors in the US from 2010-2018

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Transfusion-Transmissible Infections Monitoring System (TTIMS)

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Abstract

BACKGROUND: Monitoring of transfusion-transmissible infections (TTIs) in the blood supply is essential for blood safety, as the donor population is not static, and changes in policy, donor behavior, or other factors could increase the risk of recipient infection. We assessed patterns of recently acquired HIV infection in US blood donors, including before and after the implementation of the 12-month deferral for men who have sex with men (MSM).

STUDY DESIGN AND METHODS: A large convenience sample of donations testing HIV-1 NAT and serology reactive, were further tested using the Sedia HIV-1 Limiting Antigen (LAg)-Avidity EIA. Samples were analyzed across available demographic and donation data to provide an assessment of recently acquired HIV infection in US blood donors from 2010 to 2018.

RESULTS: Overall 317 of 1154 (27.5%; 95%CI 24.9 – 30.1%) donations from HIV NAT and serology reactive donors had recently acquired HIV infection. There was no evidence of change in the percentages of recent HIV infection by year over the study period, either in all donors or in male donors, including after the MSM policy change. In multivariable logistic regression analysis donors aged ≤24 years were over 2.7 times more likely and repeat donors were 2.2 times more

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likely to have recently acquired HIV infection compared to donors aged ≥55 years and first-time donors, respectively.

CONCLUSION: Patterns of recently acquired HIV infection varied by demographics, but not over time. These findings suggest no impact of the MSM policy change on recently acquired HIV infection in US blood donors.

Introduction

The prevention of transfusion-transmissible infections (TTIs) is dependent on several layers of safety, including donor recruitment and education efforts so that potential donors who are not likely to qualify for donation self-defer, the Donor Health Questionnaire (DHQ) intended to exclude high-risk donors, and rigorous laboratory testing of all donations.[1,2] Residual risk of HIV transfusion transmission in the US has dropped significantly since the implementation of 3rd generation serological assays and nucleic acid testing (NAT).[2,3] However, the blood donor population is not static and donor behavior could be influenced by a number of societal factors. For example, the increase in the availability of medicines for HIV treatment and prevention[4] could alter who seeks to donate. More directly, changes in donor eligibility can impact blood safety if individuals at higher risk for TTIs enter the donor pool.

The Transfusion-Transmissible Infections Monitoring System (TTIMS) was established in 2015 to monitor trends in prevalence, incidence, and associated risk factors for HIV, HBV and HCV infection in the US blood supply.[5] One objective of TTIMS is to monitor ‘recent’ HIV infections among blood donors as this could be a signal of risk to the blood supply. Several biomarker assays have been developed to distinguish long-standing (prevalent) from recently acquired (incident) HIV infection[6-8] and can be used to study trends and correlates of recently acquired infections in the entire blood donor population.TTIMS consolidates data and biospecimens from four blood collection organizations (BCOs): the American Red Cross (ARC), Vitalant (VTL), OneBlood, and the New York Blood Center, which together collect about 60% of the US blood supply. The four BCOs represented in TTIMS collect blood donations from nearly all of the forty-eight contiguous states and the District of Columbia.

In 2015, the US Food and Drug Administration (FDA) issued revised guidance that recommended deferring men who have sex with men (MSM) for 12 months from last male sex, instead of indefinite deferral following MSM sex at any time since 1977.[9] The BCOs participating in TTIMS all implemented a 12-month MSM deferral policy between August and December 2016.

Here we report a descriptive epidemiologic analysis of recently acquired HIV infection over an extended time period, including five years before the start of TTIMS, among donors whose donations tested HIV NAT and serology reactive. As a secondary objective, we examine percentages of recently acquired HIV infection before and after the change to the 12-month donor deferral for MSM.

Materials and Methods

The eligible study sample included available donations identified as HIV NAT and serology reactive ('HIV concordant positive') through routine BCO screening and confirmatory procedures. Samples collected from 2010 to August 2015 represent a convenience sample of HIV-1 concordant positive samples held in repositories at the blood screening laboratories or BCOs (Creative Testing Solutions, Inc. or the ARC) stemming from operational procedures before the initiation of TTIMS. Samples collected after September 2015 were actively accrued into the TTIMS biospecimen repository.

Routine HIV Testing

As part of routine screening, all donations were tested in parallel using FDA-licensed NAT for HIV RNA in a minipool format of 16 donations and individual sample serology for antibodies. Additional confirmation testing was conducted using alternate methods/reagents. Concordant positive samples were included in this study.

Limiting Antigen Avidity Testing

The Sedia HIV-1 Limiting Antigen (LAg)-Avidity EIA (Sedia Biosciences®, Portland, OR), a research use only assay, was used to classify HIV confirmed positive samples as having recently acquired or long-standing infection.[10]Batched LAg testing was conducted on previously frozen coded individual plasma samples following thawing and centrifugation in the same laboratory at Vitalant Research Institute (VRI). Samples were analyzed and classified according to manufacturer's instructions. Briefly, following the completion of the testing procedures the optical density (OD) is read and then normalized to an internal calibrator to produce a normalized OD or ODn. Higher ODn values, indicative of higher avidity antibodies, are associated with long-standing infections. Initial ODn results ≤2.0 were retested in triplicate and the median value of these replicate tests was considered the final result. The mean duration of recent infection (MDRI) – i.e., the average time post-infection that HIV-1-infected individuals appear recent – based on an ODn cutoff of 1.5 on the Sedia LAg assay is reported as 130 days (95% CI 118 – 142 days).[11] Very recently acquired HIV infections based on testing HIV NAT only reactive were not included in this analysis because they are nonreactive on the LAg Avidity assay.

Viral Load Measurements

For all samples with sufficient residual volume for testing viral loads were measured using the Hologic® (San Diego, CA) Aptima HIV-1 Quant Assay. The assay provides a direct measurement of viral RNA concentration by transcription-mediated amplification (TMA). The lower and upper limits of quantitation (LLOQ and ULOQ) of the assay are 30 and 10 million HIV RNA copies/mL and the 95% lower limit of detection (LOD) is 12 HIV RNA copies/mL.[12]

Demographic Data

Donor age, sex, race/ethnicity, zip code of residence, and first-time or repeat status were provided by each BCO. Age groups were defined as: 16-17, 18-24, 25-39, 40-54, and 55+ years. To assess possible geographic differences, donors were grouped into four US

Census regions[13] based on zip code of residence. Race categories were also defined based on the 2010 US census categories in which ethnicity is reported separately from race.[14] Donors who identified as Hispanic were categorized into an ethnicity category and data were supplemented with additional information from the BCOs, where available.

Statistical Analyses

The percentage of HIV confirmed positive donation samples that were classified as recently acquired ('percentage recent') HIV were estimated by year, demographic and geographic groups. For univariate analyses, Clopper-Pearson exact 95% confidence intervals (95% CI) are reported for percentages and a Pearson's Chi-squared test was used to assess evidence of difference in the percentage recent by these categorical variables. To assess the difference between the mean viral load in infections classified as recent or long-standing, an unpaired parametric Welch t-test was used. A multivariable model to assess factors associated with recently acquired HIV was estimated using logistic regression. For all statistical tests, p-values ≤ 0.05 or 95% CIs that excluded 1.0 were considered significant. To assess the relationship between Abbott PRISM HIV O Plus signal-to-cutoff ratios (S/CO) and LAg ODn values, we fit a polynomial regression model. Analyses were performed in R version 3.6.1.[15] Figures were generated using GraphPad Prism v7.03 for Windows (GraphPad Software, La Jolla California) and the ggplot2 R package.[16]

Assessing Impact of Recency Definition

We conducted sensitivity analyses to assess the impact of alternate definitions of recency. One definition included a minimum viral load threshold, which although unlikely in the donor population is useful for populations with highly prevalent use of antiretroviral treatment (ART) since ART tends to disrupt HIV antibody markers of recent infection. ART reduces the viral load and consequently HIV antigenic stimulation[17] which leads to waning of the avidity of HIV antibodies over time.[18] By including both the ODn value (≤ 1.5) and viral load (≥ 1000 copies/mL) in a recency definition,[19] the rate of misclassification resulting from possible ART use and natural viral suppression ('elite control') can be reduced. A second definition used an ODn threshold of 2.0, which increases the number of infections defined as recently acquired.[20]

Human Subjects Protections

Each BCO and the FDA obtained institutional review board approval for this research. Donors at each BCO provided consent for donation that included allowing possible use of their demographic/testing information and samples for further research related to blood safety.

Results

The number of HIV concordant-positive samples available for the study was 1154. Of these, 674 were collected before the start of TTIMS and 480 were collected from September 2015 to December 2018. Most samples were from males (n=941, 81.5%) and first-time donors (n=770, 66.8%). Additionally, more HIV concordant-positive donations came from the Southern US (n=647, 56.1%) than the other three regions (Table 1).

The overall percentage recent among HIV concordant positive donors was 27.5% (95% CI 24.9 – 30.1%), without a significant change year over year, including in the time period following the implementation of the 12-month MSM deferral criteria. The percentage recent ranged from a high of 32.7% in 2014 to a low of 22.5% in 2018. Among only male donors, the overall percentage recent was 29.0% and ranged from 23.6 – 34.1% and there was no evidence of significant change year over year (Figure 1). Recent infections were associated with higher viral loads, and ODn values correlated with the PRISM S:CO values, R^2 = 0.548, (Supplement Figures 1A-B).

There were significant differences in the percentage recent between demographic groups. As expected, HIV concordant-positive donations from repeat donors, who by definition have become HIV-positive since their previous HIV-negative donations, were more likely to have recently acquired HIV infection compared to first-time donors, at 38.9% and 21.8%, respectively ($p < 0.001$).

In univariate analyses males were more likely than females to have recently acquired infection ($p=0.014$). Recent infection also varied by age group ($p < 0.001$) with the two youngest groups, aged 16-17 years and 18-24 years having the largest percentage recent, at 36.4% and 40.8%, respectively. Race was not associated with recent infection status. There was no association between US census region and recent HIV infection (Table 1). The multivariable model of factors associated with recent infection identified two significant donor characteristics. The adjusted odds of recent HIV infection were over 2.7 times higher in younger aged donors grouped into 16-17 and 18-24 years compared to donors 55 years of age or older. The adjusted odds of recent infection were 2.2 times higher in repeat compared to first-time donors. There was a borderline significant, 0.57 times, lower odds of recent infection in donors from the west census region compared to south, and also borderline significant, 0.64 lower odds, of recent infection in those with missing ethnicity compared to non-Hispanic donors. No other factors were significantly associated with recently acquired infection in the multivariable model, including male sex.

When the percentage recent is stratified by sex, age, and donation history, similar patterns are evident (Figure 2). The percentage recent in donations among those aged 16-17 years was generally the highest (female/first-time: 25.0%, female/repeat: 50.0%, male/first-time: 32.3% and male/repeat: 66.7%) and remained high among donors aged 18-24 years (female/first-time: 23.1%, female/repeat: 50.0%, male/first-time: 37.0% and male/repeat: 48.5%). For all four sub-groups, the percentage recent was lower in donors aged 25-39 years (female/first-time: 9.3%, female/repeat: 27.3%, male/first-time: 16.3% and male/repeat: 35.3%) and a similar pattern was present for donors aged 40-55 years. A possible exception to this general pattern of recent infection in donations from younger donors was observed in donations from female first-time donors aged 55 years or older, whose donations had the highest percentage recent infection among all donations from female first-time donors (30%), however this finding was not significant (p-value=0.087).

Percentages of recently acquired infection in repeat donors decreased according to increasing interdonation interval. Of the 384 repeat donors, those with shorter interdonation intervals (IDI) had the highest percentage of recent infections (Table 2). Of those who had

previously donated less than 4 months before their HIV-positive donation, 88.2% had a recent infection and of those who donated between 4 and 7 months since their last donation 68.1% had a recent infection, whereas for those who last donated more than 16 months ago, 22.0% had a recent infection.

In a sensitivity analyses, the impact of alternate recency definitions was assessed and minimal differences were found. There was a small number of donations where viral loads were <1000 copies/mL or where LAg ODn values fell between 1.5 and 2.0 (Supplement Figure 1B) that were reclassified. Reclassification of results based on these alternate definitions had no impact on the recent infection patterns or statistical findings in our analyses.

Discussion

We assessed donations from donors with HIV concordant-positive donation test results to identify their characteristics and found that over 25% showed evidence of having acquired HIV in the recent period before donation (on average within ~4 months). Repeat and younger donors were more likely to have recent HIV infection. The primary explanation for why a higher percentage of donations from repeat donors are recently acquired infections compared to first-time donors is because repeat donors could only have become infected in the period since their last donation, while first-time donors could have acquired HIV at any time before their first donation.

We found no evidence of a change in the percentage recent infection over the 9-year period studied. Importantly, no change could be discerned in first-time donors or in repeat donors over the study period, which includes the 12-month MSM donor deferral policy change implemented in late 2016. In addition, no change was observed in recent infections from donations from male donors year over year, or in those from first-time male donors year over year (data not shown), the sub-groups where a direct impact of the change in the MSM donor deferral policy would be expected. There is no evidence in these data that the change to a 12-month deferral policy for MSM led to an increase in donors with recent HIV infection. In separate publications, the TTIMS program has reported HIV incidence rates in first-time donors[21] and in repeat donors (Steele et al. Transfusion – Submitted) comparing indefinite and 12-month MSM deferral policy periods.

The known epidemiology of HIV infection in the US predicts that younger males are most likely to acquire infection. These patterns would be expected to be mirrored to some degree in first-time donors, but at a lower level given donor selection procedures. The pattern of younger male and female repeat donors having high percentages of recently acquired HIV is of greater concern. In this analysis we have not included assessment of risk behaviors in donors with recent HIV infection. The assessment of risk behaviors as part of TTIMS coupled with HIV recency testing results will be conducted to evaluate possible explanations for the high percentages of recently acquired infection in younger repeat donors. Answering this question hinges on gaining a deeper understanding of the timing of behaviors in this subgroup. It is possible that blood donation as a behavior started before these donors participated in risk behaviors for HIV acquisition. This could occur if

these donors first donated at high school blood drives and subsequently became sexually active. If this speculation can be demonstrated with evidence in future analyses, the finding would suggest the need to develop more effective messages for repeat donors that emphasize blood centers understand risk behaviors change over time. Overcoming self-perceptions that include defining oneself as an established blood donor may make it difficult to convince these repeat donors to disclose behaviors that would make them ineligible for donation after they have already started a donation career. The planned assessment of risk behaviors relative to the time of donation will provide insights into this important question.

Donors interested in obtaining the results of testing for HIV or other infectious diseases by donating blood, this motive is referred to as "test-seeking"[22] where the concern is an increase in the likelihood of nondisclosure of risk. There are few formal studies of testing-seeking[23-27] and no data on this topic from recent studies in the US. Our study provides some insights into the potential for test-seeking in HIV-positive repeat donors in the US. The relationship between IDI and percentage recent in repeat donors in this analysis shows recent infection to be more common in persons with shorter IDIs. These data do not support notions of ‘test seeking’ linked to HIV risk behavior events because the longer the IDI the lower the percentage recent. If donating in these repeat donors was for the purpose of test seeking triggered by specific risk events or behaviors one would expect the percentage recent to be more similar across all IDI groups.

There are two limitations in our study. First, this analysis focused on HIV concordant-positive donations, and some of our results may have changed if we had included HIV NAT-yield (i.e., donations from HIV NAT-reactive donors who have not yet seroconverted) in our definition of recent infection. While NAT-yield donations are important for monitoring transfusion-transmission risk, they are rare[26] limiting their utility to monitor broader epidemiologic trends. Because of small numbers, the exclusion of HIV NAT-yield donations is unlikely to have impacted our results.

The most important limitation to this study is that we were unable to include all HIV concordant-positive donations interdicted by routine screening before and during TTIMS. From the TTIMS period, 85.4% (480/562) of qualifying donations were successfully tested using the LAg avidity assay. From the period before TTIMS, only previously archived HIV concordant-positive donations were available and the total number of HIV concordant-positive donations from the TTIMS participating BCOs during the period 2010 – August 2015 was not available. While demographic characteristics may change over time due to the collection practices of the BCOs or by changes in the donor base, we believe sample availability was likely random and hence unlikely to vary by percentage recent status. Accordingly, results are expected to be impacted non-differentially by sample availability, making the findings potentially less precise but unbiased.

The results presented here are unique for US donors because our analyses assess patterns of HIV recency over a 9-year period. Patterns and trends in recent infection, as identified by LAg avidity assays, can be used to monitor changes in new HIV infections in donors as well as their demographic and geographic correlates. This approach and the recently acquired HIV infections reported here establishes a baseline for comparing further changes in donor

eligibility policy. The SARS-CoV-2/COVID-19 pandemic has impacted blood donations significantly due to cancellations of mobile blood drives. Thus, the characteristics of donors may be changing. Furthermore, the FDA revised several donor deferral recommendations on April 2, 2020, including reducing the deferral period to 3-months since last sex for MSM, for females who have had sex with MSM, those with recent tattoos and piercings, and for travelers to and residents of malaria-endemic areas[28] could influence patterns of recent infection in donors. The use of biomarkers of recent HIV infection may be able to provide an early indication of changes in the donor pool if the percentage of recently acquired HIV infection shifts.

In summary, recently acquired HIV infections in donations from US blood donors are more common among repeat and younger donors. The overall percentage recent HIV infection has remained stable over the period 2010 - 2018. The same monitoring approach used here can be used in the future to assess whether demographic changes to the donor pool, policy changes (such as the new reduction in the MSM deferral period), or any unforeseen risks (such as increasing identification of donors with undisclosed HIV infections) are influencing patterns of incident infection among US blood donors.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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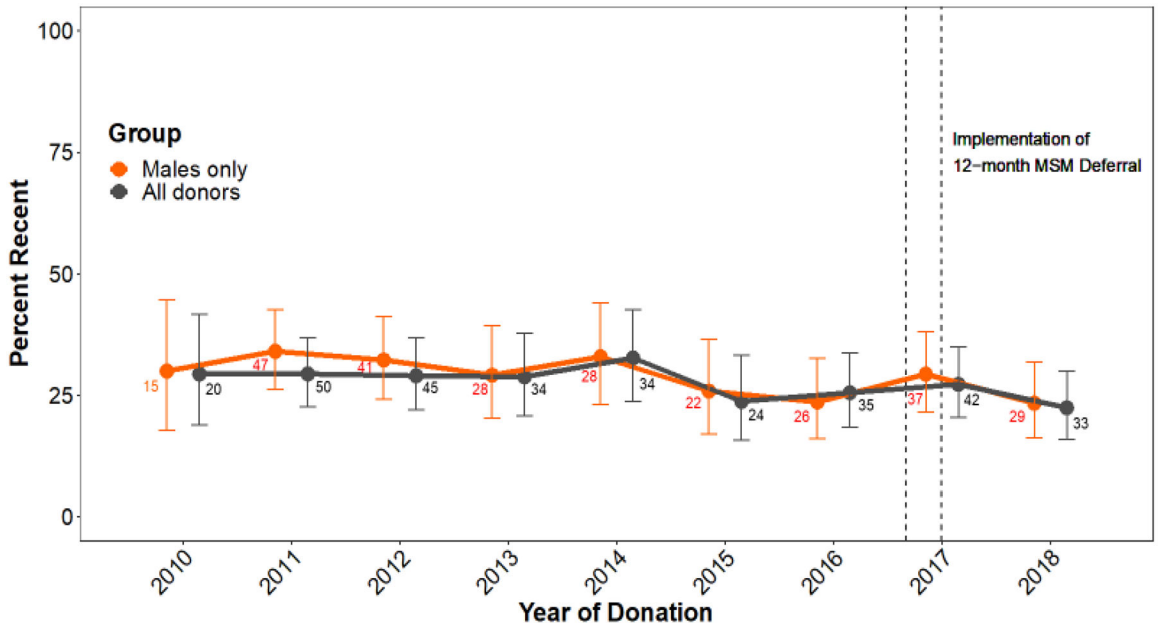

Figure 1.

Percentage of HIV concordant-positive donors with recently acquired HIV infections Error bars represent the 95% confidence interval for the percentage recent. The numbers next to each point indicate the number of samples that tested as recently acquired HIV in the corresponding group and year. The vertical lines indicate the range of MSM policy change implementation dates in late 2016 for the four participating blood collection organizations.

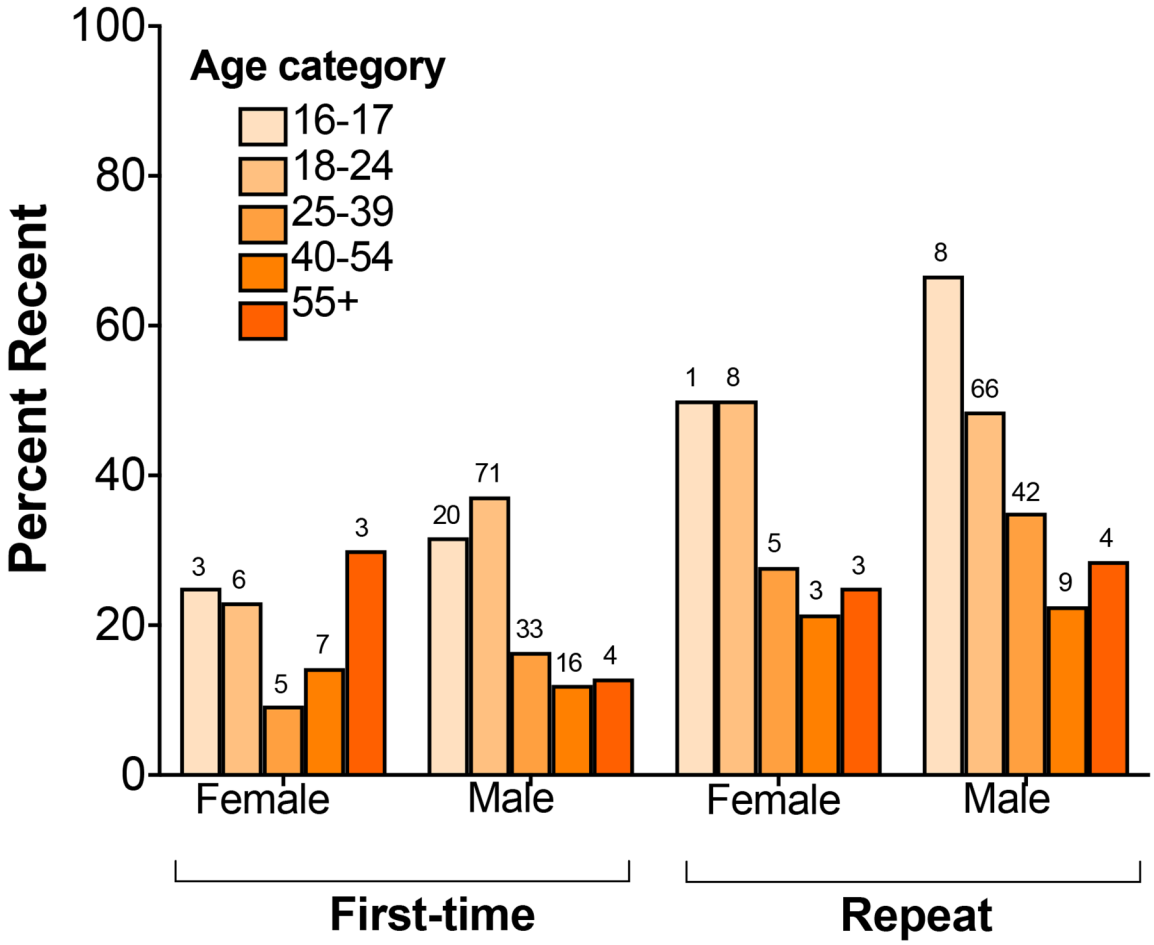

Figure 2.

The percentage of HIV concordant-positive donors with recently acquired infections by first-time/repeat status, sex and age group. The numbers above each bar indicate the number of samples that tested as recently acquired HIV in the corresponding group.

Table 1

Characteristics of donors with concordant-positive HIV infection, percentage of those infections that are recently acquired based on limiting antigen avidity testing, and multivariable model of factors associated with recently acquired HIV in these donors in the US from 2010-2018.

Donor Characteristic	Total N=1154	Recent n (%) n=317	p-value	Adjusted Odds of Recently Acquired Infection**	
Donation History				**Odds Ratio**	**95% CI**
Repeat	384	149 (38.8)	< 0.001	2.21	1.65 – 2.94
First-time	770	168 (21.8)		Reference	
Sex					
Male	941	273 (29.0)	0.014	1.26	0.87 – 1.87
Female	213	44 (20.7)		Reference	
Age Group					
16-17	89	32 (36.0)	< 0.001	2.80	1.30 – 6.22
18-24	369	151 (40.9)		2.71	1.44 – 5.41
25-39	393	85 (21.6)		1.15	0.60 – 2.30
40-54	236	35 (14.8)		0.81	0.40 – 1.70
55+	67	14 (20.9)		Reference	
Race					
White/Caucasian	317	89 (28.1)	0.87	Reference	
Black/African American	444	125 (28.1)		0.93	0.65 – 1.33
Asian	19	5 (26.3)		0.82	0.25 – 2.39
American Indian or Alaska Native	5	1 (20.0)		0.59	0.03 – 4.54
Other	27	7 (25.9)		1.21	0.42 – 3.21
Multiple	22	3 (13.6)		0.37	0.08 – 1.21
Unknown/Missing	320	87 (27.2)		1.22	0.77 – 1.94
Ethnicity*					
Hispanic	179	48 (26.8)	0.023	0.57	0.32 – 1.03
Not Hispanic	248	85 (34.3)		Reference	
Unknown/Missing	727	184 (25.3)		0.64	0.45 – 0.92
Region of the Country					
Midwest	141	47 (33.3)	0.30	Reference	
Northeast	180	51 (28.3)		0.88	0.53 – 1.47
South	647	177 (27.4)		0.79	0.52 – 1.20
West	158	35 (22.2)		0.57	0.32 – 0.99
Unknown or US Territories	28	7 (25.0)		0.74	0.25 – 1.98

*Ethnicity was not available in our datasets for all TTIMS blood centers for the entire period. For Vitalant the percentage recent was not significantly different for Hispanic (11/46, 23.9%) and non-Hispanic 31/90, 34.4%) donors, p=0.289.

**Multivariable model adjusts for all listed variables.

Table 2

Percentage recent infection in US repeat blood donors grouped by interdonation interval (time since last donation) in days and months from HIV NAT concordant positive donations during the period 2010 – 2018.

Interdonation Interval (days)	Interdonation Interval (~months)	Total n=384	Recent n (%)
0 to 120	up to 4	34	30 (88.2)
121 to 210	4 to 7	47	32 (68.1)
211 to 300	7 to 10	28	16 (57.1)
301 to 390	10 to 13	41	16 (39.0)
391 to 480	13 to 16	16	7 (43.8)
≥481	>16	218	48 (22.0)