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DETECTION OF ANTIBODIES TO THE HEPATITIS B VIRUS CORE ANTIGEN IN DONORS OF YAKUTIA AS A METHOD OF ENHANCING VIRAL SAFETY

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The article presents the results of the study on antibodies to the hepatitis B virus core antigen (anti-HBcore) among donors of the Republican Blood Transfusion Station during the period of 2021–2024. The purpose of this study is to determine the most effective method of identification and exclusion from blood donation of individuals with latent infection and past hepatitis B virus infection. In addition, the article reviews virus-safe blood components procurement, reduction of discarded blood and minimization the risk of post-transfusion complications during hematransfusions.

Throughout the study period, the overall detection rate of anti-HBcore was 26.3%, with no statistically significant gender-based difference (25.3% in men vs. 28.2% in women; p = 0.912). Donor age appeared to be one of the main factors influencing anti-HBcore prevalence. The findings indicate that routine anti-HBcore testing at every donation made by the age group of over 30-35 years old is recommended.

Keywords: donor, hepatitis B virus, hepatitis B core antibodies, hematransfusion safety.

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Introduction. An essential prerequisite of hemotransfusion therapy is the assurance of the infectious safety of blood and its components [7, 10, 13]. At present, in Russia, the cases of HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV) transmission to recipients are not being registered [8,12]. This is largely due to continuous monitoring of all stages of the process, thorough and attentive donor selection, proper blood testing, and pathogen inactivation. According to official data, in 2020, out of 1,205,295 donors in Russia, more than 9,000 cases of infections were detected: HIV (9.4%), HBV (18.8%), HCV (37.8%), and syphilis (37.3%) [3, 4].

The prevalence of chronic HBV infection in the Republic of Sakha (Yakutia) remains consistently high and exceeds the average national level by 2.3 times. In 2024, 214 new cases of chronic HBV were reported in the republic, with an incidence rate of 21.45 per 100,000 popu-

lation (compared with 9.37 per 100,000 in the Russian Federation) [6]. This fact underlines the persistent risk of HBV infection among recipients of allogeneic transfusions, despite the widespread use of highly sensitive laboratory testing methods of donor blood.

Ensuring viral safety in hematransfusion practice requires comprehensive prevention of transfusion-transmitted infections (TTIs) [8, 9]. Since 2021, mandatory testing for anti-HBcore has been introduced in Russia in accordance with Order No. 1166n of the Ministry of Health of the Russian Federation, dated October 28, 2020, "On the approval of the procedure for donor medical examination and the list of medical contraindications (temporary and permanent) for blood and/or blood component donation, as well as deferral periods in the presence of temporary medical contraindications."

High sensitivity and specificity of diagnostic tests, together with the expansion of infectious marker screening, have significantly reduced the probability of transfusion-related HBV transmission [15]. Nevertheless, latent HBV infection (LHBV) in a donor, if blood or components are collected and subsequently transfused, may result in the development of clinical hepatitis in the recipient [14]. Standard donor screening can fail to detect HBV during the serological "window period," in cases of "wild-type" virus with suppressed replication, gene expression or in infection with mutant HBV strains, which are undetectable by reagents [11, 14].

The introduction of PCR testing for HBV DNA has shown that this marker is detectable only in a small proportion of HBsAg-negative donors worldwide. The detection of virus DNA depends on regional infection prevalence. Donors with LHBV and mutant HBV strains can only be identified through anti-HBcore testing, about 50% of whom also test positive for anti-HBs [5]. Therefore, blood screening for anti-HBcore is necessary to ensure transfusion safety. Following the implementation of this new approach, no proven cases of transfusion-related HBV transmission have been recorded [11].

Thus, continuous research and development of methods for detecting anti-HBcore in donors remains highly relevant [11, 2].

Objective of the study: To assess the prevalence of anti-HBcore antibodies among donors in the Republic of Sakha (Yakutia).

Materials and methods. The study material comprised blood donations made at the Blood Transfusion Station of the Republic of Sakha (Yakutia) in 2021–2024. In total, 59,456 donations were analysed, including 616 samples tested for anti-HBcore.The results interpretation included the analysis of the following: enzyme-linked immunosorbent assay (ELISA), chemiluminescent immunoassay, Architect HBsAg Qualitative II, Architect Anti-HBc II Reagent Kit, and polymerase chain reaction (PCR). Statistical analysis was conducted using IBM SPSS Statistics v26. Descriptive statistics and Pearson's χ^2 test were applied, with significance set at $p < 0.05$.

Results and discussion. During the study period of 2021 to 2024, 59,456 donations were collected and presented by gender on Table 1. This gender analysis demonstrates that male donations are significant and represent 68,5% of the total amount of donations between 2021 and 2024.

Yakutia is distinguished by a predominance of male donors (68.5%), compared with the donors of other regions with the following male representation: Khabarovsk krai - 53.91%, Sakhalin Region - 55.93% and the Republic of Dagestan - 56.2.0% [5].

There were 616 blood donor samples collected with uncertain results from recurring immunological tests for hepatitis B virus markers, and this accounted for 1.04% out of those 59,456 of total donations. All of them were included into the study to reveal the antibodies to hepatitis B core antigen. Male donations represented 64,3%, whilst female ones - 35.7%, which differed significantly from the overall gender distribution of all donations (Table 2).

The analysis of the frequency of the antibodies to the hepatitis B virus core antigen (anti-HBcore) in donor samples revealed the following: in 2022 there was a remarkable difference between male donations (14.8%) and female donations (26.0%), and 17.6% and 22.2% respectively in 2023 However, during the entire study period the overall detection rate of anti-HBcore was 26.3% (considering anti-HBcore positive was detected in 162 out of 616 blood samples), with no statistically significant gender-based difference (25.3% in men vs. 28.2% in women; $p = 0.912$) (Table 3). These numbers not only exceed the average across regions in the Far East Federal district, but also in the entire Russia [1, 5].

Table 1

Donation distribution by gender (absolute number in %)

Donor gender	Year				
	2021	2022	2023	2024	Total
Male	9 737 (67)	10 073 (68.6)	10 288 (69.4)	10 659 (69.2)	40 757 (68.5)
Female	4 800 (33)	4 620 (31.4)	4 535 (30.6)	4 744 (30.8)	18 699 (31.5)
Total	14 537	14 693	14 823	15 403	59 456

Table 2

Number of anti-HBcore tests by gender (absolute number in %)

Donor gender	Year				Total
	2021	2022	2023	2024	
Male	27 (64.3)	81(61.8)	102 (61.8)	186 (66.9)	396 (64.3)
Female	15 (35.7)	50 (38.2)	63 (38.2)	92 (33.1)	220 (35.7)
Total	42	131	165	278	616

Table 3

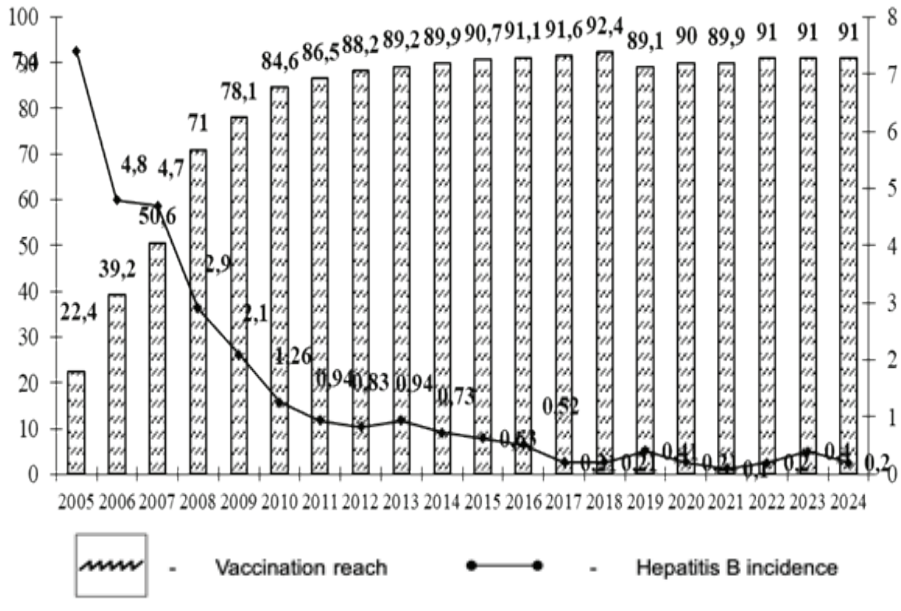
Frequency of anti-HBcore detection by gender (absolute number in %)

Gender	2021	2022	2023	2024	General	p-value
Male	25 (92.6)	12 (14.8)	18 (17.6)	45 (24.2)	100 (25.3)	0.912*
Female	14 (93.3)	13 (26.0)	14 (22.2)	21 (22.8)	62 (28.2)	
Total	39 (92.9)	25 (19.1)	32 (19.4)	66 (23.7)	162 (26.3)	

NB: *- χ^2 Pearson's criteria

Screening tests conducted as part of a research project, approved by the Ethics Committee of the National Medical Research Center for Hematology of the Ministry of Health of Russia (2019), revealed anti-HBcore in 21.6% of donors in the Republic of Sakha (Yakutia) [1].

Further analysis examined the distribution of the anti-HBcore positive donors based age groups (Table 4). In the group aged younger than 20 years, the anti-HBcore was not detected. The lowest prevalence was observed in the 21-30 age group, representing 3.8% and likely due to the mass immunisation program initiated in the Republic of Sakha (Yakutia) in 2005 (Figure). In the group age of 31-40 years the prevalence of anti-HBcore was 20.3% The highest proportion of positive anti-HBcore cases was observed among donors aged 41–50 years and over 50 years (58.8% and 41.0% respectively), with the latter two groups being the highest. Similar results were found in other studies conducted in the Russian Federation, where the highest frequency of anti-HBcore detection was registered in the age group of 50 years and older (23.39%), the lowest was in the age group of 21-30 years old (3.37%), whilst 31-40 years old was at 11.49%, and 41-50 years old at 22.48% [4, 1]. Thus, the donor age was found to be one of the main factors influencing the frequency of anti-HBcore detection.



Dynamics of the hepatitis B incidence and vaccination reach of the population in the Republic of Sakha (Yakutia), 2005 - 2024

Simultaneously, along with determining the antibodies to Hepatitis B Virus Core Antigen (anti-HBcore), the structure of discarded donor blood was studied. Those donations were rejected due to hepatitis B and represented 45.3% - 90.1% of all cases where the blood was discarded and associated with transfusion-transmittable infections (TTI). The discarded donor blood components due to anti-HB core ranged between 23.3% - 42.7%. The absolute volume of discarded donor blood increased from 39.5 liters in 2021 to 54.6 liters in 2024 (Table 5).

Table 4

Frequency of anti-HBcore detection based on donor age (number, %)

Age group	Anti-HBcore (n)		
	Male, %, (n, anti-HBcore positive / tested)	Female, %, (n, anti-HBcore positive / tested)	Total, % out of tested, (n)
<=20	0 (0/12)	-	0 (0/12)
21-30	5 (7/141)	0 (0/42)	3.8 (7/183)
31-40	21.2 (28/132)	18.6 (13/70)	20.3 (41/202)
41-50	64.2 (43/67)	53.6 (37/69)	58.8 (80/136)
>50	47.8 (22/46)	32.4 (12/37)	41.0 (34/83)
Total % (anti-HBcore positive / tested)	25.3 (100/398)	28.2 (62/218)	26.3 (162/616)

Table 5

Discarded blood due to transfusion - transmissible infections (TTIs)

Year	Total discarded due to TTIs (HBV, HCV, HIV, Syphilis), liters	Discarded due to hepatitis B (liters, % of total discarded)	Discarded due to anti-HBcore (liters, % of total discarded)
2021	39.5	35.6 / 90.1	12.2 / 30.9
2022	34.2	15.5 / 45.3	8.0 / 23.3
2023	34.5	19.5 / 56.5	11.6 / 33.6
2024	54.6	28.5 / 52.1	23.3 / 42.7

The results of the study of the anti-HBcore and also the detection of the Hepatitis B virus in 90.1% discarded donor blood is the evidence of high morbidity of chronic Hepatitis B virus among the population. The most obvious reasons for the rise of the discarded donor blood from 39 liters to 54 liters in 2024 are: 1) an increase in the amount of donations and blood cells and 2) predominancy of donors aged 35 years and above.

Based on the above, it is confirmed that in the Sakha Republic (Yakutia) there is a detrimental situation regarding hepatitis B virus among individuals over 30 years old.

Conclusion. As the findings indicate, we can conclude that in order to support and enhance viral safe transfusion it is advisable to prioritise blood collection from younger donors (under 35 years), who are protected by the mass HBV immunization program. This measure would significantly reduce the volume of discarded blood due to HBV.

To prevent HBV transmission during hematransfusions and minimize the risk of post-transfusion complications, routine anti-HBcore testing at every donation made by the age group of over 30-35 years old is recommended.

In future, it is suggested to expand the research on the detection of the anti-HBcore among donors of diverse ethnic backgrounds and examine the possible association with erythrocyte antigen group affiliation. These studies will have important scientific and practical implications for ensuring virologically safe and immunologically compatible transfusions.

The authors declare no conflict of interest.

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