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BLOOD DONORS & BLOOD COLLECTION

TRANSFUSION

Modeling US blood donor deferrals under a policy of individual risk assessment for HIV risk sexual behavior

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Abstract

Background: In May 2023, the Food and Drug Administration (FDA) released final guidance for blood donor eligibility that recommended the elimination of 3-month deferral for men who have sex with men (MSM) and the related deferral for women who have sex with MSM. In its place, FDA introduced an individual risk assessment policy of asking all presenting blood donors, regardless of sex or gender, if they have had a new partner or more than one sexual partner in the last 3 months and deferring those who also report anal sex (penile–anal intercourse) during this period. We modeled the possible impact of this policy on the US blood donor base.

Study Design and Methods: We developed a computational model to estimate the percentage of blood donors who would be deferred under a policy of individual HIV risk assessment.

The model incorporated demographic information about donors and national survey data on HIV risk behaviors and included age and sex distributions and dependencies.

Results: Our model estimates that approximately 1.2% of US blood donors would be deferred under the individual HIV risk assessment paradigm.

Discussion: The model predicts a relatively minor effect of replacing the time-based deferral for MSM with individual risk-based deferral for sexual behavior.

Abbreviations: ADVANCE, assessing donor variability and new concepts in eligibility; AIDS, acquired immunodeficiency syndrome; CI, confidence interval; FAIR, for the assessment of individualised risk; FDA, Food and Drug Administration; HIV, human immunodeficiency virus; MSM, men who have sex with men; NHANES, national health and nutrition examination survey; NICHD, national institute of child health and human development; NSSHB, national survey of sexual health and behavior; PEP, post-exposureprophylaxis; PERT, programevaluation and review technique; PrEP, pre-exposureprophylaxis; SP, source plasma; TTIMS, transfusion-transmissible infections monitoring system; vCJD, variant creutzfeldt-Jakob disease.

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As US blood centers implement this new policy, the effect may be mitigated by donor gains, which warrant further study. The new policy is unlikely to adversely affect the availability of blood and blood components.

KEYWORDS

anal sex, blood donor deferral, blood donor loss, HIV risk assessment, modeling, MSM deferral, sexual partner, transfusion

1 | INTRODUCTION

The emergence of AIDS in the early 1980s necessitated changes in US blood donation policies.[1] More than 12,000 people alive in the United States in 1987 were estimated to have acquired a transfusion-associated HIV infection between 1978 and 1984.[2] Although the extent of the risk was unknown in the early 1980s, the Food and Drug Administration (FDA) and others responsible for US blood safety introduced policies to reduce the risk of HIV transmission by blood and blood products.

The first donor deferral policy was established in 1983, which, based on the limited knowledge and testing technology available at that time, was the only way to reduce the risk of transmitting AIDS through blood transfusion.[3] Men who have sex with men (MSM) were identified as having the highest risk for infection. Sexual exposure risk for HIV for both men and women was particularly associated with receptive penile–anal intercourse.[4] Throughout this article, penile–anal intercourse and penile–anal sex are referred to as anal sex.

In March 1983, the FDA recommended that educational programs be instituted at blood establishments so that those individuals and groups considered to be at high risk for AIDS refrain from donating until testing could be implemented. The educational materials and deferral policies focused on possible sexual risk exposure in MSM and others disproportionately affected by AIDS, including people who exchanged sex for money or drugs and people who used intravenous drugs.[5–7] Beginning in 1985, the FDA recommended that blood establishments indefinitely defer male donors who have had sex with another man, even once, since 1977.[8] This indefinite deferral for MSM was recommended until 2015.

Although considered to be discriminatory by some, indefinite deferral of MSM reduced the risk of HIV transmission by blood and blood products and saved a significant number of lives, particularly during the 1980s when HIV screening and diagnostic tests had not yet been developed. With the implementation of policies to defer MSM, the estimated risk of receiving an HIV-infected blood product fell from 1.1% in 1982 to 0.2% in 1984.[9] Upon implementation of the first HIV antibody donor screening assays in 1985, the estimated risk of receiving HIV-infected blood fell to 0.0025% and then further to approximately 1 in 1.6 million donations following the adoption of highly sensitive HIV antibody assays and nucleic acid tests (NATs).[10,11]

In response to the improved HIV testing, advances in HIV epidemiology, and results from international experience, the FDA recommended a change from indefinite deferral to a 1-year deferral policy for MSM in 2015.[12] At that time, the FDA committed to monitoring the safety of the blood supply using the Transfusion-Transmissible Infections Monitoring System (TTIMS).[13,14] Data from TTIMS showed no difference in the overall incidence of HIV among blood donors following the 2015 policy change.[11] Based on these data and other factors, in April 2020, the FDA further shortened the deferral period for MSM to 3 months.[8] Recent analyses using data from TTIMS reported no difference in the overall incidence of HIV among blood donors following the 2020 policy change.[15]

While this marked a shift in policy, the approach still focused on a blanket, time-based deferral of MSM based on sexual behavior risk factors for HIV. Whether or not MSM could safely contribute to the blood supply was the subject of several ongoing studies including *For the Assessment of Individualised Risk* (FAIR) in the United Kingdom,[16,17] *#iCruise* in Canada,[18–20] and *Assessing **D**onor **V**ariability **A**nd **N**ew **C**oncepts in **E**ligibility* (ADVANCE) in the United States.[14]

The United Kingdom and Canada implemented revised blood donor deferral policies based on individual risk in 2021 and 2022, respectively.[21,22] In 2023, based on the experiences of individual risk assessment from other countries, data from TTIMS, preliminary findings from the ADVANCE study, and the sensitivity of HIV NAT for donor screening, the FDA recommended eliminating the screening questions specific to MSM and women who have sex with MSM. In final guidance issued in May 2023, the FDA recommended replacing time-based deferrals for MSM with an individual risk-based assessment for all donors, regardless of sex or gender.[23] Under the individual risk assessment approach, all donors who report having a new sexual partner or more than one

sexual partner in the past 3 months would be asked about a history of anal sex in the past 3 months; donors who answer both questions affirmatively are deferred from donation for a minimum of 3 months. The final guidance also recommended deferral of individuals taking medications to treat or prevent HIV infection (e.g., antiretroviral therapy, pre-exposure prophylaxis [PrEP], and post-exposure prophylaxis [PEP]). The recommendations contained in the guidance apply to the collection of blood and blood components, including source plasma (SP).

Herein, we describe the development of a computational model to estimate the impact on US blood donor deferrals of the change in policy from a 3-month deferral specific to MSM, to an individual risk assessment applicable to all donors, regardless of sex, gender, or sexual orientation.

2 | STUDY DESIGN AND METHODS

We conducted two independent analyses. The first analysis included blood donor deferral modeling, which incorporated the published information available about donors and sexual behaviors. The second analysis used the 2022 U.S. National Survey of Sexual Health and Behavior (NSSHB) data that were designed to address the specific sexual behavior questions among participants with a history of blood donation. The flow of our analyses

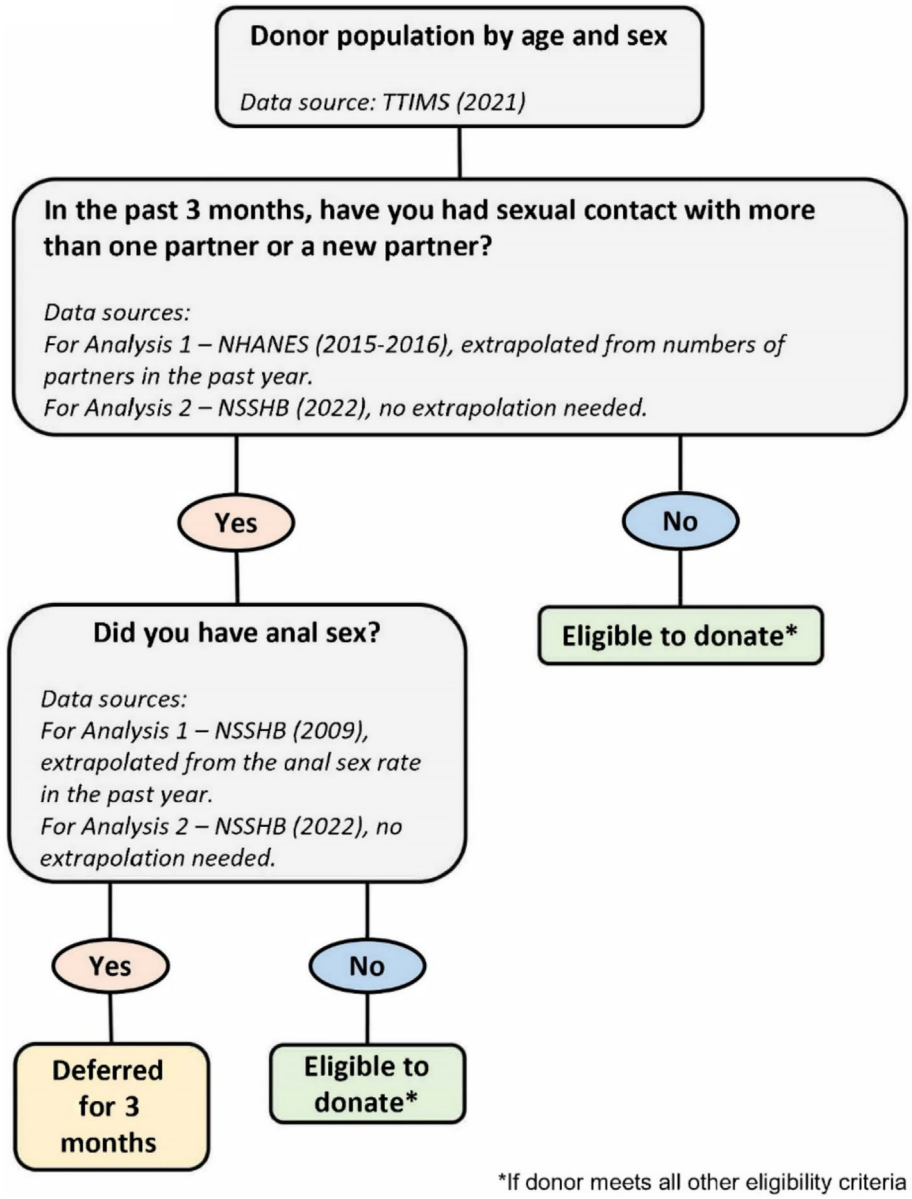

FIGURE 1 Donor Individual Risk Algorithm and Key Data Sources. TTIMS, Transfusion-Transmissible Infections Monitoring System; NHANES, National Health and Nutrition Examination Survey; NSSHB, National Survey of Sexual Health and Behavior.

is described in Figure 1. The data sources, data treatment, and computational approaches are explained below.

2.1 | Analysis 1

Because HIV risk behaviors vary by age and sex, we obtained 2021 blood donor data by age and sex from the TTIMS program (Ed Notari, personal communication, 2022), a representative 60% sample of the US blood supply (Figure 2).[24] This dataset was used to model the age and sex distributions of blood donors for both Analyses 1 and 2.

In our model, a blood donor had to have reported both sexual partner(s) risk and anal sex in the past 3 months to be considered deferred. Our team and an FDA staff librarian performed a literature search on US sexual behaviors and an internet query for organizations with relevant information or survey data. The literature searches and discussions with experts identified over 50 articles and three national surveys on sexual behavior in the United States which we reviewed for relevance and inclusion in the computational model. However, none of these studies provided precise data for the behaviors of concern for the 3-month timeframe, precluding them from being used directly to quantify risk.

Given this data gap, and assuming an independent relationship between the risk factors, and extrapolations for the timeframe of interest, we developed an initial computational model to extrapolate and incorporate independent information about donor and sexual behaviors, from different sources, including their age and sex distributions and dependencies. We processed the published information into distribution forms, when possible, to include the uncertainty for each input.

The National Health and Nutrition Examination Survey (NHANES)[25] captures data for sexual behavior in the US population, including new sexual partners (defined as "persons that one never had sex with before") and numbers of partners. However, the survey reports behavior from the past year as opposed to the last 3 months. To estimate the 3-month risk, we assumed the 12-month risk derived from NHANES was evenly distributed over the year, (e.g., an individual has had multiple partners in the past 3 months if this individual had four or more partners in the past year). For an individual with fewer than four partners but having new partner(s) in the past year, we assumed a 25% chance of having had a new partner in the past 3 months. Applying this algorithm to the 2015–2016 NHANES survey data, we extrapolated the chance of having new or multiple partners in the past 3 months for men and women aged 18–59 years old (unweighted sample sizes are 1655 and 1764, respectively).

As the TTIMS donor data (Figure 2) and data on anal sex from NSSHB 2009 have a wider age range than the NHANES survey data, we made additional assumptions to account for the donor age groups 16–17 years and "ages 60 and above" that were not surveyed by NHANES (Figure 3). To be conservative, we assumed the chance of having new or multiple partners for ages 16–17 the same as for 18- to 19-year-olds. Similarly, we assigned those over 60 years the same frequencies as the 50- to 59-year-olds.

Frequency of anal sex was estimated using the summarized results from the 2009 NSSHB.[26] While there were multiple, similar surveys over the years, this study provided an adequate sample size, age range and

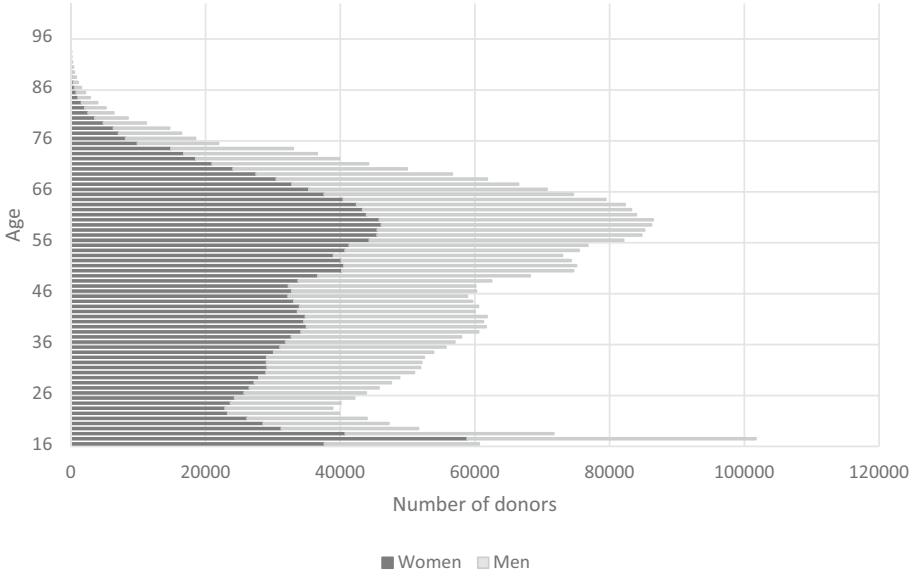

FIGURE 2 Numbers of donors by age and sex from the TTIMS program, which represents approximately 60% of the blood supply. TTIMS, Transfusion-Transmissible Infections Monitoring System.

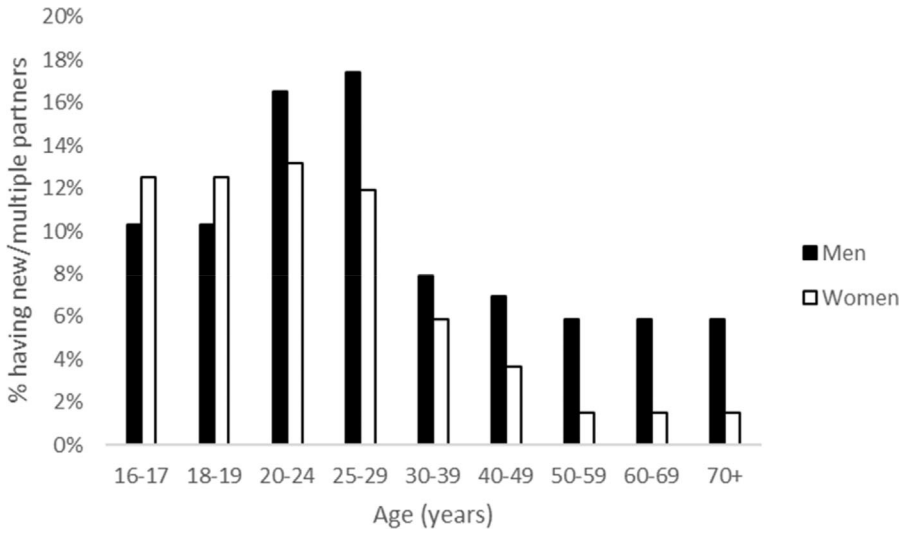

FIGURE 3 Mean Proportion of Having New or Multiple Sexual Partners for Men and Women in the United States by Age, Based on NHANES (2015–2016).

distribution, and known confidence intervals (CIs) for each value. Recent (past month, year) and lifetime prevalence of sexual behaviors were reported in a nationally representative probability sample of 5865 individuals aged 14–94. The data were reported for men and women by the following age groups: 14–15, 16–17, 18–19, 20–24, 25–29, 30–39, 40–49, 50–59, 60–69, and 70 years and above. We applied the same age group breakdown for the model except for 14- to 15-year-olds, who are not eligible for blood donation. No data for anal sex for the interval of the past 3 months were available in this study or other prior US national studies. Therefore, we estimated the possible value for the 3-month period based on data for the past year as described above. Both insertive and receptive anal sex were reported for men in this study. To be conservative, the model overestimated future deferrals and used the sum of both insertive and receptive sex for men in the past year, despite an overlap between the groups where a portion of men may already be deferred under the old policy and our model estimates new deferrals. Although the measures were conservative, we did not expect an excessive overestimation because people with multiple partners tend to have a significantly greater proportion of anal sex than those with one partner,[26] and the anal sex rates in NSSHB 2009 data were overall rates for all survey participants.

2.2 | Analysis 2

To address the specific data gap and in collaboration with the Indiana University researchers responsible for the NSSHB, the relevant sexual behavior questions and the timeframe of interest (3 months) were included in the NSSHB study to be conducted in late 2022. NSSHB is an ongoing study of thousands of individuals, supported in 2022 through NICHD (Grant number R01HD102535). Questions about blood donation (current, past, never) were also added to this survey to further identify the targeted donor group. We performed this separate analysis using the 2022 NSSHB data that provided the direct results for the specific sexual behavior questions in the past 3 months among the participants with history of blood donation. The new model estimates were compared to those based on data from the published surveys identified in our literature search.

The NSSHB 2022 study by the Indiana University team incorporated nested questions about the past 3 months of sexual behaviors and blood donation history into the questionnaire. The results of the NSSHB 2022 were compiled in 2023 and used to generate separate model estimates to compare with those based on the previously published data described earlier. Data were weighted to account for any differential non-response using an iterative proportional fitting procedure and benchmarks from the latest Current Population Survey.[27]

2.3 | Statistical software

Monte Carlo simulations and visualizations were performed using @Risk software (version 8, Palisade Corporation) and R programming language (Version 4.2.2. http://www.r-project.org) to incorporate input uncertainties and generate statistical distributions of risk outcomes.

3 | RESULTS

3.1 | Model inputs

We performed two analyses, the first using the published survey results identified in the literature search and the second using the NSSHB data collected in 2022.

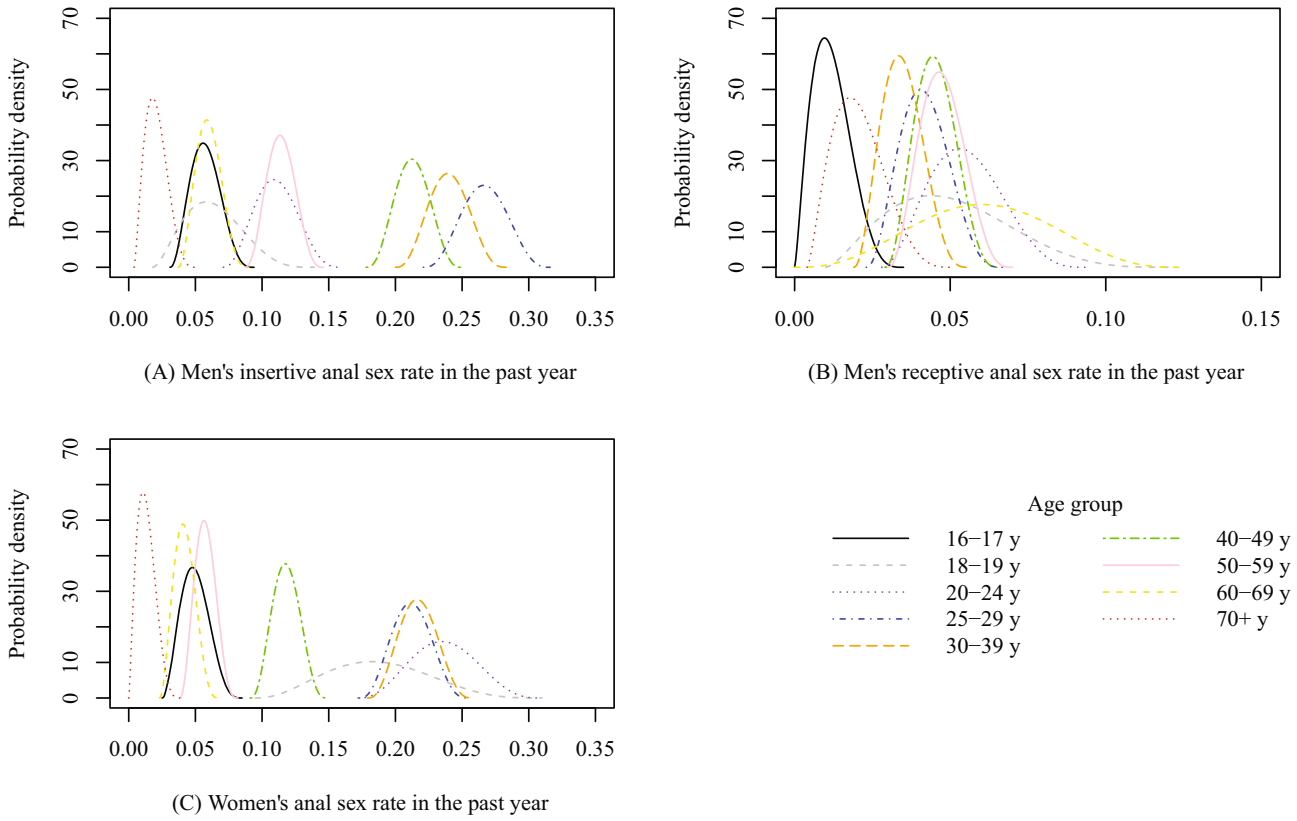

FIGURE 4 Input Distributions for Anal Sex Rates in the Past Year for Men and Women in the United States by Age Based on NSSHB (2009).

TABLE 1 Rates of HIV risk behaviors among participants in the 2022 National Survey of Sexual Health and Behavior (NSSHB) with a history of blood donation, by age group.

	Age group (years)						
Behavior last 3 months	**16–24 (*N* = 133)**	**25–29 (*N* = 226)**	**30–39 (*N* = 623)**	**40–49 (*N* = 711)**	**50–59 (*N* = 872)**	**60–69 (*N* = 1024)**	**70+ (*N* = 939)**
2+ sex partners	7.9%	6.4%	6.6%	7.3%	2.8%	2.5%	0.8%
• Of those with 2+ partners, proportion who had anal sex	3.7%	32.5%	29.3%	37.5%	18.1%	12.3%	6.4%
1 new sexual partner[a]	2.3%	2.8%	2.9%	1.5%	1.0%	0.5%	0.7%
• Of those with 1 new partner, proportion who had anal sex	0.0%	8.6%	27.4%	0.0%	1.5%	31.4%	14.2%

Note: Data from men and women were combined for each age group. Data were weighted to account for any differential non-response using an iterative proportional fitting procedure and demographic benchmarks from the latest current population survey. Rates are presented as weighted percentages; NSSHB, National Survey of Sexual Health and Behavior.

[a]A new partner refers to a person that one never had sex with before.

For the first analysis, with the assumptions and extrapolations described in the Methods, we were able to estimate the mean proportions of having new or multiple partners for men and/or women by age groups based on NHANES data (Figure 3). With the mean proportions and sample size for each age group, we then used a binomial distribution to incorporate the mean estimate and its uncertainty into the model simulation. For the anal sex variable in the model, we converted the data from the 2009 NSSHB study into model input distributions by fitting them with a PERT distribution, a modified version of the Beta distribution defined by three parameters, to demonstrate rates in the past year for men and women (Figure 4).

For the second analysis, unpublished survey results of NSSHB 2022 based on 4528 individuals with a self-

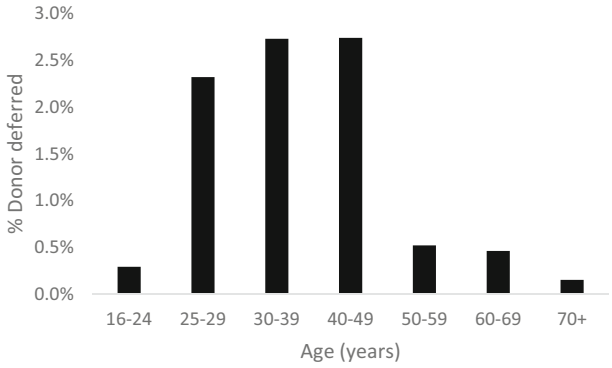

FIGURE 5 Estimated Mean Percent Donor Deferred Based on NSSHB (2022). The mean proportion of donors that would be deferred for each age group was estimated. NSSHB, National Survey of Sexual Health and Behavior.

reported history of blood donation were examined and proper grouping and stratification were determined. Due to smaller sample sizes in younger age groups, we combined data of men and women and some age groups (Table 1). The mean proportion of donors that would be deferred for each age group was estimated and is shown in Figure 5.

3.2 | Model estimates

Probabilistic models incorporating the TTIMS blood donor data and the input distributions of sexual behaviors (as mentioned above) were developed to estimate the percent donor deferral and its uncertainties under the individual HIV sexual risk behavior donor deferral policy. Both analyses, either based on published data or the new NSSHB 2022 data, generated the same mean value of 1.2% for the overall percentage of US donors who would be deferred, with slightly different but overlapping CIs (Table 2 and Figure 6).

Table 2 also shows the model estimates for the overall proportions of sexual behaviors. In addition to the donor deferral, the estimated proportions of new or multiple partners (just above 6%) and anal sex rates (close to 20%) are also highly consistent between the two analyses. These side-by-side comparisons with diverse data sources further verified the assumptions, methods, and robustness of the models. The results may shed light on other sexual behavior risk-related research.

4 | DISCUSSION

We modeled the effect of a new blood donor eligibility policy to address the concern that an increase in donor deferrals could impact the availability of US donor blood

TABLE 2 Estimated mean rates of individual HIV risk behavior and donor deferral (including both sexes), by source of data.

Parameter	Estimated mean percentage (2.5th$^{\%ile}$–97.5th$^{\%ile}$)	
	Analysis 1: TTIMS (2021), NHANES (2015–2016) and NSSHB (2009)	**Analysis 2: TTIMS (2021) and NSSHB (2022)**
New or multiple partners, past 3 months	6.4% (5.8%–7.1%)	6.3% (5.4%–7.2%)
Anal sex, past 3 months	18.1% (16.8%–19.4%)	19.9% (15.3%–25.0%)
Donor deferral	1.2% (1.0%–1.3%)	1.2% (0.9%–1.6%)

Abbreviations: NHANES, National Health and Nutrition Examination Survey; NSSHB, National Survey of Sexual Health and Behavior; TTIMS, Transfusion-Transmissible Infections Monitoring System.

for transfusion. Our estimate of a 1.2% increase in donor deferrals due to individual HIV risk assessment is unlikely to result in blood shortages. This estimate is slightly higher than the Canadian Blood Service's estimate of 0.7% of donors, which would be deferred using the same behavior-based screening questions.[21] The difference may be attributable to a lower reported rate of anal sex during the past 3 months among Canadian donors (10%) than US donors (18.1% and 19.9% for Analyses 1 and 2, respectively). However, the finding that 17% of Canadian donors were uncomfortable with questions about anal sex is suggestive of underreporting.[21]

In 2003, a model of the impact of changing the indefinite deferral for MSM to a 12-month deferral period predicted a 1.3% increase in the number of donations in Canada.[28] Although we did not model the potential increase in blood donors as a result of the change to individual HIV risk assessment, it is possible that the predicted increase in donor deferrals may be offset by an increase in eligible donors who perceive the new policy to be more inclusive.

Previous estimates of donor loss due to changes in donor eligibility criteria were shown to be higher than actual deferrals. For example, following the FDA's recommendations in 1999 of travel deferrals to prevent potential transmission of variant Creutzfeldt–Jakob disease, the estimated deferral rate based on a donor survey (3.5%) was higher than the actual deferral rate at the same blood centers (1.6%).[29,30] The FDA eliminated the vCJD deferrals in 2022 because of the available data on the absence of cases in the US and worldwide and the modeling of the potential risk.

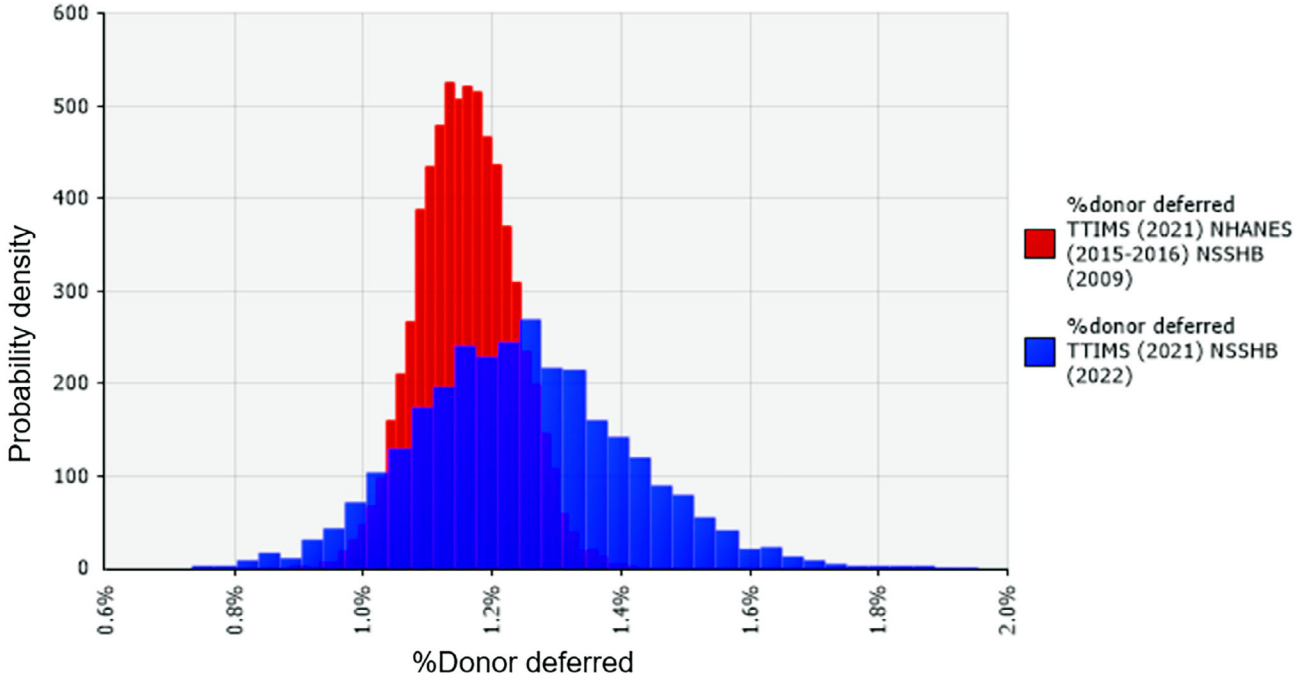

FIGURE 6 Probability Distributions of Donor Deferral Estimates for the US TTIMS blood donor data and the input distributions of sexual behaviors were used to estimate the percent donor deferral and its uncertainties under the individual HIV sexual risk-behavior donor deferral policy. Mean value (1.2%) of deferred donors estimated from using TTIMS (2021), NHANES (2015–2016), and NSSHB (2009) data was the same as that estimated from using the TTIMS (2021) and NSSHB (2022) data. TTIMS, Transfusion-Transmissible Infections Monitoring System; NHANES, National Health and Nutrition Examination Survey; NSSHB, National Survey of Sexual Health and Behavior.

TTIMS closely monitors the incidence and prevalence of relevant transfusion-transmissible infections (i.e., HIV, syphilis, hepatitis B and C) in blood donations and is used to evaluate changes in rates after policy updates. TTIMS will be used to monitor the impact of the individual risk assessment going forward.[13] The FDA's final guidance (May 2023) has revised recommendations for evaluating HIV blood donor risk using individual risk-based questions relevant to HIV risk. It is supported by scientific data, including the epidemiology of HIV infection, the performance of the HIV donor screening tests,[19] the experiences in the United Kingdom and Canada, and the preliminary findings of the ADVANCE Study.[14]

There are limitations to the model. For Analysis 1, the available data did not provide direct statistics for proportions of the US population that have had new or multiple sexual partners and anal sex in the past 3 months. The independent relationship between risk behaviors is a simplified method and can only be verified upon the availability of such data, underscoring the need for ongoing public health surveillance surveys related to sexual behavior. In Analysis 2, we provided such validation by collecting data based on nested questions for querying the past 3 months of sexual behaviors. However, we had to combine data from men and women from all age groups to minimize the impact of smaller sample sizes.

Our blood donor data were based on the most recent data from TTIMS (2021), which incorporated the 3-month MSM deferral (Ed Notari, personal communication, May 2022). To verify whether the demographics used were reproducible and not affected by the ongoing COVID-19 pandemic, we verified our 2021 estimates by comparing with pre-pandemic (2019) data from TTIMS when there was a 12-month MSM deferral policy in place and the donor demographics were similar (personal communication, Ed Notari, May 2022).

We also performed a preliminary analysis of the donor deferral among US SP donors using demographic data from Rosa-Bray et al.[31] instead of data from TTIMS. To convert the slightly different age grouping in the population to our designed grouping, we assumed a uniform distribution of donors in each age group and redivided them. We estimate that approximately 2% of SP donors would potentially be deferred under the individual risk-based deferral policy, consistent with the younger age demographic of these donors. Further analyses with more comprehensive data for SP donors are warranted.

Despite the limitations, this analysis presents an assessment for US donor HIV risk sexual behavior deferral with a change to an individual risk-based deferral policy based on the most relevant US data available. The model estimates a small increase in donor deferrals that are consistent across

analyses using diverse data sources. The FDA will continue to closely monitor the donor blood supply, via TTIMS and other systems, to ensure maintenance of a safe and sustainable supply of donor blood.

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CONFLICT OF INTEREST STATEMENT

The authors have disclosed no conflicts of interest.

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