Human immunodeficiency virus prevalence, incidence, and residual risk of transmission by transfusions at Retrovirus Epidemiology Donor Study-II blood centers in Brazil

Ester C. Sabino, Thelma T. Gonçalez, Anna Bárbara Carneiro-Proietti, Moussa Sarr, João Eduardo Ferreira, Divaldo A. Sampaio, Nanci A. Salles, David J. Wright, Brian Custer, and Michael Busch for the NHLBI Retrovirus Epidemiology Donor Study-II (REDS-II), International Component

BACKGROUND: In Brazil nationally representative donor data are limited on human immunodeficiency virus (HIV) prevalence, incidence, and residual transfusion risk. The objective of this study was to analyze HIV data obtained over 24 months by the Retrovirus Epidemiology Donor Study-II program in Brazil.

STUDY DESIGN AND METHODS: Donations reactive to third- and fourth-generation immunoassays (IAs) were further confirmed by a less-sensitive (LS) IA algorithm and Western blot (WB). Incidence was calculated for first-time (FT) donors using the LS-EIA results and for repeat donors with a model developed to include all donors with a previous negative donation. Residual risk was projected by multiplying composite FT and repeat donor incidence rates by HIV marker–negative infectious window periods.

RESULTS: HIV prevalence among FT donors was 92.2/10^5 donations. FT and repeat donor and composite incidences were 38.5 (95% confidence interval [CI], 25.6-51.4), 22.5 (95% CI, 17.6-28.0), and 27.5 (95% CI, 22.0-33.0) per 100,000 person-years, respectively. Male and community donors had higher prevalence and incidence rates than female and replacement donors. The estimated residual risk of HIV transfusion transmission was 11.3 per 10^6 donations (95% CI, 8.4-14.2), which could be reduced to 4.2 per 10^6 donations (95% CI, 3.2-5.2) by use of individual-donation nucleic acid testing (NAT).

CONCLUSION: The incidence and residual transfusion risk of HIV infection are relatively high in Brazil. Implementation of NAT will not be sufficient to decrease transmission rates to levels seen in the United States or Europe; therefore, other measures focused on decreasing donations by at-risk individuals are also necessary.

The human immunodeficiency virus (HIV)/AIDS epidemic began in Brazil in the early 1980s, and Brazil now has the largest HIV-1–infected population in South America, with 544,846 reported cases of AIDS and 630,000 individuals known to be living with HIV in 2009.[1] The epidemic in Brazil is considered a "concentrated epidemic," with an overall prevalence below 1% in the general population,[2] but levels as high as 50% among vulnerable population such as males who have sex with males, injection drug users, or sex workers.[3] The incidence of AIDS cases varies across Brazilian regions, with the highest incidence rates concentrated in the South and the Southeast (29.3 and 19.2/100,000), followed by the Midwest, North, and Northwest (16.4, 15.4, and 11/100,000).[1]

To address the growing HIV/AIDS epidemic,[4] the Brazilian government implemented early measures such as

ABBREVIATIONS: IA(s) = immunoassay(s); ID = individual donation; LS = less sensitive; WB = Western blot; WP = window period.

From the Pró-Sangue Foundation, São Paulo, Brazil; Blood Systems Research Institute, San Francisco, California; Hemominas Foundation, Belo Horizonte, Minas Gerais, Brazil; Westat, Rockville, Maryland; the University of São Paulo, Sao Paulo, Brazil; and Hemope Foundation, Recife, Pernambuco, Brazil.

Address reprint requests to: Ester C. Sabino, Department Infectious Disease, University of Sao Paulo, Avenue Dr Eneas de Carvalho Aguiar 470, São Paulo, SP 05403-000, Brazil; e-mail: sabinoec@usp.br.

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creating free voluntary counseling and testing centers, offering free health services for the diagnosis, treatment and prevention of HIV and other sexually transmitted diseases, and providing technical and financial support toward maximizing the safety of the blood supply. However, despite offering these programs that benefit individuals and society, many at-risk and HIV-infected persons in Brazil do not utilize these services to get tested.[5] Furthermore, there are significant regional variations in the rates and demographics of people seeking HIV testing in Brazil, including disparities by sex and socioeconomic characteristics.[5] For instance, in the general population, 27.2% of HIV testing is performed during prenatal care and 23.2% during the process of blood donation.[5] Among men, blood donation has been the most common site for HIV testing (36%-39%),[5] which poses a threat to blood supply, since previous studies have indicated that 9% of donors were motivated to give blood for the purpose of obtaining test results and these "test seekers" have higher rates of blood-borne infectious markers and herpes 2 antibodies.[6]

Monitoring HIV prevalence and incidence among donors is important for evaluating the safety of the blood supply and also for tracking the epidemic and efficacy of public health intervention measures and policies.[7-11] There are few published studies on HIV prevalence and incidence among Brazilian donors or estimates for residual risk of transfusion-transmitted HIV infection in Brazil. This is in part due to the lack of mandatory confirmatory testing at the time of donation; most blood centers only confirm screening immunoassay (IA)-reactive results for those donors who return for counseling and retesting, and approximately 40% of the HIV-IA repeat-reactive individuals in Brazil never return for counseling either at the blood banks or at local voluntary counseling and testing centers.[12] Moreover, until recently there has not been the capacity to merge and analyze data across multiple blood centers. Representative national data on HIV infection rates and residual risk among Brazilian donors and transfusions are needed, particularly because due to economic constraints HIV (and hepatitis C virus [HCV]) nucleic acid testing (NAT) implementation has been delayed over the past decade with launch of NAT testing now planned for 2011 to 2012. The objective of this study was to analyze HIV data obtained in the three large Brazilian blood centers who are part of the National Heart, Lung, and Blood Institute [NHLBI] International Retrovirus Epidemiology Donor Study-II (REDS-II) program.[13]

MATERIALS AND METHODS

Participating blood centers in Brazil

This study is part of the NHLBI REDS-II international program that conducts research studies involving safety and adequacy of the blood supply in participating countries. The REDS-II study in Brazil includes three blood centers, Pró-Sangue Foundation in São Paulo and Hemominas Foundation in Minas Gerais, both in the Southeastern part of Brazil, and Hemope Foundation in the State of Pernambuco, which is located in the Northeastern part of the country. Details regarding the organization of the REDS-II Brazil program including donor demographics relative to population characteristics at the three core centers have recently been published.[13]

Data collection and storage

Demographic data from all donors from January 1, 2007, to December 31, 2008, were extracted from the computer systems of each center and sent to a data warehouse at the University of São Paulo. These data included coded donor identification, age, sex, self-reported skin color (captured as five options but recoded into white, black, mixed, or other), and educational attainment. Standardized testing data on all blood donations are also collected, prepared, and electronically sent a single data warehouse in São Paulo. After integration and quality control the data are transferred on a monthly basis to the REDS-II coordinating center in the United States (Westat, Rockville, MD) for compilation and analysis.

HIV testing procedures

All samples were screened at each center with two tests (fourth- and third-generation IAs) performed in parallel. When a donor tested repeat reactive by either of the two screening IAs, the unit was discarded and the sample was sent to the central study laboratory in São Paulo, for further testing. Samples reactive on both IAs were sent to Blood Systems Research Institute (San Francisco, CA) to classify the infection as recent (i.e., incident) or remote using the standardized testing algorithm for recent HIV seroconversion (STARHS), which is based on a sensitive or less-sensitive enzyme immunoassay (LS- or "detuned" EIA).[14] Samples were considered confirmed seropositive if they were highly reactive by the LS-EIA; if they were weakly or nonreactive by the LS-EIA Western blot (WB) was performed as well as selective polymerase chain reaction testing. The sensitivity, specificity, and positive predictive value of this supplemental testing algorithm have recently been reported.[15]

Calculation of prevalence, incidence, and residual risk

Prevalence

Analysis of HIV prevalence was restricted to first-time (FT) donors and was calculated based on rates of confirmed positive FT donors divided by number of FT donors, overall, by center, by donation type, and by donor demographic subcategories.

Incidence among FT blood donors

For all HIV-positive donations in 2007 we used a microelisa assay (LS-Vironostika, HIV-1 bioMérieux, Raleigh, NC) for anti-HIV, which was modified for detuned EIA application by increasing the sample dilution from 1:76 to 1:20,000 and reducing the sample incubation time from 100 to 30 minutes while retaining the kit-specified conjugate incubation time of 30 minutes.[16] Donors with remote HIV infection will remain positive in this detuned procedure whereas recently infected or false positive donors will give negative assay results.[16,17] For HIV-positive donations in 2008 we used the LS-HIV Vitros assay (Ortho Diagnostics, Raritan, NJ); this test was similarly detuned relative to the licensed screening assay to yield a recent infection window period (WP) identical to that of the LS-Vironostika assay.[18] Both these incidence assays have been developed to discriminate donors as recently infected for approximately 170 days after seroconversion by sensitive IAs at the cutoffs employed. For LS-IA nonreactive samples, if the donor had returned for confirmation we used the final WB results obtained on the follow-up samples by the blood banks to classify the donor as HIV infected or not infected. If the donor had not returned for follow-up testing, the sample from the index donation was tested by WB. The following formulas were used to estimate incidence among FT donors:

$$\text{FT incidence} = (\text{number of recently infected FT donors} \times 365 \text{ days}/170 \text{ days})/\text{number of FT donations}.$$

Confidence intervals (CIs) for FT incidence rates are derived from Poisson regressions and ignore the minimal additional variability attributable to variance on the estimated 170 detuned WP. HIV incidence rates among FT donors was calculated overall, by center, by donation type, and by donor demographic subcategories.

Incidence among repeat donors

An outline for the calculation of the study period incidence rate among repeat donors is shown in Fig. 1. For each repeat donor donation during the study period there is an associated interdonation interval (donation date – previous donation date). If the previous donation date is in the study period (i.e., 2007-2008), then the person-time is equal to the interdonation interval, and if the donation is confirmed positive then an incident infection within the study period is known to occur (right-hand column of Fig. 1).

If the previous donation date precedes 2007, the person-time is truncated to time within the study period (donation date-December 31, 2006). If the donation is confirmed positive, then an incident infection is known to have occurred within the interdonation interval; however, the incident is not necessarily within the study period. Assuming that the incident infection event was equally likely to occur on any date within the interdonation interval, the probability that it occurred within the study period can be estimated as a fraction of time (i.e., person-time/interdonation interval). This probability is used to define a fractional incident infection (left-hand column of Fig. 1). The study period incident rate is estimated as the sum of incident infections and fractional incident infections divided by the sum of person-time and was calculated overall, by center, by donation type, and by donor demographic subcategories.

Residual risk calculation

Residual risk was calculated using a 15.0-day infectious WP for current fourth-generation EIA screening (which detects HIV-1 p24 antigen as well as antibodies to HIV-1 and -2), a 5.6-day WP for individual-donation (ID) NAT, and a 9.0-day WP for minipool NAT.[14] We used the following formula to compute residual risk:

$$\text{Residual risk} = \text{Composite incidence rate} \times \text{Infectious WP}/365.25 \text{ days}.$$

We calculated the composite incidence rate as being equal to

$$(\text{FT\%} \times \text{FT donor incidence}) + (\text{Rpt\%} \times \text{repeat donor incidence}),$$

where FT% and Rpt% are the proportions of FT and repeat donations in our study sample, respectively. CIs were computed using a normal approximation and estimating standard errors by Taylor series expansion.

Statistical analyses

HIV prevalence among FT donors per 100,000 donations was computed, with related 95% CIs. HIV incidence among FT donors (per 100,000 person-years) was computed as the number of new infections divided by the total number of FT donations times the estimated 170-day detuned WP. For repeat donors, we computed the incidence rate of HIV infection per 100,000 person-years as the number of new events divided by the number of person-years of follow-up (see section "Incidence among repeat donors" above). Differences in prevalence rates among the FT donors by sociodemographic characteristics, type of donation, and location were assessed by logistic regression models. Reliable multivariable analyses could not be performed for HIV incidence among FT or repeat donors due to small numbers. Hence, only unadjusted Poisson regression models were used to assess differences in incidence rates among FT and repeat donors by sociodemographic characteristics, location, and donor type. All statistical tests were performed using computer software (SAS 9.1, 2004, SAS Institute, Cary, NC), with a two-sided p value of less than 0.05 considered to be significant.

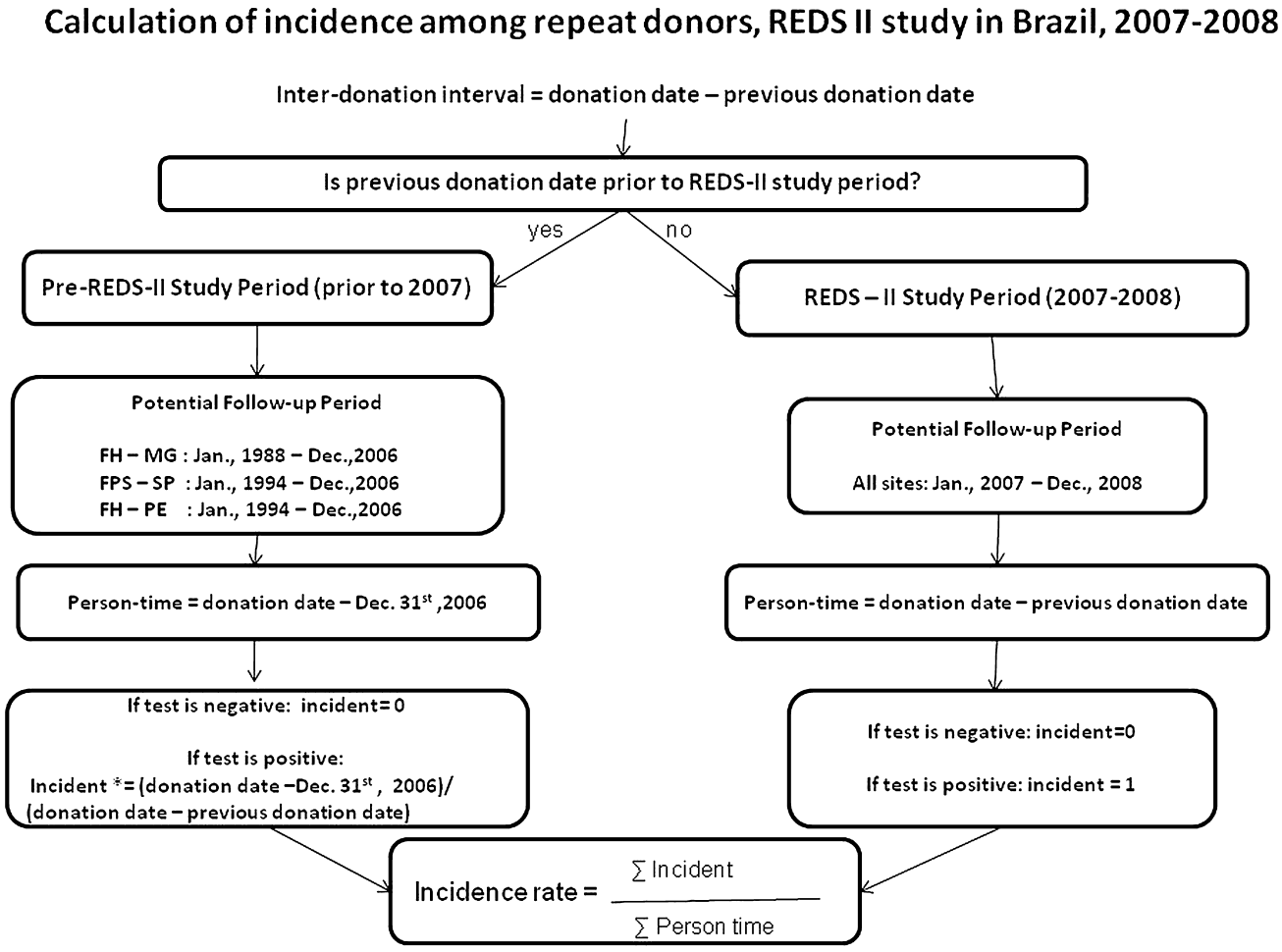

Fig. 1. Calculation of incidence among donations from repeat donors, REDS-II study in Brazil, 2007 to 2008. *Incident represents probability that HIV incident infections occurred during the REDS-II study period (assuming that incident infections are equally likely to occur on any date within the interdonation interval). FH-MG = Hemominas Foundation in Minas Gerais; FPS-SP = Pró-Sangue Foundation in São Paulo; FH-PE = Hemope Foundation in the State of Pernambuco.

RESULTS

From January 1, 2007 to December 31, 2008, a total of 615,317 blood donations were made in the three blood centers participating in this study; 189,802 of these donations (31%) were by FT donors and 425,515 donations (69%) by repeat donors.

HIV prevalence and incidence in FT donors

Of the 189,802 FT blood donations, 175 individuals were HIV antibody confirmed positive, resulting in a prevalence of 92.2 per 100,000 donors. As shown in Table 1, unadjusted analyses demonstrated that HIV prevalence rates were highest in Recife (119.1/100,000), in community blood donors (110.3/100,000), in the 25- to 45-year-age group (115.0/100,000), in male donors (126.4/100,000), and in nonwhite (111.0/100,000) individuals. After logistic regression, only sex (males higher than females), type of donation (community donors higher than replacement donors), and educational level (donors who completed 11 years of educational levels had lower prevalence) remained associated with HIV infection status (see adjusted odds ratios in Table 1).

Among FT blood donors HIV incidence was 38.5 per 100,000 person-years (Table 2). HIV incidence among community FT donors was more than twofold higher than among replacement donors (55.0/100,000 vs. 19.5/100,000 person-years, $p = 0.006$). HIV incidence was highest among individuals who had less than 8 years of education (50.1/100,000 person-years) although not significantly higher than other education categories ($p = 0.42$), and there was a trend toward higher incidence among males (48.7/100,000 vs. 22.9/100,000 person-years in males vs. females, $p = 0.06$).

TABLE 1. Correlates of HIV infection among FT blood donors, REDS-II study in Brazil, 2007 to 2008

	HIV prevalence per 100,000 donations							
Characteristics	Number of donations	Number positive	Prevalence	(95% CI)	p value	AOR	(95% CI)	p value
Overall	189,802	175	92.20	(78.55-105.86)				
Blood center								
Recife	58,751	70	119.15	(91.25-147.04)	0.03	1		0.77
Belo Horizonte	45,081	32	70.98	(46.40-95.57)		1.20	(0.74-1.97)	
São Paulo	85,970	73	84.91	(65.44-104.38)		1.31	(0.72-2.39)	
Type of donation								
Community	10,1529	112	110.31	(89.89-130.73)	0.02	1		<0.01
Replacement	88,237	63	71.40	(53.77-89.02)		0.48	(0.30-0.75)	
Age (years)								
<25	74,742	53	70.91	(51.83-89.99)	0.01	1		0.11
≥25 to <35	62,779	74	117.87	(91.03-144.71)		1.58	(0.96-2.58)	
≥35 to <45	31,774	37	116.45	(78.95-153.95)		1.10	(0.58-2.10)	
≥45 to <55	16,016	6	37.46	(7.49-67.43)		0.54	(0.18-1.58)	
≥55	4,420	5	113.12	(14.02-212.22)		2.01	(0.68-5.98)	
Sex								
Female	75,119	30	39.94	(25.65-54.22)	<0.01			<0.01
Male	11,4683	145	126.44	(105.87-147.00)		3.44	(1.97-6.02)	
Education								
<8 years	12,947	19	146.75	(80.81-212.69)	0.02	1		0.04
Completed 8 years	17,138	21	122.53	(70.16-174.91)		0.80	(0.42-1.50)	
Completed 11 years	63,291	41	64.78	(44.96-84.60)		0.46	(0.25-0.82)	
Completed college	15,776	12	76.06	(33.04-119.09)		0.64	(0.30-1.36)	
Race								
Black	16,083	15	93.27	(46.09-140.44)	0.01	1		0.43
Mixed	68,449	76	111.03	(86.08-135.98)		0.71	(0.36-1.42)	
White	69,093	42	60.79	(42.41-79.17)		1.14	(0.61-2.15)	
Other	2,460	0	0.00					
Year								
2007	95,179	81	85.10	(66.58-103.63)	0.30	1		0.22
2008	94,623	94	99.34	(79.27-119.41)		0.73	(0.44-1.21)	

AOR = adjusted odds ratio.

HIV incidence in repeat blood donors

A calculation based on repeat donors who had multiple donations in the 2-year study period yields an incidence rate estimate of 26.7 (95% CI, 17.7-31.8) per 100,000 person-years, with 30 seroconvertors observed. However, this estimate excludes more than half of repeat donors during the study period. By including all repeat donors who had previously donated in the centers, there were an additional 115 confirmed incident HIV cases, and the calculated incidence rate decreased to 19.3 (95% CI, 13.9-24.7) per 100,000 person-years. However, this second incidence rate estimate accumulates person time from the prestudy period (some person-time from the 1990s is accumulated). We have developed a model (see Materials and Methods) to estimate the incidence rate during the study period that includes the 30 seroconverters known to be incident in the study period and estimated that 34.6 of the 115 additional observed seroconverters were incident infections acquired in the study period. By using this method the study period the incidence rate estimate was 22.5 (95% CI, 17.05-28.04) per 100,000 person-years.

The demographic characteristics associated with HIV incidence among repeat donors are also presented in Table 2. In the unadjusted analysis, males (p = 0.04) and younger donors (p = 0.03) had higher incidence rates than females and older donor groups. Community donors (25.5 per 100,000 person-years) also had a trend toward a higher incidence than replacement donors (15.8 per 100,000 person-years), but this was not significant (p = 0.10).

Table 3 presents the composite incidence rates per site, taking into account the proportion of FT and repeat donors per center, and also presents the residual transfusion transmission risk projections based on current infectious WP estimates.[14,19] Incidence was relatively high in all three centers, as was the residual transfusion HIV risk in the context of current donor serologic screening. Even considering the use of single-donation NAT, residual risk would remain high in Brazil, at approximately one WP donation derived unit transfused per 250,000 donations or four WP units transfused per 1,000,000 donations.

DISCUSSION

This study investigates HIV prevalence and incidence at three major blood centers in Brazil. The results show that overall prevalence of HIV among blood donors ($92.20/10^5$) is much higher compared to the rates among blood

TABLE 2. Incidence* per 100,000 donations among FT and repeat donors, REDS-II study in Brazil, 2007 to 2008

	FT donors			Repeat donors		
Characteristics	Incidence	(95% CI)	p value	Incidence	(95% CI)	p value
Overall	38.49	(25.55-51.42)		22.55	(17.05-28.04)	
Blood center			0.84			0.55
Recife	43.88	(19.06-68.71)		26.98	(18.54-35.43)	
Belo Horizonte	33.36	(8.65-58.07)		20.09	(11.07-29.11)	
São Paulo	37.49	(18.52-56.46)		20.48	(13.98-26.99)	
Type of donation			<0.01			0.10
Community	55.02	(33.87-76.17)		25.51	(19.90-31.11)	
Replacement	19.48	(5.98-32.98)		15.83	(8.53-23.13)	
Age (years)			0.02			0.03
<25	28.75	(10.93-46.56)		27.10	(14.82-39.38)	
≥25 to <35	61.60	(33.15-90.06)		27.96	(19.75-36.16)	
≥35 to <45	27.05	(0.54-53.55)		23.68	(14.89-32.46)	
≥45 to <55	0	(0.00-40.24)		8.22	(1.08-15.36)	
≥55	97.22	(0.00-231.93)		0.00	(0.00-25.45)	
Sex			0.06			0.04
Female	22.88	(7.03-38.74)		13.09	(6.39-19.78)	
Male	48.71	(29.99-67.43)		26.11	(20.46-31.77)	
Education			0.42			0.73
<8 years	16.59	(0.00-49.12)		14.64	(1.61-27.67)	
Completed 8 years	50.15	(1.01-99.28)		27.87	(11.76-44.00)	
Completed 11 years	16.97	(2.10-31.85)		21.50	(13.52-29.48)	
Completed college	13.62	(0.00-40.31)		20.07	(6.35-33.78)	
Race			0.15			0.79
Black	26.72	(0.00-63.74)		21.99	(4.62-39.35)	
Mixed	53.36	(28.00-78.72)		18.31	(10.18-26.44)	
White	18.66	(3.73-33.59)		23.66	(14.39-32.94)	
Other	0.00	(0.00-262.02)		47.80	(0.00-126.10)	
Year			0.04			0.99
2007	51.92	(34.50-78.12)		22.50	(14.63-34.60)	
2008	24.98	(13.83-45.10)		22.57	(16.78-30.34)	

* FT donor incidence rate based on 34 recently HIV-infected cases (as determined by detuned assay); repeat donor incidence rate based on estimated 64.6 incident HIV cases within the 2-year study period.

TABLE 3. Composite incidence and residual risk (and 95% CIs) according to blood center, REDS-II study in Brazil, 2007 to 2008

	Composite incidence per 100,000	Residual risk per 1,000,000 (95% CI), According to window phase		
Blood center	person-years (95% CI)	Ag + Ab IA* (15.0 days)	MP-NAT (9.0 days)	ID-NAT (5.6 days)
Recife	31.8 (21.5-42.2)	13.1 (8.3-17.8)	7.8 (5.1-10.6)	4.9 (3.2-6.6)
Belo Horizonte	24.2 (13.8-34.9)	10.0 (5.4-14.6)	6.0 (3.3-8.7)	3.7 (2.0-5.4)
São Paulo	25.9 (17.8-33.9)	10.6 (6.9-14.4)	6.4 (4.2-8.5)	4.0 (2.6-5.3)
Brazil	27.5 (22.0-33.0)	11.3 (8.4-14.2)	6.8 (5.1-8.4)	4.2 (3.2-5.2)

* Ag + Ab IA = immunoassay that detect antigen p24 and anti-HIV; MP = minipool.

donors in the United States ($2.92/10^5$),[7] Canada ($1/10^5$),[20] Australia[8]($1.1/10^5$), and regions of Europe (1.8, 3.8, and $37.6/10^5$ donations in Western, Central, and Eastern Europe,[9] respectively). However, the prevalence in Brazilian donors is lower than the rates reported in the Ukraine (128.4/100,000)[10] and many countries in sub-Saharan Africa.[21,22]

In a previous study from our group focused within the city of São Paulo, we have shown that the prevalence of HIV in FT donors decreased over time from $204/10^5$ (95% CI, $183/10^5$-$228/10^5$) in 1996 to $131/10^5$ (95% CI, $109/10^5$-$156/10^5$) in 2001.[11] The current data demonstrate a further decrease in prevalence among FT donors in the city of São Paulo to $85/10^5$ (95% CI, $65/10^5$-$104/10^5$) in 2007 to 2008. Since the prevalence in the general population in Sao Paolo is estimated at 400 to 600 per 10^5,[23] our data show that blood donor candidates are effectively selected based on donor qualification criteria to represent a lower risk subset of the population, although the ratio of infection prevalence among FT donors to the general population prevalence is not as low in Brazil (approx. 0.2) as in the United States (approx. 0.05).[24] Hence, additional education and deferral effort is warranted to further reduce the rates of HIV infection among individuals presenting to and accepted for donation in Brazil. In this direction Brazil does request all individuals to disclose number of sexual partners in the previous year and unprotected sex with casual partners with center specific deferral criteria.

In the general population in Brazil, males still have a higher prevalence of HIV compared to females; however, the male-to-female ratio has decreased over time in the broader epidemic, from 3.1 before 1987 to 1.5 in 2009.[1] The ratio of male-to-female prevalence among FT donors in our study was 3.2. One possible explanation for this higher sex prevalence ratio among donors relative to the general population ratio is that infected females are better diagnosed in Brazil due to prenatal care and they have more access to testing in other settings. Another explanation is that males are more inclined to be test seekers at blood centers, as documented by several previous surveys conducted by our group.[6,25]

HIV prevalence rates varied across the blood centers and was approximately 30% higher in Recife (119.15/10^5) compared to Belo Horizonte (70.98/100,000). However, in the multivariable model only male, community donors and lower levels of education remained associated with elevated HIV prevalence. The higher prevalence seen in Recife is therefore probably due to the fact that Hemope Foundation in the State of Pernambuco has more male FT donors compared to the other two sites.[13]

Defining incidence among FT donors is challenging, since there is no perfect assay that can discriminate recent from long-standing infections.[26] The available assays have a number of potential limitations: they tend to misclassify as "recently infected" persons with late-stage AIDS as well as persons with viral suppression by antiretroviral therapy in whom antibodies titers and avidity wane, although these limitations are probably less important for allogeneic blood donors who are newly diagnosed and generally healthy. HIV subtype may also interfere, but in the three centers subtype B HIV-1 is present in more than 80% of the HIV-infected donations (data not shown). We had an additional challenge since we had to change incidence assays during the course of the study because one of the commercial kits was discontinued and this may have resulted in the imputed incidence being higher in FT donors in 2007 compared to 2008. Contrary to what we observed with prevalence rates in FT donors declining relative to our earlier studies, the estimated incidence among FT donors in São Paulo increased slightly (albeit nonsignificantly) from 25/100,000 person-years (95% CI 10/100,000-40/100,000 person-years) in 2001[11] to 37/100,000 person-years (95% CI, 19/100,000-56/100,000 person-years) in this study. This could be due to a limitation of the incidence assays and STAHRS methods, which are not precise for imputing very low-level incidence rates such as those observed in donor populaitons.[26] Another possible explanation is that the progressively enhanced procedures used by the centers to defer at-risk donors are less effective for recently infected individuals compared to those with long-standing infections.

Defining incidence among repeat donors also poses challenges. If a short period of time is used to monitor a donor population, only very frequent donors are counted and few incident cases are documented. On the other hand, if a very large period is used, we may underestimate incidence due to the fact that the return rate is probably lower for HIV seroconvertors compared to negative donors. Due to these considerations, we developed a new model in which all repeat donors were taken into consideration, but only the time from the beginning of the study period to their first observed donation was counted. This resulted in more than doubling the number of confirmed incident cases but avoided dilution of the denominator by long-interval donations.

The incidence among repeat donors (22.6/100,000 person-years; 95% CI, 17.1/100,000-28.0/100,000 person-years) was 40% lower than among FT donors (38.5/100,000 person-years; 95% CI, 25.6/100,000-51.4/100,000 person-years), consistent with findings from the United States and other countries. In a previous study in São Paulo, the calculated incidence among repeat donors was 25.9/100,000 person-years (95% CI, 18.2/100,000-36.1/100,000 person-years) during the 1996 to 1998 periods. Accordingly, it seems that although prevalence among FT donors has decreased, the incidence has remained the same in the past 15 years for FT and repeat donors. This incidence among Brazilian repeat donors is approximately 20-fold higher when compared to similar studies in France,[27] the United States,[7,14,24] Canada,[20] Australia,[8] Germany, and Greece[10] and two times higher compared to incidence rates in Serbia and Montenegro.[10]

Studies worldwide have demonstrated that the blood donor selection is an important component of blood safety and that replacement blood donors generally present an increased risk of HIV infection.[28,29] This study goes in the other direction and confirms our previous study focused in São Paulo that community donors have a higher HIV prevalence.[11] Similar results with respect to risk of transfusion-transmitted HCV among family replacement relative to community donors have recently being described in several African countries[30-32] and Spain.[33] Our current and previous[11] studies show that "community" donors, that is, donors that come spontaneously to the blood center, were more likely to be HIV positive when compared to replacement blood donors who donate in the name of a specific recipient to "replace" the blood supply. This finding has several explanations, some of them related to cultural or social aspects of blood donation in Brazil. Our results suggest that replacement blood donors, that is, those who donate blood to help a friend, family, or relative, do not want to harm their loved ones by their donations. In this sense, replacement blood donors who are at risk might avoid blood donation, either because they do not want to disclose any risk factor that they might have or had or because they are unwilling to be responsible for any blood contamination exposure toward their relatives or friends. Community volunteer donors

come to donate to help the general (unspecified) recipient population, and although they might in principle have a stronger social commitment, there is not a strong relationship between the donor and the recipient to prevent the harm of failure to fully disclose risk.

Indeed, studies from several countries that have interviewed HIV-positive blood donors have demonstrated that a substantial proportion of infected donors were aware of risk exposures but did not disclose their risks in the predonation questionnaire.[34-36] One previous study from our group showed that 9% of the individuals who came to donate at Pró-Sangue Foundation in São Paulo[6,25] were test seekers. These test seekers tend to be male, community, and lapsed donors and were more likely to have positive serologic markers for HSV-2.[6,25] Since blood donation is a valued activity in the community, they may get social approval for donating blood. The donation setting may be ideal for some at-risk individuals, since they get tested in a highly respected "laboratory," without arousing suspicion in partners, family, and friends and get positive recognition for the donation. This situation could be addressed by blood banks by various modification to current practices, such as by postponing the delivery of test results to the donors so that they would know that they cannot get the results immediately and by education of the population and prospective donors on the risks to patients that this behavior elicits.

Furthermore, our study shows that although NAT for HIV and HCV is being implemented in Brazil to reduce the relatively high current residual risk, it will not be sufficient to decrease the risk of transfusion-transmitted HIV in Brazil to US and European levels. Other strategies are necessary to reduce HIV incidence, although these may not be so easy to develop measures specific to at risk individuals. As an example, we recently analyzed tools like CUE[34] and educational material[37] but these initiatives were not proven to be effective. Perhaps changes in the HIV testing procedures in the general community that would reach less educated males may be more effective than trying to change procedures in the donor screening setting.

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CONFLICT OF INTEREST

No conflict of interest.

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