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ORIGINAL ARTICLE

The Prevalence of Transfusion-Transmitted Infection Markers among Blood Donors at Saudi Hospital, Makkah

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SUMMARY

Background: **Testing of blood donors for markers of transfusion-transmitted infections (TTIs) such as HBV, HCV, HIV, HTLV, syphilis, and malaria is mandatory in Saudi Arabia. This study determined the prevalence of all tested TTIs among blood donors in the western region of Saudi Arabia .**
Methods: **This retrospective study included 5,473 blood donors who attended the blood donation center at the Security Force Hospital (SFH) located in the western region of Saudi Arabia from January 1, 2015 to December 31, 2018. The prevalence of TTIs was determined and classified as per year, gender, age, type of donors (first-time vs. returned donors), category of donation (replacement vs. volunteer), and blood group.**
Results: **All donors (100%) were screened for TTIs by serological assays and nucleic acid tests (NATs). "Reactive" samples to serological assays were as follow: 57 (1.07%) HBsAg, 292 (5.34%) HBsAb, 388 (7.1%) HBcAbs, 13 (0.24%) HCV, 5 (0.09%) HIV, 8 (0.15%) HTLV-I and -II, 21 (0.83%) syphilis, and 0 (0%) malaria. The NAT results for HBV, HCV, and HIV revealed 50 (0.91%), 1 (0.0002%), and 3 (0.05%) reactive samples, respectively. Reactive donations to screening serology tests of syphilis and HTLV-I/-II were neither confirmed nor declined by their corresponding confirmatory assays. Most "reactive" samples to TTI tests were associated with male gender, first-time donor, replacement donation, and O+ blood group.**
Conclusions: **This study highlights the strong adherence to TTI testing policy and low prevalence of TTI markers among blood donors in the western region of Saudi Arabia.**
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KEYWORDS

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INTRODUCTION

Blood transfusion poses a significant risk of transmitting infectious pathogens from infected donors to uninfected recipients [1]. Hence, it is mandatory under the current policy in many countries, including Saudi Ara-

bia, to test all blood donors for exposure to five transfusion-transmitted infections (TTIs) [2]. In Saudi Arabia, donors attending blood donation centers need to fill out the donors' questionnaire, followed by a brief interview and a physical examination [2]. Only those that meet the donors' selection criteria, which comply with the American Association of Blood Banks (AABB) standards, proceed to the donation step [3]. In line with the World Health Organization (WHO) and European Union (EU) recommendations, all donated units received in the blood donation centers are screened by serological assays for the presence of TTI markers, including their antigens and antibodies (Table 1).

These serological screening tests have remarkably reduced the risk of unsafe transfusion. However, these tests may fail to detect recent infections if the donated units were obtained during the infection window period [4-6]. Hence, nucleic acid tests (NATs) for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) are conducted in parallel to complement the serological tests and eliminate the potential false-negative results [7]. Only seronegative and NAT-negative units are accepted, and no further tests for infectious diseases are conducted. Reactive units to any of the serological assays or NATs are discarded, and donors are notified to repeat testing on fresh samples before being permanently deferred as donors [2]. Few studies have reported the prevalence of infectious diseases among blood donors in different cities/regions of Saudi Arabia [8-13]. Although informative, the focus of these studies in many cases has been limited to only one type of TTI over a short period. More studies are required to obtain broader and more precise knowledge about: (1) the prevalence of TTIs among blood donors in the country, (2) adherence to TTI testing policy, and (3) effectiveness of the current testing protocol to provide safe blood transfusion.

In this study, we aimed to (1) collect and analyze the demographic data of blood donors who attended the Special Force Hospital (SFH) located in Makkah, Saudi Arabia from 1 January 2015 to 31 December 2018, (2) determine the prevalence of all tested TTIs among blood donors utilizing data from both serology assays and NATs, and (3) classify the "reactive" donations for serological assays or NATs according to gender (female vs. male), type of donors (first-time vs. returning donors), and category of donations (replacement vs. volunteer) and blood groups.

MATERIALS AND METHODS

Ethics Approval

The present study was approved by the Institutional Review Board of SFH (registration number: 0211-1208 18).

Study population

A 4-year retrospective study was used to assess the prevalence of TTIs among blood donors visiting SFH Blood Bank Center in the western region of Saudi Arabia from January 1, 2015 to December 31, 2018. All eligible blood donors' data that fulfilled the national blood bank selection criteria were included in this study. These criteria were based on a predefined measure, namely age between 18 and 65 years, weight > 50 kg, and no medical history. Donors' information was obtained from the donor registry. The information collected from the database included year, gender, age, blood groups, type of donation, frequency of blood donation, and the outcome variables of TTIs markers.

Laboratory tests

Besides ABO group testing, all donations included in this study were serologically tested for HbsAg, HbsAb, HbcAb, anti-HCV, HIV1/2 Ag/Ab, anti-HTLV 1- and -2, syphilis, and malaria. In addition, they were subjected to molecular investigation for HBV, HCV, and HIV using nucleic acid detection technique. Serological assays and NATs were performed using commercially available kits.

Statistical analysis

Data retrieved from the SFH Blood Bank and Pathological Laboratory Data Management System were transferred to Excel spreadsheets (Microsoft Corp., Redmond, WA, USA). The data was subsequently cleaned, recorded, and analyzed using Excel or GraphPad prism. Two-tailed paired *t*-tests were used to determine statistical significance between the prevalence of TTIs among male vs. female, first-time vs. returned donors, and replacement vs. volunteer. Linear regression analysis (independent variable: year of donation, dependent variable: percentages of the prevalence of TTIs among blood donors) were used to determine any significant increasing or decreasing trend in the seroprevalence of TTI markers among donors over the years. Chi squared test was used to assess the potential association between the type of blood group and the prevalence of TTIs. $p \leq 0.05$ was considered statistically significant.

RESULTS

In all, 5,473 whole blood donations were accepted at the SFH between January 2015 and December 2018. The characteristics of the study population and their demographic data are shown in Table 2. Briefly, male (5,424), first-time (4,631), and replacement (4,944) donors were in the majority as compared to female (48), returned (842), and volunteer donors (529). Most donors were associated with blood group O+ (48.38%) followed by A+ (26.62%), B+ (13.85%), AB+ (3.34%), A- (2.06%), B- (1.1%), and AB- (0.26%).

The distribution of blood donors who donated blood at the SFH from January 2015 to December 2018 is shown

Table 1. Summary of transfusion-transmitted infections and their serological and molecular screening markers.

Pathogens	Serological marker	Serological assays/systems	Molecular marker	Molecular assays/systems
Hepatitis B virus (HBV)	HBV surface antigen (HBsAg) HBV antibody (HbsAb) HBV core antibody	The ARCHITECT HBsAg, Anti-HBs, and HBc II Qualitative assays	NAT HBV	The Cobas® MPX Test: Multiplex HIV, HCV & HBV nucleic acid test used on Cobas® 6800 System
Hepatitis C virus (HCV)	Anti-HCV	The ARCHITECT Anti-HCV assay	NAT HCV	
Human immunodeficiency virus type I and II (HIV-I and HIV-2)	HIV-I/II Ag/Ab	The ARCHITECT HIV Ag/Ab Combo assay	NAT HIV	
Human T-lymphotropic virus type I and II (HTLV-I and HTLV-2	Anti-HTLV-1/-2	The ARCHITECT rHTLV-I/II assay	NT	
Treponema pallidum (Syphilis)	*Anti-Treponema pallidum*	The ARCHITECT Syphilis TP assay	NT	
Plasmodium species (4 types that cause Malaria)	*Anti- Plasmodium*	Standard Diagnostics Inc.	NT	

NAT - nucleic acid testing, NT - not tested.

Table 2. Demographic characteristics of blood donors who donated blood at the SFH from January 2015 to December 2018.

Demographic data		n	%
Year	2015	1,123	20.5
	2016	1,756	32.1
	2017	510	9.3
	2018	2,084	38.1
Gender	female	49	0.9
	male	5,424	99.1
Category of donation	replacement	4,944	90.3
	volunteer	529	9.7
Type of donor	first-time	4,631	84.6
	returned	842	15.4
Blood group	A -ve	113	2.06
	A +ve	1,457	26.62
	B -ve	60	1.1
	B +ve	758	13.85
	AB -ve	14	0.26
	AB +ve	183	3.34
	O -ve	238	4.35
	O +ve	2,648	48.38
	unknown	2	0.04

Data are presented as frequency (n) and percentage (%).

Table 3. Frequency of TTI serological and molecular markers among the donors by year (2015 - 2018).

Mar	Test/year	2015		2016		2017		2018		Total		p	Sig
		n	%	n	%	n	%	n	%	n	%		
Serological	HBsAg	16	1.42	18	1.03	3	0.59	20	0.96	57	1.04	0.31	No
	HBsAb	52	4.63	105	5.98	29	5.69	106	5.09	292	5.34	0.77	No
	HBcAb	76	6.8	138	7.9	37	7.3	137	6.6	388	7.1	0.73	No
	Anti-HCV	5	0.45	5	0.28	2	0.39	1	0.05	13	0.24	0.20	No
	HIV Ag/Ab	1	0.09	2	0.11	1	0.2	1	0.05	5	0.09	0.94	No
	syphilis	5	0.45	9	0.51	4	0.78	3	0.14	21	0.38	0.68	No
	malaria	0	0	0	0	0	0	0	0	0	0	N/A	No
	Anti-HTLV-1/-2	1	0.09	5	0.28	0	0	2	0.1	8	0.15	0.72	No
Molecul	HBV	14	1.25	16	0.91	3	0.59	17	0.82	50	0.91	0.24	No
	HCV	0	0	0	0	0	0	1	0.05	1	0.02	0.22	No
	HIV	1	0.09	0	0.11	1	0.2	1	0.05	3	0.05	0.94	No
Number of donors		1,123		1,756		510		2,084		5,473			

Data are presented as frequency (n) and percentage (%) of reactive and positive results relative to number of donors. $p \leq 0.05$ indicates statistical significance.
HBV - Hepatitis B virus, HCV - Hepatitis C virus, HIV - human immunodeficiency virus, HBsAg - Hepatitis B surface antigen, HBsAb - Hepatitis B surface antibody, HBcAb - Hepatitis B core antibody, HIV Ag/Ab - human immunodeficiency virus antigen/antibody, Anti-HTLV-1/-2 - anti-Human T-Cell Lymphotropic Virus Types I and II.

Table 4. The prevalence of TTI markers among blood donors according to sex, type of donor, and category of donation.

Test	Female		Male		First-time		Returning		Replacement		Volunteer		Total
	n	%	n	%	n	%	n	%	n	%	n	%	n
HBsAg	1	1.75	56	98.25	55	96.49	2	3.51	55	96.49	2	3.51	5
HBsAb	3	1.027	289	98.97	259	88.70	33	11.30	260	89.04	32	10.96	292
HBcAb	4	1.03	384	98.97	346	89.18	42	10.82	345	88.92	43	11.08	388
Anti-HCV	0	0	13	100	10	76.92	3	23.08	11	84.61	2	15.38	13
HIV Ag/Ab	0	0	5	100	5	100	0	0	5	100	0	0	5
Syphilis	0	0	21	100	15	71.43	6	28.57	19	90.48	2	9.52	21
Malaria	0	0	0	0	0	0	0	0	0	0	0	0	0
Anti-HTLV-1/-2	0	0	8	100	8	100	0	0	7	87.5	1	12.5	8
NAT HIV	0	0	3	100	3	100	0	0	3	100	0	0	3
NAT HBV	1	2	49	98	47	94	3	6	48	96	2	4	50
NAT HCV	0	0	1	100	0	0	1	100	1	100	0	0	1
p-value	0.01				< 0.0001				< 0.0001				
Significance	yes				yes				yes				

Data are presented as frequency (n) and percentage (%) relative to the number of reactive and positive results. $p \leq 0.05$ indicates statistical significance.

in Figure 1. Data show a statistically significant difference between the distribution of male vs. female ($p < 0.0001$), first-time vs. returned ($p < 0.0001$), and replacement vs. volunteer donors ($p = 0.002$) in the 4-year study period.

All potential donors (100%) were tested for TTIs by serological assays (Table 3). Donated units were mostly reactive to HBV parameters: 388 (7.1%) HBcAb, 292

Table 5. The prevalence of TTI markers among blood donors according to their blood groups.

Marker	A NEGATIVE		A POSITIVE		AB NEGATIVE		AB POSITIVE		B NEGATIVE		B POSITIVE		O NEGATIVE		O POSITIVE		Total	p-value	Sig.
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n		
HBsAg	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0	1	20.0	2	40.0	5	0.75	no
HBsAb	0	0.0	15	26.3	0	0.0	1	1.8	0	0.0	10	17.5	0	0.0	31	54.4	57	< 0.0001	yes
HBcAb	3	0.8	97	25.0	1	0.3	8	2.1	6	1.5	57	14.7	15	3.9	201	51.8	388	< 0.0001	yes
ANTI-HCV2	3	1.0	72	24.7	1	0.3	6	2.1	6	2.1	42	14.4	15	5.1	147	50.3	292	< 0.0001	yes
HIV Ag/Ab	0	0.0	2	15.4	0	0.0	1	7.7	0	0.0	0	0.0	0	0.0	10	76.9	13	0.71	no
Syphilis	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	2	25.0	0	0.0	4	50.0	8	0.07	no
Malaria	0	0.0	8	38.1	0	0.0	0	0.0	0	0.0	3	14.3	1	4.8	9	42.9	21	0.09	no
Anti-HTLV-1/-2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0	0	N/A	N/A
NAT HIV	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	33.3	1	33.3	3	0.74	no
NAT HBV	0	0.0	12	24.0	0	0.0	1	2.0	0	0.0	9	18.0	0	0.0	28	56.0	50	< 0.0001	yes
NAT HCV	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	1	0.99	no

Data are presented as frequency (n) and percentage (%) relative to number of reactive and positive results. $p \leq 0.05$ indicates statistical significance.

HBV - Hepatitis B virus, HCV - Hepatitis C virus, HIV - human immunodeficiency virus, HBsAg - Hepatitis B surface antigen, HBsAb - Hepatitis B surface antibody, HBcAb - Hepatitis B core antibody, HIV Ag/Ab - human immunodeficiency virus antigen/antibody, Anti-HTLV-1/-2 - anti-Human T-Cell Lymphotropic Virus Types I and II.

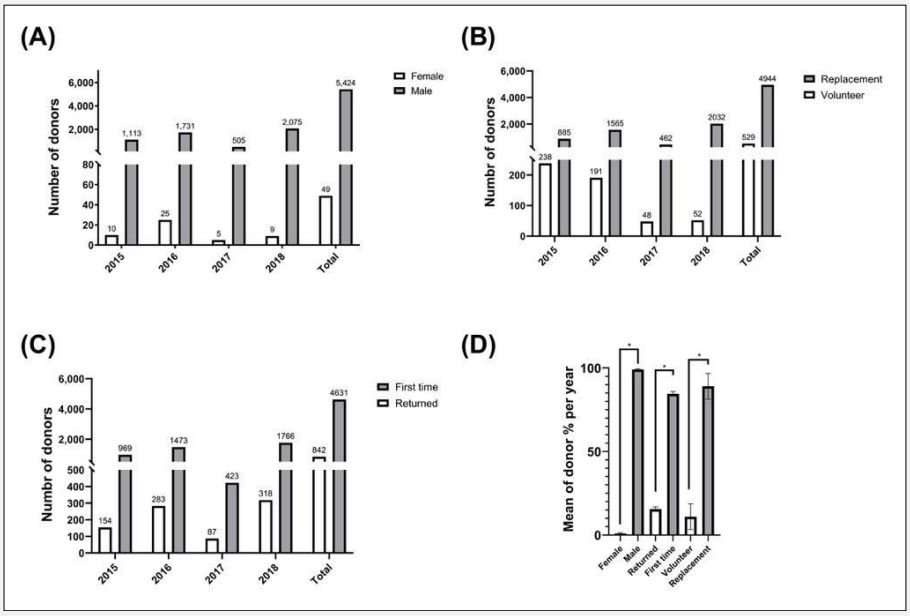

Figure 1. Gender, type of donors, and category of donation distribution of blood donors who donated at the SFH from January 2015 to December 2018.

Actual numbers are shown in (A), (B), and (C). Data in (D) are presented as mean percentage (%) relative to the total number of donors. $p \leq 0.05$ indicates statistical significance.

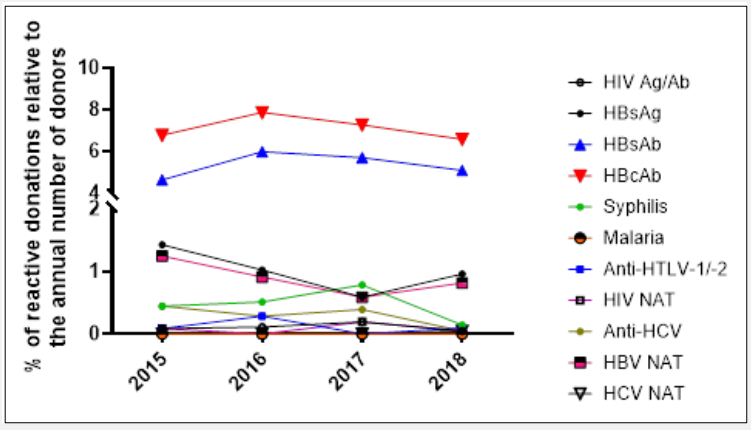

Figure 2. The trend of TTI prevalence among the donors over years.

Data are presented as percentage (%) relative to the annual number of donors.

(5.34%) HbsAb, and 57 (1.04%) HbsAg followed by 21 (0.38%) syphilis, 13 (0.24) anti-HCV, 8 (0.15%) anti-HTLV1/II, and 5 (0.09%) HIV Ag/Ab. All donations were non-reactive to the malaria test (0%). We did not find any significantly increasing or decreasing trends in the seroprevalence of TTI markers among donors over

the years. However, the trend of serological makers was not statistically significant.

Regardless of the serology test results, all donated units were tested by NATs for HBV, HCV, and HIV to confirm the positivity rates. The overall positivity prevalence of HBV, HCV, and HIV among the 5,473 donors were 50, 1, and 3, respectively (Table 3). The most prevalent infection of TTI throughout the 4 years was HBV. The frequency of TTIs was highest in 2018 (0.34%) and lowest in 2017 (0.07%). The distribution of HBV, HCV, and HIV over the 4-year period showed no statistically significant differences (0.92, 0.74, and 0.74, respectively) (Figure 2).

Next, we classified the "reactive" donations for serological assays or NATs according to gender (female vs. male), type of donors (first-time vs. returning donors), and category of donations (replacement vs. volunteer) (Table 4) or according to blood group (Table 5). The majority of cases was associated with male, first-time, replacement, blood group O+ donors, although this can also be because most donations received during the study period belonged to these categories (Table 2).

DISCUSSION

The screening of all blood donors for blood-borne diseases such as hepatitis B, hepatitis C, HIV, HTLV, syphilis, and malaria is essential to increase the safety and accessibility of blood for transfusion. Therefore, all blood transfusion services undertake quality-assured screening of all donors for TTI markers [1,2]. It is the core component of every national blood program to ensure that all relevant national and international policies are considered [2].

Currently, there is a lack of comprehensive large-scale retrospective studies addressing the prevalence of TTIs among blood donors in the Saudi Arabia. Besides, there is a lack of knowledge about the adherence and compliance of the blood donation centers to the current protocol of testing. In the current study, the data of blood donors who visited the SFH in the western region of Saudi Arabia between January 1, 2015 and December 31, 2018, were analyzed to improve our understanding of the current status of adherence to TTI testing policy and TTI prevalence rates in the country (Table 2 and Figure 1).

Apart from malaria, all other TTIs were detected in this study population (Table 3). Reactivity to HBV ranked topmost with HBsAg being serologically detected in 57 (1.04%) and HBV DNA being detected in 50 (0.91%) donors. The percentages were higher with other HBV serological parameters with HBsAb and HbcAb detected in 292 (5.34%) and 388 (7.1%) donors, respectively. These data suggest the presence of acute, past, chronic, and occult infections among the blood donors in addition to immunized individuals. Our findings correlate with previous reports that estimated the HBsAg seroprevalence range to be between 1% and 3% among blood donors in several cities/regions in Saudi Arabia [8,9,13-15]. Also, the prevalence of HBsAg among donors in our study (1.04%) is comparable to that reported from neighboring countries 1.18% Egypt, 0.9% Lebanon, and 2.8% Oman. However, the prevalence of HBSAb (5.34%) is remarkably lower than that observed in Iran (31.9%) [16-19]. In 1988, the first large-scale epidemiological study in Saudi Arabia reported that > 70% of Saudi children were positive to at least one HBV marker [20,21]. The massive decline in the prevalence rate observed in recent years is highly likely because of the introduction of HBV vaccine to the Saudi infants/children immunization program in 1990 [21,22].

The seroprevalence of anti-HCV was 0.24% (13 donors) in this study; only a single donor tested positive by NAT confirming a case of active HCV infection (Tables 3). These numbers are low in comparison to neighboring counties such as Egypt which reported a 3.5% prevalence rate [23]. Over two decades ago, the seroprevalence of anti-HCV was reported to be 3.6% among blood donors in the western region of Saudi Arabia [11]. A later study conducted in the eastern region reported a steady decrease in the number of reactive donors to anti-HCV from 1.04% in 1998 to 0.59% in 2001 [12]. Very recently, 12 (0.40%) of the 3,028 blood donors in Majmaah, Saudi Arabia, tested reactive to the HCV screening serology test [9]. The present study's findings combined with these previously published studies highlight a decreasing trend in the number of HCV-positive blood donors in Saudi Arabia. This number is expected to continue to decrease in the future with the current services provided by the Ministry of Health such as infectious disease premarital screening, TTI testing, and free HCV treatment [2,24-26].

Five donors tested were reactive to the HIV serology test (0.09%). NAT confirmed three cases of HIV infection (Table 3). The status of the other two cases were undetermined although they are likely false-positive serological results. We found it interesting to continue screening serology tests in the presence of highly sensitive and specific NAT tests. It is important to assess the cost-effectiveness of the current practice and propose changes, if necessary, without jeopardizing the safety of blood transfusion. Regardless, the prevalence rate of HIV infection in our study correlates with previous reports from other regions [9,27]. These rates demonstrate a low overall prevalence of HIV infection among blood donors in Saudi Arabia in comparison to reports from other countries (e.g., Ethiopia, India, and Brazil) [28-30].

The number of donors who tested reactive to syphilis and HTLV-1/-2 were 21 and 8, respectively (Table 3). However, none of them were confirmed and their statuses remain undetermined. The low prevalence of HTLV-1 and -2 among blood donors in Saudi Arabia (0.15%) has been repeatedly reported in many studies [9,10,15,31-33]. Besides, all blood units in SFH are subjected to leukocyte depletion prior to transfusion which should greatly minimize the risk of HTLV trans-

mission [34,35]. We support the previous discussion raised by Hindawi et al. in 2018 to selectively conduct HTLV-1 and -2 screening for donors at high risk of infection (e.g., donors from endemic areas such as Iran, and many west African and south American countries) [10,36]. In fact, some countries such as Finland and Norway have already omitted HTLV screening or only selectively perform it in the case of first-time donors [37]. However, prior to adopting this practice in Saudi Arabia, it is of great importance to confirm the availability and efficacy of the current leukocyte depletion system [10].

We did not detect any malaria cases among the blood donors (Table 3). Similar findings were previously reported in another region of Saudi Arabia [9]. Data pertaining to malaria were missing in other studies [12,13, 15,27]. We believe that screening for malaria should be continued at the moment, along with close monitoring and investigation of the number of cases among blood donors in different regions across the country. The continuous absence of cases may require an adjustment to the current policy of TTI testing as this would enhance cost-effectiveness.

Despite the important findings of the study, certain limitations should be addressed. One of them is the fact that this is retrospective research based on information from a blood donation center. The research was confined to the information included in these records, which included tabulated results of screening tests and basic demographic information. Because population data for all fundamental demographic categories were not available, some of the analysis that accounted for population fluctuations was limited. Furthermore, the research would have benefitted from a larger time frame than the existing one. Finally, because the donation data are not linked to the medical records, it was unable to analyze the fate of donors who tested positive for any of the viruses.

Overall, this study demonstrated a strong adherence and compliance to the TTI screening policy, a high safety profile of blood transfusion, and low prevalence rates of TTIs in the western region of Saudi Arabia. However, data were obtained from a single donation center which may not represent the status on the national level. Further assessment and comparison of TTI prevalence rates among blood donors between different cities/regions may propose an adjustment or customization of testing in every donor/region in the future.

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Declaration of Interest:
The authors listed in this manuscript certify that they are not affiliated or involved in any organization or entity with any financial interest (such as honoraria, educational grants, participation in speakers' bureaus, membership, employment, consultancies, stock ownership, or other equity interest, and expert testimony or patent-licensing arrangements); or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical Approval:
The present study was approved by the Institutional Review Board of SFH (registration number: 0211-1208 18).

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