Residual risk of transmission of human immunodeficiency virus and hepatitis C virus infections by blood transfusion in northern Brazil

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BACKGROUND: Nucleic acid test (NAT) blood screening for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) was introduced in northern Brazil in July 2012. There are several Brazilian articles that have evaluated transfusion transmission risks for HIV and HCV. However, to our knowledge, this article is the first to evaluate the impact of HIV and HCV NAT implementation for blood screening in northern Brazil. The aim of this study was to determine the prevalence and incidence rates of HIV and HCV among blood donors and to compare the residual risk of transfusion transmission of these infections, before (2009-2011) and after (2012-2014) NAT implementation.

STUDY DESIGN AND METHODS: HIV and HCV prevalence and incidence were calculated based on rates of confirmed positive samples. Residual risk estimates were based on the incidence and window model described previously. Logistic and Poisson regressions were used in the statistical analysis. A p value of not more than 0.05 was considered significant.

RESULTS: HIV and HCV prevalence were 209.9 and 66.3 per 100,000 donations, respectively. Residual risk for HIV and HCV decreased significantly throughout the two study periods, mainly for HCV in which the reduction was one in 169,492 to one in 769,231 donations. For HIV, the decrease was one in 107,527 to one in 769,231 donations. HIV and HCV incidence rates were 21.13 and 3.06 per 100,000 persons/year before NAT and 14.03 and 2.65 per 100,000 persons/year after NAT.

CONCLUSION: The HIV and HCV NAT implementation significantly increased the transfusion safety in northern Brazil, bringing benefits to recipients due to better quality of blood products produced.

Blood transfusions are an essential component of health care that save millions of lives each year worldwide. Around the world, more than 92 million blood donations are collected every year.[1,2] The purpose of blood transfusion services (BTSs) is to ensure an adequate, efficient, and above all, safe supply of blood products to the population.[3] In Brazil, the BTSs are regulated by the Ministry of Health (Federal Government). Monetary incentives to blood donors are forbidden. Candidates' donations that are at risk for sexually transmitted disease are excluded based on a previous interview and medical evaluation according to the recommendations of the AABB.[4]

The major concern related to transfusion safety is transfusion-transmissible infections (TTIs).[5] The risk of

ABBREVIATIONS: BTS(s) = blood transfusion service(s); CMIA(s) = chemiluminescent microparticle immunoassay(s); EIA(s) = enzyme immunoassay(s); FT = first time; ID = individual donation; MP(s) = minipool(s); py = person-years; TTI(s) = transfusion-transmissible infection(s); WP(s) = window period(s).

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TABLE 1. Donor screening tests for HIV and HCV from 2009 to 2014

		Year of Study					
Screening test	Assay	2009	2010	2011	2012	2013	2014
HIV							
Murex HIV-1.2.O	EIA	X	X	X			
Murex HIV Ag/Ab	EIA	X	X	X	X		
NAT HIV/HCV	RT-PCR				X	X	X
Architect HIV Ag/Ab	CMIA					X	X
HCV							
Murex Anti-HCV	EIA	X	X	X	X		
NAT HIV/HCV	RT-PCR				X	X	X
Architect Anti-HCV	CMIA					X	X

TTIs depends on the capability to exclude high-risk donors as well as to identify and remove potentially infectious components such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infections.[6-8] Various types of assay have been developed for blood screening over the past three decades.[9] Enzyme immunoassays (EIAs) and chemiluminescent microparticle immunoassays (CMIAs) have been the predominant screening method for viral antibodies and/or antigens.[10,11] However, the disadvantage of these methods is the long diagnostic time, known as the "window period" (WP),[3,8,11-14] which is approximately 66 to 70 days for HCV infection and approximately 22 days (just antibody) and 15 to 17 days (antibody plus p24 antigen) for HIV infection.[14-16]

To increase transfusion safety, nucleic acid amplification testing (NAT) to detect HIV-1 and HCV RNA was approved by the Food and Drug Administration in 1999.[3] Since then, NAT began to be implemented in several countries for screening blood donors and, consequently, decreasing the residual risk of TTIs by reducing the WP for HIV to 5.6 days when applied in individual donation (ID-NAT) and to 9 to 11 days when applied in minipool samples (MP-NAT) and for HCV to 4.9 days in ID-NAT and 7.4 to 11 days in MP-NAT.[16-18] However, the NAT detection may be compromised in the immediate period after infection by the absence of detectable plasma viremia.[19-22]

In Brazil from 2010, a national NAT platform for the simultaneous detection of HIV and HCV was developed by Bio-Manguinhos (NAT HIV/HCV Bio-Manguinhos-FIOCRUZ) and gradually implemented in BTSs throughout the country by the Ministry of Health.[23] In the Center for Hemotherapy and Hematology of Pará (HEMOPA) Foundation, responsible for the most hemocomponents transfused in the State of Pará (northern Brazil with approximately eight million inhabitants), it has been implemented in 2012 and currently used concomitantly with one serologic test for both viruses. The HEMOPA Foundation is a network of nine BTSs in the state of Pará. The BTSs coordinator is located in the city of Belém (responsible for all laboratory screening methods). From 2013, the HIV and HCV NAT screening became mandatory in all Brazilian BTSs.[4]

Given the absence of studies evaluating the impact of NAT implementation in northern Brazil, the aim of this study was to determine the prevalence and incidence rates of HCV and HIV among the HEMOPA Foundation's blood donors and to compare the residual risk of TTIs for HIV and HCV before and since the implementation of the Brazilian NAT platform in blood donors screenings.

MATERIALS AND METHODS

Data source

Data from all blood donations from January 1, 2009, to December 31, 2014, were extracted from the computer systems of the HEMOPA Foundation. These data included coded donor identification, the number of blood donations stratified for sex, age group (18-29, 30-39, 40-49, 50-60 years), self-reported skin color (captured as five options but recoded into white, black, mixed), blood bank (Belém, Castanhal, Santarém, Marabá, Altamira, Tucuruí, Redenção, Capanema, or Abaitetuba), educational attainment (illiterate, middle school, high school, or university), type of donor (first-time [FT] or repeat), type of donation (replacement or community), the sum of intervals (in days) between the first and last donation for each repeat donor (donor with a history of donation both during and before the study period), the number of repeat donors who made a negative blood donation followed by a positive donation (seroconvertors), the number of confirmed positive donations, screening assays, and confirmatory tests.

HIV and HCV serologic and molecular screening

Two of the following serologic kits were used in parallel for HIV screening according to Table 1: EIA screening by the Murex HIV-1.2.O kit (third-generation) and Murex HIV Ag/Ab (fourth-generation) kit and CMIA screening by the Architect HIV Ag/Ab kit (fourth-generation), all manufactured by Abbott Laboratories. For HCV screening, one of the following serologic kits was used: EIA Murex anti-HCV (Version 4.0) or CMIA Architect anti-HCV, both third-generation

and manufactured by Abbott Laboratories. The serologic results were considered positive when at least two positive readings were identified and were all in agreement. Samples with positive and inconclusive readings and/or with positive and a negative reading were considered inconclusive.

Molecular screening for both viral agents (from July 2012) was performed by the NAT HIV and HCV kit (Table 1) manufactured by Bio-Manguinhos/FIOCRUZ, which is multiplexed and performed in MPs of six samples. ID-NAT was applied to identify the positive samples in MP-NAT. All tests were applied according to the manufacturer's recommendations.

HIV and HCV confirmatory tests

In the period of 2009 to 2011, Western blot testing was added to the screening algorithm for HIV serologic reactive samples. From 2012 to 2014, confirmatory testing was performed by Western blot only in samples without ID-NAT confirmation. The confirmatory test for HCV serologic reactive samples was performed by ID-NAT in the period 2009 to 2014.

Calculation of HIV and HCV prevalence

The HIV and HCV prevalence was restricted to FT donors. It was based on rates of confirmed-positive donations divided by the number of donations before and after the NAT implementation by type of donor, type of donation, blood bank, and donor characteristics.

Estimative of incidence rates and residual risk

The incidence rate was defined as the number of confirmed seroconverters or viral RNA converters over the total number of person-years (py) at risk. The number of py at risk was obtained by summing of the interdonation intervals (in days) between first and last donation for each repeat donor. For seroconverting donors, an adjustment was made by assuming that seroconversion occurred at the midpoint between the last seronegative donation and the seropositive donation; thus, for these cases the time at risk was from the first donation to half way between the last two donations.

Estimates of the residual risk of transfusion-transmitted viral infection were based on the incidence and window model described by Schreiber and colleagues.[24] The study period was divided in two parts, before (2009-2011) and after (2012-2014) NAT implementation, to perform the analyses. The residual risk is obtained by multiplying the incidence rate for the WP expressed as a fraction of the year, according to the formula RR = incidence rate × (WP screening test/365 days). The serologic WP (16 days for HIV and 70 days for HCV) was used to calculate the residual risk for HIV and HCV until the introduction of NAT screening (2009-2011) and the NAT WP (9 days for HIV and 10 days for HCV) was used in the period after the NAT introduction (2012-2014).[16-18] In the transition year (2012) the weighted means of WPs were adjusted by length of time used.

Statistical analysis

All analyses were performed using a statistics package (SPSS v20.0, SPSS, Inc.). Univariate and multivariate logistic regression were used to assess differences in prevalence rates. The GENLIN command was used to estimate Poisson regression and assess differences in residual risk for HIV and HCV. Poisson regression also was used to assess the confidence intervals (CIs) for both incidence and residual risk. A p value of less than 0.05 was considered significant.

RESULTS

From January 1, 2009, to December 31, 2014, a total of 528,921 blood donations were collected at the nine BTSs of the HEMOPA Foundation. Across all centers, 363,141 (69%) of all donations came from repeat donors. A majority of donations (69%) came from male donors, donors of the age group between 18 and 29 years old (45%), and donors with high school education level (59%). Donors of mixed race (78%) composed the main donor pool. Of these donations, 70% were drawn in the central blood center located in Belém city and the majority (71%) were community type (Table 2).

HIV and HCV prevalence

Of the 165,780 FT donors, 348 individuals were confirmed HIV positive, resulting in a prevalence of 209.9 per 100,000 donations. As shown in Table 3, unadjusted analyses demonstrated that HIV prevalence rates were significantly higher before NAT (243.8/100,000), in male donors (227.3/100,000), donors in the 18- to 29-year age group (153.3/100,000), in Redenção (231.4/100,000), in high school donors (220.5/100,000), and in black race (281.5/100,000). After logistic regression (multivariate analyses), only age (donors with age between 18 and 29 years old had higher prevalence) and blood center (Redenção had higher prevalence) remained associated with HIV infection status.

For HCV, a total of 110 were confirmed positive resulting in a prevalence of 66.4 per 100,000 donations, much lower than HIV. Unadjusted analyses demonstrated that HCV prevalence rates were significantly higher only in the 50- to 60-year age group (351.9/100,000) and in Santarem (87.8/100,000). The results of logistic regression analysis showed that these characteristics are associated with HCV infection status (Table 4).

Incidence rates and residual risk

A total of 363,131 repeat donors, 163,736 before and 199,395 after NAT implementation, were included in

TABLE 2. Donation characteristics

Characteristic	Number (%)
All period	528,921
Before NAT	243,895
Since NAT	285,026
Type of donor	
FT	165,780 (31)
Repeat	363,141 (69)
Sex	
Male	366,252 (69)
Female	162,669 (31)
Type of donation	
Replacement	151,096 (29)
Community	377,825(71)
Age group (years)	
18-29	234,198 (44)
30-39	163,028 (31)
40-49	88,150 (17)
50-60	36,912 (7)
Blood center	
Belém	370,508 (70)
Castanhal	25,657 (5)
Santarém	32,707 (6)
Marabá	36,433 (7)
Altamira	16,250 (3)
Tucuruí	10,985 (2)
Redenção	12,392 (2)
Capanema	10,147 (2)
Abaetetuba	13,842 (3)
Education	
Illiterate	692 (0)
Middle school	107,566 (20)
High school	309,552 (59)
University	111,111 (21)
Race	
Black	20,369 (4)
Mixed	414,374 (78)
White	94,178 (18)

incidence rates and residual risk estimates. Of these, 258 HIV-positive and 37 HCV-positive donors were classified as seroconvertors. The HIV incidence rates were 21.13 and 14.3 per 100,000 person/year in the periods 2009 to 2011 and 2012 to 2014, respectively. For HCV, incidence rates were 3.06 (2009-2011) and 2.65 (2012-2014) per 100,000 persons/year. The residual risk for HIV and HCV decreased significantly throughout the study period ($p < 0.0001$), mainly for HCV in which the reduction was 0.59 (2009-2011) to 0.13 (2012-2014), per 100,000 donations ($p < 0.0001$), corresponding to a 4.54 times lower risk. For HIV, the decrease was 0.93 (2009-2011) to 0.38 per 100,000 donations ($p < 0.0001$), 2.45 times lower risk (Table 5). After NAT implementation, six HIV NAT-yield donations but none of HCV were identified which represents a HIV NAT yield of one in 47,506.

DISCUSSION

The possibility of transmitting diseases by blood transfusion is a major preoccupation related to transfusion safety.[5] Among the greatest impact virus transfusion transmissions are HIV and HCV due to the severity of complications caused by infection by these viruses, such as severe immunosuppression, opportunistic infections, and malignant neoplasms in the case of HIV and the appearance of liver cirrhosis and hepatocellular carcinoma in the case of HCV.[7,8,23]

The transmission of one of these agents by transfusion can occur when the newly infected donor is not identified by the screening clinic, the analyte (target component screening test—e.g., antibody, antigen, nucleic acid) is not identified by laboratory screening, or the viral agent survives in storage conditions and production of blood products and is able to cause the infection when inoculated intravenously.[5,25]

In Brazil, a considerable proportion of the donor population believes that blood banks are a convenient place to obtain free testing, and they believe that it is acceptable not to answer the screening questions truthfully to be tested since infections will be accurately detected and the infected units interdicted.[26] A study performed in southeastern Brazil showed that almost 50% of the recently detected HIV-positive blood donors were aware of their HIV risk behaviors, but did not report them during predonation interviews.[27] Test-seeking motivation, undisclosed risk factors, and the low knowledge of WP risk are essential points related to blood safety and reinforce the importance of effective laboratory screening.

Specific serologic tests for HIV and HCV began between the years 1980 and 1990, with very significant results in reducing the risk of transmission of these pathogens by transfusion.[28] Indeed, the risk of being infected by a contaminated blood unit today is considerably lower when compared to 30 years ago, but unfortunately still persists.[29,30] This risk is mainly linked to donations in the WP after a recent, undetected infection.[10]

Given these facts and the absence of studies, this article describes the prevalence and incidence of HIV and HCV among allogeneic donations of the HEMOPA network in northern Brazil. In addition, we identify the impact of the recent inclusion of HIV and HCV NAT in laboratory screening of donors by estimating the residual risk of transfusion transmission of HIV and HCV infections.

The results of this study demonstrated that donors of the northern region are relatively young with 76% below 39 years of age and that males are predominant representing 69% of donors; the majority (69%) are repeat donors and are community donors (71%). These results corroborate with a REDS-II study performed in southeastern and northeastern Brazil that documented that more than 60% of the studied donor population are below 35 years of age and that males are predominant, accounting for 70% of the donors; 67% are community donors and 69% are repeat donors.[31]

The prevalence of HIV among donors found in this study was very high (209.9/100,000) compared with the other Brazilian regions like northeastern Brazil (119.15/

TABLE 3. Prevalence of HIV infection per 100,000 donations among FT blood donors in Pará state of Brazil, 2009 to 2014

Characteristic	Number of donations	Number HIV-positive	Prevalence (95% CI)	p value	AOR (95% CI)	p value
All periods	165,780	348	209.9 (189.0-233.1)			
Before NAT	77,917	190	243.8 (211.2-289.6)	0.005	1	0.58
Since NAT	87,863	158	179.8 (155.6-213.7)		0.7 (0.5-0.9)	
Sex						
Male	114,388	260	227.3 (203.9-263.3)	0.025	1	0.24
Female	51,392	88	171.2 (144.8-212.4)		0.7 (0.5-0.9)	
Type of donation						
Replacement	46,418	93	200.4 (166.2-257.3)	0.62	1	0.41
Community	119,362	255	213.6 (199.3-243.7)		1.0 (0.8-1.3)	
Age group (years)*						
18-29	76,259	203	266.2 (232.1-316.7)	<0.0001	1	0.002
30-39	53,050	90	169.7 (142.6-213.9)		0.6 (0.4-0.8)	
40-49	26,525	38	143.3 (102.4-207.3)		0.5 (0.3-0.7)	
50-60	9,946	17	170.9 (113.6-278.3)		0.6 (0.3-1.0)	
Blood center						
Belém	116,119	261	224.8 (201.4-258.9)	<0.0001	1	0.004
Castanhal	8,050	17	211.2 (133.8-345.2)		0.9 (0.5-1.5)	
Santarém	10,255	20	195.0 (138.6-300.6)		0.8 (0.5-1.3)	
Marabá	11,415	19	166.4 (113.7-266.4)		0.7 (0.4-1.1)	
Altamira	5,099	10	196.1 (113.4-367.3)		0.8 (0.4-1.6)	
Tucuruí	3,441	5	145.3 (69.4-344.2)		0.6 (0.2-1.5)	
Redenção	3,889	9	231.4 (127.4-440.2)		1.0 (0.5-2.0)	
Capanema	3,176	2	63.0 (29.6-231.7)		0.2 (0.0-1.1)	
Abaetetuba	4,336	5	115.3 (58.4-271.0)		0.5 (0.2-1.2)	
Education						
Illiterate	36	0	0.0	0.03		
Middle school	36,453	77	211.2 (170.5-263.8)		1	0.88
High school	96,154	212	220.5 (195.4-257.3)		1.0 (0.8-1.3)	
University	33,137	59	178.0 (138.0-229.5)		0.8 (0.6-1.1)	
Race						
Black	4,973	14	281.5 (241.3-332.4)	0.045	1	0.31
Mixed	132,624	275	207.4 (187.7-231.6)		0.7 (0.6-0.9)	
White	28,183	59	209.3 (166.8-272.4)		0.7 (0.5-1.0)	

AOR = adjusted odds ratio.

100,000) and southeastern Brazil (70.98/100,000 in Belo Horizonte and 84.91/100,000 in São Paulo)[18] and developed countries like the United States (2.92/100,000),[32] Europe (1.8, 3.8, and 37.6/100,000 donations in Western, Central, and Eastern Europe,[33] respectively), Canada (1/100,000),[34] and Australia (1.1/100,000).[35] HCV prevalence was 66.4 per 100,000 donations, very low compared to the rates among blood donors documented in southeastern (287/100,000 in São Paulo and 78/100,000 in Belo Horizonte) and northeastern (131/100,000) Brazil,[31] in the United States (163.4/100,000[36] and 225/100,000[37]), and in Spain (155/100,000).[38]

The results of this study showed a prevalence significantly higher among the age group of 18 to 29 years, for HIV, and among the age group of 50 to 60 years, for HCV. A study found a significant relationship between young individuals (younger than 25 years of age) and HIV test-seeking motivation,[39] which could be a possible explanation for our finding, since test-seeking blood donors are not uncommon in Brazil blood centers.[26] Studies have reported a direct proportional relationship between increasing age and the prevalence of HCV.[31,40,41] The same relationship was observed in our study. These factors probably related to an increased exposure over time to the main risk factors.

The residual risk of HIV and HCV transmission during a blood transfusion was estimated by the incidence and window model of Schreiber,[24] the most widespread model to estimate transfusion risks.[41] The incidence and window model and its adaptions were applied successfully worldwide to provide viral-TTI estimates.[3,16,18,31,42-53] Estimates of the risk of TTIs are essential for monitoring the safety of the blood supply and evaluating the potential effect of new screening tests.[24]

The residual risk estimates for HIV and HCV obtained in developed countries, albeit showing some variation, are uniformly low.[54] These reports clearly show an even greater reduction of residual risk after NAT implementation.[16,30,35,44,47,50] The residual risk of HIV transmission during blood transfusion varied from approximately one in 435,000 (Italy)[46] to one in 1,370,000 (France)[45] donations before NAT, whereas residual risks after NAT varied between one in 1,000,000 (Span)[44] and one in 8,300,000 (France).[45] Even more striking was the reduction for HCV,

TABLE 4. Prevalence of HCV infection per 100,000 donations among FT blood donors in Pará state of Brazil, 2009 to 2014

Characteristic	Number of donations	Number HCV-positive	Prevalence (95% CI)	p value	AOR (95% CI)	p value
All periods	165,780	110	66.3 (55.0-79.9)			
Before NAT	77,917	60	77.0 (62.6-101.2)	0.67	1	0.8
Since NAT	87,863	50	56.9 (44.5-82.7)		0.7 (0.5-1.0)	
Sex						
Male	114,388	71	62.1 (55.2-86.9)	0.52	1	0.7
Female	51,392	39	75.9 (63.8-101.4)		1.2 (0.8-1.8)	
Type of donation						
Replacement	46,418	34	73.2 (53.7-103.6)	0.67	1	0.8
Community	119,362	76	63.7 (57.4-85.2)		0.8 (0.5-1.3)	
Age group (years)						
18-29	76,259	15	19.7 (11.2-36.8)	<0.0001	1	<0.001
30-39	53,050	29	54.7 (43.1-82.7)		2.7 (1.4-5.1)	
40-49	26,525	31	116.9 (85.4-172.0)		5.0 (3.2-11.0)	
50-60	9,946	35	351.9 (253.8-499.2)		17.9 (9.7-2.8)	
Blood center						
Belém	116,119	83	71.5 (62.3-97.4)	<0.0001	1	<0.001
Castanhal	8,050	3	37.3 (11.2-114.5)		0.5 (0.1-1.6)	
Santarém	10,255	9	87.8 (57.2-172.6)		1.2 (0.6-2.4)	
Marabá	11,415	7	61.3 (37.4-131.3)		0.8 (0.3-1.8)	
Altamira	5,099	2	39.2 (18.3-141.6)		0.5 (1.1-2.2)	
Tucuruí	3,441	2	58,1 (22.8-211.2)		0.8 (0.1-3.3)	
Redenção	3,889	1	25.7 (7.4-153.8)		0.3 (0.0-2.5)	
Capanema	3,176	1	31.5 (10.5-181.7)		0.4 (0.0-3.1)	
Abaetetuba	4,336	2	46.1 (13.2-173.9)		0.6 (0.1-2.6)	
Education						
Illiterate	36	0	0.0	0.41		0.67
Middle school	36,453	30	82.3 (66.2-123.7)		1	
High school	96,154	65	67.6 (55.3-91.4)		0.8 (0.5-1.2)	
University	33,137	15	45.3 (27.4-74.6)		0.5 (0.2-1.0)	
Race						
Black	4,973	3	60.3 (22.4-181.6)	0.3	1	0.44
Mixed	132,624	84	63.3 (55.8-82.4)		1.0 (0.3-3.3)	
White	28,183	23	81.6 (51.4-128.3)		1.3 (0.4-4.5)	

AOR = adjusted odds ratio.

TABLE 5. Incidence rates and residual risks for HIV and HCV in the years before (2009-2011) and after (2012-2014) implementation of NAT

	2009-2011	2012-2014	p value
HIV			
Number confirmed positive	136	122	
Incidence rate per 100,000 py	21.13	14.03	
95% CI	17.58-24.68	11.65-16.75	
Residual risk (per 100,000)	0.93	0.38	<0.0001
95% CI	0.8-1.1	0.32-0.46	
Residual risk (1 in)	107,527	263,158	
HCV			
Number confirmed positive	18	19	
Incidence rate per 100,000 py	3.06	2.65	
95% CI	1.81-4.94	1.60-4.12	
Residual risk (per 100,000)	0.59	0.13	<0.0001
95% CI	0.51-0.66	0.08-0.21	
Residual risk (1 in)	169,492	769,231	

with risks decreasing from approximately one in 81,500 (Korea)[30] to one in 860,000 (France)[45] donations before NAT (third-generation EIA) and from approximately one in 232,000 (Italy) to one in 3,636,000 (Australia)[35] after NAT.

Studies in developing countries documented substantially greater risk than exists in developed countries.[55-57] For example, a study conducted in sub-Saharan Africa found a residual risk for HIV of one in 1000 donations and for HCV of one in 400 donations.[55] Another study found a

risk of one in 1515 donations for HIV and of one in 329 donations for HCV.[56] In Pakistan, after NAT implementation, the residual risks are one in 62,600 of HIV and one in 13,900 of HCV.[57]

Studies performed in southern, southeastern, and northeastern parts of Brazil found a high residual risk such as in other developing countries. A study performed in southern Brazil demonstrated a residual risk decrease of one in 5000 to one in 48,777 for HIV between the years 1991 and 1999 (anti-HIV).[58] A more recent study in the same region found risks of one in 26,200 and one in 52,500, before and after NAT.[6] A study performed by Sabino and coworkers[18] in three Brazil blood centers, located in the southeastern and northeastern part of Brazil, found a residual risk of one in 88,500 for HIV (anti-HIV plus p24 antigen) and estimated a decrease with NAT introduction to one in 147,000 with MP-NAT (approx. 1.66 times lower) and one in 238,000 with ID-NAT (2.69 times lower). For HCV, two studies performed in southern Brazil found similar residual risk estimates of one in 13,721 and one in 19,300 donations (with anti-HCV tests) with a projection of risk reduction to one in 127,000, with NAT introduction.[6,42] A study conducted in the southeast and northeast regions of Brazil found residual risks of one in 200,000 donations, with anti-HCV tests.[31] Some of these studies conducted in Brazil used different models to estimate the incidence rate; this fact may lead to a bias when comparing these studies with most of the studies, including ours, which are based on the model by Schreiber and coworkers.[24] Unfortunately, it is difficult to have total homogeneity of the methods because each author has its particularity for choosing the method. We chose the most widespread model for estimating residual risk to minimize this type of bias.

This study estimated for the first time the incidence and residual risk of transmission of HIV and HCV by transfusion in northern Brazil. Our results showed a significant reduction of residual risk for HIV and HCV after NAT implementation, mainly for HCV in which the reduction was one in 169,492 to one in 769,231 donations, corresponding to a 4.54 times lower risk. For HIV, the decrease was one in 107,527 donations before NAT to one in 263,158 donations after NAT, corresponding to a 2.45 times lower risk. These results show that the residual risks of HIV and HCV transmission by transfusion in northern Brazil are lower than those reported in the south, southeast, and northeast regions of Brazil[6,18,58] and even lower than those found in other developing countries.[55-57] However, compared with developed countries, it is still considerably high even after the NAT introduction. It is hoped that effective measures related to recruitment and procedures for clinical screening of blood donors further reduce these risks.[54] The implementation of NAT HIV and HCV in northern Brazil significantly increased transfusion safety, bringing benefits to recipients, due to better quality of blood products produced at the HEMOPA Foundation.

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CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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