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ORIGINAL ARTICLE

Evaluation of ELISA Test Results of the Changing Blood Donor Profile in Istanbul, Single Center Experience (2020 - 2024)

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SUMMARY

Background: **Ensuring a safe blood supply is a critical responsibility of transfusion services. In Türkiye, demographic shifts, including a growing number of immigrant donors, have necessitated ongoing evaluation of transfusion-transmissible infections (TTIs) and screening protocols to analyze the prevalence of hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis among blood donors and to evaluate demographic trends and false-positive rates in serological screening.**
Methods: **This retrospective study analyzed ELISA screening results from 110,419 blood donations collected between 2020 and 2024 at a regional blood center in Türkiye. Demographic data, seroprevalence of TTIs, confirmatory testing outcomes, and changes over time were examined.**
Results: **Most donors were male (89.4%) and Turkish citizens (95.8%), with a mean age of 34.5 years. HBV reactivity was observed in 0.4% of donors, significantly higher among Turkish nationals and older individuals ($p < 0.05$). HCV and HIV reactivity were each detected in 0.2% of donors, while syphilis antibodies were found in 0.2%. Foreign donors, particularly women, exhibited higher reactivity for HBV and HCV. Co-infections were identified in a subset of donors (2.9% of syphilis-positive cases). False-positive rates were notably high for anti-HCV (85.6%) and anti-HIV (80.2%), with HBsAg showing the lowest (4.6%).**
Conclusions: **The evolving donor profile and increasing false-positive rates highlight the need for more specific screening assays and revised donor management strategies. Continuous surveillance and multicenter studies are essential to maintain transfusion safety in an increasingly diverse population.**
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INTRODUCTION

Blood transfusion has been an integral and life-saving procedure of modern medical science since Dr. James Blundell performed whole blood transfusion to a human

in 1818 [1]. It continues to be an important treatment option for many life-threatening diseases and also for sustaining life after severe blood loss [1].

One of the most important duties of blood banks is to produce safe blood products that patients need. One of the undesirable reactions that may develop in patients with blood and blood product transfusions is infection. In Turkey, with the Blood and Blood Products Law No. 5624 in 2007, HBsAg, anti-HCV, anti-HIV1/2-HIV p24 and syphilis antibody screening tests are implemented as mandatory tests to prevent infections transmitted through blood transfusion [2]. Despite modern blood banking technologies, the transmission of these infections through transfusion has still not been prevented [3]. The assay chosen for Safe Blood screening must be highly sensitive and specific. The aim is to detect all potentially infected donations while minimizing waste due to false positive results.

In a study conducted by the Turkish Red Crescent on blood donors in Turkey, seropositivity rates for HBV, HCV, and HIV were defined as 1.76%, 0.07%, and 0.008%, respectively, and it was determined that HBV and HCV decreased compared to previous years, while there was an increase for HIV [4]. In a study evaluating 10-year blood donors of a public hospital, 2.03% HBsAg positivity, 0.44% anti-HCV positivity, 0.33% VDRL/TPHA, and 0.06% anti-HIV positivity were detected, and it was reported that the positivity rates decreased over the years [5].

Since 2011, there has been a lot of immigration from foreign countries to our country due to socio-economic and war reasons [6]. The blood donor profile in Turkey has changed with foreign nationals who immigrated and later became blood donors by obtaining Turkish citizenship.

This study aimed to retrospectively evaluate the screening test results of donors who applied to Başakşehir Çam and Sakura City Hospital Temporary Regional Blood Center between 2020 and 2024 to evaluate the change in seropositivity rates over the years and to evaluate the test performances.

MATERIALS AND METHODS

How the study was conducted

Donor consent Ethics Committee Approval

This is a retrospective study. This study was conducted in accordance with the principles of the Declaration of Helsinki. All data of donors between 4-1-2020 and 4-30-2024 were obtained from our hospital's blood center automation system. Information was obtained from the hospital automation system for retrospective publications and permission was obtained from the ethics committee to conduct the study (Ethics committee approval was received from Başakşehir Çam and Sakura Provincial Ethics Committee Ethics No.: KAEK/28.08.2024. 185). All data used are routine tests applied to blood donors. In our country, anyone between the ages of 18 - 60 who feels healthy can be a blood donor. Within the scope of these tests routinely applied to every donor, all donors were informed that they were volunteers, that they would be informed about blood donation, what tests would be performed when they donated blood; if any of the tests were positive, further tests, namely confirmation tests, would be performed for this test, they would be invited to our hospital and informed about their tests, whether they would be repeat donors or not based on the confirmation test result would be recorded in our country's data information, and they could donate blood after reading and signing the form containing this matter. Our study was conducted by retrospectively obtaining the tests performed on blood donations collected in this way from the hospital automation system. In addition, since the study was conducted retrospectively on unidentified data, informed consent was not obtained.

Where the study was conducted

This study was conducted retrospectively at the Health Sciences University Başakşehir Çam and Sakura City Hospital Regional Blood Center. Our hospital was established in April 2020 and has a bed capacity of 2,648 and is a hospital where 25,000 outpatient clinic examinations are performed per day. Patients are accepted from all over Turkey and abroad and approximately 100,000 units of blood (erythrocyte suspension, platelet suspension, fresh frozen plasma and granulocyte suspension, cryoprecipitate) are transfused annually.

Selection of blood donors evaluated

Data on donors between April 2020 and April 2024 were obtained from our hospital's blood center automation system. Data on age, gender, citizenship number, ELISA test results, and verification test results were collected for each blood donor. Citizenship identification numbers were used to create a unique group for the blood donor population. Foreign nationals who obtained residence permits in Turkey and became Turkish citizens were registered in the automation system by adding identification numbers starting with the numbers 98 and 99. The distinction between Turkish citizens and foreign patients was evaluated separately with this differential registration system. Duplicates were deleted using the identification numbers of each donor who applied to more than one of our hospitals. A total of 110,437 different donors were identified from the automation system.

Study plan

The average age of the blood donors included in the study, the minimum and maximum values, the ratio of Turkish citizens to women and men, the number of foreign nationals residing in Turkey and the ratio of women and men, and the number of donors to our hospital's blood center were defined. Two separate groups were created and the ELISA test result statistics were evaluated.

GROUP 1
Blood donors who are citizens of the Republic of Turkey were included in this group. After gender discrimination, ELISA test results were evaluated one by one by dividing the age ranges for each gender into groups as 18 - 29, 30 - 39, 40 - 49, and over 50. ELISA test result positivity statistics for this group were defined.

GROUP 2
This group consists of foreign nationals with ID numbers starting with 98 - 99 who have obtained residence permits in Turkey and have acquired Turkish citizenship. Intensive migration to our country began in 2011. However, our hospital has started its activities since April 2020. For this reason, foreign Turkish citizens who have donated blood since 2020 were divided into gender and age groups as 18 - 29, 30 - 39, 40 - 49, and over 50, and their ELISA tests were evaluated

Tests used
HBsAg (Hepatitis B surface antigen in human serum was qualitatively identified), AntiHCV (detects anti-HCV antibodies using peptides representing Core, NS3 and NS4 proteins and recombinant antigens), HIV1-2, p24 Ag (HIV Duo human serum HIV 1 p24 antigen and HIV, HIV 1 (groups M and O) were identified), syphilis total antibody test (qualitatively detects total IgM and IgG antibody levels formed against TpN15, TpN17 and TpN47 antigens). It was processed according to the company recommendations. Evaluation was performed according to the following criteria: for HBsAg and Anti HCV, COI < 0.90 nonreactive, 0.90 ≤ COI < 1.0 Intermediate value, COI ≥ 1.0 Reactive; for anti HIV1-2 and p24 tests, COI ≥ 1 Reactive, COI < 1 nonreactive; and for syphilis total antibody tests, S/CO ≥ 1.0 Reactive, S/CO < 1.0 nonreactive. lecsys® brand kits (Roche Diagnostics, Mannheim, Germany) were used.
All tests were performed on the cobas e801 immunoassay analyzer, electrochemiluminescence immunoassay (ECLIA), according to the manufacturer's recommendations.

Confirmatory tests
HBV DNA for HBsAg test, HCV RNA for anti-HCV test, TPHA and RPR for syphilis total antibody test, western blot, LIA, and GEENIUS tests are applied for anti HIV1-2 p24 test.
For HBV DNA and HCV RNA tests, cobas® 6800/ 8800 automated systems that perform Polymerase Chain Reaction (PCR)-based nucleic acid detection were used (Roche Diagnostics, Mannheim, Germany). Samples giving reactive results for HIV were tested with WB/LIA/GENNEIUS methods in the Public Health Reference Laboratory of the Ministry of Health.

Screening and confirmation test algorithm used in blood banks
A blood sample is taken for each serological test from the donor who is considered suitable according to the donor evaluation criteria in our Blood Bank and the serum is tested separately with ELISA method anti-HCV, anti-HIV, 1.2 and p24. The donor whose test result is non-reactive is approved to become a blood donor. For the donor who is reactive, the same blood sample is tested 3 times and in case of 2 reactive results, a confirmation test is run. The blood and blood products of the blood donor who gives a reactive result are destroyed. However, the decision is made according to the results of the confirmation tests in order to provide the donor's treatment and prevent him from donating again.

Statistical method
The data of the study were analyzed using SPSS Version 26.0 statistical package program (IBM SPSS Statistics for Windows; IBM Corp., Armonk, NY, USA). Categorical variables were presented with numbers and percentages; continuous variables were presented with "mean ± standard deviation" and "median (minimum - maximum)" values. In comparison between groups, categorical variables were presented with chi-squared test; for continuous variables, when 2 groups were compared, independent samples *t* test; statistical significance level was accepted as "$p < 0.05$".

Ethics committee approval
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the local ethics committee. The ethical approval was obtained from Başakşehir Çam and Sakura City Ethical Committee (Ethical No: KAEK/28.08.2024.185). The need for informed consent was waived by Çam and Sakura City Hospital Ethics Committee, as the study was designed as a retrospective analysis and involved no direct contact with patients

RESULTS

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the local ethics committee (The ethical approval was obtained from Başakşehir Çam and Sakura City Ethical Committee Ethical No.: KAEK/28.08.2024.185).
A total of 110,419 donors who applied to Başakşehir Çam and Sakura City Hospital, Regional Blood Center between 2020 - 2024 were included in the study. 105,784 (95.8%) of the donors were Turkish citizens; 4,635 (4.2%) were foreign national Turkish citizens. The basic descriptive characteristics of the donors included in the study are shown in Table 1.
The mean age of all donors was 34.5 ± 10.1, median 34.0 (minimum 18 - maximum 66). Of all donors, 89.4% were male and young (18 - 29 years), male donors were more common in both groups. A difference was found between the groups in terms of gender distribution of Turkish and foreign blood donors, with a higher rate of male donors among foreign nationals. The mean age of Turkish blood donors was higher than that

Table 1. Basic descriptive characteristics of donors.

	Nationality			p
	All donors (n = 110,419) n (%) [a]	TR blood donor (n = 105,784) n (%) [a]	Foreign blood donor (n = 4,635) n (%) [a]	
Years				
2020	2,373 (2.1)	2,293 (2.2)	80 (1.7)	< 0.0001 [c]
2021	8,632 (7.8)	8,410 (7.9)	222 (4.8)	
2022	18,030 (16.3)	17,155 (16.2)	875 (18.9)	
2023	53,188 (48.2)	50,937 (48.2)	2,251 (48.6)	
2024	28,196 (25.5)	26,989 (25.5)	1,207 (26.0)	
Gender n (%) [a]				
Male	98,690 (89.4)	94,397 (89.2)	4,293 (92.6)	< 0.0001 [c]
Female	11,729 (10.6)	11,387 (10.8)	342 (7.4)	
Age				
Mean ± SD	34.5 ± 10.1	34.6 ± 10.1	31.7 ± 8.6	< 0.0001 [d]
Median (minimum - maximum)	34.0 (18 - 66)	34.0 (18 - 66)	30.0 (18 - 61)	
Age groups				
18 - 29	40,639 (36.8)	38,440 (36.3)	2,199 (47.4)	< 0.0001 [c]
30 - 39	34,155 (30.9)	32,560 (30.8)	1,595 (34.4)	
40 - 49	26,180 (23.7)	25,530 (24.1)	650 (14.0)	
≥ 50	9,445 (8.6)	9,254 (8.7)	191 (4.1)	
HBsAg				
Reactive	289 (0.4)	242 (0.2)	47 (1.0)	< 0.0001 [c]
Non-reactive	110,124 (99.6)	105,537 (99.8)	4,587 (99.0)	
Independent [b]	6 (< 0.01)	5 (< 0.01)	1 (< 0.01)	
Anti-HCV				
Reactive	115 (0.1)	98 (0.1)	17 (0.4)	< 0.0001 [c]
Non-reactive	110,292 (99.9)	105,634 (99.9)	4,618 (99.6)	
Independent [b]	12 (< 0.01)	12 (< 0.01)	-	
Anti-HIV 1.2, HIV1 P24 Ag				
Reactive	174 (0.2)	166 (0.2)	8 (0.2)	1.000 [c]
Non-reaktive	110,245 (99.8)	105,618 (99.8)	4,627 (99.8)	
Syphilis antibody				
Reactive	235 (0.2)	224 (0.2)	11 (0.2)	< 0.0001 [c]
Non-reactive	110,183 (98.8)	105,560 (98.8)	4,623 (99.7)	
Independent [b]	1 (< 0.01)		1 (< 0.01)	

[a] Column percentage, [b] Independent samples *t* test, [c] chi-squared test.

of foreign nationals (34.6 ± 10.1 and 31.7 ± 8.6, respectively) ($p < 0.0001$).

When looking at the nationalities of donors by year, it was observed that there was an increase in foreign donors between 2020 and 2023 (2024 data is from the first quarter of the year).

Of all donors, 0.4% (289 donors) had reactive HBsAg results; 0.1% (115 donors) had reactive anti-HCV results, 0.2% (174 donors) had reactive anti-HIV1-2, HIV1 p24 ag results and 0.2% (235 donors) had reactive syphilis antibodies. anti-HCV reactivity rates were higher in foreign donors and HBsAg reactivity was higher in Turkish donors ($p < 0.0001$). There was no statistically significant difference between the groups in terms of syphilis antibodies and anti-HIV1-2, HIV1 p24 ag reactivity ($p > 0.05$) (Table 1).

In 6 of all donors, both anti-HIV1-2, HIV1 p24 Ag and syphilis antibody results were found to be reactive, and

Table 2. Percentage distribution of all applicants with reactive ELISA test results according to age groups.

Age groups	HBsAg reactive n (%) [a]	Anti-HCV reactive n (%) [a]	Anti-HIV1.2, HIV1 P24 Ag reactive n (%) [a]	Syphilis antibody reactive n (%) [a]
18 - 29 (n = 40,639)	37 (0.1)	39 (0.1)	68 (0.1)	53 (0.1)
30 - 39 (n = 34,155)	98 (0.3)	35 (0.1)	53 (0.1)	60 (0.2)
40 - 49 (n = 26,180)	93 (0.4)	31 (0.1)	43 (0.1)	79 (0.3)
≥ 50 (9,445)	61 (0.6)	10 (0.1)	10 (0.1)	43 (0.5)
	p < 0.0001 [b]	p = 0.901 [b]	p = 0.586 [b]	p < 0.0001 [b]

[a] Row percentage, [b] chi-squared test.

Table 3. ELISA Reactivity of Turkish and foreign blood donors by age and gender.

	Nationality					
	TR blood donor			Foreign blood donor		p [b]
	male N/n (%) [a]	female N/n (%) [a]	p [b]	male N/n (%) [a]	female N/n (%) [a]	
HBsAg reactive	94,397/221 (0.2)	11,387/21 (0.2)	1.000	4,293/44 (0.1)	342/3 (0.9)	< 0.0001
18 - 29	33,685/26 (0.1)	4,755/3 (0.1)		2,056/8 (0.4)	143/0	
30 - 39	29,624/72 (0.2)	2,936/2 (0.1)		1,487/22 (1.5)	108/2 (1.9)	
40 - 49	22,996/76 (0.3)	2,534/8 (0.3)		587/9 (1.5)	63/0	
≥ 50	8,092/47 (0.6)	1,162/8 (0.7)		163/5 (3.1)	28/1 (3.6)	
	p < 0.0001 [c]	p < 0.0001 [c]		p < 0.0001 [c]	p = 0.148 [c]	
Anti-HCV reactive	94,397/88 (< 0.1)	11,387/10 (0.1)	0.477	4,293/14 (0.3)	342/3 (0.9)	0.068
18 - 29	33,685/28 (0.1)	4,755/4 (0.1)		2,056/7 (0.3)	143/0	
30 - 39	29,624/27 (0.1)	2,936/2 (0.1)		1,487/5 (0.3)	108/1 (0.9)	
40 - 49	22,996/27 (0.1)	2,534/2 (0.1)		587/1 (0.2)	63/1 (1.6)	
≥ 50	8,092/6 (0.1)	1,162/2 (0.2)		163/1 (0.6)	28/1 (3.6)	
	p = 0.749 [c]	p = 0.777 [c]		p = 0.833 [c]	p = 0.265 [c]	
Anti-HIV1.2, HIV1 P24 Ag reactive	94,397/152 (0.2)	11,387/14 (0.1)	0.020	4,293/7 (0.2)	342/1 (0.3)	0.696
18 - 29	33,685/55 (0.2)	4,755/8 (0.2)		2,056/5 (0.2)	143/0	
30 - 39	29,624/50 (0.2)	2,936/1 (< 0.01)		1,486/1 (0.1)	108/1 (0.3)	
40 - 49	22,996/38 (0.2)	2,534/4 (0.2)		587/1 (0.2)	63/0	
≥ 50	8,092/9 (0.1)	1,162/1 (0.1)		163/0	28/0	
	p = 0.707 [c]	p = 0.382 [c]		p = 0.590 [c]	p = 0.537 [c]	
Syphilis antibody reactive	94,397/209 (0.2)	11,387/15 (0.1)	0.020	4,293/7 (0.2)	342/4 (1.2)	0.001
18 - 29	3,3685/46 (0.1)	4,755/7 (0.1)		2,056/0	143/0	
30 - 39	29,624/54 (0.2)	2,936/0		1,486/4 (0.3)	108/2 (1.9)	
40 - 49	22,996/68 (0.3)	2,534/6 (0.2)		587/3 (0.5)	63/2 (3.2)	
≥ 50	8,092/41 (0.5)	1,162/2 (0.2)		163/0	28/0	
	p < 0.0001 [c]	p = 0.101 [c]		p = 0.910 [c]	p = 0.199 [c]	

[a] The percentage of those with reactive results is given, [b] The percentage of reactive results is compared according to gender, [c] The percentage of reactive results is compared according to age group.

Table 4. Results of ELISA and confirmatory tests.

Gender	HBV			HCV			HIV			SYPHILIS				
	ELISA HBsAg	PCR HBV DNA		ELISA anti-HCV	PCR HCV RNA [b]		ELISA anti-HIV1.2, HIV1 P24 Ag	HIV WB/LIA/ GEENIUS		ELISA syphilis antibody	VDRL/ RPR		TPHA	
	Reac-tive	(+) %	(-) %	Reac-tive	(+) %	(-) %	Reac-tive	(+) %	(-) %	Reac-tive	(+) %	(-) %	(+) %	(-) %
Male	265	244	13	102	7	48	159	32	115	216	41	172	120	36
Female	24	24	-	13	2	7	15	-	15	19	5	13	9	2
Total (%)	289	268 95.4	13 4.6	115	9 14.1	55 85.9	174	32 19.2	130 80.2	235	46 19.9	185 80.1	129 77.2	38 22.7

Since confirmatory testing could not be performed on all donors with reactive results, true positivity rates in the donor community were not calculated.

Table 5. Reactivity rates in ELISA tests in blood donors by year.

Year	HBsAg (reactive)				Anti-HCV (reactive)				Anti-HIV (reactive)				Syphilis (reactive)			
	TD		FN		TD		FN		TD		FN		TD		FN	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
2020 N n (%) [a]	2,037 5 (0.3)	256 0	75 -	5 -	5 (0.3)	1 (0.4)	-	-	6 (0.3)	1 (0.4)	-	-	4 (0.2)	1 (0.4)	-	-
2021 N n (%)	7,592 23 (0.3)	818 1 (0.1)	209 2 (0.1)	13 -	9 (0.1)	1 (0.1)	-	-	16 (0.2)	-	2 (0.1)	-	18 (0.2)	1 (0.1)	1 (0.5)	-
2022 N n (%)	15,153 39 (0.3)	2,002 5 (0.3)	817 18 (2.2)	58 1 (1.7)	27 (0.2)	3 (0.1)	5 (0.6)	-	29 (0.1)	3 (0.1)	3 (0.4)	-	36 (0.2)	4 (0.2)	1 (0.1)	3 (5.2)
2023 N n (%)	45,165 98 (0.2)	5,772 9 (0.2)	2,063 19 (0.9)	188 1 (0.5)	31 (0.1)	3 (0.1)	4 (0.2)	2 (1.1)	76 (0.1)	7 (0.1)	1 (0.1)	1 (0.5)	100 (0.2)	4 (0.1)	4 (0.2)	1 (0.5)
2024 N n (%)	24,450 56 (2.3)	2,539 6 (0.2)	1,129 5 (0.4)	78 1 (1.3)	16 (0.1)	2 (0.1)	5 (0.4)	1 (1.3)	25 (0.2)	3 (0.1)	1 (0.1)	-	51 (0.2)	5 (0.1)	1 (0.1)	
p [b]	0.264	0.564	0.021	0.897	< 0.0001	0.339	0.339	0.925	0.003	< 0.622	0.021	0.935	0.642	0.332	0.537	0.046

N Number of people in the group, [a] ELISA test result, reactive numbers and percentages are based on N (N values are given once and not repeated in other columns), [b] chi-squared in trend test, TD Turkish donors, FN Foreign national.

one each with HBsAg and anti-HIV1-2, HIV1 p24 Ag, anti-HCV and HBsAg results was found to be reactive; anti-HCV and syphilis antibody results were found to be reactive together.

A statistically significant difference was found between age groups in terms of HBsAg and syphilis antibody reactivity in all donors. Reactive test percentage increased with age for both tests ($p < 0.0001$). No relationship was found between anti-HCV and anti-HIV1-2, HIV1 p24 ag reactive test rate and age group ($p > 0.05$) (Table 2).

When evaluated according to age groups in male and female Turkish blood donors and male donors of foreign origin, HBsAg reactivity rate increased with increasing age ($p < 0.0001$). However, no difference was observed in female donors of foreign origin ($p > 0.05$). When syphilis antibody reactive test rate was evaluated separately in females and males, syphilis antibody reactive test rate in males in Turkish donor group increased with age ($p < 0.0001$). In female donors of foreign origin, it was seen more frequently in 30 - 39 and 40 - 49 age groups (1.9%, 3.2%). Reactive test rate of other

ELISA tests was not related to either males or age ($p > 0.05$) (Table 3).

Confirmatory testing could not be performed on all donors who were ELISA reactive. Donors were asked to come back to our blood center for these tests, but some did not return for this test. Among those who came to our invitation, the false positive rate for HBsAg was 4.6%, for anti-HCV 85.9%, for anti-HIV1-2 p24 test 80.2%, and for syphilis antibody 22.7%. VDR/RPR test was investigated as an answer to the question of whether the infection was an early stage infection in donors. 80.1% of all donors were negative. 19.9% were determined to have early stage syphilis (Table 4).

When the HBsAg test reactive percentage in foreign males is evaluated according to years, it is seen that there was an increase in foreign donors in 2022 (2.2%), this rate decreased in the following years, but in the year reflecting the first quarter of 2024, there was an increase in Turkish men and foreign women ($p < 0.05$). It was observed that anti-HCV reactivity was higher in Turkish male citizens in 2020 (0.3%) and decreased over the years, while this decrease did not occur in foreign nationals. ($p < 0.05$), anti-HIV high levels in both Turkish and foreign male donors varied according to years ($p < 0.05$); The reactive anti-HIV test percentage was highest in Turkish male citizens in 2020; it was highest in foreign male citizens in 2022. No statistically significant difference was detected in other groups in terms of ELISA test results according to years.

A total of 13 donors had false positive HBsAg ELISA test results (HBsAg ELISA test was reactive; PCR HBV DNA was negative) and the mean HBsAg level in this group was 1.6 ± 0.4 (median 1.7; minimum 1.04; maximum 2.20). Fifty-five donors had false positive ELISA anti-HCV test results (ELISA anti-HCV test was reactive; PCR HCV RNA was negative) and their mean anti-HCV level was 3.47 ± 4.5 (median 2.12; minimum 1.01 - maximum 24.10). For 130 donors, anti-HIV ELISA test results were false positive (anti-HIV ELISA test was reactive; HIV WB/LIA/GEENIUS was negative). The mean anti HIV level in these individuals was 3.07 ± 3.99 (median 1.80; minimum 0.27 - maximum 71.10). The syphilis total antibody ELISA test result was false positive in 38 individuals (syphilis total antibody ELISA test reactive; TPHA test negative); the mean syphilis total antibody level in these individuals was 2.94 ± 3.29 (minimum 1.01 - maximum 17.3).

DISCUSSION

Obtaining blood safely for blood transfusion is an important task of blood banking [3]. Blood service units do not have many tools other than the blood donor inquiry form and a few simple examination and testing tools for the acquisition of safe blood. Therefore, it is of great importance that the donor inquiry form is filled out sincerely by the donor. For the selection of the blood donor, which is the most important step of safe blood, the World Health Organization and Turkey have indicated regular, voluntary, and unconditional donors as the ideal donors according to the blood and blood product preparation legislation [7,8]. In our country, blood donations must be from voluntary donors [9]. Despite donor acquisition studies conducted in our country, the ideal donor profile has still not been reached [10]. While the voluntary blood donation rate reaches up to 5% of the country's population in developed countries, this figure is reported as approximately 1.5% in our country [11].

Since 2011, Turkey has been hosting a refugee population of up to 4 million, with the actual number likely higher among undocumented immigrants. What began as temporary accommodations has turned into a more permanent situation [6]. The COVID-19 pandemic and significant earthquakes have increased the demand for blood and blood products, leading to challenges in supply. Consequently, our center has had to rely on patient relatives, classified as replacement blood donors, to procure blood.

In Turkey, anyone aged 19 - 66 who feels healthy and has a Turkish citizen ID can voluntarily donate blood [9]. This includes immigrants who have obtained Turkish citizenship, allowing them to join the blood donor community. The changing demographics of blood donors necessitate close monitoring of ELISA tests, which are essential for the safe production of blood products. In our study, we retrospectively examined 110,419 donors over four years, comprising 89.4% males and 10.6% females, with 95.8% being Turkish citizens and 4.2% foreign nationals. The average age of donors was 34.5 years. Similar to many countries, the majority of donors were male [2,10,13], and the proportion of foreign donors has increased over the years, with a younger average age compared to Turkish donors.

In our study, HBsAg results were found to be reactive in 0.4% of all donors. Among the age groups, HBsAg reactivity increases with age. Especially in the ≥ 50 age group, it was 0.6 - 0.7% in Turkish donors, while it was 3.1 - 3.6% in foreign donors. This increase was statistically significant especially in males ($p < 0.0001$), but not in females ($p = 0.148$). When compared with the literature information, it was observed that the frequency of HBsAg reactivity was lower in our donor population. The HBV rate in post-transfusion hepatitis is defined as 0.3 - 1.7% [16]. In our country, HBsAg prevalence in the blood donor population varies between 0.48 - 2.55% depending on the region and the frequency of infection decreases from east to west and by year [4,5,17]. In studies conducted abroad, HBsAg rates in donors varying from country to country (0.06%, 14.86% and 6.7%) are reported [18-20]. In the Turkish Clinical Microbiology and Infectious Diseases Society Viral Hepatitis Working Group Consensus Report-2023 Update, it was reported that although there was a decrease between 1990 - 2017, the HBV incidence decreased from 4.6 to 1.9 per 100,000, and the age group with the highest number of HBV notifications was the 30 - 44 age group,

followed by the 20 - 29 age group, and the 45 - 64 age group was in third place. [15]. It has also been determined that only approximately 12% of these people are aware of the situation [14,15]. This situation is important in terms of revealing that awareness is extremely low in our country. It is noteworthy that, contrary to literature information, the HBV screening test positivity among blood donors in our center increases with age and is more common in those over the age of 50, and it was found to be statistically significant ($p < 0.0001$). When foreign blood donors and Turkish national blood donors were compared, HBsAg reactivity in foreign donors (1.0%) was significantly higher than in Turkish donors (0.2%) ($p < 0.0001$). It was higher in foreign female donors (0.9%) than in males (0.1%) ($p < 0.0001$), this difference was statistically significant.

The total prevalence of HCV worldwide is estimated to be 2.5%, and this rate is reported to vary from 2.9% in Africa to 1.3% in the Americas [21]. Tozun et al. reported that HCV prevalence in Turkey is approximately 1.0% and approximately 1.0 - 1.3 million people are infected [14]. In studies conducted among blood donors in public hospitals in our country, anti-HCV reactivity was reported as 0.07%, 0.44%, 0.17% [4,5,20], and in studies conducted abroad, anti-HCV reactivity in blood donors was reported as 0.8%, 8.69%, 1.5% [18,19,20]. In our study, this rate was 0.1% in all blood donors. According to the literature, this is a low rate. However, this rate, anti-HCV reactivity rates were significantly higher in foreign nationals who were Turkish citizens (0.4%; $p < 0.0001$) and it was determined that these donors were women, which increased over the years.

Notably, there have been no prior studies in Turkey directly comparing infectious marker prevalence between Turkish and foreign donors, underscoring the necessity for multicenter investigations.

HIV/AIDS remains a significant public health threat globally, affecting all segments of society and reducing healthy life expectancy. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), it was reported that there will be 39.9 million people living with HIV worldwide by 2023, 86.6% of whom will be aware of their infection and 13.7% will be unaware [22]. Turkey has been defined as a low-prevalence country and the prevalence of HIV/AIDS has been reported to be increasing especially among the young population aged 25 - 29 [22,23].

In our country, the reported anti-HIV 1-2 seroprevalence among blood donors ranges from 0.007% to 0.33% in various studies [4,5,20]. Internationally, the rates are reported as 0.6%, 2.21%, and 0.03% [18-20]. In our study, the anti-HIV 1-2 reactivity rate was generally found to be low among all donors in our center (0.2%). However, it is noteworthy that the reactivity rate was higher in Turkish male donors than in female donors (0.1%), suggesting that gender-related risky behaviors (e.g. unprotected sexual intercourse, multiple partners) may be more common. No difference was observed for foreign donors, but the effect of the small sample size should be considered due to the small number of donors.

Syphilis is more common in developing countries and among young adults in low socioeconomic groups in developed countries [24]. According to the CDC (2023), syphilis cases in the USA rose by 32% from 2020 to 2021, reaching the highest level in 70 years [25]. A recent study in Turkey using the reverse algorithm found a 4% seropositivity rate [26]. Among blood donors in Turkey, the rate was between 0.057% and 0.33% [5,20], showing a decreasing trend, while international studies reported rates from 0.005% to 3.9% [18,19]. In our study, syphilis antibodies were found in 0.2% of donors. Reactivity increased with age and was higher in men (0.2%) than women (0.1%) ($p < 0.05$). Unlike other studies suggesting rates decrease with age, our findings show an increase in older age groups [26,27].

In our study, 6 donors were reactive for both HIV and syphilis, and 1 each for HBV + HIV, HCV + HBsAg, and anti-HCV + syphilis. Co-infection was found in 2.9% of syphilis-positive donors, higher than the 1.1% reported in an Italian study [28]. Another study in Turkey reported 19.3% syphilis positivity among HIV-positive patients, especially in men who have sex with men [27]. Although donor screening includes a questionnaire to exclude risky individuals, many syphilis-positive donors are unaware of their status. Early detection through donor screening helps initiate timely treatment and supports infection control.

Confirmatory testing for transfusion-transmitted infections (TTIs) serves a distinct purpose from routine blood screening. While the primary aim of blood screening is to ensure the microbial safety of the blood supply, confirmatory tests are designed to verify the infectious status of donors with repeated reactive results and to ensure their deferral from future donations. Additionally, these tests provide more accurate epidemiological data on infection prevalence within the donor population.

In the present study, a total of 814 (0.7%) out of 110,419 ELISA-based screening tests had been found seropositive, and 661 of these donors had responded to the recall invitation. Of those tested, 438 (66.2%) were confirmed positive, accounting for 0.3% of all donations. The distribution of confirmed positivity among reactive cases was highest for HBV (95.4%), followed by syphilis (22.7%), HIV (19.2%), and HCV (14.1%).

Due to the inability to perform confirmatory testing on all reactive donors, the actual prevalence of TTIs in the donor population could not be fully determined. Thus, the confirmation rate does not reflect true population-level infection rates.

Analysis of false positivity and signal-to-cutoff (s/co) index values for the screening tests indicated that anti-HCV yielded the highest false positivity rate (85.6%), with most cases clustering in the 1.0 - 2.5 s/co index range. This was followed by the anti-HIV 1/2 p24 antigen test (80.2%, mainly near the 1.0 s/co threshold), and

the syphilis antibody test (77.3%), with values typically between 1.0 - 2.0 s/co. In contrast, the HBsAg test exhibited the lowest false-positive rate (4.6%), thereby causing the least donor loss.

These findings are consistent with a large-scale study conducted in Switzerland involving 423,543 donors, which reported false positivity rates between 0.02% and 0.2% for HIV, syphilis, and HBV, with the highest rate again observed in anti-HCV tests. The high frequency of false reactivity has been shown to cause unnecessary anxiety among blood donors and underscores the need for a standardized approach in donor screening to minimize false-positive results [29].

Globally, a variety of assays are utilized for TTI screening due to the lack of consensus on the optimal testing protocol. The choice of screening test depends on multiple factors, including diagnostic performance, cost, labor intensity, technical complexity, and turnaround time. Ideally, a screening assay should be cost-effective, non-invasive, and capable of accurately distinguishing infected individuals from uninfected ones [30].

An ideal screening test in blood banking should possess high sensitivity to avoid false negatives and adequate specificity to minimize false positives, which lead to unnecessary donor deferral and blood discard. In our study, high false-positive rates were observed for HBV, HIV, and syphilis screening assays, as many reactive results were not confirmed. While ensuring transfusion safety remains the priority, the use of highly specific assays is essential to reduce donor anxiety and prevent wastage of safe blood. Given the increasing demand for blood due to aging populations and chronic diseases [31], standardized, evidence-based selection of test kits is crucial for effective donor screening and resource optimization.

As a result, Hepatitis viruses, HIV, and syphilis continue to pose significant risks for transmission through blood transfusion. Ensuring microbial safety requires strict adherence to proper procedures during blood collection, screening, and processing. While global and national data indicate rising trends in HIV and syphilis infections, these trends may be reflected in the blood donor population as well, emphasizing the critical role of highly sensitive and specific screening assays in blood safety.

Our study observed an increasing number of foreign donors in recent years, introducing additional factors that may influence transfusion safety - such as language barriers, differing vaccination backgrounds, limited awareness of blood donation practices, and the evaluative capacity of healthcare providers. These variables highlight the necessity of tailored strategies for donor assessment and screening in diverse populations.

Contrary to the decreasing trends reported in national literature, our findings revealed a recent increase in HBV reactivity among Turkish male and foreign female donors, as well as persistently higher HCV rates among foreign nationals. While HIV reactivity declined in Turkish males post-2020, it was notably elevated among foreign males in 2022 before declining. Syphilis rates showed no consistent trend over time but increased with donor age.

Additionally, when screening test performance was assessed using confirmatory results, high false-positive rates were observed for HCV, HIV, and syphilis, indicating a need for improved specificity in testing algorithms. These findings underscore the importance of ongoing evaluation and optimization of donor screening protocols, especially in the context of changing donor demographics and emerging public health trends.

Limitations

This study was retrospective in design and conducted at a single center, which may limit the generalizability of the findings. The sample size of foreign-origin donors was relatively small, warranting further investigation through multicenter and more comprehensive studies to ensure robust conclusions. Additionally, microbiological screening tests for foreign donors were not available outside the scope of this study, precluding comparative analysis of reactivity rates between Turkish and foreign donors. Not all reactive blood donors had undergone confirmatory testing; the true prevalence of transfusion-transmitted infections in the donor population cannot be determined with certainty.

CONCLUSION

To ensure the sustainability and safety of the blood supply, it is essential to closely monitor foreign donors through multicenter and longitudinal studies. Given the increasing demand for blood and blood products, efforts should be directed toward minimizing unnecessary blood disposal resulting from false-positive screening results. Additionally, to mitigate anxiety among temporarily deferred donors and facilitate their reintegration into the donor pool, current screening procedures should be re-evaluated through comparative studies.

These steps are critical for optimizing donor management strategies and enhancing the overall efficacy of blood transfusion services.

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Ethics Approval:

This study was conducted in accordance with the principles of the Declaration of Helsinki. The ethical approval was obtained from local Ethical Committee (No.: KAEK/28.08.2024.185).

Informed Consent:
Not applicable, due to the retrospective nature of the study.

Data Availability:
All data used in this study can be obtained from the author upon request.

Declaration of Interest:
The authors declare that they have no conflicts of interest.

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