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Human T-Lymphotropic Virus Type 1 and Type 2 Seroprevalence, Incidence, and Residual Transfusion Risk Among Blood Donors in Brazil During 2007–2009

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Abstract

Human T-lymphotropic virus type 1/2 (HTLV-1/2) infection is endemic in Brazil but representative donor prevalence and incidence data are lacking. All blood donations (2007–2009) from three blood centers in Brazil were studied. Samples reactive on one HTLV screening test (EIA) were retested with a different EIA; dual EIA reactivity correlated strongly with a confirmatory Western blot. Prevalence, incidence, and residual transfusion risk were calculated. Among 281,760 first-time donors, 363 were positive for HTLV on both EIAs (135 per 10^5, 95% CI 122–150). Prevalence differed considerably by region, from 83 to 222 per 10^5. Overall incidence rate was $3.6/10^5$ person-years and residual transfusion risk was $5.0/10^6$ per blood unit transfused. The logistic regression model showed significant associations with: age [adjusted odds ratio (aOR) = 5.23 for age 50+ vs. <20], female sex (aOR = 1.97), black (aOR = 2.70 vs. white), and mixed skin colors (aOR = 1.78 vs. white), and inversely with education (aOR = 0.49, college vs. less than high school). HTLV testing with a dual-EIA strategy is feasible and can be useful in areas with low resources. Incidence and residual risk of HTLV-1 transmission by transfusion were relatively high and could be reduced by improving donor recruitment and selection in high prevalence areas. Blood center data may contribute to surveillance for HTLV infection.

Introduction

Human T-lymphotropic virus type 1 (HTLV-1) was the first human retrovirus to be discovered, in 1980, and HTLV-2 was discovered soon afterward, in 1982.[1,2] They are usually referred as HTLV-1/2, due to cross-reaction on screening enzyme immunoassays (EIAs). Confirmation of EIA results is necessary with a more specific test such as Western blot (WB), and discriminatory testing is required to differentiate HTLV type (1 and/or 2),[3] but both are often not performed in low income countries because of cost.[4]

Although the exact number of individuals who are seropositive for HTLV-1 and -2 is not known, it is estimated that 15 to 20 million persons are seropositive worldwide, mostly with HTLV-1.[5,6] The areas of the world with the highest prevalence rates for HTLV-1 include southwestern Japan, several sub-Saharan African countries, Central and South America,[7] and localized areas of Iran and Melanesia.[5] In the Americas, higher prevalence rates are found in some countries in the Caribbean, such as Jamaica[8] and Trinidad and Tobago. Somewhat lower seroprevalence rates are found in several countries in South America, including Brazil and Colombia.[7,9] HTLV-2 is endemic among Amerindians in North, Central, and South America and African Pygmies, and has spread epidemically among injection drug users in North America and Europe.[5]

The major modes of transmission for both viral types are by sexual contact, from mother to child via breast-feeding, and parenterally by blood transfusion and injection drug use.[5,10] Two main diseases have been causally linked to HTLV infection: adult T-cell leukemia/lymphoma (ATL) and HTLV-associated myelopathy/tropical spastic paraparesis (HAM/

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TSP) are linked to HTLV-1[5,10] and HAM/TSP only with HTLV-2.[11,12] Although these diseases have a relatively low penetrance (5–10% of all infected individuals), they carry high mortality (ATL) and disability (HAM/TSP).[10] While the disease spectrum of viruses is not fully known, uveitis and infectious dermatitis have also been associated with HTLV-1, and HTLV-2 has been linked to pulmonary inflammation and increased cancer mortality.[10–14]

HTLV-1/2 infection is endemic in Brazil[15,16] and testing blood donors for these viruses is mandatory in the country since 1993. Several studies show that the infection is more prevalent in women and occurs in clusters of higher prevalence.[15–17] However, recent data from a representative national study of Brazilian blood donors were lacking. We present herein the results of a collaborative study in three blood centers from different geographic regions in Brazil.

Materials and Methods

Population

We studied all blood donations in 2007 through 2009 in three Brazilian blood center databases, combined in a single data warehouse. The participating centers were Fundação Pró-Sangue (FPS) in São Paulo State (Southeast region), Hemominas, in Minas Gerais State (Southeast region), and Hemope in Pernambuco State (Northeast region), as previously described.[18] We calculated prevalence in first time blood donors (those who had never donated previously in each center) and incidence among all repeat donors whose previous donation in the blood center was negative. Donor characteristics were recorded at the time of donation; according to common practice in Brazil, skin color was recorded instead of race and ethnicity, and was self-reported. This study was approved by the Federal Committee on Human Subjects (CONEP) of the Ministry of Health in Brazil.

Serological tests

Serum samples were screened with one EIA for HTLV-1/2 [Ortho HTLV-I/HTLVII Ab-Capture ELISA Test System, Raritan, New Jersey; or Abbott Murex HTLV I + II, Dartford, UK]. Samples with EIA optical density to cut-off ratios below 0.9 were considered negative, between 0.9 and 1.1 borderline, and higher than 1.1 positive. Repeatedly reactive samples were sent to the study central laboratory in São Paulo and tested with a second EIA different from the one used for screening [BioMérieux, Vironostika HTLVI/II, Boxtel, The Netherlands; Ortho or Abbot Murex]. For the second EIA the samples were considered either positive or negative, according to the manufacturer's instructions.

For the year 2007, WBs [HTLV version 2.4, Genelabs Diagnostics (GLD), Singapore] were performed on all samples positive on the second EIA. We also reviewed the WB results for the subset of individuals reactive on the first EIA and negative or borderline on the second EIA, but who returned to the blood center after notification of a positive result and had a confirmatory test performed on that follow-up sample, per blood center routine practice. We used the following manufacturer's criteria to determine final status: "HTLV, type indeterminate" had the presence of p19 and p24 and p21; "HTLV-2" had the presence of p24 and GD21 and rgp46II; "HTLV-1" had the presence of p19 and GD21 and rgp46I; and "Indeterminate" had any band pattern that did not fulfill the above criteria. All laboratory tests used in this study are licensed for routine use in Brazil.

Statistical analysis

Prevalence and 95% confidence intervals for first time donations were calculated by year, sociodemographic characteristics, type of donation, and location. Adjusted odds ratios (aORs) were derived from a logistic regression model. Variables were included in the regression model if they achieved a p-value ≤ 0.05 in the univariate analysis. While there were 363 donations from FT donors that were positive for HTLV (repeatedly reactive on screening EIAs and reactive on second EIAs), there were an additional 27 donations from FT donors that were repeatedly reactive on screening EIAs but not tested by a second EIA. Based on Fig. 1, among 216 repeatedly reactive screened EIA donations there were 139 positive on second EIA and 77 negative on second EIA. Therefore, we used a 139/216 probability that each of the 27 donations not tested by a second EIA was positive for HTLV to impute data for missing second EIAs.

We computed the incidence rate of HTLV infection per 100,000 person-years by dividing the number of newly identified infections in repeat donors screened in 2007–2009 by the number of person-years of follow-up represented by the interdonation intervals defined by current and previous donation of repeat donors. Unadjusted Poisson regression models were used to compute the 95% confidence intervals around the incidence rates and to assess differences in incidence rates by sociodemographic characteristics, location, and donor type (an adjusted model was not developed due to the small number of incident events). There were nine potential incidents (akin to the 27 potential prevalent cases described above) in which similarly a 139/216 probability was imputed. The pre-REDS-II donation dates were used when available to determine interdonation intervals, and those dates could go back to 1988 for Minas Gerais, 1994 for São Paulo, and 1998 for Recife. Residual transfusion risk was calculated using the incidence and window period model assuming the value of 51 days for the HTLV immunological window and 100% transmission by preseroconversion window-phase donations.[19] A two-sided p-value <0.05 was considered to be statistically significant. All statistical tests were performed using SAS 9.2 software (SAS Institute, 2008).

Results

Dual EIAs and WBs were performed on all available samples from HTLV-1/2 primary EIA repeat-reactive donations collected in 2007, and the correlations between dual EIA reactivity and WB results were analyzed (Fig. 1). Of the 291 units detected as initially EIA reactive, 236 were repeatedly reactive and 55 borderline when retested with the same EIA. Of those 216 and 50 were available, respectively, for second EIA and WB testing. Of the 139 samples positive by both assays, 129 were confirmed as positive by WB indicating a positive predictive value (PPV) of the dual EIA testing strategy of 92.8% (95% CI 87.3–96.1) given initial EIA reactivity. Only one case confirmed by WB was positive in the original assay (Abbott) and negative by the second EIA (BioMerieux), yielding a negative predictive value of 99.6% (255/256) (95% CI 97.8–99.9) for the alternate EIA strategy given initial EIA

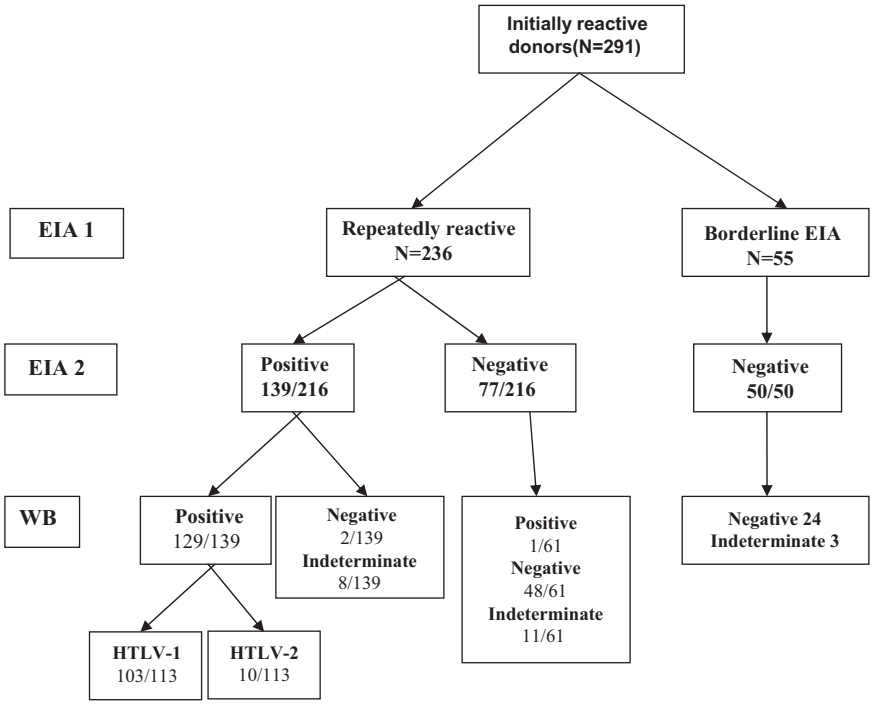

FIG. 1. Human T-lymphotropic virus type 1/2 (HTLV-1/2) western blot results according to classification of 2007 calendar year blood donations by the HTLV-1/2 dual enzyme immunoassay (EIA) algorithm. Western blot: HTLV version 2.4, Genelabs Diagnostic.

reactivity. With respect to HTLV subtypes, the WB results indicated that of the 113 HTLV-1/2 confirmed positive donors, 103 were HTLV-1 and 10 HTLV-2; hence ~90% of HTLV-1/2 infections among Brazilian donors were HTLV-1.

During the 3-year period of the study (2007–2009) at the three blood centers in Brazil, 281,760 donations were made by first time donors and 637,693 from repeat donors. A total of 363 ($128.83/10^4$ donations) of 281,760 first time donations were found to be reactive by both EIAs and therefore considered positive for the purposes of this study (Table 1).

Significantly different rates of HTLV prevalence were found in first-time donors by donor age, gender, education status, and race (Table 1). Prevalence increased with age, ranging from a prevalence of 53 per 10^5 in the <20-years-old group to 386 per 10^5 in the 50+-year-old group ($p<0.0001$). Seroprevalence was significantly higher among female (165 per 10^5) versus male (105 per 10^5) donors. Analysis by both age and gender revealed increasing HTLV prevalence by age in both genders, rising from 45 per 10^5 (age <20) to 221 per 10^5 (age 50+) in men (Chi-square test for trend $p<0.0001$) and from 62 per 10^5 (age <20) to 577 per 10^5 (age 50+) among women (Chi-square test for trend $p<0.0001$) but with a higher slope in females than in males (Fig. 2).

On the other hand, an inverse relationship was observed for education with a higher HTLV prevalence rate of 224 per 10^5 among those who did not graduate high school versus 75 per 10^5 among those with a college degree or higher ($p<0.001$). Prevalence was also higher among those with black skin color (214 per 10^5) versus mixed (158 per 10^5) or white (79 per 10^5) skin color. Prevalence among replacement donors (146 per 10^5) was not significantly higher than that among community volunteer donors (126 per 10^5). HTLV prevalence rates differed by region (Table 2), ranging from 83 per 10^5 in Minas Gerais to 101 per 10^5 in São Paulo and 222 per 10^5 in Pernambuco, with little variation over the 3 years of the study.

Center-specific analyses revealed significantly higher HTLV-1/2 prevalence among female first time donors in all blood centers, with the largest difference between the male and female donors seen in Recife, followed by Belo Horizonte and then São Paulo. The highest prevalence rates in the blood centers was found among those with black skin color, followed by the mixed skin color group and then the white skin color group. The highest prevalence in São Paulo was seen among the "other" (nonwhite, nonblack) skin color group. There was also a statistically significant inverse relationship between education level and HTLV prevalence in Recife and São Paulo, but not in Belo Horizonte. The highest prevalence rates were found among those who did not graduate high school, while the lowest rates were seen among those with a college degree or higher.

In the multivariable logistic regression model (Table 3), HTLV-1/2 seropositivity remained significantly associated with location (aOR = 1.91 for blood center location at Recife vs. São Paulo), age (aOR = 5.23 for age 50+ vs. <20), female sex (aOR = 1.97), black (aOR = 2.70 vs. white) and mixed skin colors (aOR = 1.78 vs. white), and lower education level (aOR = 0.49 for college vs. less than high school education).

The overall incidence rate, i.e., the number of repeat donors who seroconverted for HTLV-1/2 in the study period, was 3.59 per 100,000 person-years (2.61–4.80) for the three blood centers combined (Table 4). Residual risk calculated based on this incidence was $5.0/10^6$ per repeat donor blood units transfused. HTLV incidence rates significantly differed by region, ranging from 1.73 per 10^5 in São Paulo to 2.82 per 10^5 in Minas Gerais and 7.16 per 10^5 in Recife ($p<0.01$). HTLV incidence significantly differed by gender ($p=0.01$), with a higher incidence among females (5.74 per 10^5) versus males (2.78 per 10^5). HTLV incidence also varied significantly by skin color ($p=0.01$), with higher rates among those with "other" skin color (15.20 per 10^5) versus mixed (3.75 per 10^5) or white (2.40 per 10^5) or black (0.55 per 10^5) skin color.

Table 1. Human T-Lymphotropic Virus Prevalence in First Time Donors by Demographic Characteristics and Type of Donation

	Donations (N)	*HTLV positive* (N)	*Prevalence/100,000 donations*	*(95% CI)*	p-*value*
Overall	281,760	363	135.2	(122.2–149.5)	
Donation year					
2007	93,712	124	140.5	(118.5–166.7)	0.04
2008	93,274	103	111.1	(91.7–134.7)	
2009	94,774	136	153.0	(130.0–180.0)	
Age					
<20	36,860	19	53.3	(34.2–82.9)	<0.0001
20–29	131,261	97	76.8	(63.2–93.4)	
30–39	63,164	105	178.4	(148.4–214.6)	
40–49	34,929	85	250.7	(203.4–309.0)	
50+	15,446	57	385.7	(299.4–496.9)	
Gender					
Female	112,586	186	170.9	(148.4–196.8)	<0.0001
Male	169,174	177	111.1	(96.3–128.1)	
Education					
<High School	25,965	55	224.2	(173.5–289.8)	<0.0001
High School	29,594	60	211.4	(168.1–270.8)	
Complete 3 years of College	111,136	102	97.6	(80.8–117.8)	
College+	27,679	20	74.6	(48.5–114.8)	
Type of donation					
Community	150,113	184	125.6	(108.9–144.8)	0.15
Replacement	131,593	179	145.8	(126.6–167.9)	
Skin color					
Black	26,106	54	214.4	(164.9–278.3)	<0.0001
Mixed	107,006	158	157.9	(135.8–183.5)	
White	104,597	79	78.6	(63.3–97.6)	
Other	3,580	5	139.7	(58.1–335.1)	

Number positive is based on two enzyme immunoassay (EIA) results; prevalence and 95% CI include an adjustment for the handful of screened EIA positives in which no confirmatory EIA test was done (see Materials and Methods).
HTLV, human T-lymphotropic virus.

Overall, there was no significant difference in the incidence of HTLV by donor type, education, or age.

Discussion

This study, the largest to date among blood donors in Brazil, found HTLV-1 and -2 seroprevalence rates in the order of 1 to 2 per thousand first time donors, which is higher than in the United States and Europe but lower than in the Brazilian general population.[20–23] Over 90% of the HTLV-1/2 infections were HTLV-1, consistent with previous reports from single centers.[6] Previously recognized associations with age, female gender, skin color, and socioeconomic status were confirmed. Broad scale geographic data such as this will allow

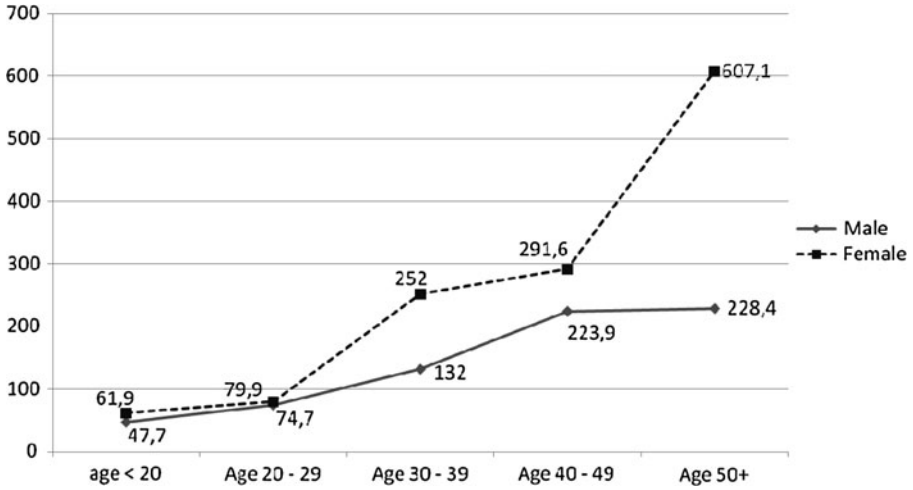

FIG. 2. HTLV prevalence rates (positivity based on two EIAs) among Brazilian first-time donors according to age and gender, 2007–2009.

Table 2. Human T-Lymphotropic Virus-1/2 Prevalence Among First Time Donors in Three Brazilian Blood Centers, 2007–2009

Blood center region	*Donations* (N)	*HTLV positive* (N)	*Prevalence/100,000 donations*	*(95% CI)*	p-*value*
São Paulo	125,182	126	100.7	(84.5–119.8)	< 0.0001
Recife	89,371	184	222.4	(193.6–255.5)	
Minas	67,207	53	82.7	(63.6–107.5)	
Total	281,760	363	135.2	(122.2–149.5)	

Number positive is based on two EIA results; prevalence and 95% CI include an adjustment for the handful of screened EIA positives in which no confirmatory EIA test was done (see Materials and Methods).

better monitoring of secular trends in HTLV prevalence by Brazilian blood bankers and public health authorities.

The prevalences found for HTLV-1 and -2 confirm previous studies that Brazil is an endemic country for these viruses.[6,15,16] The overall HTLV prevalence found in blood donors from the three centers in Brazil ($135.2/10^5$) is comparable to donors in countries in South America[5,7,9] and lower than among donors in countries in Central America,[8] Caribbean, Africa, Iran, and Melanesia.[5,10] It is, however, much higher than those found in blood donors in Europe ($2.0–5.0/10^5$), and the United States and Canada ($10–30/10^5$).[5] In Japan, after introduction of HTLV screening in blood banks, the prevalence in blood donors in the endemic areas dropped considerably.[5] It is noteworthy that in many endemic countries in South and Central Americas, the Caribbean region, and Africa, screening for HTLV is not currently performed in all blood banks, although it is transmitted in a very effective way through cellular components of the blood[12] and these regions do not perform leukoreduction (removal of leukocytes from donated blood by filtration) routinely, a procedure that could significantly reduce the risk of HTLV transmission through cellular blood components (red blood cell and platelet concentrates).

Table 3. Correlates of Human T-Lymphotropic Virus Positivity Among First Time Donors Using a Multivariate Logistic Regression Model

	p-*value*	*Odds ratio*	*95% CI*
Blood center	< 0.0001		
São Paulo		1	
Recife		1.91	(1.44–2.54)
Minas		0.91	(0.63–1.32)
Age	< 0.0001		
< 20		1	
20–29		1.15	(0.64–2.06)
30–39		2.84	(1.60–5.05)
40–49		3.80	(2.80–6.87)
50+		5.23	(2.77–9.89)
Gender	< 0.0001		
Male		1	
Female		1.97	(1.52–2.53)
Education	0.005		
< High School		1	
High School		1.09	(0.76–1.57)
Complete 3 years of College		0.73	(0.52–1.02)
College+		0.49	(0.29–0.83)
Skin color	< 0.0001		
White		1	
Black		2.70	(1.83–3.99)
Mixed		1.78	(1.30–2.43)
Other		2.15	(0.78–5.92)

Number positive is based on two EIA results; odds ratio and 95% CI include an adjustment for the handful of screened EIA positives in which no confirmatory EIA test was done (see Materials and Methods).

The associations of HTLV-1/2 seroprevalence with age and gender seen in this study are similar to those reported by other studies in endemic countries. Higher prevalence and increasing slope with age in women compared to men have been attributed to the increased role of sexual transmission in the infection of women.[5,11,12] However, increasing prevalence with age has also been attributed to a birth cohort effect in Jamaica, Japan, and the United States,[5,8,12,21] namely that younger generations had lower HTLV infection rates than older generations.

The differences in prevalence among the three centers were expected, and probably reflect population origins beyond those reflected in the demographic variables we analyzed. Previous studies show that HTLV-1 tends to concentrate in persons from lower socioeconomic levels, black or mixed skin color, and women.[5] Pernambuco State in Northeastern Brazil, where one of the centers (Hemope) is located, has the most notable history among our three centers of imported slave labor from Africa. Both HTLV-1 and sickle cell trait and disease are known to be endemic in Central Africa, and are found at high prevalence in Pernambuco State. São Paulo, which has immigration both from the Northeast region of Brazil and from Japan, a country known for its high prevalence rates of HTLV-1,[5] showed in the present study an intermediate prevalence of HTLV-1/2 among blood donors.

There are few incidence data for HTLV-1/2 infection and associated diseases in Brazil and therefore blood services are useful to estimate the incidence of this infection/disease. In the United States, Stramer *et al.*[24] analyzed more than 4.2 million person-years of observation at the American Red Cross during 2008–2009 and found an HTLV incidence rate of 0.3 per 100,000 person-years (95% CI, 0.18–0.52). In the present study, we observed an HTLV incidence of 3.1 per 100,000 person-years during the 3-year study period, 10 times higher than found that in the United States, emphasizing the need for ongoing HTLV testing of blood donors for HTLV in Brazil. A significantly higher incidence in females and those of mixed/other skin color suggests ongoing HTLV transmission in those population subgroups. Interestingly, incidence did not differ with age, suggesting that low-level transmission may continue throughout life in Brazil.

The residual risk for HTLV-1/2 transmission by blood transfusion estimated in the present study (5.0 per million

Table 4. Human T-Lymphotropic Virus Incidence by Sociodemographic Characteristics, Location, and Donor Type

Characteristics	N	*Total HTLV incident cases*	*Total person-years*	*HTLV incidence rate per 100,000 person-years*	*95% CI*	p-*value*
Overall	640,439	36	1,162,949.47	3.59	(2.61–4.80)	
Blood center						
São Paulo	278,415	9	519,423.18	1.73	(0.90–3.33)	0.0003
Recife	218,312	19	337,485.17	7.16	(4.80–10.66)	
Minas	143,712	8	306,041.12	2.82	(1.45–5.50)	
Donor type						
Community	462,612	19	710,917.09	3.21	(2.13–4.84)	0.40
Replacement	177,777	17	451,978.55	4.19	(2.67–6.57)	
Gender						
Female	169,297	17	318,296.37	5.74	(3.63–9.09)	0.02
Male	471,142	19	844,653.10	2.78	(1.86–4.17)	
Age						
< 20	13,302	1	7,013.96	14.26	(2.01–101.21)	0.77
≥ 20– ≤ 29	212,078	8	314,456.73	2.95	(1.55–5.62)	
≥ 30– ≤ 39	211,214	13	439,655.94	3.54	(2.16–5.82)	
≥ 40– ≤ 49	139,883	10	282,143.78	4.00	(2.23–7.17)	
≥ 50 +	63,941	4	119,618.91	3.88	(1.56–9.64)	
Education						
< High School	61,395	5	125,500.86	4.50	(1.97–10.26)	0.68
High School	73,792	2	135,389.82	1.95	(0.06–6.52)	
Complete 3 years of Collage	236,526	13	422,663.06	3.38	(2.01–5.68)	
College +	73,457	4	146,794.64	2.72	(1.02–7.26)	
Skin color						
Black	66,955	0	117,379.37	0.55	(0.05–6.31)	0.04
Mixed	272,195	15	468,168.19	3.75	(2.35–5.99)	
White	251,367	10	443,073.05	2.40	(1.32–4.38)	
Other	7,808	2	13,158.43	15.20	(0.38–6.08)	

Number incidence is based on two EIA results; incidence rate and 95% CI include an adjustment for the handful of screened EIA positives in which no confirmatory EIA test was done (see Materials and Methods).

donations) is lower than the 8.6 per million donations risk previously reported from Southern Brazil.[24] Still, the risk is strikingly higher than that estimated for Canada ($0.95/10^6$) and the United States ($0.42/10^6$).[24,25] According to the authors of the latter report, such low levels of incidence and residual risk for HTLV may not be low enough to abandon testing of previously screened repeat donors in North America, but should allow reentry of HTLV false-positive individuals to the eligible donor pool.[25]

Data from blood donors can be extrapolated to other groups, but with caution, since blood donors are selected to be at low risk of parenterally transmissible infections. Data from metropolitan areas of Europe suggest that the seroprevalence of HTLV-1 in pregnant women may be up to 100 times higher than in blood donors.[22] Since blood donors come from a relatively healthier stratum of the population, and in the studied centers tend to be younger and males,[18] we estimate that the HTLV prevalence in the general population of the Brazilian States where the study was conducted is several times higher, and therefore worthy of public health surveillance. This "sentinel" aspect of the blood banking activity should be emphasized: the reasons for deferring blood donors may point to local health problems and be a "thermometer" of adult population well being.[22,26] Blood bank data will also be useful for monitoring secular trends in HTLV prevalence over time.

The dual EIA algorithm we employed, which involves testing each sample that was repeat-reactive with the primary screening EIA using a different EIA, as previously suggested by Seed *et al*.,[27] was shown to have high positive and negative predictive values, and could thus be utilized in blood services that usually do not perform confirmatory tests for HTLV due to the high cost of commercial WBs and unavailability of commercial HTLV PCR tests. This is the case for the majority of blood services in Brazil, where screening for HTLV is obligatory, but not the confirmation. A previous study with PCR analysis of samples from HIV-positive patients from southern Brazil suggested that viral lysate EIAs were less sensitive for HTLV-2, and WB gave indeterminate results for HTLV-2 (particularly subtype 2-b) in Brazil.[28] So it is possible that some HTLV-2-infected individuals may not have been detected by the EIAs used in our studies and that some of our WB indeterminates were actually infected with HTLV-2, collectively leading us to underestimate the prevalence of that infection. However, due to differences in the Brazilian region and blood donors versus the HIV patient population, we believe that HTLV-2 prevalence in our study would be only minimally affected by this issue.

The Brazilian public health system, to which HTLV-seropositive donors are referred, is still not prepared to confirm and counsel the donor, therefore creating a difficult public health situation. In some States (e.g., Pernambuco, Bahia,

Minas Gerais, Rio de Janeiro) this gap is filled in by research groups that supply the confirmation tests, follow-up with donors and families, and take preventive measures, such as counseling about sexual and mother-to-child transmission. But other States with a very high prevalence (e.g., Maranhão State)[6,7] neither do confirmatory tests/follow-up, nor have a researchers and/or public health center to which the donors can be referred.

The strengths of the current study include the inclusion of large numbers of blood donors tested for HTLV antibodies using consistent laboratory procedures. Data on demographic characteristics were also available from a research database formulated from operational blood bank computer systems. Limitations include the lack of specific confirmatory testing on the entire data set, although we believe that the alternate EIA testing strategy is an acceptable alternative for epidemiologic research. We should caution that the positive predictive value of the dual EIA strategy would likely be lower in countries with lower HTLV prevalence than Brazil.

Since approximately 8% of dual EIA reactive donors are not infected based on WB results, we recommend that a WB be performed on dual EIA reactive samples before or in conjunction with donor notification and counseling. Our estimate of residual risk was not adjusted to reflect the approximately 30% rate of transmission associated with refrigerator stored nonleukoreduced RBC components, and hence the reported estimates for residual risk of transfusion transmission of HTLV-1/2 likely are higher than the actual risk. Finally, our operational blood donor database did not include information on sexual behavior or parenteral exposures to allow a detailed assessment of these behavioral risk factors. However, targeted case-control studies would be possible in the future.

In conclusion, we have presented large-scale HTLV seroprevalence and incidence analysis based on screening Brazilian blood donors. We hope to continue to collect similar data in order to monitor secular trends, and to increase the size of the research database by including blood centers from other Brazilian geographic regions. We also plan to monitor HTLV-1/2 incidence, which will allow for a more precise estimation of residual risk of HTLV-1/2 transmission by transfusions in Brazil. Further evaluation of other testing strategies will also be possible using samples collected within this research framework.

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Author Disclosure Statement

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