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Changes in the prevalence, incidence and residual risk for HIV and hepatitis C virus in Southern Brazilian blood donors since the implementation of NAT screening

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ABSTRACT

Introduction: Previous studies have shown high residual risk of transfusing a blood donation contaminated by human immunodeficiency virus (HIV) or hepatitis C virus (HCV) in Brazil and motivated the development of a Brazilian platform for simultaneous detection of both viruses by nucleic acid amplification test (NAT) denominated HIV/HCV *Bio-Manguinhos*/*Fundação Oswaldo Cruz* (FIOCRUZ). The objective of this study was to verify seroprevalence, incidence and residual risk for both viruses before and after the implementation of NAT. **Methods:** Over 700,000 blood samples from all blood banks in the southern Brazilian State of Santa Catarina were analyzed during the period between January 2007 and July 2013. **Results:** Compared with the period preceding the NAT screening, HIV prevalence increased from 1.38 to 1.58 per 1,000 donors, HIV incidence rate increased from 1.22 to 1.35 per 1,000 donor-years, and HIV residual risk dropped almost 2.5 times during the NAT period. For HCV, seroprevalence increased from 1.22 to 1.35 per 1,000 donors, incidence dropped from 0.12 to 0.06 per 1,000 donor-years, and residual risk decreased more than 3 times after the NAT implementation. **Conclusions:** NAT reduced the duration of the immunologic window for HIV and HCV, thus corresponding to approximately 2.5- and 3-fold respective residual risk reductions.

Keywords: HIV. HCV. Blood donors. Prevalence. Incidence. Residual risk.

INTRODUCTION

Blood safety in transfusion medicine critically depends on donor recruitment, clinical examination for signs and symptoms of past or present infections and exclusion of those who represent a risk of transmitting these infections to the blood recipients; this screening relies either on pre-donation interviews or laboratory screening via serological or nucleic acid amplification test (NAT) analyses[1]. However, despite an increase in sensitivity with this screening, there is still some residual risk that the donated blood may be contaminated by an infectious agent. The quantification of residual risk is an important part of blood safety policies worldwide[2]. In Brazil, the methodology of residual risk estimation had been disseminated in the Portuguese language by the end of the 1990s[3,4] and has been sporadically applied in the country since then[1,5-10]. The results of these studies showed high prevalence, incidence and residual risk in Brazil compared with the United States of America (USA), Europe, Japan and Australia, thus reinforcing the need to monitor these parameters in a systematic way and to use them to evaluate the effectiveness of transfusion safety measures.

By the end of 2010, the Brazilian Ministry of Health had started the development of a NAT platform for the simultaneous detection of human immunodeficiency virus (HIV) and hepatitis C virus (HCV). After piloting the platform in three blood banks in 2010, the Brazilian NAT kit was licensed for routine blood bank screening in 2011 and has since been gradually implemented throughout the country. Two window-period transmissions of HIV were reported during the piloting phase, both of them in 2009[11].

The objective of this paper is to compare the prevalence, incidence and residual risk for HIV and HCV before and after the implementation of the Brazilian NAT platform by the Centre for Hematology and Hemotherapy of the Santa Catarina State (HEMOSC - *Centro de Hematologia e Hemoterapia do Estado de Santa Catarina*) in July 2010.

METHODS

The study population included all HEMOSC blood donors eligible for blood screening after clinical examinations and pre-donation interviews between January 2007 and July 2013.

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HEMOSC is a network of six blood banks from the Cities of Blumenau, Chapecó, Criciúma, Joaçaba, Joinville and Lages that provides 99.5% of the blood and hemocomponents transfused in the State of Santa Catarina of approximately six million inhabitants. It was certified with the ISO9001: 2010 quality control stamp. Since 2007, all blood screening has been performed in the central laboratory in the state capital of Florianópolis.

Data were extracted from the HEMOSC computerized donor records and included demographic information (age, sex, location of residence); laboratory test results for HIV, HCV, human T lymphotropic virus (HTLV), hepatitis B virus (HBV), *T. cruzi* and *T. pallidum*; and details regarding previous donations (dates, test results, impediments). The anti-HIV-1,2 O Prism and anti-HCV Prism tests, both manufactured by Abbott Laboratories (Wiesbaden, Germany), were used for HIV and HCV serological screening. In addition, a fourth-generation antigen/antibody kit, the Enzygnost Integral II (Siemens, Marburg, Germany), was used between January 2007 and July 2010 before NAT screening for HIV and HCV was introduced. Along with the NAT implementation, the combined antigen/antibody kit for HIV was substituted with the anti-HIV Combo test (Architect Laboratories, Wiesbaden, Germany). The Brazilian duplex HIV/HCV NAT platform was developed and supplied by Bio-Manguinhos/Fundação Oswaldo Cruz (FIOCRUZ, Rio de Janeiro, Brazil) as a six-sample mini-pool. All NAT-screen-positive samples were also tested by INNO-LIA immunoblot (Innogenetics, Gent, Belgium).

An exact Poisson distribution was used to determine the 95% confidence interval (CI) for the number of HIV- and HCV-positive samples. For repeat donors, the HIV and HCV seroconversion date was estimated as a mid-point between the last negative donation and the first positive test result[12]. Residual risk was calculated by the incidence/window method, which multiplies the probability of viral conversion during the inter-donation interval by the immunologic window duration[12]. The probability was calculated as the conversion incidence rate, which divides the number of converting repeat donors by their time at risk. The latter was estimated by summing the inter-donation intervals between the last two donations for the screen-negative donors and half the intervals for the screen-positive donors. This calculation assumes that the risk of conversion is equally spread over the intervals, so that their mid-point is the best unbiased estimate on the group level.

Based on the kit manuals provided by their manufacturers, the window durations were as follows: 22 days for the Prism anti-HIV test, 32.8 days for the Prism anti-HCV test, 17 days for the Enzygnost Integral II test, 14 days for the HIV Combo Architect test and 9 days for both HIV and HCV NAT screening.

Stata software, version 11.0 (StataCorp, College Station, TX, USA), was used for all statistical calculations.

RESULTS

During the period analyzed, 293,725 blood donors provided 719,223 blood samples that were screened for the aforementioned infectious agents. Before and after the NAT was implemented in HEMOSC, there were 168,318 and 125,378 blood donors, respectively, whose blood samples were screened. The number of samples includes repeated tests for screen-positive test results.

The blood donor profile was somewhat altered after the NAT implementation. The participation of first-time donors increased from 69.7% to 91.6%, as did that of women (from 38.1% to 44.6%) and of donors from Blumenau, where blood bank expansion took place after the NAT screening was introduced. The blood donors whose previous donations occurred within 12 months of their last donation decreased from 10.1% to 0.6%, whereas those with longer inter-donation intervals decreased from 20.2% to 7.8% of all donors. In contrast, there was an increase in the recruitment of blood donors from the youngest (16-24 years) age group. Donor race, educational level and prevalence of co-infections (i.e., infections other than HIV or HCV) remained roughly the same before and after the NAT was introduced.

HIV prevalence rates per thousand donors were 1.38 and 1.58 before and after NAT implementation, respectively **(Table 1)**. The repeat donors had a significantly higher prevalence than the first-time donors, particularly those with shorter inter-donation intervals. The HIV prevalence was twice that in male donors compared with female donors. Older age, lower educational level and co-infection (mainly with HBV) all increased the likelihood of an HIV-positive test result. Significantly higher HIV prevalence rates were observed for the donors from Florianópolis, Criciúma and Joinville compared with those from Blumenau, Chapecó and Joaçaba, with the City of Lages holding an intermediary position.

HCV prevalence rates per thousand donors were 1.22 and 1.35 before and after NAT implementation, respectively **(Table 2)**. The first-time donors had a significantly higher prevalence than the repeat donors, as did men compared with women. The donors from Florianópolis and Criciúma showed significantly elevated HCV prevalence rates compared with those from Blumenau, Joaçaba and Joinville. There were clear increases in prevalence in older donors, those with lower educational levels and those with co-infections.

The risk factors associated with incidence showed similar magnitudes and directions for both HIV and HCV. HIV incidence was more than ten times higher in the repeat donors with shorter (<12 months) inter-donation intervals compared to those with longer intervals. Male donors had twice the incidence of female donors. The donors between 25 and 34 years of age showed the highest incidence, as did those residing in Criciúma and those with co-infections.

A sharp increase in HIV prevalence among male donors aged 16-24 years was noted **(Figure 1)**. A similar trend was observed for young women until 2012, after which a sharp decline in prevalence was observed **(Figure 2)**.

Residual risk was calculated as the product of the incidence of viral conversion and the duration of the immunological window period **(Table 3)**. For example, the 17-day window for HIV serological tests before NAT implementation is equivalent to 0.0465 years; when multiplied by the HIV-conversion

TABLE 1 - HIV prevalence and incidence by risk factors.

Variables	n	All HIV+	Prevalence (CI 95%)[a]	Incident cases	Incidence (CI 95%)[b]
All[c] Period	293,696	430	1.46 (1.33-1.61)	163	0.86 (0.73-1.00)
before NAT	168,318	232	1.38 (1.20-1.55)	86	0.72 (0.57-0.89)
since NAT	125,378	198	1.58 (1.36-1.80)	77	1.11 (0.87-1.38)
Repeated donation					
no (first-time donors)	232,240	267	1.15 (1.02-1.30)	-	-
yes, previous donation ≤ 12 months prior	17,711	62	3.50 (2.63-4.37)	62	6.25 (4.80-8.02)
yes, previous donation >12 months prior	43,745	101	2.31 (1.86-2.76)	101	0.56 (0.46-0.68)
Sex					
male	173,774	322	1.85 (1.66-2.07)	133	1.02 (0.86-1.21)
female	119,950	108	0.90 (0.74-1.09)	30	0.51 (0.34-0.72)
Age group (years)					
16-24	95,797	117	1.22 (1.01-1.46)	45	0.28 (0.20-0.37)
25-34	97,659	168	1.72 (1.47-2.00)	71	0.92 (0.72-1.15)
35-44	59,091	86	1.45 (1.16-1.80)	30	0.54 (0.36-0.76)
45-65	41,177	59	1.43 (1.09-1.85)	17	0.43 (0.25-0.69)
Blood bank location					
Blumenau	34,771	26	0.86 (0.58-1.23)	4	0.83 (0.22-2.12)
Chapecó	36,991	24	0.84 (0.57-1.19)	7	0.22 (0.09-4.56)
Criciúma	45,199	59	1.90 (1.52-2.35)	27	1.53 (1.01-2.23)
Florianópolis	71,852	69	1.99 (1.68-2.34)	74	0.83 (0.65-1.04)
Joaçaba	25,284	13	0.59 (0.33-0.98)	2	0.56 (0.07-2.02)
Joinville	58,869	59	1.65 (1.34-2.01)	38	0.80 (0.57-1.09)
Lages	20,758	17	1.35 (0.90-1.95)	11	0.47 (0.23-0.84)
Educational level (years of school completed)					
0 years of school completed	401	2	4.99 (0.60-17.9)	0	0
incomplete primary school (1-7)	36,289	69	1.90 (1.48-2.41)	16	0.63 (0.36-1.01)
completed primary school (8)	29,035	68	2.34 (1.82-2.97)	21	1.00 (0.62-1.53)
incomplete secondary school (9-10)	20,390	36	1.77 (1.24-2.44)	17	1.51 (0.88-2.41)
completed secondary school (11-12)	110,210	148	1.34 (1.13-1.58)	67	0.94 (0.73-1.19)
incomplete college education (13-14)	44,344	58	1.31 (0.99-1.69)	20	1.09 (0.67-1.69)
completed college education (>14)	42,481	37	0.87 (0.61-1.20)	19	0.54 (0.33-0.85)
post-graduate education	754	0	0	0	-
no information	9,820	160	1.33 (1.13-1.56)	3	0.90 (0.71-1.14)
Co-infection[d]					
absent	277,368	373	1.35 (1.21-1.49)	156	0.83 (0.70-0.97)
present	16,356	57	3.40 (2.58-4.40)	7	5.57 (2.24-11.47)

[a]per 1,000 donors; [b]per 1,000 repeat donor-years; [c]excluding inconclusive test results; [d]with hepatitis B virus, hepatitis C virus, human T-cell lymphotropic virus, *Tryapanosoma pallidum* or *Tryapanosoma cruzi.* **HIV:** human immunodeficiency virus; **NAT:** nucleic acid amplification test.

TABLE 2 - HCV prevalence and incidence by risk factors.

Variables	n	All HIV+	Prevalence (CI 95%)[a]	Incident cases	Incidence (CI 95%)[b]
All[c] Period	293,510	375	1.28 (1.15-1.41)	19	0.10 (0.06-0.15)
before NAT	168,229	206	1.22 (1.06-1.39)	15	0.12 (0.07-0.21)
since NAT	125,310	169	1.35 (1.14-1.55)	4	0.06 (0.02-0.15)
Repeated donation					
no (first-time donors)	232,127	356	1.53 (1.38-1.70)	-	-
yes, previous donation ≤12 months prior	17,688	10	0.57 (0.29-1.51)	10	1.01 (0.48-1.85)
yes, previous donation >12 months prior	43,724	9	0.002 (0.03-0.14)	9	0.05 (0.02-0.09)
Sex					
male	173,651	252	1.45 (1.28-1.64)	12	0.09 (0.04-0.16)
female	119,888	123	1.02 (0.85-1.22)	7	0.12 (0.05-0.24)
Age group (years)					
16-24	95,787	46	0.48 (0.35-0.64)	1	0.06 (0.00-0.33)
25-34	97,586	91	0.93 (0.75-1.15)	3	0.04 (0.00-0.12)
35-44	59,046	125	2.12 (1.76-2.52)	10	0.18 (0.08-0.33)
45-65	41,120	113	2.75 (2.26-3.30)	5	0.13 (0.04-0.29)
Blood bank location					
Blumenau	37,767	17	0.49 (0.28-0.78)	0	0
Chapecó	36,980	22	0.59 (0.37-0.90)	0	0
Criciúma	45,166	99	2.19 (1.78-2.68)	4	0.22 (0.06-0.58)
Florianópolis	71,797	132	1.83 (1.53-2.18)	6	0.07 (0.02-0.15)
Joaçaba	25,270	20	0.79 (0.48-1.22)	2	0.56 (0.07-2.02)
Joinville	58,815	57	0.97 (0.73-1.25)	3	0.06 (0.01-0.18)
Lages	20,744	28	1.35 (0.90-1.95)	4	0.17 (0.04-0.43)
Educational level (years of school completed)	401	4	9.97 (2.72-25.34)	0	0
0 years of school completed	36,260	80	2.20 (1.75-2.74)	9	0.35 (0.16-0.67)
incomplete primary school (1-7)	29,018	59	2.03 (1.55-2.62)	0	0
completed primary school (8)	20,376	31	1.52 (1.03-2.16)	1	0.09 (0.00-0.49)
incomplete secondary school (9-10)	110,156	123	1.12 (0.93-1.33)	6	0.08 (0.03-0.18)
completed secondary school (11-12)	44,315	34	0.76 (0.53-1.07)	2	0.11 (0.01-0.39)
incomplete college education (13-14)	42,457	34	0.80 (0.55-1.18)	1	0.03 (0.00-0.15)
completed college education (>14)	754	0	0	0	0
post-graduate education	9,802	133	1.11 (0.93-1.31)	0	0.07 (0.02- 0.17)
no information					
Co-infection[d]					
absent	276,719	303	1.09 (0.97-1.22)	0	0.10 (0.06-0.15)
present	16,820	72	4.28 (3.35-5.39)	19	0.63 (0.02-3.53)

[a]per 1,000 donors; [b]per 1,000 repeat donor-years; [c]excluding inconclusive test results; [d]with hepatitis B virus, hepatitis C virus, human T-cell lymphotropic virus, *Tryapanosoma pallidum* or *Tryapanosoma cruzi.* **HCV:** hepatitis C virus; **NAT:** nucleic acid amplification test.

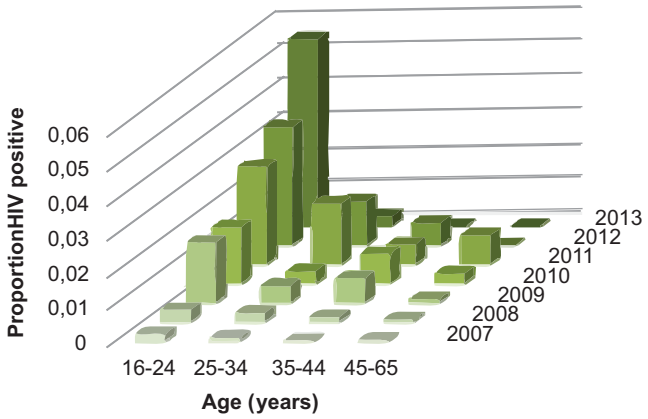

FIGURE 1 - Proportion of male repeat donors infected by HIV, by age group. HIV: human immunodeficiency virus**.**

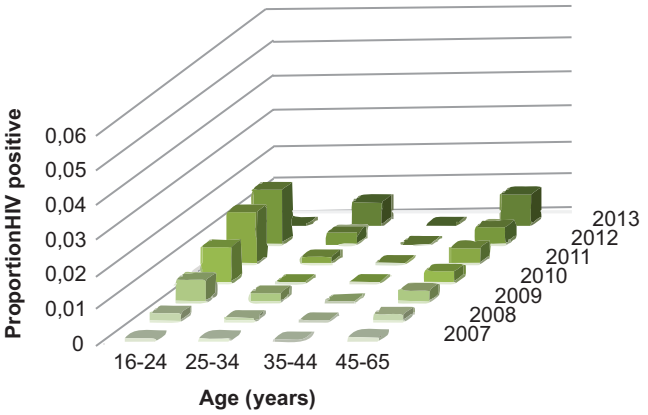

FIGURE 2 - Proportion of female repeat donors infected by HIV, by age group. HIV: human immunodeficiency virus**.**

incidence of 1.91 per 1,000 person-years in repeat donors with inter-donation intervals of ≤ 12 months, the residual risk is 8.89 per 100,000 person-years. Since the NAT screening was introduced, the same group reduced both its window period (from 17 to 9 days, or 0.0246 years) and its incidence (from 1.91 to 1.80 per 1,000 person-years), thus producing an HIV residual risk of 4.44 per 100,000 person-years, which is a two-fold reduction compared with the period when only serological screening was conducted. For repeat donors with inter-donation intervals of >12 months, the HIV residual risk was reduced 2.62 times. During the NAT screening period, HCV residual risk was reduced 4.26 and 4.53 times for repeat donors with shorter and longer inter-donation intervals, respectively.

Overall, HIV incidence and prevalence increased by 54.2% (from 0.72 to 1.11 per 1,000 person-years) and 14.5% (from 1.38 to 1.58 per 1,000), respectively, after NAT implementation, but the differences did not reach statistical significance (**Table 1**). However, the incidence of HIV conversion in all repeat donors decreased by 24.1%, from 0.54 to 0.41 per 1,000 person-years, thus contributing to the residual risk reduction. The magnitude of the HIV window reduction was even larger, decreasing by 47.1% (from 17 to 9 days). In contrast, HIV residual risk in all repeat donors decreased 2.5 times after NAT implementation, from 2.51 to 1.01 per 100,000 person-years **(Table 3)**.

Overall, HCV incidence and prevalence increased by 100% (from 0.06 to 0.12 per 1,000 person-years) and 10.6% (from 1.22 to 1.35 per 1,000), respectively, after NAT implementation **(Table 2),** but the increases were not statistically significant. Although the incidence of HCV conversion in all repeat donors increased by 18.5% (from 0.54 to 0.64 per 1,000 person-years) after NAT implementation, HCV residual risk during the NAT screening period still decreased approximately three-fold compared with the period using only serologic screening **(Table 3)**. This risk reduction was likely driven by a large HCV window reduction of 72.4% (from 32.6 to 9 days) in the NAT screening period.

DISCUSSION

Increased participation by first-time donors (from 70% to over 90%) and women (from 38% to almost 45%), in parallel with decreased participation by repeat donors with an inter-donation interval of 12 months or less (from 10% to <1%), might have affected the overall HIV and HCV incidence rates reported in **Tables 1** and **2**. However, these factors did not change the incidence of viral conversion **(Table 3)** since the last screen-negative donation or the corresponding residual risk estimates because co-infection with another infectious agent (mainly HBV) screened them out anyway. The interaction of these factors is complex. The vast majority of publications have reported a higher prevalence of blood-borne infections in first-time donors compared with repeat donors, including in Brazil[1,5-9,10], thus implying higher disease incidence as well. However, the present study showed evidence to the contrary, with HIV and HCV prevalences being approximately three- and two-fold higher, respectively, in the repeat donors compared with the first-time donors. The increase in HIV prevalence was much higher among male donors of 16-24 years of age in comparison with any other demographic segment (**Figures 1** and **2**), reinforcing the hypothesis of test-seeking behavior among the former. Independent evidence of such behavior was obtained in the State of São Paulo, where 9% of all donors were estimated to be HIV test seekers with a high risk for sexually transmitted diseases[10,13]. In the State of Santa Catarina, a sudden rise in HIV prevalence among blood donors was observed in the beginning of the 2000s after a consistent downward trend in the 1990s, possibly associated with HIV test seeking[7]. The HIV incidence per thousand repeat blood donors per year increased from 0.36 (CI 95% 0.13-0.79) at the end of the 1990s[5] to 0.86 (0.73-1.00) during the 2007-2013 period, as shown in the present study. This worrying result requires a rethinking of current prevention strategies and immediate action to reduce HIV transmission among the blood donor population.

It is important to recall that that the number of converting repeat donors is typically lower for the incidence rate of viral conversion used for the residual risk calculation because of exclusion of HIV-positive donors using other screen-positive test results. The latter are mainly markers of sexually transmitted

TABLE 3 - HIV and HCV residual risk by donor type before and after implementation of NAT screening.

		Viral conversion			Residual risk		
Virus	Repeat donors	n[a]	Person-years	Incidence (CI 95%)[b]	Odds (CI 95%)[c]	per 100,000 (CI 95%)[c]	Reduction factor
HIV	Previous donation ≤ 12 months prior						
	before NAT	34	17,811	1.91 (1.32-2.67)	1:11,242 (1:8,042-1:16,267)	8.89 (6.15-12.43)	2.00
	since NAT	28	15,644	1.80 (1.19-2.59)	1:22,529 (1:15,657-1:34,677)	4.44 (2.88-6.39)	
	Previous donation >12 months prior						
	before NAT	52	142,510	0.36 (0.27-0.48)	1:59,547 (1:44,735-1:79,530)	1.68 (1.26-2.23)	2.62
	since NAT	40	150,94	0.26 (0.19-0.36)	1:155,967 (1:112,643-1:213,429)	0.64 (0.47-0.89)	
	All repeat donors						
	before NAT	86	160,320	0.54 (0.43-0.66)	1:39,765 (1:32,535-1:52,373)	2.51 (2.00-3.07)	2.48
	since NAT	68	166,586	0.41 (0.32-0.52)	1:98,906 (1:77,984-1:126,723)	1.01 (0.79-1.28)	
HCV	Previous donation ≤ 12 months prior						
	before NAT	39	18,091	2.16 (1.53-2.95)	1:5,183 (1:3,795-1:7,318)	19.29 (13.66-26.35)	4.26
	since NAT	2	1,080	1.85 (0.22-6.69)	1:22,099 (1:6,061-1:155,967)	4.56 (0.54-16.50)	
	Previous donation >12 months prior						
	before NAT	47	132,63	0.35 (0.26-0.47)	1:31,989 (1:23,822-1:43,063)	3.13 (2.32-4.20)	4.53
	since NAT	1	3,589	0.28 (0.01-1.55)	1:144,827 (1:26,162-1:4,055,150)	0.69 (0.02-3.82)	
	All repeat donors						
	before NAT	66	122,244	0.54 (0.42-0.69)	1:20,727 (1:16,221-1:26,658)	4.82 (3.75-6.16)	3.06
	since NAT	3	4,668	0.64 (0.13-1.88)	1:63,362 (1:21,570-1:311,934)	1.58 (0.32-4.64)	

[a]Number of converting donors without another screen-positive test result; [b]Viral conversion incidence per thousand person-years; [c]Residual risk and 95% CI, assuming an HIV immunological window period of 17 or 9 days for before or since NAT implementation, respectively, and an HCV window period of 32.6 and 9 days for before or since NAT implementation, respectively. **HIV:** human immunodeficiency virus; **HCV:** hepatitis C virus; **NAT:** nucleic acid amplification test.

diseases such as hepatitis B and syphilis, which indicate risky sexual behavior. The exclusion of these blood donors reduced the HIV incidence per thousand repeat donors per year from 6.25 (**Table 1**) to 1.91 and 1.81 (**Table 3**) for the periods before and after NAT implementation, respectively. As a consequence, the HIV incidence used for the residual risk calculation decreased slightly over the compared periods despite a considerable increase of HIV prevalence in young male donors over

the same time period. Taken together, these findings suggest that halving the HIV residual risk after the implementation of NAT **(Table 3)** was mainly due to a reduction in the immunological window period rather than a reduction in the incidence of HIV conversion. Among the repeat donors for whom the previous inter-donation interval was longer than 12 months, HIV residual risk was reduced 2.62-fold during the NAT screening period.

Overall, the HCV incidence in HEMOSC was halved after the NAT implementation (**Table 2**). Although this change did not reach statistical significance, it contributed to a more than four-fold reduction in the HCV residual risk in repeat donors, suggesting that the downward trend reported in the 1990s, during which the HCV residual risk decreased to 51 per 100,000 repeat donors per year[6], is continuing. The present study showed a further reduction of this risk to an approximately five-fold lower level. However, HCV incidence was approximately twenty times higher in the repeat donors whose last inter-donation interval was shorter than 12 months compared with those having longer intervals. Despite relatively rare sexual transmission of HCV, this infection is still a marker of risky behavior for various blood-borne diseases. Therefore, the magnitude of the above difference in HCV incidence rates reinforces the hypothesis of HIV test seeking among some repeat donors with shorter inter-donation intervals.

The similarities in magnitude and direction of both prevalence and incidence regarding the risk factors analyzed underline the notion of prevalence as a cumulative incidence and its use for estimating the viral conversion risk in first-time donors[14]. In Brazil, higher HIV prevalence rates among men and those with lower educational levels were reported for both the general population[15] and blood donors[10], including in the capital of Florianópolis compared with other regions of the State of Santa Catarina[1,16]. The present study showed that the City of Criciúma had the highest HIV and HCV risk among blood donors. An HCV incidence of 3.11 per 100,000 donor-years and an HCV residual risk of 0.5 per 100,000 were reported for the capitals of the federal States of São Paulo, Rio de Janeiro and Minas Gerais in 2007, along with a downward trend over time[17]. This finding is in line with similar trends among HEMOSC blood donors.

Increases in the overall HIV and HCV incidence rates during the NAT screening period may be a consequence of higher NAT sensitivity compared with serological testing. For HIV, a high prevalence of 1.46 per thousand donors in the present study was close to the prevalence of 1.51 reported in South Africa but is considerably higher than the prevalence rates of 0.23 reported in the Mediterranean and Central Europe and 0.34 reported in Southeast Asia[18].

This paper is the first report on the performance of Brazilian HIV/HCV NAT screening on prevalence and incidence in blood donors. An HIV residual risk of 2.51 per 100,000 per year observed in HEMOSC between 2007 and 2013 is close to the value of 2 per 100,000 per year reported at the turn of the century in the Florianópolis metropolitan area[5,7] and in the City of Lages[9] but lower than the 3.82 estimated for the entire State[1]. The data compiled from the blood banks of São Paulo, Belo Horizonte and Recife during the 2007-2008 period produced an HIV residual risk of 1.13 per 100,000 and projected its reduction by a factor of 1.66 when using six-sample mini-pools and an immunologic window duration of nine days, or by a factor of 2.69 when using individual NAT screening and a window period of 5.6 days[10]. An HIV residual risk of 2.51 per 100,000 in HEMOSC and its reduction by a factor of 2.49 when using six-sample mini-pools for NAT screening are reasonably close to the aforementioned projections.

Among the present study limitations, it is worth mentioning the lack of publications on the Brazilian NAT kit's limits of detection and the focus on residual risk. The latter is the risk of transfusing an infected blood unit; however, the risk of a recipient becoming infected with the transfusion-transmitted agent still depends on the minimal infectious dose and the host immunological response. Recent studies have emphasized the risk of a recipient developing a transfusion-transmitted infection[18,19], which will also be estimated for the Brazilian NAT data in the near future. Another limitation is the low precision of rare events, such as viral conversion, thus limiting the comparisons across regions and/or countries. Finally, although the so-called NAT yield (the proportion of serologically negative and NAT-positive cases) is a direct measure of the NAT's impact on blood safety, the only way to compare the impact before versus after NAT implementation is to use the incidence/window period model that is available for both periods.

Despite large reductions in HIV and HCV residual risk after the implementation of NAT screening in the State of Santa Catarina, the overall HIV incidence of over one per thousand donor-years is almost one hundred times higher compared with countries such as France, Germany, the USA, Canada and Australia[20-26]. More effective prevention measures need to be implemented in the Brazilian general population before transfusion risk can be reduced further[1]. Otherwise, technological advances, such as individual NAT screening, will still have a limited beneficial impact on blood safety. Therefore, better integration between blood safety policies and policies that prevent sexually transmitted diseases in the general population should dominate the research and development agenda in this area.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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