

PAPER DETAILS

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PAGES: 1246-1251

ORIGINAL PDF URL: <https://dergipark.org.tr/tr/download/article-file/2508612>

Six-year seroprevalence results for blood center mandatory donor screenings: single center experience

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Cite this article as: Gareayaghi N, Akkuş S, Hamzeli, Kocazeybek B. Six-year seroprevalence results for blood center mandatory donor screenings: single center experience. J Health Sci Med 2022; 5(5): 1246-1251.

ABSTRACT

Aims: Infections transmitted through blood and blood product transfusions are one of the most important health problems today. In Turkey; Microbiological screening for hepatitis B, hepatitis C, syphilis and HIV infections is mandatory for each unit of blood and blood components prepared for transfusion, regardless of the time between donations. In this study, it was aimed to determine the prevalence of HBV, HCV, HIV and syphilis in blood donors who applied to our Blood Center and to compare them with the prevalences in other regions of Turkey.

Material and Method: The study was conducted between January 2016 and June 2022 and included 68195 donors. Screenings for HBsAg, anti-HCV, anti-HIV and syphilis tests were performed with commercial kits using the Electro-Chemiluminescence Immunoassay (ECLIA) principle. Positive results were confirmed by validation studies.

Results: As a result of screening, 279 (0.4%) of 68195 donors tested positive for HBsAg, 56 (0.08%) for anti-HCV, 25 for anti-HIV (0.03%) and 197 (0.28%) for syphilis. Of the total donors, 2129 (3.1%) were volunteers and 66,066 (97%) were non-volunteer relatives. In total, 0.8% of the donors were positive for screening.

Conclusion: The significant (0.8%) positivity detected in the HBsAg, anti-HCV, anti-HIV and syphilis tests of the donors showed that blood transfusion screening tests were vital. In addition, considering the window period of infections and the pre-seroconversion period, it was concluded that there is a need for methods with high sensitivity and solutions such as avoiding unnecessary transfusions.

Keywords: Hepatitis B, HIV, HCV, syphilis, blood donors

INTRODUCTION

Vitally important blood and blood products, which are used for treatment purposes in many diseases, are very costly and have a short period of use. These products cannot be produced synthetically yet under laboratory conditions and should be obtained from healthy individuals in the society (1).

Donor questioning and screening tests are applied for providing safe blood for the transfusion process. Donors are registered in blood transfusion centers, provided with a detailed 'Donor Inquiry Form' and physically examined. For safe blood supply; the World Health Organization (WHO) recommends supporting voluntary blood donors who donate regularly (2).

Immunological, and non-immunological infectious complications are among the various problems

encountered in treatments performed with blood and blood products transfusion and conditions caused by microorganisms are common complications of blood transfusion. Although infections can be transmitted by bacteria, viruses, parasites, fungi and prions, in practice, especially human immunodeficiency virus (HIV 1-2), hepatitis C virus (HCV) and hepatitis B virus (HBV) have gained importance in terms of transfusion safety as the most important viral agents (3-5).

Furthermore, in addition to various viral agents such as Hepatitis A, Hepatitis D, Hepatitis E, Hepatitis G viruses, human parvovirus B19, human Herpes virus type 8, human Epstein Barr virus, cytomegalovirus, bacteria and parasites such as *Treponema pallidum*, *Salmonella* and *Brucella* can be transmitted by transfusion. Most of the infectious agents transferred from donors to recipients

are able to maintain their viability in stored blood for a long time resulting in latent or asymptomatic infections (3,6).

In order to ensure transfusion safety, serological tests are requested from eligible donors (7). According to the regulation on the blood and blood products law in our country, HBsAg, anti-HCV, anti-HIV 1/2 and syphilis standard tests are enforced as mandatory screenings. In Türkiye, the prevalences of HBV, HCV, HIV and VDRL in blood donors vary between 2.80-10.75%, 0.0-1.5%, 0-0.86%, and 0.02-0.2% respectively. Despite this, the risk of contamination with blood and blood products is estimated to be 1/100 000 for HCV, 1/63 000 for HBV and 1/680 000 for HIV (1).

In our study, it was aimed to determine the HBsAg, Anti-HCV, Anti-HIV and syphilis seropositivity rates by retrospectively examining the information of the donors who applied to our Blood Transfusion Center in the last 6.5 years, and to draw attention to viral or bacterial agents with increasing frequency.

MATERIAL AND METHOD

The study was carried out with the permission of the Health Sciences University, Şişli Hamidiye Etfal Training and Research Hospital, Health Practice and Research Center, Clinical Research Ethics Committee (Date: 24/05/2022, Decision No: 3567). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

The study was planned as a descriptive seroprevalence study. The results of blood donation screening tests of 68195 donors who applied to the Health Sciences University Şişli Hamidiye Etfal Training and Research Hospital's Blood Center between January 2016 and June 2022, filled the donor inquiry forms prepared and evaluated in accordance with the 'Blood and Blood Products Law No. 5624 and the provisions of the related legislation and donor selection criteria' and signed the 'Informed consent form' were included in our study. The demographic data of the donors registered in the automation system of the hospital were retrospectively analyzed (8).

Serological study

Individuals who were evaluated as safe and risk-free by questioning were accepted as donors. Anti-HCV, anti-HIV, Syphilis antibodies and HBsAg antigens were investigated by Electro-Chemiluminescence Immunoassay (ECLIA) method from blood samples obtained from suitable donors. (Roche Cobas 6000 e601 Analyzer, Roche Diagnostics, USA). Positive tests were confirmed by repeating in the validation laboratory.

Statistics

The patients' data were evaluated descriptively and the percentages of the data were determined. The data were evaluated separately with classifications such as age and gender. SPSS v.26 was used for these descriptive data analysis.

RESULTS

Of 68195 donors, 279 (0.4%), 56 (0.08%), 25 (0.03%) and 197 (0.28%) were found to be respectively; HBsAg, anti-HCV, anti-HIV and syphilis positive. Of the total donors, 2129 (3.1%) were volunteer and 66066 (97%) were non-volunteer (patient relatives).

In our study, the general prevalence of transfusion-transmitted infections in a total of 68195 donors over 6.5 years was 0.54% (373 of 68195) and 279 (0.4%), 56 (0.08%), 25 (0.03%) and 197 (0.28%) donors were respectively; HBsAg, anti-HCV, anti-HIV and syphilis positive. The distribution and positivity rates of HBsAg, Anti-HCV, Anti-HIV and syphilis between 2016 and 2022 are given in **Table 1**.

Table 1. Distribution of HBsAg, Anti-HCV, Anti-HIV and syphilis in blood donors by years

Year	Number of donors	HBsAg (+)	Anti-HCV (+)	Anti-HIV (+)	Syphilis (+)
2016	14.619	83 (0.56%)	2 (0.01%)	10 (0.06%)	32 (0.21%)
2017	15.417	59 (0.38%)	3 (0.019%)	7 (0.04%)	46 (0.29%)
2018	12.611	68 (0.53%)	13 (0.10%)	1 (0.007%)	49 (0.38%)
2019	8.647	25 (0.28%)	11 (0.12%)	0 (0%)	21 (0.24%)
2020	6.389	23 (0.35%)	11 (0.17%)	1 (0.01%)	26 (0.40%)
2021	6.793	13 (0.19%)	12 (0.17%)	4 (0.06%)	15 (0.22%)
2022	3.719	8 (0.21%)	4 (0.10%)	2 (0.05%)	8 (0.21%)
Total	68195	279 (0.40%)	56 (0.08%)	25 (0.03%)	197 (0.28%)

* First 6 months of 2022

In the 6.5-year period, 5370 (8%) of the 18-65 aged 68195 blood donors were female and 62825 (92%) were male with a female/male ratio of 1/11.7. The majority of all donors, 43072 (63.1%) were aged between 25 and 44 (**Table 2**).

Table 2. Distribution of HBsAg, Anti-HCV, Anti-HIV and syphilis in blood donors by age and gender

Age range	Gender	Number of donors	HBsAg	Anti-HCV	Anti-HIV	Syphilis
18-24	Female	1323	4	1	0	2
	Male	11977	38	1	1	16
25-44	Female	2919	13	1	4	23
	Male	40153	133	33	14	87
45-65	Female	1125	9	5	1	17
	Male	10658	82	15	4	52
>65 age	Female	3	0	0	0	0
	Male	37	0	0	1	0
Total		68195	279	56	25	197

Of the total donors, 2129 (3.1%) were volunteer and 66066 (97%) were non-volunteer (patient relatives). By analyzing the number of donors by years, a gradual decrease in donation was observed. Additionally, the number of volunteer donors has been determined to be quite low compared to non-volunteer donors (**Table 3**).

Table 3. Distribution of volunteer and non-volunteer (patient relatives) donors by years.		
Year	Volunteer donor	Non-volunteer donor
2016	627	13.992
2017	568	14.849
2018	392	12.219
2019	237	8410
2020	160	6229
2021	101	6692
2022	44	3675
Total	2129	66.066

HBsAg, anti-HIV, anti-HCV and several of the syphilis parameters were determined to be simultaneously positive in five of 68195 donors in our study (**Table 4**).

Table 4. Simultaneous positivity rates of HBsAg, Anti-HCV, Anti-HIV, syphilis in blood donors						
year	Age	Gender	HBsAg (+)	Anti-HVC (+)	Anti-HIV (+)	Syphilis (+)
2016	39	Male	+	+		
2016	48	Male	+	+		+
2017	35	Male			+	+
2018	30	Male				
2018	27	Male			+	+

DISCUSSION

Providing safe blood transfusion is a primary goal of the blood centers. Recently, significant progress in terms of the safety of blood products has been made in developing and developed countries. Detailed examination of donors, questioning of their diseases and habits, routine screening of blood products for various pathogens are indispensable practices for the reliability of blood and blood products (9). Owing to the careful selection of blood donors, the advances in screening tests and the use of advanced methods; the risk of transfusion-transmitted infection, which is one of the most important complications of blood transfusion, is decreasing day by day. However, despite all the developments in modern medicine, the infection transmitted by transfusion has not been completely resolved yet. This situation continues to be an important health problem all over the world, especially in underdeveloped countries (7).

Despite all the precautions and technological developments, it is still not possible to identify individuals infected with infectious agents such as HBV, HCV and HIV by routine screening tests, as there is a possibility of transmission

during the so-called "window period" between the infection and the attainment of measurable levels of antibody titers (9). The window period is approximately ten days for HCV, and the rate of transmission through fresh blood products is estimated to be 1 in 1.6 million units. Nowadays, the positive developments in the sensitivity of HIV antibody tests have shortened the window period from approximately 45 days to 22-25 days, reducing the rate of transfusion-associated HIV transmission to 1 in 1.8 million units (10).

In terms of safety of the blood supplied from the donors and transfused to the recipients; WHO (World Health Organization) has stated that blood must not pose any danger or disease and not contain infectious agents or harmful foreign substances. The safe human-to-human transfusion of blood and certain blood compounds is an extremely critical process. The "Safe Blood" WHO announcement at 2000 highlights the importance of this issue. In the world where millions of units of blood and blood components are transfused yearly, it is a serious public health problem that post-transfusion infections due to microorganisms, especially viruses, are still not prevented in some recipients (11). In order to solve this issue, it is worth noting that approaches such as regular donations from safe people should be popularized. For safe blood supply, screening studies for HBsAg, anti-HCV, anti-HIV and syphilis are routinely carried out in our country's blood banks.

In various regions of Türkiye; many studies have been conducted to determine the seroprevalence of HBsAg, Anti-HCV, Anti-HIV 1/2 and syphilis in blood donors (Table 5). In this study, which we conducted with a similar purpose, out of 68195 donors 279 (0.40%), 56 (0.08%), 25 (0.03%) and 197 (0.28%) were detected respectively as HBsAg, anti-HCV, anti-HIV and syphilis positive between 2016 and 2022.

In İstanbul; Ulutürket al. (9) detected HbsAg in 2.83% of 75747 donors between 1998 and 2008, Şanlı et al. (12) detected HbsAg in 2.03% of 51120 donors between 2003 and 2012 and Karagöz et al. (13) detected HbsAg in 1.4% of 10568 donors between 2009 and 2011 and reported that the rate of HBsAg positivity decreased within the process.

Considering the data of studies reported from various regions of our country, we see that HBsAg seropositivity rates vary between 0.5% and 3.17% (14-31) (**Table 5**). The rate of 0.40% we found in our study is below the reported rates. In addition, we see that HBsAg seropositivity rates are gradually decreasing every year in the period of 2016-2022 covered by our study. We think that the awareness of the society about HBV infection, vaccine applications and the effective implementation of the measures taken within the scope of safe blood supply are among the reasons responsible for this decrease.

Anti-HCV positive donors have been detected in the rates of 0.4% in Ulutürk et al. (9), 0.44% in Şanlı et al. (12) and 0.2% in Karagöz et al. (13) studies. As a result of the studies conducted on blood donors from various regions of our country, we see that the anti-HCV seropositivity rates vary between 0.05% and 0.92% (14-31) (**Table 5**). It is seen that the rate of 0.08% anti-HCV seropositivity detected in our study is low and consistent with the data of our country; especially the rates reported from our city.

HIV seropositivity rates in blood donors reported by Ulutürk et al. (9), Şanlı et al. (12) and Karagöz et al. (13) studies were respectively; 0.001%, 0.06% and 0.03%. According to the reports of studies performed in various regions of Türkiye; the seropositivity rates of HIV in blood donors are between 0.0% and 1.06% (14-31) (**Table 5**). The rate of 0.03%, which we found in our study, is among these seropositivity rates and compatible with the data of Türkiye.

The incidence of syphilis, which ranks third after chlamydia and gonorrhea among sexually transmitted diseases in European Union countries, was reported as 4.5/100 000 in 2009 (32). The source of epidemiological data on syphilis in our country is largely based on donor screenings made by blood banks or data obtained from

sex workers (33). 0.16% of Ulutürk et al. (9), 0.33% of Şanlı et al. (12) and 0.7% of Karagöz et al. (13) donors were reported as syphilis antibody positive and according to studies from various regions of our country, syphilis seropositivity rates in blood donors range from 0% to 2.33% (14-31) (**Table 5**). The rate of 0.28%, which we found in our study, was among these seropositivity rates being compatible with the data of our country. Our study's rate also was found to be close to the incidence of the European Union sexually transmitted diseases in 2009.

A gradual decrease in HBsAg and syphilis screening test positivity has been observed in our hospital over the years. However, it is still not reset. The presence of anti-HCV and anti-HIV positivity points the importance of screening tests before blood transfusion. Although there is a decrease in the frequency of infectious diseases transmitted by blood transfusion in parallel with the advances in technology and science, a transfusion application with zero risk of infection does not seem to be possible in the near future. In addition, since the best transfusion is non-transfusion; limiting transfusion to absolute indications only seems to be the most effective protective method from the transfusion-transmitted infections.

Table 5. Seropositive rates of HbsAg, anti-HCV, anti-HIV and Syphilis detected in blood donors in different regions of our country

Province	Year	Researchers	Number of donors	HbsAg (%)	Anti-HCV (%)	Anti-HIV (%)	Syphilis (%)
İstanbul	1998-2008	Ulutürk et al.	75747	2.83	0.4	0.001	0.16
İstanbul	2003-2012	Şanlı et al.	51120	2.03	0.44	0.06	0.33
İstanbul	2009-2011	Karagöz et al.	10568	1.4	0.2	0.03	0.7
Zonguldak-Düzce-Sakarya-Kocaeli	2009-2014	Altındiş et al.	150787	0.8	0.38	0.0025	0.004
İzmir	2002-2006	Ağuş et al.	61409	2	0.54	0.028	-
İzmir	2004-2010	Uzun et al.	80454	1.31	0.38	0.002	0.04
Denizli	1999-2007	Akalın et al.	50521	0.97	0.44	0	0
Denizli	2007-2008	Balcı et al.	13334	1.3	0.5	0.023	0.13
Isparta	2000-2007	Kaya et al.	51361	1.1	0.44	0.09	0.08
Diyarbakır	2000-2010	Dayan et al.	266035	3.17	0.64	0.0004	0.07
Van	1995-2003	Dilek et al.	39002	2.55	0.17	0.036	0.057
Erzurum	2000-2011	Çelebi et al.	204000	3.14	0.92	1.06	2.33
Erzurum	2002-2003	Uyanık et al.	5028	2.6	0.4	0	-
Tokat	2003-2010	Bulut et al.	15696	1.29	0.16	0	0.02
Afyon	2001-2010	Altındiş et al.	37343	1.38	0.35	0.02	0.04
Çorum	2008-2013	Güreser et al.	13780	0.99	0.34	0.08	0.09
Kırıkkale	2003-2004	Deveci et al.	784	1.4	0.2	0	0
Adana	2007-2009	Yıldız et al.	62461	1.66	0.05	0.003	0.1
Malatya	2000-2007	Köroğlu et al.	13564	3.1	0.47	0.07	-
Kahramanmaraş	2012-2018	Kirişçi et al.	1326	0.5	0.15	0	0.07
Mersin	2006-2008	Öner et al.	30716	2.2	0.4	0.2	0.1
Hatay	2003-2004	Ocak et al.	12313	2.02	0.52	0.02	0.03
İstanbul *	2016-2022	Gareayaghi et al.	68195	0.4	0.08	0.03	0.28

*our study

CONCLUSION

As a result; the significant (0.8%) positivity detected in the HBsAg, anti-HCV, anti-HIV and syphilis tests of the donors showed that blood transfusion screening tests were vital. In addition, considering the window period of infections and the pre-seroconversion period, it was concluded that there is a need for methods with high sensitivity and solutions such as avoiding unnecessary transfusions.

In addition, it is thought that it would be beneficial to conduct more comprehensive and continuous epidemiological studies in order to understand the high follow-up and treatment costs of the diseases caused by these factors and to evaluate the sufficiency of the protective and control measures.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of the Health Sciences University, Şişli Hamidiye Etfal Training and Research Hospital, Health Practice and Research Center, Clinical Research Ethics Committee (Date: 24/05/2022, Decision No: 3567).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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