IJPSR (2025), Volume 16, Issue 1 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 30 November 2024; received in revised form, 21 December 2024; accepted, 22 December 2024; published 01 January 2025

ESTIMATE THE SEROPREVALENCE OF TTI IN BLOOD DONORS AND COLLATE THE RISK OF TTI BETWEEN VOLUNTARY DONORS AND REPLACEMENT DONORS

V. Sivaranjani [*1], R. Sreedevi [1], T. Anitha [2] and N. Meharaj [3]

Department of Transfusion Medicine [1], Tamil Nadu Government Multi Superspeciality Hospital, Chennai - 600002, Tamil Nadu, India.
Department of Transfusion Medicine [2], Chengalpet Medical College and Hospital, Chengalpet - 603001, Tamil Nadu, India.
Bharat Medical College and Hospital [3], Tambaram - 600073, Tamil Nadu, India.

Keywords:

Seroprevalence, Transfusion transmitted infections, Hepatitis B virus, Hepatitis C virus, Human immunodeficiency virus

Correspondence to Author:
V. Sivaranjani

Senior Assistant Professor, Department of Transfusion Medicine, Tamil Nadu Government Multi Superspeciality Hospital, Chennai - 600002, Tamil Nadu, India.

E-mail: sivaranjanis1982@gmail.com

ABSTRACT: Introduction: The goal of BTS (Blood Transfusion Service) is to provide safe and quality blood and blood products to needy patients. In developing and underdeveloped countries, there exists a gap between the demands and supply of blood products. Since 100% voluntary blood donation is not achieved, we rely on replacement donors also. Hence this study was attempted to assess the seroprevalence of TTI (transfusion-transmitted infection) in blood donors and to compare the seroreactivity rate between voluntary and replacement donors. **Materials and Methods:** This retrospective study was done on the blood donors over the period of 4 years from January 2020 to December 2023 in a tertiary care hospital. Donor samples were screened for the five mandatory TTIs, viz., HIV (human immunodeficiency virus), HBV (hepatitis B virus), HCV (hepatitis C virus), syphilis, and malaria. **Results:** A declining trend in HBV was evident from 2020 to 2023. Prevalence of syphilis was highest in 2022. No marked change noted with HIV and HCV. The TTI rate in non-remunerated voluntary blood donors (NRVBD) was 1.06%, and in replacement donors (RD) it was 1.04%. No statistical significance found between the NRVBD and RD with regard to seroprevalence of HIV, HBV, HCV, and syphilis or overall prevalence of TTI. **Conclusion:** Replacement or Unpaid family donors can be accepted by following strict donor criteria, thorough pre-donation counseling, promotion of self-exclusion of donors with high-risk behavior, and practicing more sensitive TTI screening techniques.

INTRODUCTION: Blood transfusion is inevitable in the field of medicine. Blood banking is involved in the process of collection, processing and issue of safe and quality blood products to the needy patients.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(1).227-33

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(1).227-33

Comprehensive legislation to ensure quality control on collection, testing, storage, distribution and infusion of blood and blood components was formulated by the Drug Controller General of India [1].

WHO estimates that blood donation by 1% of the population is generally the minimum needed to meet a nation's most basic requirements for blood [2]. In India, there are huge variations in the estimated demand, supply and utilization of blood and blood products due to the low volume of

voluntary blood donation, lack of awareness, irrational demand, poor supply chain management system etc [3]. The demand for blood in developing countries is to support acute hemorrhage during pregnancy-related complications, new-born care especially in pre-term infants, management of sepsis, hemorrhagic disease of the new-born, chronic anemia, HIV (Human immunodeficiency virus) related anemia, micronutrient deficiencies etc [4].

Non-remunerated Voluntary donors (NRVBD) are recognized to be the safest donors because they are motivated by altruism and the desire to help others and by a sense of moral duty or social responsibility. A number of studies have reported significantly lower prevalence of transfusion-transmitted infection (TTI) markers among voluntary donors compared with other types of donors [5]. In South Asia region, Singapore blood services reported a declining trend of blood donors that could potentially cause challenges to face demand that was growing at 3-5%. However, in many countries, this was paralleled by reduced clinical demand through modern technologies and blood-less procedure [6]. Because of the gap in demand and supply, blood centers in India are also dependent on replacement donors (RD).

In India, mandatory screening test for blood and its products before transfusion are for HIV, HBV (Hepatitis B virus), HCV (Hepatitis C virus), Malaria and Syphilis [7]. Blood for transfusion is also a potentially scarce resource with significant risks as a biological material, including transfusion-transmitted infections [8]. Evaluation of data on the incidence of TTIs among blood donors permits an assessment of the accurate estimation of risk of TTIs, which helps in the formulation of long-term strategies to improve public health and to prevent spread of disease in local population [9]. Despite effective strategies and plans, disease transmission still occurs due to the high cost of screening, lack of trained staff, laboratory testing errors, and the inability of the test to detect the disease in the window period of infection [10].

Hence, we formulated a study to assess the seroprevalence of TTI in blood donors in the past 4 years and to compare the TTI positivity rate between voluntary and replacement donors.

The study provides the burden of TTI in the healthy population and helps us to assess the reliability of RD as a blood donor.

Aim: To determine the seroprevalence of TTI-HIV, HBV, HCV, Syphilis and malaria in blood donors during a period of 4 years in a tertiary care hospital. To compare the TTI positivity rate between NRVBD and RD.

MATERIALS AND METHOD: This retrospective study includes all the eligible NRVBD (both in-house and camp) and RD over the period of 4 years from January 2020 to December 2023 in a tertiary care hospital. The donors were requested to fill in the donor questionnaire properly, and we provided pre-donation counseling followed by a thorough physical examination. Informed consent was obtained from all the donors that their blood will be tested for the five mandatory TTIs and whether they wish to be informed about a reactive test result or not. Donors were free to self-defer if they had any risk behavior that was mentioned in the donor questionnaire.

The pilot sample was subjected to TTI screening for HIV, HBV, HCV, syphilis, and Malaria.

Human Immunodeficiency Virus (HIV) Serology: Fourth Generation ELISA was used to diagnose HIV antibodies to HIV-1 and HIV-2.

Hepatitis B Virus (HBV) Serology: Third Generation ELISA was used to diagnose Hepatitis B surface Ag (HBsAg).

Hepatitis C virus (HCV) Serology: Third Generation ELISA was used to diagnose anti-HCV antibodies.

Syphilis Serology: Rapid plasma reagin testing or venereal disease research laboratory.

Malaria: Rapid Card Test: If any of the samples was found positive in duplicate (one with the pilot tube sample and the other from the blood bag sample), then the donors were called for post-donation counseling. As per the TTI screen positivity, the donors were referred to the respective department of the hospital for further management.

Donor, if not responding to the first call, we had contacted through phone for another 2 times. Again, if there was no response, we had notified through the letter. The donors who did not respond to these notifications were considered non-responders. In each and every step we maintained confidentiality. In the letter communication, we informed them that their test result was abnormal and requested them to report to the blood bank. A TTI seroreactive donor follow-up register is maintained, in which the donor's personal details were entered.

Statistical Analysis: Data were analyzed using the SPSS (version 15) statistical software package under the Windows 7 operating system for IBM-compatible PC. The graphic presentation was achieved using Excel 2010 software. Qualitative data were described as numbers and percentages and were compared between the two groups of donors using the chi-square test. Results were considered statistically significant when the P value was <0.05 and highly statistically significant when the P value was <0.001.

RESULTS: Total number of donations from January 2020 to December 2023 was 38,770, with 38,163 male donors (97.53%) and 607 female donors (2.46%) **Table 1**. The voluntary donations and replacement donations were 25,536 (65.86%) and 13,234 (34.15%), respectively. The yearly distribution of NRVBD and RD was depicted in **Fig. 1.** Among the 25,536 voluntary donations, 24,456 donors were outdoor camp donors, and the remaining 1,080 were in-house donors. In these total donations (38,770), repeat donors were 28,432, and first-time donors were 10,338.

Nearly 23 donors who came for in-house donation had self-excluded after pre-donation counseling.

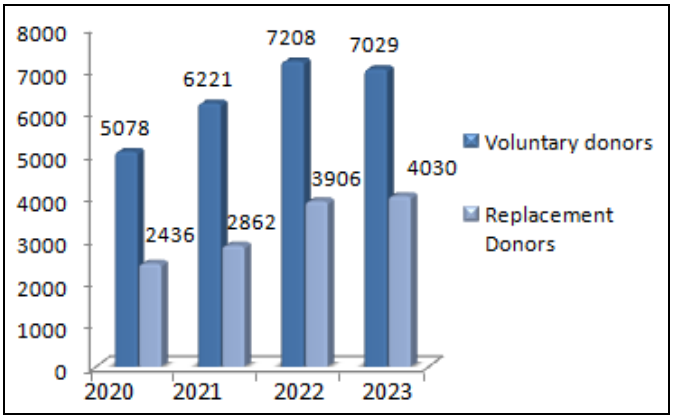

FIG. 1: YEARLY DONOR DISTRIBUTION

TABLE 1: SEX DISTRIBUTION IN DONORS

Year	Males	Females
2020	7428	86
2021	8978	105
2022	10920	194
2023	10837	222
Total	38163 (98.43%)	607 (1.57%)

Total numbers of TTI-positive donors were 408 (1.05%). First-time donors had higher TTI positivity rate (1.66%) than repeat donors (0.83%) with the statistical significance of p-value at 0.000. The prevalence of TTI in male and female donors was 1.06% and 0.329%. Among the TTI-positive donors, 406 were males and 2 were female donors. Both TTI-positive female donors had HBV. The prevalence of HIV, HBV, HCV, and syphilis was 0.043% (17), 0.74 % (286), 0.103% (40), and 0.167% (65), respectively **Table 2**. Since all donors were negative for malaria, we had excluded it from analysis.

TABLE 2: PREVALENCE OF TTI – HIV, HBV, HCV AND SYPHILIS IN EACH YEAR

Year	HIV	HBV	HCV	Syphilis	TTI-positivity rate
2020	02	69	11	03	1.13%
2021	01	72	07	05	0.93%
2022	07	81	10	43	1.26%
2023	07	64	12	14	0.87%
Total	17 (0.043%)	286(0.74%)	40(0.103%)	65 (0.167%)	

TABLE 3: PREVALENCE OF TTI – HIV, HBV, HCV AND SYPHILIS IN NRVBD AND RD

Year	HIV- V	HIV-R	HBV-V	HBV-R	HCV-V	HCV-R	Syphilis-V	Syphilis-R
2020	2	-	42	27	6	5	2	1
2021	1	-	51	21	4	3	3	2
2022	4	3	58	23	7	3	30	13
2023	5	2	39	25	8	4	9	5
Total	12	5	190	96	25	15	44	21

V-voluntary donors; R-Replacement donors.

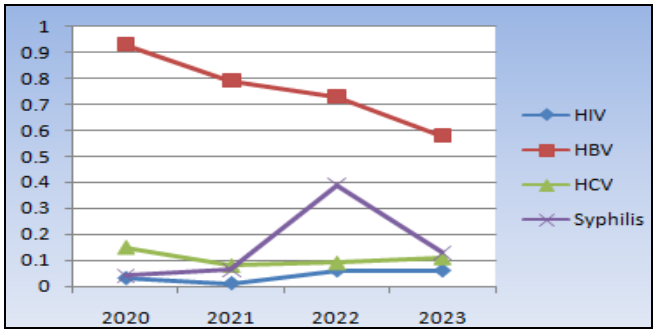

FIG. 2: TREND IN SEROPREVALENCE OF TTI – HIV, HBV, HCV AND SYPHILIS IN 4 YEARS PERIOD

The number of donors increased gradually from 2020 to 2023, and the seroreactivity decreased over the years except for the year 2022 due to the higher prevalence of syphilis **Fig. 2.** The prevalence of HBV was the highest among all TTI in the consecutive 4 years, and a changing trend in syphilis reactivity had been noted in 2022, with the highest prevalence of 43 donors **Table 2.** The total number of TTI-positive donors in NRVBD was 271, and in RD it was 137 **Table 3.** The TTI rate in NRVBD was 1.06%, and in RD was 1.04%. No significance was found between NRVBD and RD when comparing the overall TTI positivity rate and specific TTI positivity rate **Table 4.** The trends of specific TTI between NRVBD and RD during the study period were shown in **Fig. 3-6.**

TABLE 4: SPECIFIC TTI POSITIVITY RATE IN NRVBD AND RD AND COMPARED WITH CHI-SQUARE (X^2) TESTING

		NRVBD	RD	X^2	p-Value
HIV	Positive	12 (0.047%)	5 (0.038%)	0.17	0.68
	Negative	25524 (99.95%)	13229 (99.96%)		
HBV	Positive	190 (0.744%)	96 (0.73%)	0.041	0.84
	Negative	25346 (99.25%)	13138 (99.27%)		
HCV	Positive	25 (0.098%)	15 (0.11%)	0.202	0.65
	Negative	25511 (99.9%)	13219 (99.89%)		
Syphilis	Positive	44 (0.172%)	21 (0.16%)	0.097	0.76
	Negative	25492 (99.82%)	13213 (99.84%)		
Overall TTI Rate	Positive	271 (1.06%)	137 (1.03%)	0.056	0.81
	Negative	25265 (98.93%)	13097 (98.96%)		
		Repeat donors	**First-time donors**		
	Positive	236 (0.83%)	172 (1.66%)	50.607	0.000
	Negative	28196 (99.16%)	10166 (98.33%)		

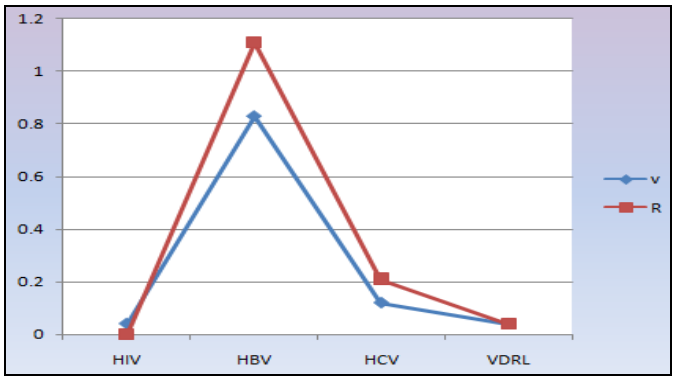

FIG 3: TTI POSITIVITY RATE IN NRVBD AND RD IN 2020. V-Voluntary, R-Replacement

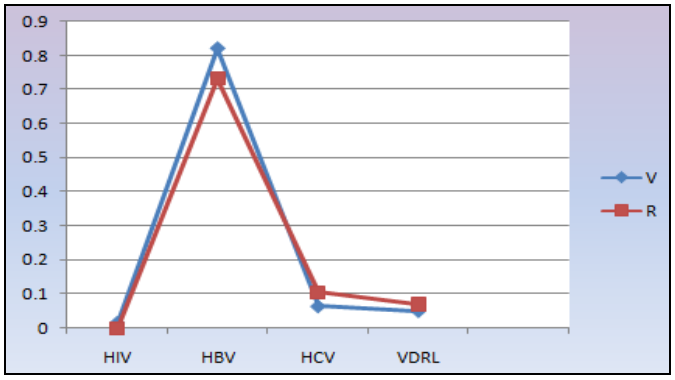

FIG. 4: TTI POSITIVITY RATE IN NRVBD AND RD IN 2021. V-Voluntary, R-Replacement

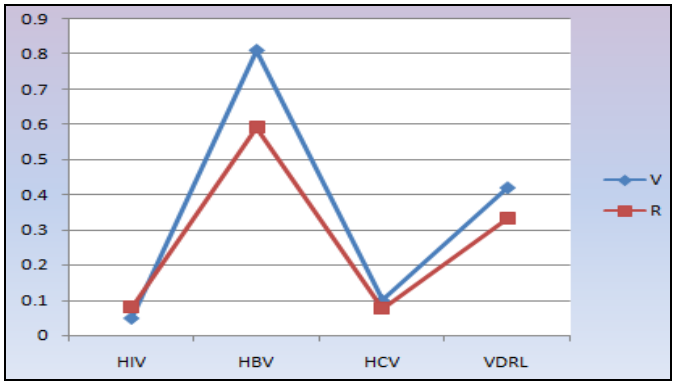

FIG. 5: TTI POSITIVITY RATE IN NRVBD AND RD IN 2022. V-Voluntary, R-Replacement

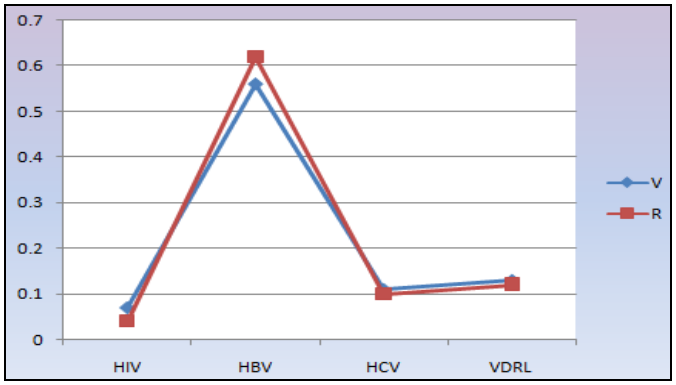

FIG. 6: TTI POSITIVITY RATE IN NRVBD AND RD IN 2023. V-Voluntary, R-Replacement

DISCUSSION: India, being a developing country, the need for blood and blood components was high since the demand always surpassed the supply. This had led us to depend on replacement or unpaid family donors. Developed countries indicated a decline in the collection and utilization of blood. In the United States, the overall blood collection declined by 9%, and the units of blood transfused dropped by 8.2% between 2008 and 2011[3]. However, the demand for blood and blood products seems to be still high in developing and underdeveloped countries. The study focused on assessing the seroprevalence of TTI among blood donors and comparing the seroreactivity among NRVBD and RD during a period of 4 years. In the total 38,770 donors, 38,163 donors (98.43%) were male donors, and the remaining were female donors (1.57%) **Table 1.** It was similar to other studies conducted by Nilam Hardik Patel et al. (95.93% were males and 4.06% were females), Chandekar, *et al*. (91.79% were males and 8.21% were female donors), and Jigna Patel et al. (97.3% were males and 2.7% were females) [10, 11, 12]. The major reason for deferral among female donors was low donor turnover and temporary deferral conditions like low hemoglobin values, underweight, and fear of pain. In the total donors, 65.86% were NRVBD and 34.15% were RD. Similar to our study, NRVBD was higher than RD in many Indian studies [9, 13]. The increase in voluntary donations was attributed to the increasing public awareness program and involvement of government bodies like NACO (National AIDS Control Organization) that actively propagate voluntary donation in our country. However, many recent studies have reported increased numbers of RD [8, 9, 12, 14]. This showed that RD was the largest group of blood donors in these regions.

The overall prevalence of TTI in total donors was 1.05%, and it was less when compared to other studies [8, 11, 12]. The prevalence of HIV, HBV, HCV, and syphilis was 0.043% (17), 0.74 % (286), 0.103% (40), and 0.167% (65), respectively **Table 2**. As in most other Indian studies HBV had the highest seropositivity rate [9, 12, 15]. A Decline in HBV seropositivity in donors was observed from 2020 to 2023. The lower prevalence of TTI in this study was attributed to large number of outdoor camps, proper pre-donation counseling, promoting self-exclusion of donors having risk behavior and proper TTI screening. Similar to the current study, low seropositivity for individual TTI (0.28% for HBsAg, 0.12% for HCV, 0.01% for HIV, and

0.004% for syphilis) and overall TTI prevalence (0.42%) was noted in a study by Adhikary M *et al.* [16]. In studies with an increased number of RD, the seroprevalence of individual TTI markers and overall prevalence of TTI were high [8, 12]. In contrary to that, a study by Cheema *et al.*, with higher unpaid family donors, reported a low overall TTI prevalence rate of 1.07% [14].

Statistical significance was found between repeat donors and first-time donors with respect to TTI prevalence, with an increased positivity rate in first-time donors. Similarly, TTI prevalence was high in first-time donors in some studies [13, 17]. This might be due to a lack of awareness about TTI among the donors, not revealing any high-risk behavior and window-period donations.

The prevalence of TTI in NRVBD was 1.06%, and in RD it was 1.04%. No statistical significance found between the NRVBD and RD with regard to seroprevalence of HIV, HBV, HCV, and syphilis or overall prevalence of TTI, whereas many studies showed a statistical significance between voluntary and replacement donors [10, 12, 17].

In these studies, the replacement or the unpaid family donors (RD) form the major donor pool; hence a significant difference was found in the TTI positivity rate between the two groups with high seropositivity among the RD. Whereas in a study by Tambse *et al.*, though the RD were lesser (8.37%) than voluntary donors (91.63%), TTI seropositivity rate was significantly high in the RD [18].

In the present study, no significant difference was found with regard to TTI positivity rate over the study period from 2020-2023 in the blood donors. Whereas in a study from 2001-2016 by Shrivastava *et al.*, the trend of percentage of seropositivity drastically decreased from 2001 to 2016 and it was statistically significant when the prevalence of HBV, HCV, HIV, and syphilis was compared. This was attributed to the achievement of 100% of voluntary blood donors since 2007 [17]. Low prevalence of TTI in RD in this study was attributed to strict donor criteria, proper pre-donation counseling, and allowing self-exclusion of donors with high-risk behavior and improved TTI screening techniques.

CONCLUSION: Blood donation by 1% of the population is generally taken as the minimum need to meet a nation's basic requirements for blood [2]. Though 100% voluntary blood donation is reiterated by WHO, developing countries like India are dependent on replacement donors also. In this study, 65.86% were voluntary donors and 34.15% were replacement donors, and we found no significant difference between the voluntary and replacement donors with respect to TTI seroreactivity. The mixed health care system with a huge proportion of unregulated private sector, changing epidemiological and demographic patterns, inequitable distribution of health services, and ever-increasing population size, and the estimation or forecasting of blood requirements in India has pose a challenge to maintain an adequate supply of safe blood and its products [3]. Hence, replacement or Unpaid family donors can be accepted by strict donor criteria, thorough pre-donation counseling, promoting self-exclusion of donors with high-risk behavior, and practicing more sensitive TTI screening techniques. By this way we can also increase the voluntary donors by creating proper awareness among the replacement donors and absorbing them into the donor pool. Hence it is essential to have a national blood policy in place to monitor the blood transfusion services, to implement more sensitive TTI screening assays like nucleic acid testing, and to form an integrated information system of TTI-positive blood donors in all blood centers.

ACKNOWLEDGEMENT: We acknowledge all the member staff of Dept. Of Transfusion Medicine, Tamil Nadu Government Multi Superspeciality Hospital, Chennai.

CONFLICT OF INTEREST: None of the authors has any type of conflict of interest regarding this study.

REFERENCES:

1. Drugs and Cosmetics Act 1940 and Rules 1945.Central Drugs Standard Control Organization, 7th Ed 2002.
2. WHO 2009b. GDBS Summary Report 2009: WHO Global Database on Blood Safety (GDBS) and Blood Safety Indicators. Geneva: World Health Organization.
3. National Estimation of Blood Requirement in India by National AIDS Control Organization (NACO), India, U.S. Centers for Disease Control and Prevention (CDC), New Delhi National Institute of Medical Statistics, India

Christian Medical College, Vellore, and Christian Medical Association of India (CMAI), India 2018.
4. WHO 2010b. WHO Experts' Consultation on Estimation of Blood Requirements 03 - 05 February 2010, WHO-HQ. Geneva: World Health Organization.
5. WHO Library Cataloguing-in-Publication Data: Towards 100% voluntary blood donation: a global framework for action. ISBN 978 92 4 159969 6 (NLM classification: WH 460).
6. Wong, Wendy 2018: Fewer youths donating blood in Singapore amid growing demand. Channel News Asis 2017 [cited 15th January 2018].
7. An Action Plan for Blood Safety: National AIDS Control Organization, Ministry of Health & Family Welfare, Government of India 2007.
8. Hassan Abdullahi Dahie, Mohamed Maalim Dakane and Nuradin Mohamed Mudei: Seroprevalence of transfusion transmissible infections (TTIS) among blood donors in SOS hospital Heliwa, Somalia. Heliyon 2024; 37905.
9. Singh P, Daiya M, Tandon SK, Puja, Bairwa S and Kalhan S: Seroprevalence of Transfusion Transmitted Infections among Blood Donors in Delhi, India - A 3 Years Retrospective Study. Ann Int Med Den Res 2017; 3(3): 10-13.
10. Nilam Hardik Patel, Jyoti Prakash Sapre, Kirti Nishant Vyas and Hitesha Nanjibhai Radadia: Seroprevalence of Transfusion Transmitted Infections among Blood donors at a Tertiary Care Hospital. Journal of Clinical and Diagnostic Research 2024; 18(2): 34-37
11. Sushama A. Chandekar, Gaythri P. Amonkar, Heena M. Desai, Nitin Valvi and Gururaj V. Puranik: Seroprevalence of transfusion transmitted infections in healthy blood donors-A 5 year tertiary care hospital experience. J Lab Physicians 2017; 9: 283-7.
12. Jigna Patel, Trupti Rajeshbhai Jansari and Amit Chauhan: Retrospective Study of Blood Transfusion Transmitted Infections (HIV, HCV, HBV, Syphilis & Malaria] among the Blood Donors in Dhiraj Hospital. Medico-legal Update 2021; 21(2): 663-668.
13. Nejat Siraj, Oliver Okoth Achila, John Issac, Efrem Menghisteab, Maedn Hailemariam, Semere Hagos, Yosan Gebremeskel and Daniel Tesfamichael: Seroprevalence of transfusion-transmissible infections among blood donors at National Blood Transfusion Service, Eritrea: a seven-year retrospective study. BMC Infect Dis 2018; 18: 264.
14. Cheema S, Rana V, Kulhari K, Yadav A and Sachdeva A: Prevalence of transfusion transmissible infections and associated factors among healthy blood donors in North Indian population – 4-year experience of licensed blood bank at tertiary care hospital. JMMS 2022; 24: 47-52.
15. Sukla Mitra, Soumitra Das and Santanu Saha: Seroprevalence of transfusion transmissible infections in blood donors of a newly established tertiary care teaching hospital near Sundarban region of West Bengal. Int J of Health Serv Res and Policy 2023; 8(1): 93-99.
16. Adhikary M, Mazumdar M, Mukhopadhyay SG, Phukan JP, Sana PK and Jain BB: Seroprevalence of transfusion-transmitted infections among blood donors in a newly established medical college of Eastern India. Iraqi J Hematol 2021; 10: 134-8.
17. Shrivastava, Manisha; Mishra, Shweta; Navaid and Seema: Time trend and prevalence analysis of transfusion transmitted infections among blood donors-a retrospective study from 2001 to 2016. IJCM 2023; 48(2): 274-280.
18. Tambse MP and Marshal S: Comparison of seroprevalence of transfusion transmissible infections between voluntary and replacement donors at a tertiary care center. Indian J Pathol Oncol 2019; 6(2): 248-251.

How to cite this article:
Sivaranjani V, Sreedevi R, Anitha T and Mehraj N: Estimate the seroprevalence of TTI in blood donors and collate the risk of TTI between voluntary donors and replacement donors. Int J Pharm Sci & Res 2025; 16(1): 227-33. doi: 10.13040/IJPSR.0975-8232.16(1).227-33.