



Original article

Correlation between serology and nucleic acid amplification test in blood donors who are reactive for hepatitis B virus, hepatitis C and human immunodeficiency virus and evaluation of the epidemiological profile of infected people in blood centers in the State of Paraná



Heloise Skiavine Madeira^a, Claudinei Mesquita da Silva^{a,b}, Neila Cristina Scapini^d,
Leyde Daiane de Peder^{a,c,*}, Jorge Juarez Vieira Teixeira^c

^a Clinical Analyses Laboratory, University Center of Assis Gurgacz Foundation, Cascavel, Paraná, Brazil

^b Post-Graduate Program in Health Sciences, Maringá State University, Maringá, Paraná, Brazil

^c Post-Graduate Program in Biosciences and Physiopathology, Maringá State University, Maringá, Paraná, Brazil

^d Hemepar, Regional Blood Center of Cascavel, Cascavel, Paraná, Brazil

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ABSTRACT

Objectives: To compare the results of conventional serological tests and molecular technology (NAT, Nucleic Acid Amplification Test), identify donors in the diagnostic window period, and determine the prevalence of hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) among the samples of blood donors blocked by serological screening.

Methods: A retrospective cross-sectional study was carried out by analyzing blood donor information contained in the database of 20 blood centers in Paraná, from January 2018 to December 2019.

Results: A total of 1,496 blood bags were reactive for HBV, HCV, or HIV in serological and/or NAT tests. The 20th Regional Health (RH) Unit had the greatest number of unfit individuals with altered screening for the three infections, with a prevalence of 0.70%. The lowest number of blocked blood donors occurred in the 15th RH, with a prevalence of 0.08%. The highest prevalence of HBV occurred in the 8th RH, with a reagent serology of 0.34% and a positive NAT of 0.17%. For HCV, the prevalence for reagent serology was 0.28%, while that for NAT was 0.02%, which occurred in the 20th RH. For HIV and for NAT, the prevalence of blood donors with positive serology occurred in the 20th RH, at 0.25% and 0.04%, retrospectively. The 13th RH had the highest prevalence of HIV in relation to NAT, that is, conventional serology in concomitance with NAT technology, at 0.07%. During the 2-year period, only 1 reactive donor in the 9th was found for NAT (HBV), in a diagnostic window.

Conclusion: In Paraná's blood centers, the inability to donate due to HBV, HCV, and HIV, occurred mainly in initial donors, men, those with >8 years of education, aged 16–45 years, married, and O positive. The most affected regions were located in the west and northwest of Paraná. Most of the results showed a discrepancy between the methodologies used.

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* Corresponding author at: University Center of the Assis Gurgacz Foundation, Cascavel, Paraná, Brazil.

E-mail address: leydepeder@yahoo.com.br (L.D. de Peder).

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1. Introduction

For a long time, blood transfusion was perceived only as a transmission of biological material, without many risks for the recipient. Only from the 1980 s, with the discovery of the human immunodeficiency virus (HIV), which causes the acquired immunodeficiency syndrome (AIDS), this notion changed, and safety in the hemotherapy field became a priority, making it necessary to conduct screening tests for infectious diseases (Seitz and Heiden, 2010; Lima and Naoum, 2011). However, the transfusion process, which is a therapeutic treatment of paramount importance, is vital to meeting

patients' needs in urgent cases and chronic diseases. Although performed within the technical standards recommended by the Ministry of Health, it is a supportive activity of high epidemiological risk, since blood is a living tissue and can transmit diseases (Camargo et al., 2007).

Considering that there are approximately five million collections and donations in Brazil every year (Panhan, 2013) and that a single blood donation is capable of saving the lives of up to four people (Brazil, 2020), the biggest threat to transfusion safety is the blood donation by people infected with HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) (Mühlbacher et al., 2013), due to an asymptomatic period. The period between the time when that infection occurs and the detection of the presence of serological markers in the blood is defined as a diagnostic window, in which the infectious agent is already present in the bloodstream. However, during this period, transmission may occur, since conventional tests do not detect the infection (Anjos and Costa, 2009).

Thus, techniques have been developed in the field of molecular biology, such as Nucleic Acid Technology (NAT, Nucleic Acid Amplification Test), which is the most advanced methodology for the identification of viral diseases. It utilizes the reaction of polymerase chain (PCR), using the amplification of viral genetic material present in the plasma of the infected individual, and showing a greater sensitivity, since small levels of viral RNA/DNA can be detected right at the beginning of the infection (Kucirka et al., 2011), making it complementary to conventional serological tests.

There are not many data in Brazil on the prevalence of infections transmitted by transfusions since the investigation of suspected cases of transmission of viral agents by blood transfusion is a time-consuming process. This is especially true because the detection may occur years after the transfusion, in addition to the fact that it involves not only the hemotherapeutic system, but also epidemiological and health surveillance. However, some HCV, HCB, and HIV cases transmitted by blood transfusion have already been reported in the literature. According to the latest *Hemovigilance Bulletin* (2015), in Brazil, in 2013, four transmissions via transfusion were recorded, two HBV, and two HIV. Although the cases of transfusion infection were not distinguished considering the type of virus, in the period from 2007 to 2014, the annual average of 7.1 suspected transmission cases of viral diseases was reported. In 2013, the average was 5.8 (Brazil, 2015).

For this reason, knowing the profile of unsuitable donors is important for the hemotherapy safety because it supports the development of strategies aimed at improving the donor selection process and the quality of the blood to be transfused (Rohr et al., 2012). Thus, with the technologies employed in favor of the safety and quality of the blood products produced, interest in the present study is raised with the aim of correlating the results of conventional serological tests and molecular technology (NAT), identifying cases of donors in the diagnostic window, as well as determining the prevalence of hepatitis B, hepatitis C, and HIV from infected blood donor samples blocked by serological screening, handled by blood centers in Paraná State from January 2018 to December 2019. In addition, the study analyzes the epidemiological characteristics of these donors to contribute to the epidemiological improvement in Paraná.

2. Methods

2.1. Study design and ethical approval

A retrospective cross-sectional study was carried out by analyzing blood donor information contained in the database SBS System (Blood Bank System) of 20 blood center units in Paraná State, from January 1, 2018, to December 31, 2019. Electronic data collection

was carried out between January and March 2020. This study was registered and approved by the Ethics Committee in Research with Human Beings at the University Center of the Assis Gurgacz Foundation under opinion 3.711.588 on November 18, 2019 (CAAE: 24134919.3.0000.5219) and by the Health Department of the State of Paraná through the Hospital do Trabalho—Curitiba, PR under regulatory opinion 3.772.096 on December 14, 2019 (CAAE: 24134919.3.3001.5225).

2.2. Donors

The research was carried out at the Regional Blood Center of Cascavel, which belongs to the Hemepar network, headquartered in Curitiba, PR. The Hemepar network has 22 blood centers, Cascavel being part of the 10th Regional Health (RH) Unit, which links information from other blood centers in the Paraná region through the system.

The study included donors reactive for HBV, HCV, and/or HIV on serological screening, who voluntarily applied for donation in the blood center units of Paraná, as follows: the 1st RH, located in Paranaguá, which covers 7 cities, with an estimated population of 278,049; Coordinating Blood Center of Curitiba, belonging to the 2nd RH, which covers 29 cities, with an estimated population of 3,654,960; 3rd RH, located in Ponta Grossa, which covers 12 cities, with the population of 637,293; 4th RH located in Irati, which includes 9 cities, with an estimated population of 174,933; 5th RH, located in Guarapuava, covering 20 cities, with 456,587 inhabitants; União da Vitória Unit, which belongs to the 6th RH, covers 9 cities, with an estimated population of 177,311; 7th RH, located in Pato Branco, integrates 15 cities with an estimated population of 267,234; 8th RH, located in Francisco Beltrão, includes 27 cities with a population of 358,144; 9th RH, located in Foz do Iguaçu, which has 9 integrated cities and a population of 404,414 people; 10th RH, located in Cascavel, covering 25 cities, with an estimated population of 550,709; 11th RH, located in Campo Mourão, covers 25 cities, with 328,863 people; 12th RH, located in Umuarama, includes 21 cities corresponding to 276,371 inhabitants; 13th RH located in Cianorte, covering 11 cities, with 160,642 inhabitants; 14th RH located in Paranavaí, which includes 28 cities, with a population of 275,974 people; 15th RH located in Maringá, which includes 30 cities, with an estimated population of 838,017; 16th RH, located in Apucarana, with 17 cities and a population of 384,198; 18th RH, located in Cornélio Procopio, including 21 cities with an estimated population of 211,413 people; Jacarezinho's Unit, belonging to the 19th RH, includes 22 cities with a population of 289,020; 20th RH located in Toledo, covering 18 cities, with 398,323 inhabitants; and 21st RH, located in Telêmaco Borba, includes 7 cities, with an estimated population of 188,456 (Brazilian Institute of Geography and Statistics, 2019). It was not possible to collect data from the Regional Blood Center of Londrina, belonging to the 17th RH, as it has its own system from the State University of Londrina (UEL), as well as the blood center from Ivai-porã, belonging to the 22nd RH, as it is only a transfusion unit, with no collections taking place.

2.3. Variables of interest

The variables analyzed in the cadastral database were age, sex, marital status, education, ethnicity, number of donations made (classified as "repetition," for those who donated more than once in the year during the study period, and "first-time" donors, who did it only once during the 2 years of observation referred to in the study). In addition, the ABO blood group, RhD type, and type of donation were analyzed as well, being classified as spontaneous, voluntary, or linked/replacement.

2.4. Nucleic acid amplification test and serology

A survey of data on hepatitis B, hepatitis C, and HIV infections was carried out to analyze the number of cases in which reactivity occurred in serological tests and/or NAT in donor samples in serological screening, verifying information for epidemiological survey of donors characterized as unfit. The epidemiological profile for infection was verified, according to each regional center, considering donors who presented with positive concomitant results between conventional serology and NAT, as well as discordant results between the methodologies utilized.

Serological tests for the detection of hepatitis B (HBsAg), hepatitis C (anti-HCV), and HIV (anti-HIV) markers were performed using the chemiluminescence methodology, which applies a chemiluminescent substance to detect the antigen–antibody and antibody–antigen reactions. For hepatitis B, only the marker indicating the infection (HBsAg) was collected. An anti-HBc is a marker that determines contact with the virus, and considering the study objective, it was not included in the research.

Regarding molecular biology, HBV, HCV, and HIV were verified using the NAT HIV/HCV/HBV Biomanguinhos–FIOCRUZ kit, which enabled detecting the viral genome in donor samples using the reaction polymerase chain in real time (RT-PCR) technology, being carried out in a pool of six donor samples. In cases where a group of tests showed a positive NAT result, the pool was dismembered, and the samples were tested individually to identify the infectious agents in question and which samples were positive.

All laboratory tests were performed in the city of Curitiba, PR, with the collection of bags and samples carried out at regional blood centers, as well as the compatibility tests of the donor sample with the recipient sample, with the exception of Foz do Iguaçu (9th RH), as well as Maringá (15th RH), which perform serological tests in their own units, and Londrina (17th RH), which perform serological tests in the Laboratory of the University Hospital (HU of UEL).

2.5. Statistical analysis

The data collection worksheets were tabulated in Microsoft Office Excel and statistically analyzed using the chi-squared test through the Bioestat Program at a significance level of 5.0%, with results considered statistically significant at $p \leq 0.05$. The results were expressed as the total number and percentage.

3. Results

Between January 2018 and December 2019, a total of 399,151 people attended the blood center units in Paraná state to donate blood (Fig. 1). However, 18% of those, (73,212 individuals) were unable to donate because they did not meet the requirements in the clinical screening process or due to cancelation of the collection (e.g., withdrawals from eligible candidates for the donation, or due to complications, such as venous puncture). Therefore, 325,934 scholarships were collected from individuals who came for donation and who were considered clinically fit for the act, corresponding to 82% of the total. Serological screening examinations were performed for these patients.

In this sense, in the screening process, it was observed that the 20th RH, located in Toledo, western Paraná, showing the greatest number of blood donors blocked by HBV, HCV, and HIV in the 2 years of study, corresponding to a prevalence of 0.70%, with the 15th RH, located in Maringá, northwest of the State, showing the lowest number of people with changes in serological screening for certain infections, with a prevalence of 0.08%.

Fig. 1 shows the number of donors, that is, individuals who were clinically fit and had their bags collected for evaluation in serological screening by the HR. Among these, it was possible to verify that the 2nd RH, located in Curitiba, presented the largest number of donations (69,016), representing 21.17%, followed by the 10th RH, located in Cascavel, which obtained 28,581 donations, equivalent to 8.76%.

Of the 325,934 bags collected by the blood center units in Paraná, 1,496 donors (0.46%) were positive in one or both of the referred tests (serology and molecular biology) for HBV, HCV, or HIV in serological screening. As shown in Table 1, in relation to age, there was a statistically significant difference, in which the number of people who had infection and were <45 years was statistically greater when compared to those >45 years, that is, the number of donors with positivity in serological screening for certain infections was statistically higher for individuals aged 16–45 years when compared to people older than 46, that is, aged 46–69 years ($p < 0.001$), with an average being 31.2 years. Regarding sex, there was no statistically significant difference ($p = 0.395$) in infection between men and women; that is, in relation to sex, the affected people had similar percentages. The number of unfit reagents in the first donation was significantly higher ($p < 0.001$), corresponding to 70.2% (1,050 donors) when compared to repeat donations. In addition, the highest percentage of those unfit due to infections occurred in individuals who donated spontaneously or voluntarily (73.5%) when compared to linked or replacement donations, which was statistically significant ($p < 0.001$). Most were married (44.3%, $p < 0.001$), and considering education, the majority (63.3%) reported having >8 years of school, that is, having at least completed elementary school ($p < 0.01$). However, with regard to ethnicity, donors with positive serology and/or NAT for certain infections, the statistically significant majority was white (58.9%) when compared to yellow, black, and brown ($p < 0.001$) population. However, 33%, referring to 493 of the unfit, did not report the race. Among the reactive donors, the majority belonged to the blood group O (50.3%; $p < 0.001$), and 86.2% were RhD positive ($p < 0.001$). The largest number of donors blocked due to positive tests (serology and/or NAT) for HBV, HCV, or HIV in serological screening in the 2 years of study, based on the total number of donors per region, occurred at the 20th RH, located in Toledo, in western Paraná, corresponding to a prevalence of 0.70%, characterized as being the most statistically significant in the age group 26–35 years (31.9%; $p < 0.001$), who were initial donors (76.4%; $p < 0.001$), married (51.4%; $p < 0.001$), those with > 8 years of education (76.4%; $p < 0.001$), white (61.1%; $p < 0.001$), had blood group O (54.2%; $p < 0.001$), and were RhD positive (80.6%; $p < 0.001$), with sex and type of donation data that showed no statistical difference ($p = 0.118$). The lowest number of people with disabilities with changes in serological screening for certain infections was found at the 15th RH, located in Maringá, with a prevalence of 0.08%, the majority being statistically significant in the age group 16–25 years (42.9%; $p < 0.001$), male (71.4%; $p < 0.01$), first donation (100%; $p < 0.001$), spontaneously or voluntarily (100%; $p < 0.001$), married (47.6%; $p < 0.001$), with >8 years of education (90.5%; $p < 0.001$), mixed race (42.9%; $p < 0.001$), and blood group A (52.4%; $p < 0.001$), positive (81%; $p < 0.001$). (Data not shown.)

Table 2 shows the number of unsuitable donors who were positively associated among the tests referred to in the serological screening, due to viral infection, in all evaluated blood centers. During the study period, 178 donors were blocked due to hepatitis B infection. Regarding the epidemiological profile, in relation to age, there was no statistically significant difference ($p = 0.496$), that is, the number of people with infection among different ages was similar. The statistically significant majority were men, representing 72.5% ($p < 0.001$), being identified on the first donation (98.3%), in which there was no statistically significant difference

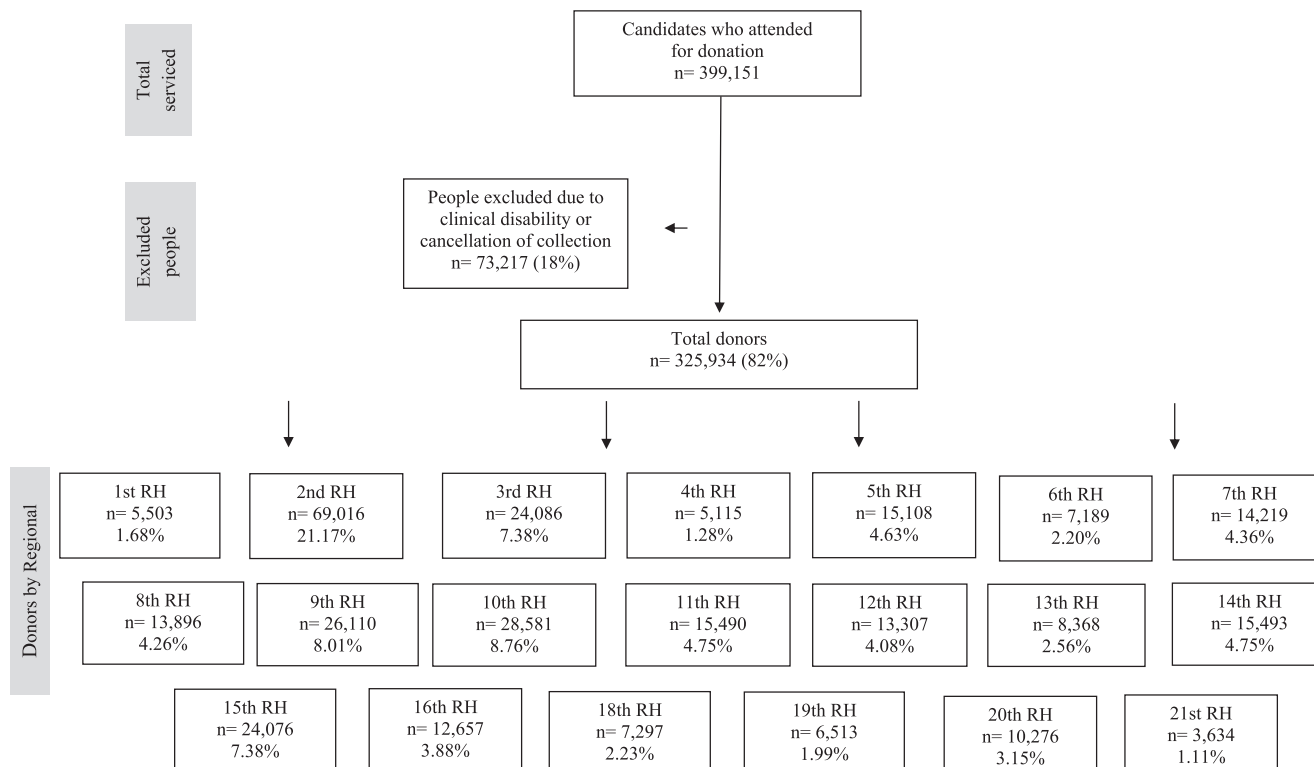


Fig. 1. Prevalence of blood donors with bags collected by Health Regions in Paraná, 2018 to 2019.

for the infection in relation to the donation being voluntary or replacement ($p = 0.269$). From the donors unfit for HBV, 83 reported being married (46.6%), with education and ethnicity being variables with data not statistically different for the infection. The prevalence of unfit donors infected with HBV was at the 8th RH, located in Francisco Beltrão, western Paraná, with 0.17%, with the majority being statistically significant men (75%; $p < 0.001$), diagnosed at first donation (100%; $p < 0.001$), spontaneously/voluntarily (70.8%; $p < 0.001$), who did not report marital status (79.2%; $p < 0.001$), with < 8 years of education (83.3%; $p < 0.001$), and non-white (100%; $p < 0.001$). Age did not show a statistically significant difference for infection ($p = 0.459$). (Data not shown.)

From the 1,496 donors unable to undergo serological screening for HBV, HCV, or HIV, 10 showed positive association between conventional serology and NAT for HCV. Of those, the number of people who had an infection and were aged ≥ 40 years (40–69 years old) was statistically higher (70%), when compared to those aged < 40 years ($p < 0.001$), the average being 46.5 years. Most men, corresponding to 80% in relation to women, were diagnosed on their first donation (100%; $p < 0.001$), by spontaneous or voluntary act (70%; $p < 0.001$), the majority being married (60%; $p < 0.001$), with education ≤ 8 years, that is, with completed elementary school or less (70%; $p < 0.001$), the majority being yellow, black, mixed race, or undisclosed, corresponding to 60% ($p < 0.001$), with statistically significant data, due to the p-value. Regarding the prevalence of the HCV infection across the health regions, the 20th RH, located in Toledo, obtained the highest percentage, with 0.019%. Regarding the epidemiological profile, those diagnosed were initial donors who made replacement donations, married, and white (100%), with statistically significant data ($p < 0.001$). Age and education did not show a statistically significant difference ($p = 1$). (Data not shown.)

Regarding HIV infection, 88 donors were blocked, and the statistically significant majority was aged 16–39 years (62.5%; $p = 0.016$), with an average of 34.8 years. In addition, male sex corresponded to 80% ($p < 0.001$), diagnosed on the first donation

(89.8%; $p < 0.01$), and when it was spontaneous (78.4%; $p < 0.001$). Regarding marital status, of those infected, the statistically significant majority were single (59.2%; $p < 0.001$). Based on education ($p = 0.085$) and race ($p = 0.904$), there was no statistically significant difference. The 13th RH, located in Cianorte, northwest of Paraná, had the highest prevalence in relation to HIV (0.072%), with the majority of those infected showing statistical significance being aged > 39 years (66.7%; $p < 0.01$), male (83.3%; $p < 0.001$), diagnosed on first donation (83.3%; $p < 0.001$), spontaneous donation (83.3%; $p < 0.001$), and non-white (83.3%; $p < 0.001$). None of them reported marital status and reported having < 8 years of education ($p < 0.001$). (Data not shown.)

In addition, comparing the data among infections, it can be seen that, in relation to age, the number of people with HIV aged 16–39 years ($p < 0.01$) was statistically higher than for other infections. For HCV, the number of people aged 40–69 years ($p < 0.01$) was statistically higher, while for HBV, there was no statistically significant difference for the age variable. Regarding gender, there was no statistical difference between infections ($p = 0.784$); that is, it was more common in men among the three infections. Regarding the type of donation, the number of people with HIV was statistically higher in repeat donations ($p = 0.029$) when compared to other infections. Based on the reagent serology on the first donation, there was no statistical difference between infections ($p = 0.732$); that is, it was more common in the first donation for the three infections. Regarding the type of donation, the number of HBV infected individuals who donated by replacement was statistically higher ($p = 0.038$) when compared to other infections, while for spontaneous/voluntary donations ($p = 0.221$), there was no statistical difference between infections; that is, it was more common in spontaneous donations for the three infections. Regarding marital status, the number of people with HCV who reported being married ($p < 0.001$) was statistically higher than that of other infections. As for HIV, the number of people who reported being single ($p < 0.001$) was statistically higher, while

Table 1
Epidemiological profile of blood donors unfit for HBV, HCV and HIV in serological screening at Blood Centers in Parana, 2018–2019.

Characteristics	Number (%)	P value
Age group (years)		
16–25	338 (22.6)	<0.001
26–35	451 (30.2)	
36–45	394 (26.3)	
46–55	234 (15.6)	
56–65	73 (4.9)	
66–69	06 (0.4)	
Gender		
Feminine	677 (45.3)	0.395
Male	819 (54.8)	
Number of donations		
First donation	1050 (70.2)	<0.001
Repeat donation	446 (29.8)	
Donation type		
Spontaneous/voluntary	1099 (73.5)	<0.001
Linked/replenishment	397 (26.5)	
Civil status		
Married	662 (44.3)	<0.001
Divorced	44 (2.9)	
Single	575 (38.4)	
Widower	13 (0.9)	
Uninformed	202 (13.5)	
Scholarity		
≤8 years of study	544 (36.4)	0.008
>8 years of study	952 (63.6)	
Race		
Yellow	08 (0.5)	<0.001
White	881 (58.9)	
Black	42 (2.8)	
Brown	72 (4.8)	
Uninformed	493 (33.0)	
ABO blood group		
A type	538 (36.0)	<0.001
AB type	42 (2.8)	
B type	164 (11.0)	
O type	752 (50.3)	
RhD		
Negative	207 (13.8)	<0.001
Positive	1289 (86.2)	

for HBV, the statistically significant majority did not report this information. According to schooling, the number of individuals infected with HCV and ≤8 years of education (p = 0.018), was statistically higher when compared to other infections. In addition, the number of individuals with >8 years of education (p < 0.01) was higher among individuals with HIV. Regarding ethnicity, there was no statistically significant difference among infections. In addition, there was no co-infection among infections during the study period analyzed during serological screening.

Table 3 shows reagent results indicating there was agreement and discrepancy between conventional serology and NAT in serological screening. In general, there was a decrease in the prevalence of blood donors blocked by reagent test for the three infections studied, compared to 2019.

The number of blood donors blocked due to HBV, HCV, and HIV in 2018, in relation to the total number of donors by region, was higher at the 20th RH, with a prevalence of 0.88%. In 2019, there was a decrease in the number of unfit people who had HBV serology and positive NAT and an increase in the number of individuals infected by HIV. Considering the results, there was a decrease in the number of unfit people compared to 2019.

As shown in Table 3, when only considering positive serology, the prevalence of infections is higher; however, when NAT is included, which is considered ideal, the prevalence becomes lower.

As verified, comparing between the tests, in the year 2018, at the 20th RH, out of 11 individuals unable to present positive serology for HBV, 5 had matching results between serology and NAT. For HCV, out of 24 unfit for positive serology, 1 presented matching results between serology and NAT. Out of 17 unfit for HIV-positive serology, 1 showed agreement between the tests.

In 2019, the highest reagent results for the three infections occurred at the 12th RH, located in Umuarama, northwest of Paraná, at 0.60%. Out of 12 unfit for HBV reagent serology, 5 were unfit according to both tests. For HCV, the only positivity was detected in conventional serology, and out of 16 unfit for HIV positive serology, only 2 were positive for NAT.

Regarding the discrepant results in serological screening with positivity only in NAT, in the diagnostic window, in the referred study during the 2 years evaluated, only 1 donor fit this situation, being a male individual, at the 9th RH, located in Foz do Iguaçu, western Paraná, aged 51 years, married, of black ethnicity, with >8 years of education, diagnosed on first donation, which was voluntary, and O positive. (Data not shown.) The diagnostic window was confirmed because later seroconversion was verified on new collection, with reagent serology observed.

As shown in Fig. 2, it was observed that the prevalence of HBV infection in blood donors, during the 2 years analyzed, occurred at a higher percentage in the 8th RH, with a 0.34% prevalence of reactive serology and a positive NAT at 0.17%. For the HCV infection, the prevalence of reagent serology was 0.28%, while for NAT, it was 0.02%, which occurred in the 20th RH. For HIV, the prevalence of blood donors with positive serology occurred in the 20th RH, with 0.25%, and for NAT positive, 0.04%. The 13th RH had the highest prevalence of HIV in relation to NAT, that is, conventional serology in concomitance with the NAT technology, at 0.07%.

4. Discussion

Clinical triage is essential in the serological screening process. In the blood centers in Paraná, 18% of the donor candidates were considered unfit due to medical exclusion or cancelation of collection. According to the Hemotherapeutic Production Bulletin—Hemoprod (2017), the national percentage of clinical disability was found at 20.5%, with the highest percentages due to anemia (14.80%), followed by behavior of risk for Sexually Transmitted Infections (STI) (13.01%). In addition, according to the published data, it appears that there is a difference between public and private services under SUS and exclusively private services, with the percentage of clinical disability being higher in public services. It is noted that Paraná has a lower rate of clinical disability when compared to the general index of blood centers in the country, since the percentage found (18%) also includes data on the candidates' dropout rates, as well as complications during the process, such as difficulty in venipuncture, inaccessibility of the vein, and slow flow. The lowest percentage of clinical inaptitude was directly associated with the quality of information provided to the population about blood donation, showing the need for quality in attracting donors, carried out by means of precise clinical and epidemiological selection, by benevolent and altruistic donors (Carrazzone et al., 2004), and the need to maintain or reduce these values as much as possible.

In serological screening, donors diagnosed with a transmissible disease do not have their bag transfused. In fact, they generate a cost to the health system due to any procedures performed, which then have to be discarded. The National Health Surveillance Agency recommends that the serological disability rate be lower than 8.3% (Ramos and Ferraz, 2010). In hemotherapy centers in Brazil, the rate of serological discharge ranges from 10% to 20%, which is higher than that in developed countries (Ferreira et al.,

Table 2
Characteristics of blood donors unfit for HBV, HCV and HIV (Serology+ and NAT+) in serological screening at Blood Centers in Paraná, 2018 to 2019.

Characteristics	HBV		HCV		HIV		p Value ^{***}
	n (%)	p Value	n (%)	p Value	n (%)	p Value	
Age group (years)							
16–39	96 (53.9)	0.496	03 (30.0)	<0.001	55 (62.5)	0.016	0.003
40–69	82 (46.1)		07 (70.0)		33 (37.5)		0.004
Gender							
Feminine	49 (27.5)	<0.001	02 (20.0)	<0.001	24 (27.3)	<0.001	0.480
Male	129 (72.5)		08 (80.0)		64 (72.7)		0.784
Number of donations							
First donation	175 (98.3)	<0.001	10 (100)	<0.001	79 (89.8)	<0.001	0.732
Repeat donation	03 (1.7)		0		09 (10.2)		0.029
Donation type							
Spontaneous/voluntary	104 (58.4)	0.269	07 (70.0)	<0.001	69 (78.4)	<0.001	0.231
Linked/replenishment	74 (41.6)		03 (30.0)		19 (21.6)		0.038
Civil status							
Married	83 (46.6)	0.016	06 (60.0)	<0.001	18 (20.4)	<0.001	<0.001
*Single	51 (28.7)		03 (30.0)		52 (59.2)		<0.001
Uninformed	44 (24.7)		01 (10.0)		18 (20.4)		
Scholarity							
≤8 years	92 (51.7)	0.810	07 (70.0)	<0.001	36 (40.9)	0.085	0.018
>8 years	86 (48.3)		03 (30.0)		52 (59.1)		0.008
Race							
White	75 (42.1)	0.138	04 (40.0)	<0.001	43 (48.9)	0.904	0.609
*Others	103 (57.9)		06 (60.0)		45 (51.1)		0.681
Total	178 (100)		10 (100)		88 (100)		

n, number of donors.

* Single, this variable includes single, divorced and widowed.

** Others include yellow, black, brown and unreported.

*** Chi-square calculated considering the values between HBV, HCV and HIV.

Table 3
Prevalence of blood donors unfit for HBV, HCV and HIV according to serology and concordant and discrepant NAT in serological screening by Regional Health, per year analyzed.

2018	Serology + NAT +			Serology + NAT –			2019	Serology + NAT +			Serology + NAT –			*Total
	HBV n (%)	HCV n (%)	HIV n (%)	HBV n (%)	HCV n (%)	HIV n (%)		HBV n (%)	HCV n (%)	HIV n (%)	HBV n (%)	HCV n (%)	HIV n (%)	
1st RH	2 (0.07)	0 (0.00)	0 (0.00)	4 (0.15)	7 (0.26)	4 (0.15)	17 (0.63)	2 (0.07)	0 (0.00)	1 (0.04)	1 (0.04)	5 (0.18)	4 (0.14)	13 (0.46)
2nd RH	7 (0.02)	1 (0.00)	13 (0.04)	39 (0.11)	95 (0.27)	38 (0.11)	193 (0.55)	6 (0.02)	1 (0.00)	3 (0.01)	22 (0.06)	37 (0.11)	43 (0.13)	112 (0.33)
3rd RH	0 (0.00)	0 (0.00)	2 (0.02)	11 (0.09)	23 (0.18)	24 (0.19)	60 (0.47)	1 (0.01)	0 (0.00)	2 (0.02)	9 (0.08)	12 (0.11)	10 (0.09)	34 (0.30)
4th RH	0 (0.00)	0 (0.00)	1 (0.04)	1 (0.04)	8 (0.30)	2 (0.08)	12 (0.45)	3 (0.12)	0 (0.00)	1 (0.04)	2 (0.08)	4 (0.16)	2 (0.08)	12 (0.49)
5th RH	5 (0.07)	1 (0.01)	2 (0.03)	11 (0.14)	28 (0.37)	10 (0.13)	57 (0.75)	2 (0.03)	0 (0.00)	1 (0.01)	5 (0.07)	13 (0.17)	8 (0.11)	29 (0.39)
6th RH	0 (0.00)	0 (0.00)	1 (0.03)	4 (0.12)	12 (0.35)	9 (0.26)	26 (0.76)	0 (0.00)	0 (0.00)	0 (0.00)	4 (0.11)	8 (0.21)	5 (0.13)	17 (0.45)
7th RH	10 (0.13)	0 (0.00)	0 (0.00)	13 (0.16)	16 (0.20)	13 (0.16)	52 (0.65)	8 (0.13)	0 (0.00)	2 (0.03)	7 (0.11)	7 (0.11)	4 (0.06)	28 (0.45)
8th RH	11 (0.16)	0 (0.00)	1 (0.01)	10 (0.14)	16 (0.23)	10 (0.14)	48 (0.69)	13 (0.19)	0 (0.00)	0 (0.00)	13 (0.19)	3 (0.04)	10 (0.14)	39 (0.56)
9th RH	13 (0.10)	0 (0.00)	7 (0.05)	9 (0.07)	22 (0.17)	9 (0.07)	60 (0.46)	14 (0.11)	0 (0.00)	3 (0.02)	5 (0.04)	26 (0.20)	14 (0.11)	62 (0.47)
10th RH	19 (0.14)	1 (0.01)	4 (0.03)	18 (0.13)	35 (0.25)	19 (0.14)	96 (0.69)	16 (0.11)	1 (0.01)	2 (0.01)	11 (0.07)	16 (0.11)	16 (0.11)	62 (0.42)
11th RH	6 (0.07)	0 (0.00)	0 (0.00)	9 (0.11)	17 (0.21)	13 (0.16)	45 (0.56)	5 (0.07)	0 (0.00)	3 (0.04)	2 (0.03)	6 (0.08)	8 (0.11)	24 (0.32)
12th RH	1 (0.01)	0 (0.00)	1 (0.01)	6 (0.08)	28 (0.38)	2 (0.03)	38 (0.52)	5 (0.08)	0 (0.00)	2 (0.03)	7 (0.12)	8 (0.13)	14 (0.23)	36 (0.60)
13th RH	2 (0.04)	0 (0.00)	3 (0.06)	0 (0.00)	3 (0.06)	0 (0.00)	8 (0.16)	2 (0.06)	0 (0.00)	3 (0.09)	1 (0.03)	0 (0.00)	0 (0.00)	6 (0.18)
14th RH	3 (0.04)	0 (0.00)	1 (0.01)	4 (0.05)	16 (0.20)	13 (0.17)	37 (0.47)	2 (0.03)	0 (0.00)	4 (0.05)	4 (0.05)	8 (0.11)	7 (0.09)	25 (0.33)
15th RH	3 (0.03)	2 (0.02)	2 (0.02)	1 (0.01)	2 (0.02)	0 (0.00)	10 (0.08)	2 (0.02)	0 (0.00)	8 (0.06)	0 (0.00)	1 (0.01)	0 (0.00)	11 (0.09)
16th RH	1 (0.01)	0 (0.00)	2 (0.03)	2 (0.03)	24 (0.32)	16 (0.21)	45 (0.60)	4 (0.08)	0 (0.00)	4 (0.08)	1 (0.02)	7 (0.14)	9 (0.17)	25 (0.48)
18th RH	2 (0.06)	0 (0.00)	2 (0.06)	4 (0.12)	7 (0.22)	9 (0.28)	24 (0.75)	1 (0.02)	1 (0.02)	1 (0.02)	2 (0.05)	7 (0.17)	3 (0.07)	15 (0.37)
19th RH	0 (0.00)	0 (0.00)	0 (0.00)	4 (0.14)	8 (0.28)	3 (0.11)	15 (0.52)	0 (0.00)	0 (0.00)	1 (0.03)	4 (0.11)	6 (0.16)	4 (0.11)	15 (0.41)
20th RH	5 (0.08)	1 (0.02)	1 (0.02)	6 (0.10)	23 (0.39)	16 (0.27)	52 (0.88)	2 (0.05)	1 (0.02)	3 (0.07)	4 (0.09)	4 (0.09)	6 (0.14)	20 (0.46)
21st RH	0 (0.00)	0 (0.00)	0 (0.00)	5 (0.31)	5 (0.31)	4 (0.25)	14 (0.86)	0 (0.00)	0 (0.00)	1 (0.05)	1 (0.05)	0 (0.00)	1 (0.05)	3 (0.15)

n: number of donors.

* Total: prevalence considering all infections, disregarding the difference between serology and NAT, by Health Region, per year.

2012). From donors blocked by positivity in one or both tests for HBV, HCV, and HIV, the disposal rate was 0.46%, equivalent to 1,496 bags. In the study by Neto (2007), in São Paulo, when evaluating the epidemiological profile of blood donors infected with HIV, a serological discharge rate of 0.38% was found. For comparison purposes, it appears that the Hemotherapeutic Network of Paraná does not have high disposal values for the three infections ana-

lyzed, since the disposal of HIV only in another region of Brazil has already shown high values when correlated. However, it should be noted that different percentages may be related to the number of samples analyzed and also to the study time.

From donors unfit for the three infections, the predominance occurred in initial donors, which is in agreement with other studies, since most of these donors had not been subjected to previous

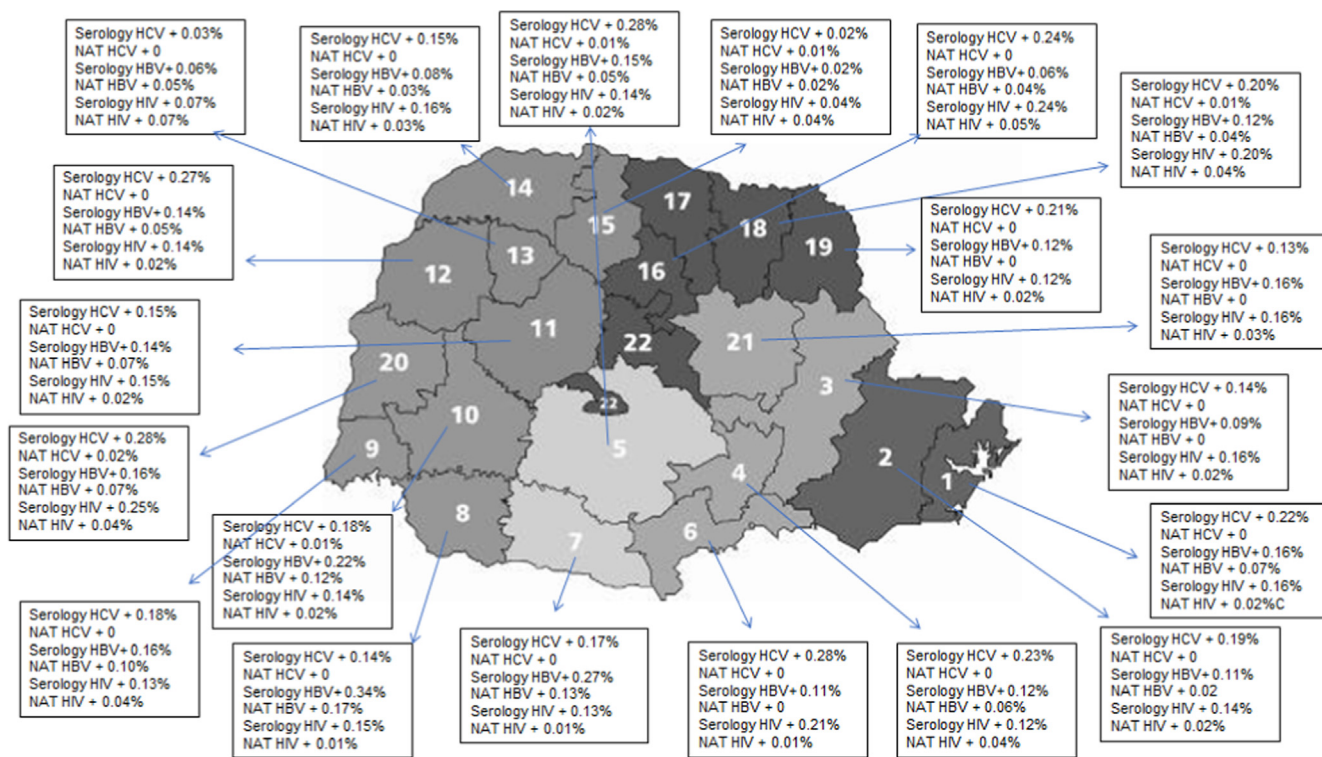


Fig. 2. Prevalence of infection in donors who are reagent for Serology and NAT for HBV, HCV and HIV in serological screening at the Health Regions in Paraná, 2018–2019.

serological screening (Salles et al., 2003). Since the primer was undergoing its first serological screening, one is more likely to have a positive result than another who has undergone previous screening (Ferreira, 2007). Furthermore, considering the blood donation by people at high risk of HIV infection, a study shows a higher prevalence of seropositivity among those who donate blood for the first time (Gonçalves et al., 2006a,b).

Regarding education, our results are similar to other studies, with greater numbers of those with education >8 years, in most donors. A study conducted at the blood center in Crato, CE, concluded that blood donation increases with the donor’s level of education (Moura et al., 2006). Data are also consistent with those reported by Barbosa et al. (2006). When verifying the sociodemographic profile of blood donors reacting to HCV in Hemosul in Campo Grande, these authors found that 47.25% of the 400 donors had completed high school.

In donors showing both serology and NAT positivity, the HBV infection was predominant. Although vaccine is available for this immune disease, hepatitis B remains one of the most important public health problems. According to the *Epidemiological Bulletin of Viral Hepatitis (2019)*, most confirmed cases of hepatitis B in Brazil are concentrated in the southeast, followed by the south, north, northeast, and midwest regions. According to Bolton-Maggs et al. (2017), HBV is still the virus that presents the highest residual risk of transfusion transmission, compared to HIV and HCV. In a study carried out in Campo Mourão, evaluating the epidemiological profile of blood donors, Ramos and Ferraz (2010), found that in 2008, the prevalent serological disabilities were hepatitis B, at 71.43%, syphilis 11.17% donors, and HIV 8.31%. Even 12 years after this study, there is also a predominance of HBV in blood centers in the State of Paraná, which may be associated with the fact that the population still had a cumulative effect of behavioral risks, mainly unprotected sex, since it is a disease transmitted mainly through sexual intercourse, the use of injectable illicit drugs, and other routes of exposure to blood and blood products (Souza et al., 2004).

The HBV infection was predominant in men, as shown in other works, in which the prevalence of HBV in men at blood banks was higher than that in women. A study cited by Corrêa et al. (2016), which analyzed the prevalence of HBV before and after the implementation of HBV–NAT in northern Brazil from 2013 to 2016, found that the main group of donors was composed of men (65.4%). This can possibly be explained by the fact that men are more exposed to the virus through sexual behavior and low vaccination coverage, or justified by the fact that normally, there is a greater number of male candidates for donations in blood banks in Brazil compared to women (Brazil, Ministry of Health, 2018) due to several reasons. For example, there are screening restrictions such as weight, and the number of women under 50 kg is much higher, in addition to pregnancy, menstrual period, and anemia risk (Butera, 2002; Gois, 2012). In a study carried out in Shiyan, China, between 2010 and 2014, there was a predominance of HBV infection in females and a decrease in seroprevalence among donors aged 18–35 years compared to those aged >45 years (Yang et al., 2016).

Sheikh et al. (2013) claimed that the massive immunization of hepatitis B led to a decline in the prevalence of HBV by preventing child groups, as well as providing immunization for adolescents and adults before they engage in risky behavior. This explanation goes against the Brazilian study by Menegol and Spilki (2013). When analyzing the age groups, the authors found reactivity for donors aged <29 years at 10.9%, and 89.1% for those aged >29 years. However, this hypothesis may not have been seen in this study, since the age range for infection with this virus occurred more homogeneously, with no statistically significant difference in terms of age. However, in relation to marital status, most occurred in donors who reported being married, as it is not similar to the study by Guedes et al. (2009), which found a higher frequency among singles, a fact that can be explained by the question that, in some cases, monogamy may not be reciprocal, and there may be exposure to different sexually transmitted infections, due to the limited use of condoms.

Until 2015, in the city of Maringá, vaccination rates for hepatitis B ranged between 98% and 100% (National Council of Health Secretaries, 2018). Such coverage may justify the low serologies found for infections in the city of Maringá, which had the lowest percentage of donors blocked due to infections, considering that the hepatitis B virus, in general, was the major cause of infection in blood donors at blood centers in Paraná. In this sense, the differences in prevalence and socio-epidemiological profile among blood centers, even when addressing a single state, can be based on the fact that, as a heterogeneous country, Brazil shows a great diversity considering ethnic distribution, and economic and cultural differences, as well as postulating that there is a variation in the prevalence of infection levels (Brazil Ministry of Health, 2013). However, some authors have demonstrated that the differences regarding the prevalence of positivity to the serological markers in question may vary between regions, due to factors such as prior screening of the blood donor, profile of the donor who looks for a blood bank, percentage of people who donate blood for the first time, and tests with different techniques used in social research (Caetano and Beck, 2006). This fact is not justified in the present study, since HemePar employs the same methodology for certain analyses.

Regarding the HCV infection, from 1999 to 2018, 174,703 cases of hepatitis C were reported in Brazil with both anti-HCV and HCV-RNA reagents (Brazil Ministry of Health, 2019). In general, in the present study, the HCV infection was less frequent than the HBV and HIV infections. According to Costa et al. (2013), the low rate of anti-HCV and HCV-RNA reagents reinforced previous findings regarding the low positivity incidence of this pathogen in blood donors. However, studies have shown that transfusion of blood and blood products, although after the standardization of serological screening processes in blood banks has significantly reduced HCV transmission, previously considered to be the main source of infection (Leao et al., 2006), due to the existence of the diagnostic window, cases of post-transfusion hepatitis can still be reported (Kupek, 2004).

Patinõ-Sarcinelli et al. (1994) investigated the prevalence of anti-HCV antibodies in voluntary blood donors in Rio de Janeiro and obtained a rate of 2.89% associated with males, non-white ethnicities, and older ages. When assessing the prevalence of hepatitis C in blood donors at the Hemopá Foundation, in the state of Pará, Oliveira-Filho et al. (2010) detected viral RNA concomitant with anti-HCV in 0.13% of the samples (304 out of 242,726 samples). As some authors describe, there is a decreasing tendency of serological inability for HCV among blood donation candidates, and among those unfit, there were reports that the prevalence increases with age and is higher in males (Hoppe et al., 2006). The finding is consistent with that evidenced in the present study, where the predominance of infection occurred in individuals aged 40–69 years, meeting data from the Ministry of Health—Epidemiological Bulletin of Viral Hepatitis (2019). Here, it was observed that the reported cases of hepatitis C occurred mostly in the older age groups; thus, it can be interpreted that the young population is more receptive to educational actions, becoming a major factor in blood donations.

The highest prevalence of HCV infection remains in men, and this result may be a reflection of the greater exposure of men to the risk factors, while women are still not that affected by infection caused by needles, contaminated syringes, inhalation of contaminated drugs, medical and dental procedures and tattoos, and the use of instruments such as nail pliers in beauty salons. As already mentioned, there is the possibility of an absolute majority of donations by the male gender, which can be justified by the fact that men are more exposed to the hepatitis C contamination risks, as well as other viral diseases, and undergo screening tests for blood donation to diagnose such infections (Josahkian et al., 2010; Martins et al., 2011).

Regarding HIV, according to the AIDS/HIV Epidemiological Bulletin (2019), from 2007 to June 2019, a total of 300,496 cases of HIV infection in Brazil were reported in Sinan, the majority in the southeast, followed by the south, northeast, north, and mid-west regions. The epidemiological data obtained in this study showed that the majority of donors who showed reactivity in HIV tests were young men, predominantly aged between 16 and 39 years, and single. In the general population of Brazil, men were even more exposed to infection (Brazil Ministry of Health, 2019). According to a study carried out at HEMOPA Foundation (PA), blood donors positive for HIV in serological screening were mostly young adults, aged 30–34 years, male (88.14%), and undergoing first donation (88.15%; Pinto et al., 2000), which corroborates with our data. In a study from China, Yang et al. (2016) found a higher rate of HIV infection among blood donors in the 36–45 age group, with women being more affected, but individuals with the level of education >8 years, specifically university students, had the highest prevalence. In addition, in São Paulo, at the blood bank of Hospital Albert Einstein, when evaluating the epidemiological profile of donors who showed reactivity to HIV, from 2004 to 2015, Levi et al. (2017) found that the average age was 33.8 years, with women being predominantly infected (80%).

The majority of HIV-positive donors were single, as well as in a study reported by Pereira (2009), in which the prevalence for single individuals was 59.1%. This reflects the fact that possibly, married people, due to a stable relationship, are less exposed, and singles who have more active sex are more exposed to the transmission. However, studies demonstrate that spontaneous and first donation donors have a higher prevalence of HIV infection than repeat donors, which agrees with the present study, which can be hypothetically explained by the fact that many individuals seek hemotherapy services to obtain free exams (Gonçalves et al., 2006a,b). However, when comparing data among the three infections, the number of people with HIV was statistically higher in repeat donation than in others, a fact that may not be in accordance with what was mentioned by Gonçalves, or even because of the fact that, nowadays, not only for HIV, but for other infections as well, individuals end up looking for hemotherapy as a disease testing center.

Regarding molecular biology, in Brazil, testing for HIV and HCV in blood bank screening become mandatory only in 2013, making it the mandatory requirement for the SUS public, through Ordinance no. 13 of May 15, 2014, on the recommendation of the National Commission for the Incorporation of Technologies in SUS (CONITEC) (Brazil Ministry of Health, 2013, 2014). In 2016, it was revoked by Administrative Rule no. 158 of February 4, 2016, including the NAT test for HBV (Brazil Ministry of Health, 2016). According to Willkommen et al. (1999), the hepatitis C virus was initially chosen to be investigated in blood centers, due to its large diagnostic window, which can range from 1.5 to 2 months when immunological tests are performed for anti-HCV. Later, the test for hepatitis B was also included, and according to the Ministry of Health reports, there are still regions in Brazil with a higher rate of this infection, regardless of the existing vaccine (Brazil Ministry of Health, 2014) and/or by the immigration of people from South-east Asia, who could possibly be carriers and vertical HBV transmitters (Perkins and Busch, 2010; Kew, 2010).

In the present study, most of the results were found to show discrepancy in the two tests used for the same sample in serological screening, which converges with most studies evidencing such research, as in the study by Lima and Naoum (2011), who compared the screening methodologies for HIV and HCV in blood banks in Brasília for 3 months. Among the 22 total positive results found, 19 were discrepant, all of which were positive in the serological test and negative in the NAT test. According to an article published in Porto Alegre, RS, in 2018, in a hemotherapy service, referring to

the years 2015–2017, 41 bags were serologically reactive for HIV (0.14%), and the reagent bags for the NAT test were 21 (0.07%; Davila et al., 2018). However, another study carried out in Guarapuava (PR) from 2013 to 2014, by screening 11,706 samples, which presented positive serology for HCV and HIV, it was found that when applying the NAT methodology, the percentage of positivity decreased from 0.31% ($n = 37$) to 0.01% ($n = 1$) for HCV and from 0.21% ($n = 25$) to 0.03% ($n = 3$) for HIV (Verdasca, 2015), as shown in the present study.

It is known that the low percentage of agreement between the positive results (reagent only in serology) can be caused by two reasons, the most common being false-positive results found in the serological screening test. However, this is already expected, since sensitivity is more important than specificity for screening tests performed in blood banks (Dwyre et al., 2011), to ensure the exclusion of any possibility of transmitting infectious diseases through transfusion, which may occur because of the presence of antibodies against residual proteins of the vector used in the production of the recombinant antigen composing the serological kit, autoimmune diseases, and protein degradation of serums improperly stored for long periods (Krajden, 2000). Another possible cause is the existence of donors carrying these viruses who have a high titer of circulating antibodies and a low viral load, not detectable in the NAT test (Davila et al., 2018). For this reason, there is the need to carry out a confirmatory test for a second biological sample. In this sense, conveying the conflicting results is important because of the impact they have on blood therapy routines, since the bags undergo all the processing and their blood components are discarded, in addition to the routine of summoning these donors to confirm the results, which is both timely and costly, although necessary for maximum excellence in transfusion safety.

Regarding false-negative results in serological screening, that is, donors who only react in NAT, of 1,496 samples tested by chemiluminescence and NAT, one donor fit this situation, reagent for HBV. It meant that at the time of blood donation, the individual still did not have antibodies against the virus but had genetic material detectable by NAT. When screening 673,859 blood donations in the NAT test for HIV and HCV and 357,137 in the NAT test for HBV, in 2014, a study by Leme and Levi (2018) detected 6 immunological windows, 4 for HIV, and 2 for HBV. Another study by Scuracchio et al. (2007), identified 2 donors by NAT in a serological window period, after screening 47,866 donations in 18 months. In Germany, a survey carried out by Fiedler et al. (2019), who verified the effectiveness of NAT for HIV, HBV, and HCV from 2008 to 2015, obtained an average of 3 to 6 donations with HBV infection per year, detected only by NAT screening, resulting in 29 positive cases during this period. In relation to HIV, 20 cases were detected by NAT, and in relation to HCV, 61 cases detected by NAT were reported. In a public blood bank in the Brazilian Amazon (HEMOAM), Souza et al. (2019) found that most donations (73.4%) were positive for HIV–NAT, with 4 donations in the diagnostic window period.

When compared to the present study, it appears that this research showed a high donor rate in the diagnostic window period, considering the proportion of the population analyzed. Such information is important to prove the need for NAT implementation, which is complementary to serology, improving transfusion safety (Pillonel and Laparche, 2004), as shown in the study by Kupek and Petry (2014). Here, when analyzing blood banks in Santa Catarina, in southern Brazil, from January 2007 to July 2013, compared with the previous period to NAT screening, the authors found that the HIV prevalence increased from 1.38 to 1.58 per 1,000 donors; the incidence rate increased from 1.22 to 1.35 per 1,000 donor-years, and the 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, the incidence dropped from 0.12 to 0.06 per 1,000 donor-years, and the residual risk decreased more than 3 times after the NAT implementation, thus raising the security issue that technology offers.

Concerning seroprevalence and NAT, in relation to blood centers, the 8th RH, located in Francisco Beltrão, in the west of the State, presented a greater prevalence of HBV, with seroprevalence of 0.34% and NAT in concomitance of 0.17%. A study carried out on donors at Ribeirão Preto Blood Center (SP) showed an HBsAg seroprevalence of 0.6% (Valente et al., 2005). Côrrea et al. (2018) found an HBsAg seroprevalence of 1.39% at the HEMOPA Foundation–Pará. A survey carried out at the University Hospital of Gondar, in northwest Ethiopia, found an HBV seroprevalence rate of 4.7% (Tessema et al., 2010).

When comparing the results of the studies, it is necessary to consider regional differences, socioeconomic and epidemiological variations in each region, the use of various serological techniques, and the number of samples in each study (Lima et al., 2012). According to the *Epidemiological Bulletin of Viral Hepatitis of the Paraná Health's Secretary* (2019), the western region is an endemic region for hepatitis, mainly for HBV infection. Recent data on the seroprevalence of HBV in blood donors are scarce; however, in a study carried out in a blood bank in Maringá, from 2004 to 2013, it was found that the reactivity for HbsAg was 0.12% (Pereira and Bonafé, 2015). It can be said that there was a wide variation in prevalence according to the regions of Brazil for HBV; however, compared to the study carried out in the northwest of the state, the prevalence of HBV in this study was higher. Nonetheless, as evidenced in other studies cited, it is one of the most frequent infections in blood banks.

For HCV, the predominance occurred in the 20th RH, located in Toledo, also in western Paraná, with a seroprevalence of 0.28%, and 0.02% for NAT. Carvalho and Dias (1995), when studying seropositivity for anti-HCV in regions of the state of Paraná, showed rates of 0.66% in Curitiba, 0.57% in Campo Mourão, 0.52% in Francisco Beltrão, 0.54% in Apucarana, 0.47% in Guarapuava, and 0.45% in Cascavel. In 2015, in blood donors in the city of Maringá, 0.07% of the analyzed grants were positive for HCV (Pereira and Bonafé, 2015). In Ethiopia, Tessema et al. (2010) also found low percentages of HCV in blood donors, with a 0.7% seroprevalence. Compared to this research, it appears that the trend over the years has been to decrease the prevalence of this infection, which may possibly reflect greater control over the transmission routes of this infection.

For HIV, the prevalence of blood donors with positive serology occurred in the 20th RH, too, with 0.25%, and for NAT positive, 0.04%. It is noted that, due to a low agreement between NAT, it can be suggested that, for this infection, there was a greater possibility of false-positive results, since in relation to the agreement between serology and NAT for HIV, the 13th RH, located in Cianorte, northwest of the state, obtained the highest prevalence (0.07%). No published research has been conducted in the Toledo region to match this. According to the study by Pereira and Bonafé (2015), in the Don Bosco blood bank (Maringá, PR) between 2004 and 2013, HIV seroprevalence was 0.05%, lower than in most Brazilian studies, according to which, in the blood center of São Paulo, from 1999 to 2003, 0.38% units were discarded in HIV serological screening (Neto, 2007). In Ethiopia, blood donors at the University Hospital of Gondar had an HIV seroprevalence rate of 3.8% (Tessema et al., 2010), data variable for each region of Brazil and countries in the world. There was a large fluctuation in prevalence in different Paraná regions, making the regional differences between one blood center and another evident. However, compared to the aforementioned study carried out in the northwest region of the state, the prevalence found in this study for HIV was higher.

The strengths of this study include the subject studied, because viral infections such as hepatitis and HIV generally pose a global public health problem. Even though it is not the main route of contamination, infection can be caused by transfusion of blood components. They are worthy of concern, since they compromise the quality of life of the recipient, generating important and serious consequences, especially viral infections, since they have a long history. The period of diagnostic window, as well as many asymptomatic cases (especially in hepatitis), which can hinder the screening process, generating a large percentage of serological discard. In this sense, the importance of implementing the technology in question, as well as the fact that the present study can contribute to updating the epidemiological data of these infections, bringing information not only to professionals working in health services, but also to society susceptible, being also fundamental to study the dynamics of infections according to the regions of Paraná.

This work has several limitations. It was not possible to collect information from blood donors in the 17th RH, located in Londrina, as it has its own system from the UEL. In addition, the reagent values in serology for certain infections may be underreported, as undetermined results in serology have not been collected, and following confirmation, more donors may have tested reagents. Furthermore, because this study is linked to the results of tests obtained only in serological screening, it was not possible to collect data from confirmatory tests, since these are part of another system. However, we believe that their inclusion in future studies will add to the research outcomes, since they may elucidate the results of false positive cases that may have occurred in serological screening.

5. Conclusion

In conclusion, at the blood centers in Paraná, the inability to donate due to HBV, HCV, and HIV occurred mainly in first-time donors, those having >8 years of education, aged 16–45 years, married, and O positive. The most affected regions were in the west and northwest of Paraná. The region with the highest prevalence of donation disability for the three infections was the 20th RH. Considering positivity in serology and NAT, male donors donating for the first time were predominant. The HBV infection was more frequent, and the most important variable for this infection were married individuals, with a higher prevalence in the 8th RH. The HCV infection was the least frequent in relation to all the evaluated RHs, characterizing the unfit donors as the majority with more advanced ages, 40–69 years, married, and with ≤8 years of education. There was a low prevalence of HCV in donors in Paraná. The greatest number of people blocked due to this infection occurred at the 20th RH. Donors blocked due to reactivity indicated in HIV tests were mostly younger, 16–39 years old, single, and with >8 years of education. The 13th RH obtained a higher prevalence of HIV in relation to other RHs. In addition, during the period of 2 years, only one reactive donor was found for NAT, for the hepatitis B virus, characterized in a diagnostic window, donor in the 9th RH, being male, aged 51 years, married, black ethnicity, with >8 years of education, diagnosed on the first donation, by voluntary act, and O positive.

Considering the lack of agreement and the reduction of positive cases when applying NAT, it is observed that the inclusion of the two techniques is necessary not only because of a legislation requirement, but also for the clarification of cases that are false-positive in serological screening and the possibility of detecting recent infections, which increases transfusion safety.

In summary, it was found that there were few current studies regarding the serological and molecular ineptitude of blood donors

in hemotherapy services in the state of Paraná, mainly in the western region, which obtained a higher index of ineptitude for these infections. In this sense, it is suggested to carry out more similar data surveys to contribute to the epidemiological improvement, as well as to guide health policies to control the expansion of the HBV, HCV, and HIV viruses and to assist in controlling the incidence worldwide.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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