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COMPARATIVE ANALYSIS OF SEROLOGICAL AND MOLECULAR TRANSFUSION TRANSMISSIBLE INFECTIONS SCREENING

Marija Tashkovska, Tatjana Makarovska Bojadjieva[2], Emilija Velkova[2], Violeta Dejanova Ilijevska[2], Elena Petkovic[1], Elena Ristovska[2], Bojan Todorovski[2], Ivana Babalj Veljanoski[1], Aleksandra Stojchevska[1]

[1]City General Hospital 8th September, Skopje, North Macedonia,
[2]Institute of Transfusion Medicine, Faculty of Medicine, Ss. Cyril and Methodius University in Skopje, North Macedonia

Abstract

Introduction. Transfusion Transmissible Infections (TTIs) remain a major concern in ensuring the blood safety. Nucleic acid testing (NAT) improves detection by shortening the window period (WP) and identifying occult infections. This study aims to determine the significance of NAT through a comparative analysis of the chemiluminescent serological technique (CMIA) and the molecular technique (NAT).

Methods. This retrospective study analyzed TTI testing data from 167979 blood donations (93,390 donors) between 2022 and 2024. Screening included HBV DNA, HCV RNA, and HIV RNA (Procleix UltrioPlex E, Panther System) and serological markers (HBsAg, anti-HCV, anti-HIV/p24) using the Architect 2000 platform. Repeatedly seroreactive samples underwent confirmatory testing (HBsAg neutralization, HCV/HIV immunoblot), while NAT-reactive samples were individually tested using the Procleix Ultrio Elite discriminatory assay.

Results. Serological testing identified 237 (0.25%) confirmed TTI cases, while NAT detected 245 (0.26%), including 22 (0.023%) NAT-only positive cases. Among these, 21 were HBV DNA-positive/HBsAg-negative. Follow-up samples from 11 donors showed seroconversion in 7 (33.3%), while 4 (19.0%) were identified as potential occult HBV infections (OBI). One HIV NAT-only case was detected. The NAT yield was 1 per 4,245 donations, decreasing over time. Residual risk per 100,000 donations declined from 10.55 to 4.59 for HBV, while remaining low for HCV and HIV (0.12 in 2024).

Conclusion. NAT enhances blood safety by detecting early and occult infections missed by serology. The declining NAT yield and residual risk emphasize improved screening efficiency. Integrating NAT with serological methods is crucial for reducing transfusion-transmitted infections.

Keywords: NAT, blood safety, transfusion-transmissible infections, residual risk

Introduction

Laboratory testing of blood donors for markers of transfusion-transmissible infections (TTIs) is a crucial safety measure to protect patients receiving blood and to prevent the spread of blood-borne infectious diseases in the community [1].

Laboratory testing for TTIs is mandatory for every blood unit from each donor, regardless of whether it is an autologous or homologous whole blood unit, as well as for apheresis donations of plasma or platelets.

According to the World Health Organization (WHO) guidelines, blood testing generally includes screening for hepatitis viruses (HBV, HCV), HIV and Treponema pallidum (TP). However, based on the prevalence of certain pathogens and epidemiological trends in a specific region, some countries may also conduct routine, seasonal, or targeted testing for HTLV (Human T-lymphotropic virus), Cytomegalovirus (CMV), hepatitis E virus (HEV), West Nile virus (WNV), malaria, etc [2,3].

Microbiological agents transmitted through blood transfusion can cause morbidity and mortality in recipients. Developing an effective, well-organized national blood screening program with

quality system is essential to ensure a safe blood supply [4]. Many factors influence blood safety, including donor selection criteria, enhanced sensitivity of serological screening tests, improvements in the preparation and quality control of blood components, and the implementation of nucleic acid testing (NAT) as routine screening [5].

The primary goal of NAT testing in blood screening is to reduce the residual risk of virus transmission associated with the window period and the detection of occult infections such as occult B hepatitis infection (OBI). NAT detects viral nucleic acids, allowing for earlier identification of infections compared to traditional serological methods.

This early detection significantly shortens the window period (WP), the time between initial infection and when the virus becomes detectable, thereby enhancing blood safety [6].

Introduced in developed countries in the late 1990s and early 2000s, NAT has been implemented in numerous countries for detecting viruses such as HIV, HBV, and HCV [7].

This advanced approach enhances the detection of infectious donations that would otherwise go unnoticed by conventional serological assays, which rely on detecting antigens or antibodies.

The introduction of molecular techniques, such as NAT technology, further prevents the transmission of TTIs to blood recipients, thereby reducing the spread of infections in the healthy population [8].

Different infection markers emerge at various intervals following infection. The period in which the donor is infectious but the asymptomatic infection is not detectable is called a window period (WP). Each transfusion-transmissible agent has a WP ranging from several days to months, depending on the agent, the screening marker used, and the screening technology employed.

During this period, the specific TTI screening marker remains undetectable in a recently infected donor. Nucleic acids, as integral components of the infectious agent, are the first detectable targets, followed by antigens, and subsequently antibodies as the immune response develops.

One or a combination of several TTI markers can be utilized to detect a particular infection during the screening process [9].

Hepatitis B virus (HBV) is a DNA virus that causes liver infection. HBV is a member of the Hepadnaviridae family of viruses. HBV is classified into eight genotypes, A to H. Each genotype has a distinct geographic distribution [10].

The incubation period averages 90 days but can range from 30 to 180 days. WHO estimates that 254 million people were living with chronic hepatitis B infection, with 1.2 million new infections each year? In 2022, hepatitis B resulted in an estimated 1.1 million deaths, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer) [11].

Despite the availability of an effective HBV vaccine, numerous new infections continue to occur annually, particularly in low-resource regions with inadequate vaccination policies. Markers of hepatitis B include HBsAg (surface antigen) synthesized by virus-infected cells, anti-HBs antibodies, HBcAg (core antigen), anti-HBc antibodies, HBeAg (envelope antigen), anti-HBe antibodies, and viral DNA [12].

NAT technology has reduced the WP to less than 30 days and enables the detection of the so-called occult form of chronic infection, characterized by the presence of viral DNA without the presence of serological markers. The persistence of HBV genomes in HBV surface antigen (HBsAg) negative individuals is termed occult HBV infection (OBI) [13].

Blood donors with OBI may transmit HBV [14]. Three immunosuppressed recipients developed fatal fulminant hepatitis B following transfusion from donors with OBI [15].

In the first 2 years of HBV NAT testing of the Australian donor population, 42 chronic OBI infections (5.55/100000 donors) were identified compared to eight acute serologic window period infections (1.06/100000 donors) [16].

The combined use of HBsAg testing and NAT effectively prevents most cases of HBV transmission by blood transfusion.

Hepatitis C virus (HCV) is a spherical, enveloped, positive-strand RNA virus with a diameter of approximately 55 nm. It belongs to the Flaviviridae family. According to the latest classification, HCV is categorized into seven genotypes based on nucleotide sequence variability observed across various geographic regions [17,18].

An estimated 50 million people worldwide are affected by chronic hepatitis C, with roughly 1 million new cases each year. According to WHO, in 2022, hepatitis C was responsible for

approximately 242.000 deaths, mainly resulting from cirrhosis and liver cancer (hepatocellular carcinoma) [19].

Markers for HCV include anti-HCV antibodies, HCV (core) antigen, and HCV RNA. The diagnosis of HCV infection primarily relies on detecting antibodies against recombinant HCV polypeptides and identifying HCV RNA through specific assays [20].

The window period with ELISA tests is 50–60 days, which can be reduced to 16–32 days when ALT testing is combined with anti-HCV antibody testing. The use of NAT techniques further shortens the window period to 3–7 days. During its infectious phase, the virus replicates rapidly, producing up to 10 trillion virions daily. HCV infection continues to be a significant global health challenge and a leading cause of liver cirrhosis, liver cancer, and the need for liver transplantation [21].

While an HCV vaccine remains unavailable, the WHO set an ambitious target in 2016 to decrease new HCV infections by 90% by 2030, aiming for the eventual elimination of the virus [22].

The human immunodeficiency virus (HIV) is an RNA virus that causes acquired immunodeficiency syndrome (AIDS). HIV remains a global health challenge, having caused approximately 42.3 million deaths. Transmission continues in all countries worldwide, and according to the WHO, around 39.9 million people were living with HIV, with 65% of them in the African region [23].

HIV exists as type 1, type 2, and type 1 subtype O. Markers of HIV infection include anti-HIV 1, anti-HIV 2, anti-HIV 1 subtype O, HIV Ag p24, and viral RNA [24].

HIV tests used for blood screening are highly sensitive in detecting established infections. The WP has progressively shortened over time with advancements in testing technology. The WP for serological tests is approximately 22 days. When p24 antigen, a key diagnostic marker for primary HIV infection that appears between infection and seroconversion is included in testing, the WP is reduced to 16 days. With NAT, the window period is further shortened to 5–9 days [25].

Despite improvements to blood screening assays, donations from infected donors remain undetectable during the window period WP, when the virus has not yet replicated above the lower limit of detection (LOD) of a screening assay [26].

In our country, as well as in most European countries and worldwide, serological testing is performed on each blood unit for hepatitis B (HBsAg), hepatitis C (anti-HCV), HIV (anti-HIV1/2, p24 antigen), and syphilis (anti-TP) using the chemiluminescent serological technique (Chemiluminescent Microparticle Immunoassay – CMIA). In 2022, molecular testing was introduced with a multiplex NAT molecular test, which enables simultaneous amplification and detection of viral DNA for HBV and viral RNA for HIV and HCV in individual blood samples (ID-NAT).

Aims

The main objective of this research is to determine the significance of NAT for the safety of blood intended for transfusion through a comparative analysis of the CMIA and the NAT.

The secondary objectives of the research are as follows:

• To determine the prevalence of serological markers for TTIs, including HBsAg, anti-HCV, anti-HIV1/2 and p24 antigen, and to compare it with the prevalence of molecular markers for TTIs such as HBV DNA, HCV RNA, and HIV RNA, with a special focus on discrepant results between the two techniques.

• To correlate the initially reactive and repeatedly reactive results with confirmed positive results for each of the tested TTI markers using both techniques: CMIA (HBsAg, anti-HCV, anti-HIV1/2, and p24) and NAT (HBV DNA, HCV RNA and HIV RNA).

• To determine the yield of molecular testing (CMIA-negative/NAT-positive result).

Matherials and methods

This is a retrospective study in which we analyzed data of TTI - testing performed on 167979 blood donations from 93390 blood donors in the period from 2022 to 2024. Test results were electronically distributed through the national transfusion IT system, e-Delphyn. Blood samples were screened for the presence of HBV DNA, HCV RNA and HIV RNA using Procleix UltrioPlex E assay (Procleix Panther System), as well to the presence of HBsAg, anti-HCV and anti-HIV/p24 using CMIA on Architect 2000 platform. Repeatedly seroreactive samples were subjected to confirmatory testing using HBsAg neutralization test and immunoblot for HCV and for HIV. Repeatedly reactive samples by NAT were subjected to individual testing using Procleix Ultrio Elite HIV, HCV and HBV discriminatory assay.

For each donor, two blood samples of 6 mL were drawn into separate tubes: one tube without an anticoagulant and the other with EDTA.

Statistical analysis: Prevalence and Overall Prevalence Rate of the TTIs were evaluated and were further analyzed by studying the trend of increase and decrease over time, where B (%) reflects the year-to-year change in prevalence. NAT yield rate was calculated as a ratio x/y, where x = 1 and y = total donations/NAT only positive donations. Residual risk was estimated according to proposed WHO guidelines [27].

Results

A total of 167979 donations were screened for HBsAg, anti-HCV and anti-HIV/p24 during the three-year period. Initial reactivity (IR) in the performed serological tests was detected in 798 (0.48%) tested samples. IR blood units were discarded in order to avoid potentially low-level viremia missed by repeat testing. From 423 (0.25%) repeatedly reactive (RR) donations, 237 (0.14%) were confirmed positive (CP) (Table 1).

Table 1. Initialy reactive, repeatedly reactive and confirmed positive blood units.

Year Blood units (No)	HBsAg No (%)			Anti – HCV No (%)			Anti – HIV/p24 No (%)		
	IR	RR	CP	IR	RR	CP	IR	RR	CP
2022 (53629)	167 (0.31)	85 (0.16)	76 (0.14)	63 (0.12)	47 (0.09)	7 (0.001)	79 (0.015)	28 (0.052)	7 (0.001)
2023 (56450)	126 (0.22)	83 (0.15)	81 (0.14)	48 (0.09)	42 (0.07)	3 (0.005)	48 (0.09)	15 (0.03)	1 (0.002)
2024 (57900)	125 (0.22)	62 (0.11)	53 (0.09)	71 (0.12)	44 (0.08)	5 (0.009)	71 (0.12)	17 (0.03)	4 (0.007)

The seroprevalence rates of TTIs were as follows: HBV - 210 (0.22%), HCV – 15 (0.016%) and HIV - 12 (0.013%) in the three -year period. The seroprevalence rates by year are presented in Table 2.

Table 2. Seroprevalence rates of TTIs.

Year	Blood donors No	HBsAg No (%)	Anti-HCV No (%)	Anti-HIV/p24 No (%)	TTI No (%)
2022	22084	76 (0.34)	7 (0.32)	7 (0.032)	90 (0.40)
2023	36670	81 (0.22)	3 (0.008)	1 (0.003)	85 (0.23)
2024	34636	53 (0.17)	5 (0.014)	4 (0.012)	62 (0.19)
Total	93390	210 (0.22)	15 (0.016)	12 (0.013)	237 (0.25)

In the period of 2022-2024 a total of 683 (0.41%) donations were NAT-IR from which 296 (0.18%) were NAT-RR and 244 (0.15%) had a positive discriminatory NAT test (dNAT).

Table 3. Initialy reactive, repeatedly reactive and dNAT positive blood units.

Year	Blood units No	NAT-IR No (%)	NAT-RR No (%)	dNAT No (%)
2022	53629	156 (0.30)	115 (0.21)	94 (0.17)
2023	56450	197 (0.35)	100 (0.18)	90 (0.16)
2024	51500	330 (0.64)	81 (0.16)	60 (0.17)

During the three-year period, the NAT prevalence was 0.24%, 0.012% and 0.014% for HBV, HCV and HIV respectively and the overall NAT prevalence for TTIs was 0.26% (Table 4).

Table 4. NAT prevalence of TTIs.

Year	Blood donors No	dHBV No (%)	dHCV No (%)	dHIV No (%)	NAT No (%)
2022	22084	83 (0.37)	4 (0.02)	7 (0.032)	94 (0.42)
2023	36670	85 (0.23)	3 (0.008)	2 (0.005)	90 (0.25)
2024	34636	53 (0.15)	3 (0.009)	4 (0.012)	60 (0.17)
Total	93390	221 (0.24)	10 (0.012)	13 (0.014)	245 (0.26)

In 2022, the overall prevalence rate was 0.45%, with HBV detected in 0.38%, HCV in 0.03%, and HIV in 0.03% of blood donors. In 2023, the overall prevalence decreased to 0.25% reflecting a 44.44% reduction compared to the previous year.

By 2024, the overall prevalence further declined to 0.19% representing a 25% decrease compared to 2023 (Table 5).

Table 5. Overall prevalence of TTI markers.

Year	Blood donors	HBV No (%)	HCV No (%)	HIV No (%)	Overall prevalence No (%)	B* (%)
2022	22084	85 (0.38)	7 (0.03)	7 (0.03)	99 (0.45)	7.14
2023	36670	88 (0.24)	3 (0.01)	2 (0.01)	93 (0.25)	-44.44
2024	34636	58 (0.17)	5 (0.01)	4 (0.01)	67 (0.19)	-25.0

* B (%) reflects the year-to-year change in prevalence

Out of 231 HBV-positive samples, 200 (86.6%) were positive by both techniques. The discrepant results showed that 10 (4.3%) were CMIA-positive only (HBsAg-positive/NAT-negative), while 21 (9.1%) were NAT-positive/CMIA-negative. Among the 15 HCV-positive samples, 10 (66.7%) were positive by both techniques and 5 (33.3%) were CMIA-positive only (anti-HCVpositive/NAT-negative).

Out of 12 HIV-positive samples, 1 (8.3%) was NAT-positive only, while 11 (91.7%) were positive by both techniques. Further testing of a new blood sample was required to determine whether the NAT-only positive donors are due to the WP-infection or occult hepatitis B infection (OBI).

Out of 93390 blood donors screened by the two techniques a total of 22 (0.023%) NAT-only cases were identified from which 21 (0.022%) were HBV DNA-positive/HBsAg-negative and 1 (0.001%) was HIV RNA-positive/anti-HIV1/2,p24-negative (Table 6).

Second blood sample was obtained from 11 donors from which 7 (0.007%) were confirmed as HBV WP infections according to the seroconversion with the appearance of HBsAg. OBI was suspected in 4 (0.004%) of the 21 HBV DNA-positive/HBsAg-negative donors with persistent absence of HBsAg and continued presence of HBV DNA.

No NAT-only positive cases were found for HCV. A gradual decrease in HBV NAT-only detection was observed in the period 2022-2023 as shown on table 6.

Table 6. Discrepant results between serological and molecular TTI testing.

Technique	HBV No (%)			HCV No (%)			HIV No (%)			Total
	2022	2023	2024	2022	2023	2024	2022	2023	2024	2022-2024
CMIA	2 (0.01)	3 (0.01)	5 (0.01)	3 (0.01)	0	2 (0.01)	0	0	0	15 (0.02)
NAT	9 (0.04)	7 (0.02)	5 (0.01)	0	0	0	0	1 (0.01)	0	22 (0.02)
CMIA + NAT	74 (0.34)	78 (0.21)	48 (0.14)	4 (0.02)	3 (0.01)	3 (0.01)	7 (0.03)	1 (0.01)	4 (0.01	222 (0.24)
Total	85 (0.38)	88 (0.24)	58 (0.17)	7 (0.03)	3 (0.01)	5 (0.01)	7 (0.03)	2 (0.01)	4 (0.01	259 (0.28)

The NAT yield, calculated as the ratio of total donations to NAT-only positive donations, decreased over the time, with a higher yield in 2022 (1 in 2454 donations) and a lower yield in 2024 (1 in 6927 donations). The overall NAT yield for the study period was 1 in 4245 donations (Table 7).

Table 7. NAT yield.

Year	Blood donors	NAT-only positive donations	NAT Yield
2022	22084	9	1 / 2454
2023	36670	8	1 / 4584
2024	34636	5	1 / 6927
Total	93390	22	1 / 4245

The estimated residual risk (RR) as number of infected blood units per 100000 donations for HBV, HCV, and HIV showed a decreasing trend over the three-year period. HBV risk declined from 10.55 in 2022 to 4.59 in 2024, HCV risk remained consistently low, ranging from 0.26 in 2022 to 0.12 in 2024. HIV risk was minimal, decreasing from 0.43 in 2022 to 0.12 in 2024 (Table 8).

Table 8. Residual risk of transmission per 100000 donations.

Year	HBV infected blood units	HCV infected blood units	HIV infected blood units
2022	10.55	0.26	0.43
2023	5.88	0.07	0.07
2024	4.59	0.12	0.12

Discussion

Today, more than 100 million blood units worldwide are tested with NAT annually, and residual risk for TTI transmission via blood components is now close to zero. This is the result of stricter selection criteria for blood donors, improved procedures for blood collection and processing, the introduction of more sensitive and specific tests for detecting TTIs, the implementation of NAT, and the use of new pathogen inactivation and reduction techniques in blood products.

Developing and underdeveloped countries are working to implement NAT, as their TTI risk is highest due to high prevalence rates and inadequate serological screening [28].

The residual risk of TTIs is an important parameter in blood safety, representing the estimated probability of undetected infection in screened blood donations [29].

Given the detection of over 22,000 NAT-only positive donations combined since its introduction, it is clear that NAT has played an important role in enhancing blood transfusion safety globally. Globally, over 3100 NAT-positive donations were identified as NAT yield in 2019 and over 22,000 since the introduction of NAT, with HBV accounting for over half [30].

In Serbia, NAT was implemented only at the Military Medical Academy in Belgrade in 2007, detecting 3 HCV-positive and 1 HBV-positive donations. Due to the lack of mandatory NAT testing,

one HIV-positive and one HCV-positive window-period donation were found in the national blood bank [31]. Croatia introduced routine NAT screening in 2013. Over three years, 545,463 samples were tested, with 108 (0.02%) NAT-reactive: 82 HBV, 16 HCV, and 10 HIV. NAT identified 50 occult HBV infections (1 per 10,900 donations) and improved blood safety [32].

Slovenia implemented HCV NAT in 2000, expanding to HBV and HIV in 2007. Over five years, 458,000 units were tested, detecting 31 NAT-positive but serologically negative cases. The risk of HBV transmission was 1:15,600, HCV 1:524,000, and HIV 0:460,000 [33].

A pilot study in China (2010–2011) found that NAT significantly improves blood safety. Among 178,447 donations screened, 169 (0.095%) were HBV NAT-positive, with 11 (6.51%) in the window period, 5 (2.96%) chronic carriers, and 153 (90.53%) occult infections. No NAT-reactive cases were found for HIV or HCV [34].

The implementation of NAT molecular testing has significantly reduced the residual risk (RR) of transfusion-transmitted infections by shortening the window period. In Brazil, NAT was introduced for HIV and HCV in 2012 and for HBV in 2015. For HBV, RR decreased from 1:144.92 to 1:294.11 donations [35,36]. For HIV and HCV, NAT reduced RR by 2.5 and 3 times, respectively [37].

This study highlights the importance of combining serological and molecular testing in blood donor screening to enhance transfusion safety. Our findings confirm that NAT improves the detection of TTIs by identifying early infections during the WP and occult infections that serological assays may miss, but serology remains crucial for identifying chronic infections.

Based on the reported prevalence rates of HBV, HCV, and HIV among blood donors, North Macedonia falls within the category of upper-middle-income countries, as classified by the World Bank. While WHO does not specifically classify countries by TTI prevalence, the country follows WHO recommendations for ensuring blood safety through rigorous donor screening and voluntary, non-remunerated blood donations [38].

The analysis of the data from 2022 to 2024 reveals notable trends in the prevalence of TTIs among blood donors. The overall prevalence rate has decreased steadily over the three years. In 2022, the overall prevalence rate was 0.45%, which dropped to 0.25% in 2023 and further to 0.19% in 2024. This decrease indicates a positive trend in the reduction of TTIs among blood donor.

From 2022 to 2023, there was a significant 44.44% decrease in TTIs (B = 44.44%), indicating substantial improvement, while from 2023 to 2024, the decrease was 25% (B = 25%), still a positive trend but at a lower rate than the previous year. These results highlight a consistent reduction in TTIs over the three-year period, reflecting improvements in blood safety, suggesting improvements in screening practices. However, continuous monitoring and evaluation are essential to ensure further reductions in TTIs.

By analyzing the prevalence rates over the years, it can be observed that starting from 2023, the prevalence begins to decline and aligns with the prevalence observed during the 2017-2019 period, which was 0.23%. In 2020, due to the COVID-19 pandemic, our country faced a blood shortage, leading to a sharp increase in the number of family donors, who accounted for up to 40% of all donors.

This was a significant rise compared to the period between 2017 and 2019, when family donors constituted only 1.0% of the donor pool. As a result, the seroprevalence of TTIs nearly doubled compared to previous years, reaching 0.39%, 0.42% and 0.40% in 2020, 2021 and 2022, respectively. The reduced prevalence of TTIs in 2023 may also be a result of donors who were vaccinated against HBV due to the routine vaccination program for newborns initiated in 2004/05.

In this three-year study, 22 (0.023%) donor samples were identified as NAT-only positive. Among them, 21 (0.022%) were HBV DNA positive/HBsAg negative, and 1 (0.001%) was HIV DNA positive/anti-HIV p24 negative. This means that 22 donations were infectious but undetectable by serological testing. Considering that each whole blood donation produces at least 3 blood products (red blood cells, platelets, and fresh frozen plasma), this means that 66 donations with detectable viremia would be identified as reactive and discarded from clinical use. We did not detect any NAT-positive donations for HCV.

The risk of potentially infectious donations is higher for HBV than for HIV. The estimated prevalence of window period (WP) infection and potential occult HBV infection (OBI) was 0.007% and 0.004%, respectively. The real prevalence of WP infections and OBI is probably higher than the estimated one because a new blood sample was not obtained from all of the recalled donors.

A global systematic review and meta-analysis found that occult hepatitis B infection (OBI) remains a transfusion risk despite routine screening, with an overall prevalence of 0.2% among HBsAg-negative donors, particularly higher in low-income countries [39].

The residual risk for HBV, HCV, and HIV in our study has shown a downward trend from 2022 to 2024. The highest residual risk is observed for HBV, indicating a higher probability of undetected infections compared to HCV and HIV, while the residual risk for HCV and HIV remains consistently low, suggesting effective donor screening measures and lower prevalence in the general population. The decline in residual risk highlights the improvement in blood donation safety protocols and the effectiveness of NAT testing in identifying infectious donations before transfusion.

When compared to global estimates, our residual risk for HBV remains higher than in high-income countries, where it is typically below 1 per 100,000 donations, but aligns more closely with the residual risk observed in upper-middle-income countries [40]. For HCV and HIV, our residual risk is relatively low and comparable to WHO-reported values for countries with effective donor screening programs.

These findings highlight the need for continuous improvement in screening strategies, particularly for HBV, to further reduce transfusion-transmitted infection risks.

Conclusion

Serological and molecular blood testing are complementary. Serological testing enables the detection of chronic infections, while molecular testing allows the early detection of infections before seroconversion and identification of occult infections, making NAT essential for blood safety.

The introduction of NAT represents a significant advancement in ensuring the highest level of blood safety regarding the transmission of TTIs, benefiting both our patients and the overall healthcare system. It aligns with global trends in blood supply safety and enhances the standard of healthcare in the country.

The NAT yield during three years period is 21 (0.02%) for HBV and 1 (0.001%) for HIV. Having in mind that the unit of whole blood is processed into three blood components such as red blood cells, fresh frozen plasma and platelets, it means that 66 blood products with the presence of viremia were marked as reactive and removed from clinical use.

The estimates of TTI prevalence in this study provide valuable data for transfusion services, indicating the effectiveness of the donor selection process and serving as a source of information on the epidemiological situation in the country.

A well-designed blood testing strategy, including the selection of appropriate techniques and an optimal panel of TTI markers, is crucial for preventing the transmission of blood borne diseases through transfusion.

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