

Frequency and Association of Transfusion-Transmissible Infections with Type of Blood Donors in A Regional Transfusion Center

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ABSTRACT

Objective: To ascertain the frequency and association of transfusion-transmissible infections (TTIs) with type of blood donors in a regional transfusion center.

Study Design: Cross sectional study.

Place and Duration of Study: Armed Forces Institute of Transfusion (AFIT), Rawalpindi Pakistan from Jan 2019 to Dec 2022.

Methodology: A total of 275,014 donors were registered during study period. Donors were categorized according to the International Standards of Blood Transfusion, into voluntary non-remunerated blood donors (VNRD) and family-replacement donors (FRD) and into first-time donors and repeated donors respectively. All blood donors were screened for hepatitis B, hepatitis C, human immunodeficiency virus I and II and syphilis through chemiluminescent microparticle immunoassay and nucleic acid amplification test respectively. Data was analyzed using the Statistical Package for the Social Sciences version 23.00 and MS Excel 2016 software.

Results: The frequency of TTIs among blood donors was 3.2%. The overall frequency of TTIs among FRD was 3.1% as compared to 0.2% in VNRD. The frequency of TTI among first-time donors was 2.9% in contrast to 0.3% in repeated donors. The most prevalent TTI was HCV (1.5%) followed by HBV (0.9%), syphilis (0.7%) and HIV (0.13%) respectively.

Conclusion: TTI frequency was high in FRD and first-time donors as compared to VNRD and repeated donors respectively. HCV was the most prevalent TTI in our study. Repeated voluntary donors have least number of TTI in this study. There was statistically significant association of TTIs p-value < 0.05 with different types of blood donors.

Keywords: Blood borne pathogens, Blood Donors, Chemiluminescence, Hepatitis, HIV, Nucleic acid amplification techniques.

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INTRODUCTION

Blood donation is an invaluable act that has the power to save lives, enhance well-being, and decrease mortality rates. The availability of safe blood in a timely manner poses a significant obstacle, particularly in developing nations, for healthcare organizations. However, this obstacle can be surmounted by ensuring a sufficient and sustainable supply of safe blood through the participation of voluntary non-remunerated blood donors (VNRD).¹ Every day, numerous lives have the potential to be preserved through voluntary blood donation.² VNRD are essential for ensuring the safety and sustainability of national blood supplies. Systems relying on family-replacement donors (FRD) pose high threat of TTIs. Currently only 10-13% of blood donations in Pakistan are voluntary.³ The safety of blood transfusions is influenced by the diverse blood donor recruitment policies implemented worldwide, resulting in

significant variations.⁴ The World Health Organization (WHO) recommended the quality-assured screening of all donated blood for at-least four transfusion-transmissible infections (TTIs), including hepatitis C (HCV), hepatitis B (HBV), human immunodeficiency virus I and II (HIV) and syphilis to ensure provision of safe and efficacious blood.^{1,5} Pakistan, being a developing nation, is undergoing a reformation of its blood transfusion system that necessitates the establishment of a network of regional blood transfusion centers throughout the country, accompanied by the recruitment and training of competent and knowledgeable staff.^{6,7} Systematic review of 33 studies showed high frequency of TTIs (2.5% to 12%) in studies with predominance of FRD in comparison to the studies with a high number of VNRDs (1.57% to 6.2 %).⁸ The frequency of TTIs was reported to be higher in replacement donors as compared to voluntary donors in other studies from Pakistan, India and Eritrea.^{7,9,10}

The patterns of TTIs can reveal the existence of hidden infections in seemingly healthy individuals

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within the general population. To the best of our knowledge, there have been no published studies in our region that provide detailed insights into the frequency and association of TTIs among different types of blood donors. Consequently, the present study was conducted with the objective to ascertain the frequency and association of TTIs with type of blood donors in a regional transfusion center during study period. The findings from this study will offer valuable data for improving donor selection policies and developing preventive and control strategies, thereby enhancing and optimizing the safety of blood transfusion services.

METHODOLOGY

This cross-sectional study was conducted in the Armed Forces Institute of Blood Transfusion (AFIT) Rawalpindi, Pakistan from January 2019 to December 2022 after receiving approval from the Ethical Review Board (AFIT-ERC-18-060). Informed consent was obtained from all eligible donors prior to their inclusion in the study. Sample size was calculated using WHO sample size calculator, using relative precision of 0.01, 99% confidence level and 0.20 anticipated population proportion of voluntary non-remunerated donors (VNRD).³ Estimated sample size was 265,396 which was exceeded during the study period and a total of 275,014 eligible blood donors were included in the study.

Inclusion Criteria: Donors of either gender with age ranging from 18 to 60 years, weighing more than 50 kg, and meeting the institutional blood donation criteria as determined by a standard donor history-based questionnaire, initial general physical examination, and pre-donation blood complete picture, were included in the study.

Exclusion Criteria: Donors who did not meet the institutional standards due to a positive history of any TTI or any other chronic disease, present history of fever or dental procedures or vaccination within the past 1-4 weeks, consumption of narcotic drugs, or involvement in extramarital sexual relations were excluded from the study.

Donors were categorized according to the International Standards of Blood Transfusion, based on their intend of donation, into two groups: voluntary non-remunerated blood donors (VNRD) and family-replacement donors (FRD). They were also classified according to the frequency of their donations as either first-time donors or repeated donors. VNRD were blood donors who willingly donated blood out

of humanitarian motives, without receiving any form of payment from the collecting facility or any other source. FRD were those who donated blood when a family member or someone from their community required it. First-time donors were characterized as individuals donating blood for the first time, whereas repeated donors were those who donated blood more than once. Furthermore, both first-time donors and repeated donors were subcategorized into first-time voluntary donors, first-time repeated donors, repeated voluntary donors, and repeated replacement donors, respectively. In the computerized Blood Bank Management Information System, a comprehensive profile including the year of donation, age, gender, type of donor and screening results were recorded for each qualified blood donor.

A 6 ml blood sample was collected from each donor. The blood samples underwent initial screening using chemiluminescent microparticle immunoassay (CMIA) on an automated immunoassay analyzer (Architect Plus i 2000 SR, Abbott Diagnostics, Abbott Park, IL) using the corresponding test kits from Abbott Diagnostics (HBsAg qualitative kit, anti-HCV kit, HIV I and II p24 Ag/Ab Combo kit, and syphilis TP kit). In cases where the initial screening showed positive results, the samples were retested in duplicate to rule out contamination and to confirm findings. Donor samples that tested reactive were separated and disposed of through incineration. To ensure quality control, internal positive and negative controls from the test kits, as well as third-party controls such as (VIROTROL 1 BioRad) were run with each test batch.

For initially seronegative cases nucleic acid amplification test (NAT) was performed on the Grifols Procleix Panther System using Ultra Elite kit and MPX Cobas Kit on the Roche Cobas 6800 platform. This test was specifically done to detect early infections during the window period. Any positive donor samples and blood components were identified and disposed of through incineration. Throughout the process, strict measures were taken to ensure quality control. This involved running kit positive and negative controls alongside each batch of tests. In cases where positive results were obtained, the affected blood donors were promptly notified on telephone and provided guidance to seek further medical assistance. Donor confidentiality was maintained throughout all the procedures.

The data analysis was conducted using the Statistical Package for the Social Sciences (SPSS)

version 23.00 and MS Excel 2016 software. For continuous variables, the mean \pm standard deviation (SD) was calculated. Categorical variables were analyzed by determining their frequency and percentages. To examine the association of TTI, Fisher's exact test was used when any frequency in 2x2 contingency table is less than 5 alternatively chi-square test was employed when any frequency is more than 5. A significance level of $p \leq 0.05$ was considered as statistically significant.

RESULTS

A total of 275,014 donors were registered at AFIT during study period. The highest number of donors were reported in 2021 with 78,392 donors (28.5%), followed by year 2022 with 76,531 donors (27.8%), 2019 with 60,572 donors (22.0%) and 2020 with 59,519 donors (21.6%). The mean age of the donors was 30.46 ± 7.08 years, ranging from 18 to 60 years. Out of the total donors, 272,909 (99.2%) were male, and 2,105 (0.8%) were female. Among the donors, the majority belonged to the FRD group, accounting for 258,784 donors (94.1%). The VNRD group constituted a smaller portion, with 16,230 donors (5.9%). Of the total donors, 203,890 (74.1%) donated for the first-time, while 71,124 (27.4%) were repeated donors. Out of 203,890 first-time donors 194,645 (70.8%) were first-time replacement donors and 9245 (3.4%) were first-time voluntary donors. Among 71,124 repeated donors 64,139 (23.3%) and 6985 (2.5%) were repeated replacement donors and repeated voluntary donors respectively. Detailed characteristics of the different types of donors can be found in Table I.

Frequency of TTIs among blood donors was 3.2% (8,998/275,014). The most prevalent TTI was HCV 4,232 (1.5%) followed by HBV 2,450 (0.9%), syphilis (1,949, 0.7%) and HIV 367 (0.13%) respectively. Among TTI positive cases majority of donors were FRD accounting for 8,554 (95%) whereas only 444 (5%) TTI positive cases were VNRD. The overall frequency of TTIs among FRD was 3.1% (8,554/275,014) as compared to 0.16% (444/275,014) in VNRD. About 8,137 (90.4%) TTI positive donors donated blood for first time and only 861 (9.6%) were repeated donors. The overall frequency of TTI among first time donors was 2.9% (8137/275,014) as compared to 0.3% (861/275,014) in repeated donors. Trends of TTIs in various donor groups was shown in Table- II.

The frequency of TTIs was high in first time replacement donors (7,768, 86.3%) followed by

repeated replacement donors 787 (8.7%), first time voluntary donors 369 (4.1%) and repeated voluntary donor group (74, 0.8%) respectively. The most prevalent TTI among first time replacement donors was HCV (3,661/3,840) followed by HBV (2,212/2,317), syphilis (1,600/1,666) and HIV (295/314) respectively. First time voluntary donors also follow same trend with HCV (179/3,840), HBV (105/2,317), syphilis (66/1,666) and HIV (19/314) respectively. As far as repeated replacement donors were concerned trend of TTIs was same with HCV leading with (361/392), the only exception observed in this category of donors was that syphilis (252/283) was more prevalent than HBV (124/133) and the least prevalent TTI was HIV (50/53) as observed in other categories. The repeated voluntary donor group with least number of TTIs 74/ 275,014 (0.02%) followed similar trend of TTIs as repeated replacement group with HCV (31/392), syphilis (31/283), HBV (9/133) and HIV (3/53) respectively. Association of TTIs with various types of donors was shown in Table III.

Table-I: Characteristics of Types of Donors (2019- 2022) (n=275,014)

	FRD n=258,784 (94.1%)	VNRD n=16,230 (5.9%)	First Time Donors n=203,890 (74.1%)	Repeat Donors n=71,124 (25.9%)
Years				
2019	56,417 (21.8%)	4,155 (25.6%)	46,285 (22.6%)	14,287 (20.0%)
2020	55,726 (21.5%)	3,793 (23.4%)	44,653 (22.0%)	14,866 (21.0%)
2021	74,133 (28.6%)	4,259 (26.2%)	58,133 (28.5%)	20,259 (28.4%)
2022	72,508 (28.0%)	4,023 (24.8%)	54,819 (26.9%)	21,712 (30.5%)
Age(years)				
≤ 20	78 (0.01%)	4 (0.01%)	65 (0.03%)	17 (0.02%)
21 - 29	132,963 (51.4%)	7,502 (46.2%)	107,290 (53.0%)	33,176 (46.6%)
30 - 39	99,078 (38.3%)	6,347 (39.1%)	75,468 (37.1%)	29,957 (42.1%)
40 - 49	23,143 (8.9%)	1,869 (11.5%)	18,049 (8.8%)	6,969 (9.8%)
>49	3,522 (1.4%)	508 (3.1%)	3,018 (1.4%)	1,005 (1.4%)
Gender				
Male	256,985 (99.2%)	15,924 (98.1%)	202,173 (99.1%)	70,736 (99.4%)
Female	1,799 (0.8%)	306 (1.9%)	1,717 (0.8%)	388 (0.5%)

Family-replacement donors: (FRD) Voluntary non-remunerated blood donors: (VNRD)

Table II: Trends of Transfusion-Transmissible Infections among Types of Donors (n=275,014)

	Type of Donors			
TTIs Positive Donors n=8,998(3.2%)	FRD n=8,554 (95%)	VNRD n=444 (5%)	First time Donors n=8,137 (90.4%)	Repeated Donors n=861 (9.5%)
Hepatitis C Virus (HCV)	4,021(47.0%)	211 (47.5%)	3,840 (47.1%)	392 (45.5%)
Hepatitis B Virus (HBV)	2,336(27.3%)	114(25.6%)	2,317(28.4%)	133 (15.4%)
Syphilis	1,852(22.0%)	97(21.8%)	1,666(20.4%)	283 (32.9%)
Human Immunodeficiency Virus (HIV)	345(4.0%)	22(5.0%)	314(3.8%)	53(6.1%)

Transfusion-Transmissible infections: TTIs, Family-replacement donors: (FRD), Voluntary non-remunerated blood donors: (VNRD)

Table-III: Association of TTIs with Types of Donors (n=275,014)

	FRD n=258,784	VNRD n=16,230	p-Value	First time Donors n=203,890	Repeated Donors n=71,124	p-Value
TTI Positive n=8,998(3.2%)	8,554 (3.3%)	444 (2.7%)	<0.001	8,137 (4.0%)	861 (1.2%)	< 0.001
TTI Negative n=266,016(96.7%)	250,230 (96.7%)	15,786 (97.3%)		195,753 (96.0%)	70,263 (98.8%)	

Transfusion-Transmissible infections: TTIs, Family-replacement donors: (FRD), Voluntary non-remunerated blood donors: (VNRD)

DISCUSSION

Transmission of TTI is a major health care challenge that requires thorough research and necessary interventions to enhance safe blood transfusions.¹¹ Out of 275,014 donors included in our study 94.1% donors were FRD and only 5.9% donors were VNRD. Another study conducted in Rawalpindi also showed predominance of FRD (90.10%) as compared to VNRD (9.9%).¹² Similar studies in Pakistan, conducted by Arshad and Saeed et al. in Karachi and Lahore, respectively have come up with similar trends.^{13,14} In contrast studies conducted in other countries like India and Brazil showed high frequency of voluntary donors about 65.3% and 79.3% respectively.^{15,16} One possible reason for predominant family replacement donors in contrast to voluntary donors is the lack of awareness about the importance and benefits of voluntary blood donation. There might be misconceptions or fears surrounding blood donation process and potential side effects that discourage individuals from participating. The

infrastructure for voluntary blood donation may be limited, making it more convenient for individuals to rely on family members for blood transfusion needs.¹⁷ A study conducted by Berhanu *et al.*, identified that negligence, lack of information, lack of convenient donation sites, fear and lack of opportunity were important predictors of voluntary blood donation.¹⁸

In this study 74.1% were first time donors and only 27.4% were repeated donors. Our findings were consistent to another study that also showed that first-time donors are the most common donors in blood transfusion centers.¹⁹ However contrary to this study high frequency of repeated donors (73.5%) as compared to first time donors (24.46%) was reported by another study conducted by Niazkar *et al.*, in South West Iran.²⁰

The frequency of TTIs in our study was 3.2% which is in line with 3.5% TTI frequency reported in another study conducted in Rawalpindi by Ghazanfar

S *et al.*,¹² However, it is comparatively low as compared to other studies conducted in Peshawar (4.6%)⁸, Lahore (5.46%)¹⁴ and Karachi (5.8%).¹³ The overall frequency of TTIs among FRD reported in this study was 3.1% as compared to 0.16% in VNRD. Similar to this study another study conducted in Peshawar also reported high frequency of TTI in replacement donors (5.42%) in contrast to VNRD (3.9%).⁸ A study conducted in Tanzania also reported similar trends.²¹ This might be because first-time donors have not been previously screened for bloodborne infections, while repeated donors undergo regular screening processes. Moreover, repeated donors have an altruistic behavior and feel responsible for the safety of blood-group recipients.

The most prevalent TTI in our study was HCV (1.5%) followed by HBV (0.9%), syphilis (0.7%) and HIV (0.13%) respectively. Similar to our study systemic analysis of 33 studies conducted by Hamid et al. also showed similar trends of TTI with HCV (2.44%) leading followed by HBV (2.04%), syphilis (1.1%) and HIV (0.038%) respectively.⁸ Another study

conducted by Marini *et al.*, also reported HCV as a most common TTI (0.1%) followed by HBV (0.03%) in donor pool.²² HCV was most prevalent in blood donors due to its high frequency in the general population. HBV has comparatively less frequency due to its vaccination on mass scale.

Repeated voluntary donors have least number of TTIs 0.02% in this study. Repeated voluntary donors should be given priority for blood donations due to their reliability, safety, contribution to a consistent supply and improved quality of blood components. Altruism, social recognition, convenient donation arrangements and positive donation experiences as key motivators for repeat blood donation.²³ In today's modern era use of digital technologies like SMS messages, web-based short videos based on the extended theory of planned behavior can also improve re-donation rates.²⁴

LIMITATION OF STUDY

Despite large sample size this study was conducted in a single regional transfusion center so results cannot be generalized. Moreover, our study included mostly family replacement donors and first-time donors due to regional donation practices, therefore study sample may lack equal representation of donor population.

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CONCLUSION

The frequency of TTIs in this study was 3.2%. TTI frequency was almost twice in FRD as compared to VNRD. TTI frequency was high in first time donors in contrast to repeated donors. HCV was the most prevalent TTI in our study. Repeated voluntary donors have least number of TTI in this study. There was statistically significant association of TTIs with different types of blood donors. By integrating these valuable findings into donor selection policies and preventive strategies, blood banks and public health authorities can significantly reduce the frequency of TTIs. Prioritizing voluntary and repeat donors, enhancing screening processes, and implementing targeted educational initiatives will lead to safer blood supplies and better overall public health outcomes.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

NS & FA: Data acquisition, data analysis, critical review, approval of the final version to be published.

TG & RL: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SA & SF: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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