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TRANSFUSION

ORIGINAL RESEARCH

Blood Donors and Blood Collection

Assessing HIV trends among blood donors in five Brazilian blood centers: The impact of individual donor assessment

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Abstract

Background: In many countries, including Brazil, time-based blood donation deferral policies for gay, bisexual, and other men who have sex with men (gbMSM) have been replaced by individual donor assessment (IDA). We examined HIV prevalence and incidence among first-time (FTD) and repeat donors (RD), comparing data from ~3.5 years before and after the IDA policy implementation in 2020.

Study Design and Methods: The Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IV-P) Brazil component collects blood donor screening data from five public centers. From January 2017 to December 2023, we report frequencies, rates, and 95% confidence interval (CI) of confirmed

Abbreviations: ANVISA, Brazilian Health Regulatory Agency; CI, confidence interval; DHQ, Donor Health Questionnaire; FPS, Fundação Pró-Sangue Hemocentro de São Paulo; FTD, first-time donor; gbMSM, gay, bisexual, and other men who have sex with men; Hemoam, Fundação Hemoam, Manaus, Brazil; Hemominas, Fundação Hemominas, Belo Horizonte, Brazil; Hemope, Fundação Hemope, Recife, Brazil; Hemorio, Fundação Hemorio, Rio de Janeiro, Brazil; HIV, human immunodeficiency virus; IDA, individual donor assessment; IRB, Institutional Review Board; NAT, nucleic acid testing; NHLBI, National Heart, Lung, and Blood Institute; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; PY, person-years; RD, repeat donor; REDS-IV-P, Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric; SOP, standard operating procedure; STF, Brazilian Federal Supreme Court; UCSF, University of California, San Francisco.

HIV-positive donations among FTD, HIV NAT-yield rates for FTD and RD, and the incidence of confirmed HIV among RD before and after the policy change. We also report multivariable regression analysis results.

Results: Confirmed HIV prevalence in FTD was 79 per 100,000 (95% CI 72–87) before and 100 per 100,000 (95% CI 90–109) after the policy change, with differences between centers. HIV NAT-yield rates decreased for RD ($p = .0025$), with no change for FTD ($p = .3$). HIV incidence in RD did not increase (12.4 [95% CI: 11.1–13.9] vs. 10.3 [95% CI: 9–11.7] per 100,000 person-years).

Discussion: Our findings showed no significant difference in HIV incidence among RD. Although HIV prevalence among FTD increased, there was no rise in HIV NAT-yield donations. The analysis highlights challenges in interpreting changes within specific groups and blood centers, underscoring the importance of multicenter monitoring of transfusion-transmitted infections.

KEYWORDS

blood donation policy, Brazil, HIV, individual donor assessment, transfusion-transmitted infections

1 | INTRODUCTION

Since the onset of the HIV epidemic in the 1980s, many countries have restricted blood donations from gay, bisexual, and other men who have sex with men (gbMSM) to reduce the risk of HIV transmission through transfusions. However, advancements in HIV testing methods, treatment and prevention strategies, and a deeper understanding of HIV transmission have significantly changed this risk, prompting a reassessment and gradual modification of deferral policies.[1]

In May 2020, the Brazilian Federal Supreme Court (STF) ruled that the regulation excluding men who had sexual relations with other men and/or their partners in the previous 12 months from donating blood was unconstitutional. As a result, a sexual orientation and gender-neutral policy was adopted. The Brazilian Health Regulatory Agency (ANVISA) recommended adding additional selection criteria to the Donor Health Questionnaire (DHQ) based on individual risk rather than sexual orientation for selecting blood donors. In addition to existing clinical screening requirements, a donor candidate is deferred for 6 months under the following conditions: (1) if they have received HIV post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP), with the deferment starting from the last dose administered; (2) if they have initiated a sexual relationship with a new partner, where the deferral period commences with the first sexual encounter; and (3) if the candidate has had more than three sexual partners in the last 3 months. Additionally, a 12-month deferral applies if they have had sex with more than one concurrent sex partner in the last year. Permanent deferral applies if the candidate has received antiretroviral therapy for HIV treatment.[2]

Unlike the UK, Canada, and the US, where research supported the implementation of individual donor risk assessments to ensure blood supply safety,[3–5] Brazil implemented a policy change without a comprehensive risk evaluation. We evaluated the impact of the policy change in Brazil by examining the prevalence of HIV among first-time (FTD) and HIV incidence in repeat donors (RD), comparing data from 3 years before and 3 years after adopting the individual donor assessment (IDA) policy. As a secondary objective, we examined rates of HIV NAT-yield infection before and after the policy change.

2 | STUDY DESIGN AND METHODS

2.1 | Study overview

The Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IV-P) Brazil program collects data on blood donor screening from five major blood centers across Brazil. These centers are Fundação Pro-Sangue in São Paulo, Hemope in Recife, Hemorio in Rio de Janeiro, Hemominas in Minas Gerais, and Hemoam in Manaus. Geographically, three of these centers are located in the Southeast, one in the Northeast, and one

in the North of Brazil. In May 2020, Hemorio revised its policy regarding blood donation deferral for gbMSM, modifying its Donor Health Questionnaire (DHQ) to adhere to an individual risk assessment approach. The remaining blood centers implemented the new policy in June 2020. We analyzed the pre- and post-policy period prevalence and incidence rates of HIV among FTD and RD, respectively, from January 2017 to December 2023. This study received approval from the Brazilian National Ethical Committee under protocol number 14561118.6.1001.0068, local ethical committees at each blood center, and the IRBs at the University of California San Francisco and Westat.

2.2 | Data collection

The REDS-IV-P program compiles blood donor demographic and HIV screening data extracted from each blood center's computer system. Blood donors' information includes donation dates, age, gender, self-reported race, education level, and type of donation. This information, along with HIV screening results for all donations, was sent to a centralized data warehouse at the University of Sao Paulo, Brazil. Data were de-identified before databases were shared for analysis. Following integration and quality control, the data were sent quarterly to the REDS-IV-P coordinating center in the USA (Westat, Rockville, MD). FTDs are defined as individuals whose first-ever recorded donation occurs during the study period, with no prior donations on record. RDs are those who have one or more donations recorded before the study period. If a donor initially classified as an FTD makes another donation within the study period, they are then reclassified as an RD.

2.3 | Blood center routine HIV testing

During this study period, all blood donations were tested for HIV using a fourth-generation HIV antigen/antibody combination chemiluminescent immunoassay. However, each center follows its own standard operating procedure (SOP) in aspects of test interpretation, resulting in variability in signal-to-cutoff (s/co) ratios used to define positivity and the s/co gray zone range for samples considered indeterminate for HIV. If a sample is found to be initially reactive or indeterminate, it is retested in duplicate. The final classification of a sample as reactive, nonreactive, or indeterminate for HIV depends on the specific combination of test results, as outlined by the SOP of the blood center and the clinical expertise of the laboratory professionals. Concurrent with serologic screening, pools of six donor samples are tested for HIV-1 RNA using a NAT assay from Bio-Manguinhos, Fiocruz. If a pool tests reactive, each donation sample within it is tested individually to identify the donor(s) with NAT-reactive HIV infection. If any nonnegative or testing inconsistency is detected during the screening process, the donors are requested to return to the blood center for confirmation retesting with a second blood sample. Because donor return for additional testing happens ~60% of the time,[6] the REDS-IV-P donor/donation database does not include the test results for the second sample collected.

For our analysis, the screening data were categorized into four groups: "confirmed HIV-positive donations," which includes all NAT-reactive and serology-reactive or indeterminate donations; "HIV NAT-yield donations" (NAT-reactive and serology-nonreactive); "unconfirmed HIV-positive donations," which includes all NAT-nonreactive or indeterminate and serology-reactive donations; and NAT-nonreactive or indeterminate and serology-nonreactive or indeterminate were considered "HIV-negative donations." Donations lacking information on either serology or NAT screening were excluded from the analysis.

2.4 | Statistical analysis

Prevalence rates were determined by calculating the rates of positive donations among FTD divided by the total number of FTD donations with complete screening results, in periods before and after the change in the blood donation policy. To assess the difference in prevalence rates pre- and post-policy change, we calculated the 95% confidence interval (CI) for the difference between prevalence in the two periods, utilizing the standard error of the difference to estimate an interval, assuming normal distributions.

Calculation of incidence rates among RDs followed the classic method described by Brambilla et al., 2017.[7] Time at risk was defined as the interval between donations for those without infection. For individuals who became infected, the time at risk was calculated as the total time uninfected between donations. For the last interval before the donation where infection was detected, half of the time between the last uninfected donation and the donation where infection was detected was considered time at risk. These calculations were performed for the pre-d post-policy periods. Donors with HIV NAT-yield donations were excluded from the calculation of both incidence and prevalence.

Multivariable Poisson regressions with log-link functions were used to investigate the effect of policy

implementation on the number of confirmed HIV cases in FTD and RD. These analyses were adjusted for potential confounding variables, including demographics (sex, age, race, educational attainment), donation type, and blood center. Donors with missing data were excluded from regression modeling. An 'Unknown/Refused' category was used for race and education to retain these individuals. Following the multivariable analysis, the data were stratified by blood center and donor type to explore potential differences in the effect of the policy change at each site. Separate models were generated for each blood center, adjusting for the same set of variables. A paired t-test was performed to compare monthly deferral rates before and after the policy change.

A secondary analysis was performed to assess HIV NAT-yield rates before and after the implementation of the policy change, both overall and by blood center. Due to small numbers, the pre-d post-policy rates of HIV NAT-yield donations, stratified by blood center, were compared using Fisher's exact test.

Graphs of quarterly infection rates were developed by calculating the prevalence or incidence of HIV for each blood center. During quarters where no cases were detected, prevalence and incidence rates were zero. Analysis and data management were conducted using SAS 9.4 (Cary, N.C.). Figures were generated in R (v4.2.2) using the ggplot2 and patchwork packages.

3 | RESULTS

During the analysis period, 2,638,084 donations were included after 33,648 donations were excluded due to missing or incomplete screening results. Among these, 910,232 donations (34.5%) were from FTDs, while 1,727,852 donations (65.5%) were from RDs. Repeat donors were predominantly male and older, whereas FTDs were more evenly distributed between genders and tended to be younger. Detailed demographic characteristics are presented in Table 1. Comparing deferral rates before and after the policy change, we observed a decline from 408,533 (22%) to 364,258 (20%). The monthly deferral rate was significantly lower after the policy change ($p < .0001$).

Of the included donations, 1388 (0.053%) were NAT-reactive and 1323 (0.05%) were either serology-reactive ($n = 1317$) or indeterminate ($n = 6$), classifying them as confirmed HIV-positive donations. The remaining 65 (0.0025% of all) NAT-reactive and serology-nonreactive donations were categorized as HIV NAT-yield donations. Additionally, 2,636,696 (99.95%) donations were NAT-nonreactive or indeterminate. Of these, 2129 were found to be serology-reactive, leading to their classification as unconfirmed HIV-positive donations due to the absence of confirmatory NAT-reactivity. The remaining 2,634,567 donations were serology-nonreactive ($n = 2,634,123$) or indeterminate ($n = 444$) and were classified as negative for HIV (Figure 1).

3.1 | First-time donor prevalence

Before the policy change, the prevalence of confirmed HIV among FTD was 79 per 100,000 (95% CI 72–87), increasing to 100 per 100,000 (95% CI 90–109) following the policy change ($p = .0012$). This statistically significant rise in HIV prevalence post-policy change was particularly noted among first-time male donors under 35 years of age and those of mixed race or who made replacement donations. Variability between blood centers, with notable increases in Hemorio, was observed (Table 2).

The quarterly analysis of HIV prevalence shows results for FTD, typically ranging from 65 to 334 cases per 100,000 donations (median: 101, IQR: 23) throughout most of the study period. After the policy change, an increase in the rate of donations with HIV was observed in the last quarter of 2020, peaking in the second quarter of 2021, when the prevalence reached 580 cases per 100,000 donations (95% CI 446–714). In 2021, there was a notable decrease in prevalence immediately following this peak, yet the prevalence remained elevated, with 229 and 404 cases per 100,000 donations in the third and fourth quarters of 2021, respectively. In 2022, the prevalence rates stabilized, returning to a similar pattern observed since 2017 (see Figure S1).

Throughout most of the period, Hemorio showed a higher prevalence of HIV than the other blood centers, with an increase in prevalence toward the end of 2020, reaching 1134 cases per 100,000 donations (95% CI 901–1367). The prevalence remained consistently high throughout 2021 before returning to the levels experienced pre-policy change (Figure 2). At Hemominas and Hemope, there was an increase in quarterly HIV prevalence in male donors just after the policy change in the third and fourth quarters of 2020. However, at Hemorio, the increase was observed in both male and female donors (Figure 3).

Multivariable regression analysis showed that after the policy change, donations from FTDs had a 1.25-fold increase in HIV prevalence compared to the period before the change (95% CI 1.08–1.44, $p = .0027$). When the data were stratified by blood center, the impact of the policy change on HIV prevalence among FTDs varied significantly across locations. Notably, there were significant increases in HIV prevalence in Hemorio and Hemoam.

TABLE 1 Demographic characteristics of first-time and repeat donors during the REDS-IV-P period.

	FTD		RD	
Characteristics	**Number of donations**	**%**	**Number of donations**	**%**
Overall	910,232	34.5	1,727,852	65.5
Gender				
Female	457,768	50.29	602,318	34.86
Male	452,463	49.71	1,125,533	65.14
Age				
<=24	308,741	33.92	223,109	12.91
25–34	291,195	31.99	473,333	27.39
35–44	185,400	20.37	521,082	30.16
45–54	90,347	9.93	343,080	19.86
55+	34,549	3.8	167,248	9.68
Race				
White	318,830	35.03	563,411	32.61
Black	70,584	7.75	142,501	8.25
Mixed (“Pardo”)	420,855	46.24	803,849	46.52
Asian	6793	0.75	14,292	0.83
Indigenous	517	0.06	1710	0.1
Unknown/Refused	92,653	10.18	202,089	11.7
Education level				
Primary School or Less	55,322	6.08	125,791	7.28
Secondary School or Less	256,476	28.18	451,207	26.11
Technical or Professional School	13,228	1.45	37,779	2.19
University/Postgraduate Degree	139,329	15.31	314,291	18.19
Unknown/Refused	445,877	48.98	798,784	46.23
Donation type				
Replacement	392,041	43.07	570,794	33.03
Community	510,209	56.05	1,117,289	64.66
Other	7982	0.88	39,769	2.3
Blood Center				
Hemope, Recife	196,160	21.55	426,203	24.67
Hemominas, Minas Gerais	115,778	12.72	236,901	13.71
FPS, Sao Paulo	239,749	26.34	444,712	25.74
Hemorio, Rio de Janeiro	249,237	27.38	319,258	17.41
Hemoam, Manaus	109,308	12.01	300,778	18.48

Abbreviations: FTD, first-time donor; RD, repeat donor.

In contrast, other centers exhibited either nonsignificant changes or trends suggesting a decrease in HIV prevalence (Figure S2 and Table S1).

3.2 | Repeat donor incidence

The HIV incidence rate per 100,000 person-years (PY) among repeat blood donors remained relatively stable (12.4 [95% CI: 11.1–13.9] vs. 10.3 [95% CI: 9–11.7] per 100,000 PY), respectively, in the periods before and after the policy change. This stability was consistent across demographic segments, including gender, race, education level, and type of donation. Although not statistically significant, a slight incidence rate decrease was observed (Table S2). Concerning the quarterly incidence data, the highest incidence rates were observed in the first quarter of 2021, with 17.9

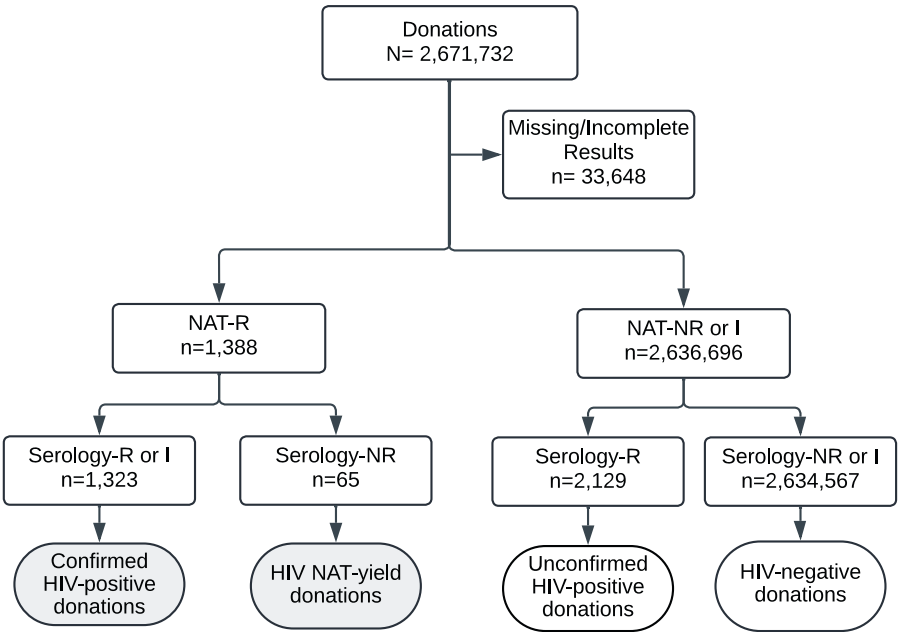

FIGURE 1 Blood Donation Screening Results from January 2017 to December 2023. [Color figure can be viewed at wileyonlinelibrary.com]

cases per 100,000 PY (95% CI: 10.9–29.2), and in the second quarter of 2021, with 18.6 cases per 100,000 PY (95% CI: 10.3–33.7). These peaks closely follow the observed increases in prevalence. The analysis by blood center indicates that Hemorio, Hemominas, FPS, Hemope, and Hemoam each exhibited similar patterns of incidence, with variation around an average specific to each center. Specifically, Hemorio showed rates ranging from 2.6 to 23.6, Hemominas reported rates ranging from 3.4 to 18.4, FPS showed variations between 1.9 and 13.6, Hemope had rates ranging from 4.8 to 24.9, and Hemoam experienced variations from 8.9 to 53.1 (see Figure S3). Multivariable regression analysis showed that there was no significant change in HIV incidence among RD, with a post-policy incidence ratio of 0.89 compared to before (95% CI 0.74–1.06, $p = .1785$).

3.3 | HIV NAT-yield donations

Overall, the HIV NAT-yield rate per 100,000 donations significantly decreased for RDs following the policy change, dropping from 3.4 to 1.1 ($p = .0025$). No significant change was observed for FTDs, with rates changing from 3.2 to 1.9 ($p = .3$). A notable decrease was seen at Hemorio, where the rate for RD significantly decreased from 12.1 to 2.3 ($p = .001$) and for FTD from 5.7 to 0.8 ($p = .035$). HIV NAT-yield rates remained stable across centers, although most individual sites experienced a decrease in rates after the policy change (Table S3).

4 | DISCUSSION

Comparing temporal trends of HIV infection from 3 years before to 3 years after implementing individual donor risk assessment, our findings showed no significant difference in the incidence of HIV infections among RD. Although HIV prevalence among FTD increased following the policy change, there was no corresponding rise in the number of HIV NAT-yield donations among FTD.

Many countries have moved from indefinite deferral of gbMSM to progressively shorter time-limited deferrals (12-month, and later 3-month deferrals since the last sexual contact), and in recent years introduced IDA. No evidence of a statistically significant increase in HIV incidence or associated residual transfusion-transmission risk has been found in the United States[8,9] the United Kingdom[10] or Canada.[11] In other words, evidence indicates that the increased number of eligible gbMSM donating blood has not negatively impacted the safety of the blood supply.

The recent change to a more inclusive IDA policy has not been in place long enough for countries to investigate its long-term impact on HIV incidence.[12–15] However, Italy and Argentina, which implemented IDAs in 2001 and 2015, respectively, provide similar evidence.[16,17] Both countries have shown no increased risk to the blood supply among donors, offering valuable insights into the likely effectiveness of the IDA approach in other settings. However, it is important to note that Brazil has a higher HIV rate than countries that have adopted the IDA approach.

TABLE 2 HIV prevalence per 100,000 donations with 95% confidence intervals in first-time donors with confirmed positive donations during the REDS-IV-P period.

	Period before policy change			Period after policy change			
Characteristics	**Donations *N* (%)**	**HIV + *N***	**HIV+ /10^5 (95% CI)**	**Donations *N* (%)**	**HIV + *N***	**HIV+ /10^5 (95% CI)**	**Δpre-post (95% CI)**
All First-time Donors	495,359 (100)	393	79 (72–87)	414,873 (100)	413	100 (90–109)	20.2 (7.8–32.6)
Gender							
Female	245,643 (49.59)	79	32 (25–39)	212,125 (51.13)	83	39 (31–48)	7 (−4–18)
Male	249,715 (50.41)	314	126 (112–140)	202,748 (48.87)	330	163 (145–181)	37 (14.6–59.4)
Age							
<=24	175,531 (35.44)	122	70 (57–82)	133,210 (32.11)	130	98 (81–115)	28.1 (7.3–48.9)
25–34	160,106 (32.32)	155	97 (82–112)	131,089 (31.60)	167	128 (108–147)	30.6 (6.0–55.2)
35–44	96,592 (19.50)	83	86 (68–105)	88,808 (21.41)	78	88 (68–107)	1.9 (−25–28.8)
45–54	45,862 (9.26)	25	55 (33–76)	44,485 (10.72)	33	74 (49–100)	19.7 (−13.4–52.8)
55+	17,268 (3.49)	8	46 (14–79)	17,281 (4.17)	5	29 (4–54)	−17.4 (−58.3–23.5)
Race							
White	179,054 (36.15)	96	54 (43–64)	139,776 (33.69)	89	64 (51–77)	10.1 (−7–27.1)
Black	38,248 (7.72)	49	128 (92–164)	32,336 (7.79)	39	121 (83–159)	−7.5 (−59.6–44.6)
Mixed (“Pardo”)	246,337 (49.73)	221	90 (78–102)	174,518 (42.07)	230	132 (115–149)	42.1 (21.4–62.8)
Asian	4233 (0.85)	3	71 (0–151)	2560 (0.62)	0	N/A	−70.9 (−151–9.3)
Indigenous	323 (0.07)	0	N/A	194 (0.05)	1	518 (0–1531)	515.5 (−492.2–1523.2)
Unknown/Refused	27,164 (5.48)	24	88 (53–124)	65,489 (15.79)	54	83 (61–105)	−5.9 (−47.5–35.7)
Education level							
Primary School or Less	39,127 (7.90)	27	69 (43–95)	16,195 (3.90)	20	124 (70–178)	54.5 (−5.5–114.5)
Secondary School or Less	168,772 (34.07)	128	76 (63–89)	87,704 (21.14)	50	57 (41–73)	−18.8 (−39.4–1.7)
Technical or Professional School	8286 (1.67)	3	32 (0–77)	4942 (1.19)	6	122 (24–219)	85.2 (−20.2–190.6)
University/ Postgraduate Degree	81,030 (16.36)	44	54 (38–70)	58,299 (14.05)	23	39 (23–56)	−14.8 (−37.6–7.9)
Unknown/Refused	198,144 (40)	191	97 (83–110)	247,733 (59.71)	314	127 (113–141)	30.4 (10.8–49.9)
Donation type							
Replacement	207,767 (41.94)	187	90 (77–103)	184,274 (44.42)	210	114 (99–130)	24 (3.9–44)
Community	281,767 (56.88)	204	73 (63–82)	228,442 (55.06)	200	88 (76–100)	15.1 (−0.5–30.8)
Other	5825 (1.18)	2	34 (0–82)	2157 (0.52)	3	139 (0–297)	104.7 (−59.6–269.1)
Blood Center							
Hemope, Recife	108,993 (22)	110	101 (82–120)	87,167 (21.01)	76	87 (68–107)	−13.7 (−40.9–13.5)
Hemominas, Minas Gerais	74,029 (14.94)	41	55 (39–72)	41,749 (10.06)	31	74 (48–101)	18.9 (−12.3–50)
FPS, Sao Paulo	138,306 (27.92)	66	48 (36–59)	101,443 (24.45)	37	37 (25–48)	−11.2 (−27.7–5.2)
Hemorio, Rio de Janeiro	122,331 (24.7)	83	68 (53–83)	126,906 (30.59)	137	108 (90–126)	40.1 (16.9–63.3)
Hemoam, Manaus	51,700 (10.44)	93	180 (144–217)	57,608 (13.89)	132	230 (191–269)	49.3 (−4.2–102.7)

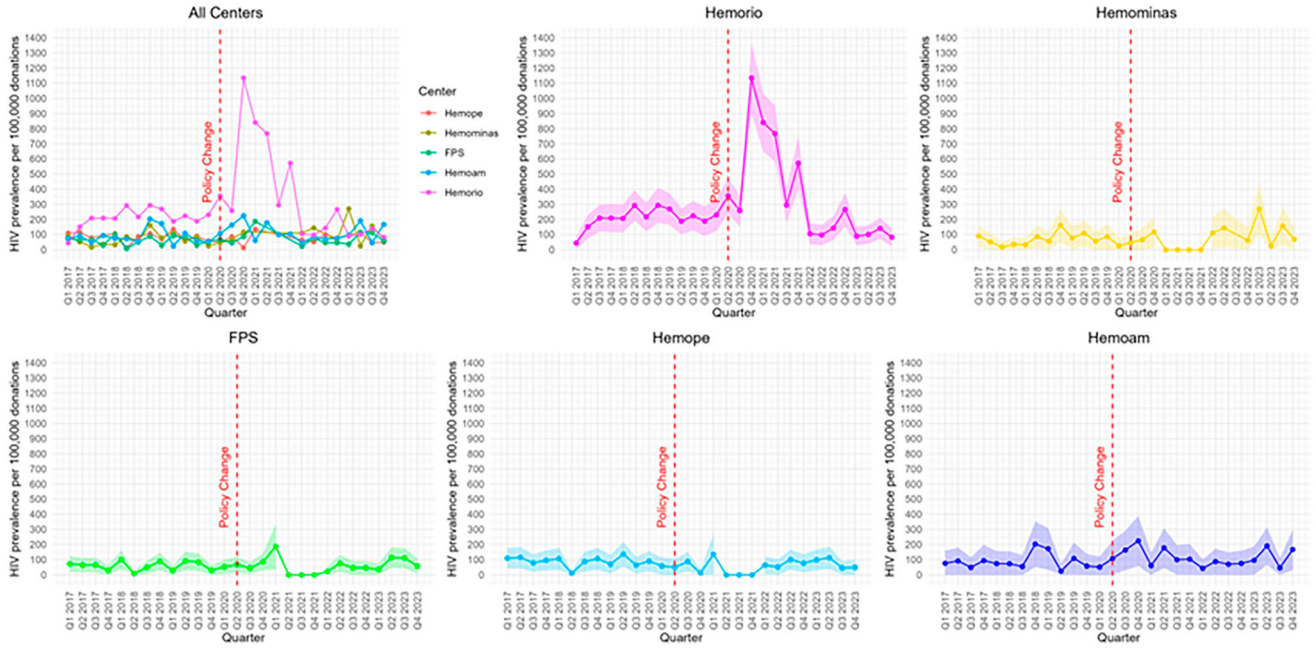

FIGURE 2 Quarterly HIV Prevalence in First-Time Donors Across Blood Centers. [Color figure can be viewed at wileyonlinelibrary.com]

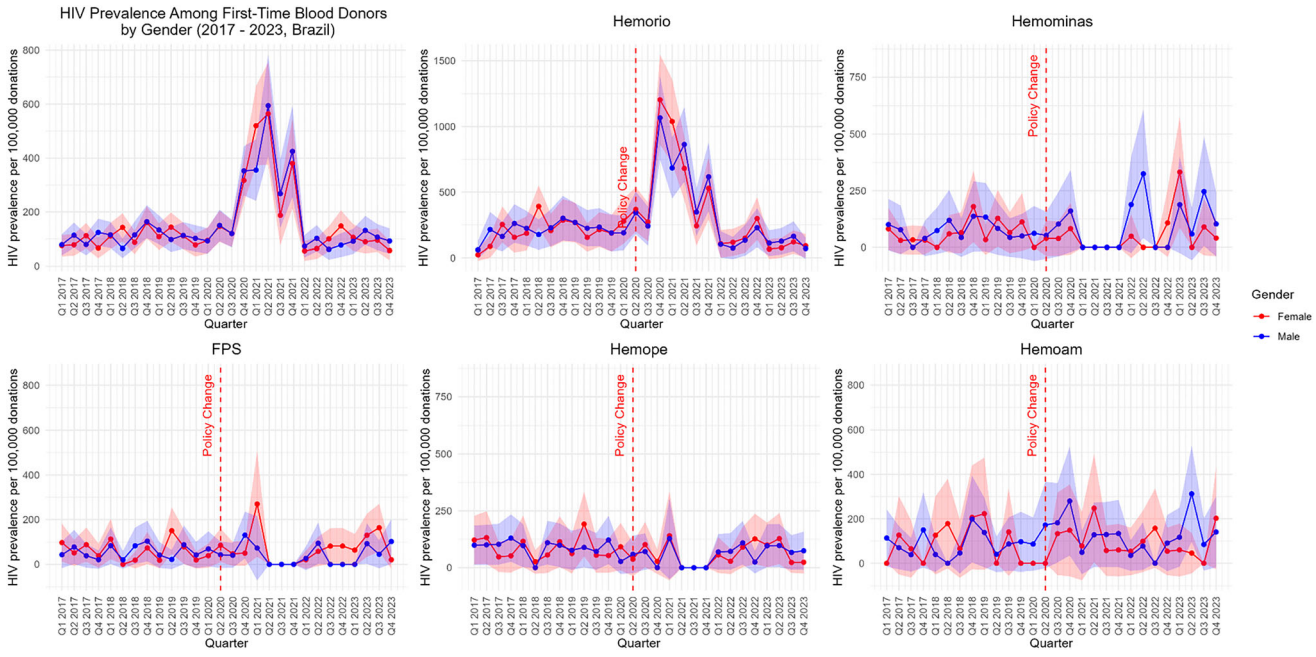

FIGURE 3 Quarterly HIV Prevalence in First-Time Donors by Gender. [Color figure can be viewed at wileyonlinelibrary.com]

Since the major source of residual HIV transmission risk through transfusion comes from donations made during the infectious window period, before NAT positivity or seroconversion, a well-established incidence-window period model has been used to transform incidence estimates into residual risk estimates.[8,18] We can therefore infer that the residual risk arising from RDs did not increase after the implementation of IDA. Our study did not calculate the incidence of HIV among FTD due to pre-policy change samples not being available for additional testing to identify recently acquired HIV infections. However, it is noteworthy that we did not find any differences in the NAT-yield rate before and after the policy change. Since these infections are closest in time to those occurring during the infectious window period, this suggests that the residual risk of HIV transmission through transfusion did not increase in the 3 years following the implementation of IDA.

Additionally, we observed no significant difference in the HIV incidence rate in RD, with this stability being consistent across different demographic segments and blood centers, also indicating a steady residual risk of HIV transmission in donations from RD. Previous research conducted in Brazil in 2007 revealed a high prevalence of HIV among FTD, at 92.2 per 100,000 donations, and an estimated incidence rate among RD of 22.5 per 100,000 person-years.[19] Over more than a decade, these estimates have remained relatively stable, irrespective of current policies, without marked fluctuations.[20]

The increase in HIV prevalence observed after the policy change was temporary, lasting through 2021, and was mainly limited to one blood center, Hemorio. Attributing this temporary increase solely to a change in donation policy is challenging because it coincided with COVID-19 pandemic mitigation measures, which could have influenced the composition of the donor pool that year. Also, Hemorio, unlike the other four blood centers, started specific promotions and advertisements targeting the LGBTQIA+ community in July 2020. We speculate that the way this message was conveyed and received by the public may explain the rise in prevalent HIV infections in donations observed in 2021. However, by 2022, prevalence rates returned to pre-policy levels, potentially due to increased public awareness about the rationale for donation deferral, the limitations of screening tests, and the importance of adhering to donor selection criteria. By addressing all donors equally and eliminating category-based differences often perceived as discriminatory, clearer and more transparent information may be communicated, potentially dispelling misconceptions and leading to more reliable responses to the Donor Health Questionnaire (DHQ). Before the policy change in Brazil, high noncompliance rates, such as not disclosing sexual orientation during the donor screening process, were reported.[21] One study showed that up to 72% of gbMSM who previously donated blood did not fully disclose past behavior.[22] Further studies are required to understand the impact of the new policy on donor compliance in Brazil.

The increase in HIV prevalence among younger, mixed-race male blood donors mirrors trends seen in the general population.[23] Currently, the HIV epidemic in Brazil is concentrated among men under 39 years of age with black or brown ("pardo") skin color. Among the male population, the most affected group is gbMSM, accounting for 52.6% of cases, according to the latest Ministry of Health report.[23] Another interesting aspect is the quarterly HIV prevalence by gender. With the policy change, newly eligible male donors, including those who were previously deferred due to their sexual orientation, are now FTDs. An increase in male donors was observed at Hemominas and Hemoam after mid-2020. However, at Hemorio, there was a similar or slightly higher and unexpected increase in the number of HIV cases among women in 2021. This reinforces the speculation that factors other than the policy change may have contributed to the significant rise in prevalence at this blood center.

The main limitation of our study was the inability to fully explain the patterns and trends in prevalent HIV infections among FTD. We could not identify specific circumstances in Rio de Janeiro that would explain the increase in HIV prevalence following the policy change, given these changes were not seen for incidence in RD or NAT-yield donations in FTD or RD. Our analysis was also confined to concordant positive donations, excluding potential serology-positive and NAT-negative donations. Additionally, while NAT-yield donations are important for monitoring transfusion-transmission risk, they are rare,[24] limiting their utility for broader epidemiologic trend monitoring.

More blood services are likely to adopt more inclusive policies toward gbMSM in the coming years. This multicenter study in Brazil investigated the impact of implementing a gender-neutral blood donor selection policy based on IDA. Our findings suggest that progress toward more inclusive blood donation policies was achieved and did not appear to impact the safety of the blood supply with respect to HIV risk.

The analysis highlights the challenges of interpreting changes within specific groups and blood centers and underscores the importance of multicenter monitoring of transfusion-transmitted infections. The risk of transfusion-transmitted HIV did not increase in the 3 years following the policy change, providing reassuring findings given the unique way in which the blood donation policy was changed in Brazil compared to other countries.

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CONFLICT OF INTEREST STATEMENT

The authors have disclosed no conflicts of interest.

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REFERENCES

1. Zucoloto ML, Gonçalez TT, McFarland W, Custer B, Galdino G, Martinez EZ. Blood donation deferral policies among men who have sex with men in Brazil. Hematol Transfus Cell Ther. 2019;41(2):164–8.
2. Agência Nacional de Vigilância Sanitária – Anvisa. Guia para inclusão de critérios na triagem clínica e epidemiológica de candidatos a doação de sangue baseados em práticas individuais acrescidas de risco para infecções transmissíveis pelo sangue. Report No.: Guia no. 34/2020 – versão 1. 2020.
3. Brailsford SR, Kelly D, Kohli H, Slowther A, Watkins NA. Who should donate blood? Policy decisions on donor deferral criteria should protect recipients and be fair to donors. Transfus Med Oxf Engl. 2015;25(4):234–8.
4. Custer B, Whitaker BI, Pollack LM, Buccheri R, Bruhn RL, Crowder LA, et al. HIV risk behavior profiles among men who have sex with men interested in donating blood: findings from the assessing donor variability and new concepts in eligibility study. Transfusion (Paris). 2023;63(10):1872–84.
5. Goldman M, Caffrey N, O'Brien SF. Screening for high-risk sexual behavior in Canada. Transfusion. 2022;62(12):2419–22.
6. Sabino EC, Salles NA, de Almeida-Neto C, Barreto AM, Basques F, Barros EA, et al. Performance of parallel screening of Brazilian blood donors with two HIV immunoassays: implications for sequential immunoassay testing algorithms in other countries. Transfusion. 2011;51(1):175–83.
7. Brambilla DJ, Busch MP, Dodd RY, Glynn SA, Kleinman SH. A comparison of methods for estimating the incidence of human immunodeficiency virus infection in repeat blood donors. Transfusion. 2017;57(3pt2):823–31.
8. Grebe E, Busch MP, Notari EP, Bruhn R, Quiner C, Hindes D, 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):1359–67.
9. Steele WR, Dodd RY, Notari EP, Haynes J, Anderson SA, Williams AE, et al. HIV, HCV, and HBV incidence and residual risk in US blood donors before and after implementation of the 12-month deferral policy for men who have sex with men. Transfusion. 2021;61(3):839–50.
10. Davison KL, Reynolds CA, Andrews N, Brailsford SR. Blood donation by men who have sex with men: using evidence to change policy. Vox Sang. 2021;116(3):260–72.
11. Goldman M, Lewin A, Renaud C, O'Brien SF. Implementation of sexual risk behavior donor screening in Canada. Transfus Clin Biol. 2024;64(7):1254–61.
12. Caffrey N, Goldman M, Osmond L, Yi Q, Fan W, O'Brien SF. HIV incidence and compliance with deferral criteria over three progressively shorter time deferrals for men who have sex with men in Canada. Transfusion. 2022;62(1):125–34.
13. Caffrey N, Goldman M, Lewin A, Osmond L, O'Brien SF. Behaviour based screening questions and potential donation loss using the "for the assessment of individualised risk" screening criteria: a Canadian perspective. Transfus Med Rev. 2022;32(5):422–7.
14. Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions To Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability [Internet]. Vol. 88, The Federal Register / FIND. Washington: Federal Information & News Dispatch, LLC; p. 30765. Report No.: 0097–6326. 2023. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human
15. NHS, Blood and Transplant. Blood Donor Selection Policy: More People Now Able to Give Blood [Internet]. UK: NHS; 2021 Available from: https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group/
16. Suligoil B, Pupella S, Regine V, Raimondo M, Velati C, Grazzini G. Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. Blood Transfus. 2013;11(3):441–8.
17. Blanco S, Carrizo LH, Moyano RW, Mangeaud A, Gallego SV. Gender-neutral donor deferral policies: experience in Argentina implementing individual risk-assessment policies. Vox Sang. 2020;115(7):548–54.
18. Weusten J, Vermeulen M, van Drimmelen H, Lelie N. Refinement of a viral transmission risk model for blood donations in seroconversion window phase screened by nucleic acid testing in different pool sizes and repeat test algorithms. Transfusion. 2011;51(1):203–15.
19. Sabino EC, Gonçalez TT, Carneiro-Proietti AB, Sarr M, Ferreira JE, Sampaio DA, et al. HIV prevalence, incidence and residual risk of transmission by transfusions at REDS-II blood centers in Brazil. Transfusion. 2011;52(4):870–9.
20. Oliveira Garcia Mateos S, Preiss L, Gonçalez TT, Di Lorenzo Oliveira C, Grebe E, Di Germanio C, et al. 10-year analysis of human immunodeficiency virus incidence in first-time and repeat donors in Brazil. Vox Sang. 2021;116(2):207–16.
21. de Almeida-Neto C, Goncalez TT, Birch RJ, de Carvalho SMF, Capuani L, Leão SC, et al. Risk factors for human

immunodeficiency virus infection among Brazilian blood donors; a multicenter case-control study using audio computer-assisted structured-interviews. Vox Sang. 2013;105(2):91–9.
22. Zucoloto M, Galdino G, McFarland W, Martinez E. Influence of risk perception on attitudes toward blood donation among Brazilian men who have sex with men who donated blood. Transfusion. 2023;63(2):323–30.
23. Epidemiological Report – HIV & AIDS 2023 [Internet]. MINISTÉRIO DA SAÚDE. 2023. Número Especial | Dezembro. Available from: www.gov.br/aids
24. Quiner C, Bruhn R, Grebe E, Di Germanio C, Kessler D, Reik R, et al. Recently acquired infection among HIV-seropositive donors in the US from 2010-2018. Transfusion. 2020;60(10):2340–7.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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