



## TRENDS IN SEROPREVALENCE OF TRANSFUSION TRANSMISSIBLE INFECTIONS AMONG BLOOD DONORS IN A TERTIARY CARE HOSPITAL OF MAHARASHTRA: A NINE YEARS STUDY

### Community Medicine

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### ABSTRACT

**INTRODUCTION:** Blood not only saves life but is also a source of transmission of many diseases if proper screening of donated blood is not done. It is mandatory to screen five transfusion transmissible infections such as HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria in every donated blood unit. Prevalence of these infections among blood donors is important for evaluating blood safety and potential risks to the population and it can serve as a reflection of prevalence of these infections in the community, as blood donors are very much a part of it.

**AIMS AND OBJECTIVES AIM:** To study trends in seroprevalence of transfusion transmissible infections among voluntary blood donors

**STUDY DESIGN:** A retrospective review of donor record over a period of 9 years from January 2007 to December 2015 was carried out in the blood bank of a tertiary care hospital in Mumbai, Maharashtra, India.

**METHODOLOGY:** A total of 53,605 healthy donors were screened for HIV, HBV, HCV, Syphilis and Malaria. Screening was done by ELISA for HIV, Hepatitis B and Hepatitis C; Syphilis was screened by VDRL test, Malaria by rapid immunochromatography/smear examination. The positive data included only the result of screening tests.

**RESULTS:** Among 53,605 donors screened, 2128 (3.96 %) were positive for the TTI. The overall prevalence of HIV, HBV, HCV, Syphilis and Malaria among the blood donors in the present study was 0.71 %, 2.11 %, 1.04 %, 0.07 % and 0.04 % respectively.

**CONCLUSION:** The study exhibits that most of the donors were voluntary with male preponderance. The prevalence of transfusion transmissible infections is low but result throws some insight into the prevalence of hepatitis B & hepatitis C in community keeping the fact in mind that there is no proper surveillance of these diseases in India. Continuous improvement and implementation of strict donor selection criteria, sensitive screening tests and establishment of strict guidelines for blood transfusion can go a long way in reducing the risk of acquiring transfusion transmissible infections.

### KEYWORDS

Transfusion transmissible infections (TTI), Blood donors, Human immunodeficiency virus (HIV); Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis, Malaria, Mumbai.

### INTRODUCTION

Transfusion of blood and blood components save millions of lives all over the world, each year and also reduces morbidity. But at the same time, blood transfusion is associated with a number of complications. With each unit of blood transfused, there is an increased risk of transmission of Transfusion Transmitted Infections (TTIs) which includes HIV, HBV, HCV, Syphilis, Malaria and many more infections. In India, it is mandatory to screen blood donors for all above infections.<sup>1</sup> The donor screening strategies include taking the elaborate medical history, performing preliminary clinical examination and screening for infectious markers. Though these screening strategies have been effective, but transmission of diseases still occurs, primarily because of the factors such as immunologically variant viruses, inadvertent laboratory testing errors, disease in pre-seroconversion or window phase of the infection, highly expensive screening tests and immune silent carriers.<sup>2,3</sup>

TTIs remain a major concern to patients, physicians and policy makers. In India, Government of India published National Blood Policy in the year 2002. The objective of the policy is to provide safe, adequate quantity of blood, blood components and products. All blood banks are empanelled by the government and all authorized centers have been instructed to follow blood safety guidelines as listed by the National AIDS Control Organization (NACO). Stricter control over the quality of blood and its products has been done to ensure that only non-reactive blood and blood components are released for clinical use.<sup>4</sup>

Trend analysis of TTIs is useful in evaluating the efficacy of the currently employed screening procedures. This enables policy makers

to suggest strategies for ensuring safe blood. Against this backdrop, this study was conducted to know the trends of various TTIs among the blood donors in a tertiary care hospital in Mumbai, Maharashtra over a period of nine years from 2007 to 2015 and recommends way ahead.

### MATERIALS AND METHODS

A retrospective review of donor record over a period of 9 years from January 2007 to December 2015 was done in the blood bank of Sir J. J. Hospital Mumbai, Maharashtra, India. Two types of blood donors viz. voluntary donors and replacement donors have been identified. A voluntary blood donor donates blood without hoping for any benefit from the donation. Replacement donors are those donors who donate blood for patients and are mostly family members, close relatives and friends of recipient. Donors were screened by doctors by asking them to answer the donor's questionnaire followed by a physical check up and their hemoglobin (Hb%) was estimated. Total 53,605 blood units from the selected healthy donors were collected over a period of nine years (01 January 2007 to 31 December 2015). The donors were Voluntary Donors (VD) and Replacement Donors (RD). The Voluntary Donations were obtained from walk in donors and in voluntary blood donation camps organized in nearby areas. A written consent from the donor was taken prior to donation. All samples were screened for HIV, Hepatitis B Surface Antigen (HbsAg), HCV, Syphilis and Malaria. Screening was done by ELISA for HIV, Hepatitis B and Hepatitis C; Syphilis was screened by VDRL test, Malaria was screened by rapid immunochromatography/smear examination. As per the guidelines of NACO, the blood units were autoclaved and then discarded whenever the donor samples were found positive for any TTI. The donor exclusion criteria were age under 18 or over 60 years, recent blood donation, history of fever, weight loss, jaundice, hypertension, hepatic

or cardiovascular or pulmonary derangement, malignancy, epilepsy, bleeding diathesis, consumption of prohibited drugs, surgical intervention, pregnancy or lactation.

The data entry was carried out using Microsoft Office Excel worksheet and percentage and proportions for each variable was calculated. The outcome variable was serological status of the selected individual, whether positive or negative for TTIs. Informed written consent was taken from all donors. The clearance from Institutional Ethics Committee was obtained.

**RESULTS**

Total 53605 healthy donors were screened during the period from 01 January 2007 to 31 December 2015. Total 52,856 (98.6%) voluntary donors and 749 (1.4%) replacement donors have been observed. The donors were predominantly males 46636 (86.9 %), while females constituted only 6969 (13.1 %) of the study population (Table 1). Overall 2128 seropositive donors (369 HIV, 1134 HbsAg, 560 HCV, 39 Syphilis and 28 Malaria) were identified corresponding to a summed-up seroprevalence of 3.96 %. Seroprevalence of HIV, HBV and HCV, Syphilis and Malaria among studied donors was 0.71 %, 2.11 %, 1.04 %, 0.07 % and 0.04 % respectively (Table 2).

**Table 1: Time trend of total blood collection, gender distribution and type of donors (2007-2015)**

Year	Total blood donors (n)	Gender		Type of donor	
		Male n (%)	Female n (%)	Voluntary n (%)	Replacement n (%)
2007	6018	5250 (87.23)	768 (12.76)	5968 (99.16)	50 (0.83)
2008	6773	6000 (88.58)	773 (11.42)	6713 (99.11)	60 (0.88)
2009	6055	5087 (84.01)	968 (15.99)	5943 (98.15)	112 (1.84)
2010	4811	4103 (85.28)	708 (14.71)	4760 (98.93)	51 (1.06)
2011	4644	4243 (91.36)	401 (8.63)	4218 (90.82)	426 (9.17)
2012	6012	5255 (87.40)	757 (12.59)	5962 (99.16)	50(0.83)
2013	6269	5428 (86.58)	841 (13.41)	6269 (100)	0 (0)
2014	6436	5486 (85.23)	950 (14.76)	6436 (100)	0 (0)
2015	6587	5784 (87.71)	803 (12.19)	6587 (100)	0 (0)
Total	53605	46636 (86.99)	6969 (13.00)	52856 (98.6)	749 (1.4)

**Table 2: Trend of seroprevalence of TTIs among blood donors (2007-2015)**

Year	HBsAg n (%)	HCV n (%)	HIV n (%)	VDRL n (%)	Malaria n (%)
2007	242 (4.02)	42 (0.7)	48 (0.8)	14 (0.23)	0 (0)
2008	171 (2.52)	34 (0.5)	37 (0.54)	2 (0.03)	5 (0.07)
2009	123(2.03)	71(1.18)	35(0.58)	2 (0.03)	20 (0.33)
2010	85 (1.77)	43 (0.9)	34 (0.7)	1 (0.03)	0 (0)
2011	102 (2.21)	44 (0.94)	70 (1.5)	3 (0.06)	0 (0)
2012	137 (2.27)	77 (1.28)	38 (0.63)	4 (0.06)	0 (0)
2013	61 (0.98)	111 (1.77)	22 (0.35)	3 (0.04)	0 (0)
2014	116 (1.8)	85 (1.32)	32 (0.49)	6 (0.09)	2 (0.03)
2015	97 (1.47)	53 (0.8)	53(0.8)	4 (0.06)	1 (0.01)
Total	1134 (2.11)	560 (1.04)	369 (0.71)	39 (0.07)	28 (0.04)

**DISCUSSION**

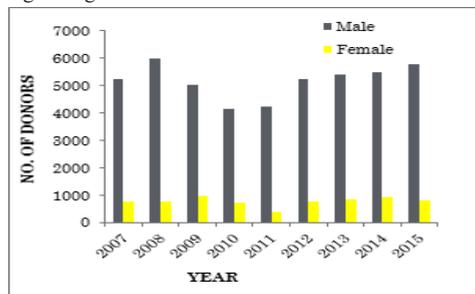
With each blood transfusion the chances of infection increases. The risk of TTI has decreased over the past two decades, because of development of newer techniques for screening of blood and its components and increased awareness among the people. Majority (90.74%) of the donors in our study were males which is comparable to the other studies. In a study conducted by Dharmesh Chandra Sharma et al,<sup>5</sup> male to female donor's ratio was 96.2% (117,369) and 3.8% (4637) respectively. This preponderance of males over females for blood donation (Figure 1) may be due to the fact that Indian females are mostly anemic and thus medically unfit for blood donation. Besides low turnout of the females for blood donation may be viewed in the light of comparatively low educational status and the general trend of not involving the female members by the heads of families in such activities. In the present study, the voluntary donors were overwhelmingly more represented than the replacement donors. Also, over a period of years there was declining trends of replacement donors and increasing trend of voluntary donors (Figure 2). These findings are

similar to the studies done by Gupta PK et al<sup>6</sup> and Pallavi P et al.<sup>7</sup> In the present study, among the total blood donors, voluntary donors (VD) constituted 98.6%, while replacement donors(RD) were 1.4%. In a study by Fessehaye N et al,<sup>8</sup> 79% were voluntary blood donors and the rest 21% were replacement donors. 73.98% of donors were voluntary donors in a study by R. Mandal.<sup>9</sup> In another study undertaken by Gupta PK et al,<sup>10</sup> voluntary donations (61.9%) were more than replacement donations (38.1%). In contrast, a

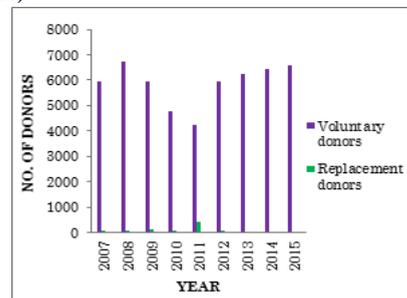
predominance of RD was observed in a study by R.N. Makroo et al.<sup>11</sup> Replacement donations [174,939 (96.93%)] represented the majority whereas, only 5,538 (3.06%) donations were from the voluntary donors. Donor motivation programmes comprising of motivational speeches, telephonic calls to registered voluntary blood donors, continuing medical education has been cited as the reasons for increase in voluntary blood donors. Proper awareness among people and periodical voluntary blood donation camps should be carried out so that healthy donors can donate blood.

The overall seroprevalence of HIV, HBsAg, HCV, Syphilis and Malaria in our study was 0.71 %, 2.11 %, 1.04 %, 0.07 % and 0.04 % respectively in the present study. Prevalence of HIV in our blood donor population was 0.71 % which is high in comparison to the studies by Chaudhary et al (0.27%), Kaure et al (0.16%) and Negi et al (0.2 %).<sup>12-14</sup> There is no co- infection between HIV and other infections noted in our study. For HIV, India is second only to South Africa in terms of overall number of people living with HIV. The National AIDS Control Organization (NACO) suggested an overall prevalence of 0.26% (2015) in India with highest prevalence of HIV in Manipur (1.15%), followed by Mizoram. The prevalence of HIV in various parts of India is different with high rate in western and southern parts.<sup>15</sup> Maharashtra, Chandigarh, Tripura and Tamil Nadu have shown estimated adult HIV prevalence greater than the national prevalence (0.26%). This could be the reason for the high HIV seroprevalence observed in the present study.

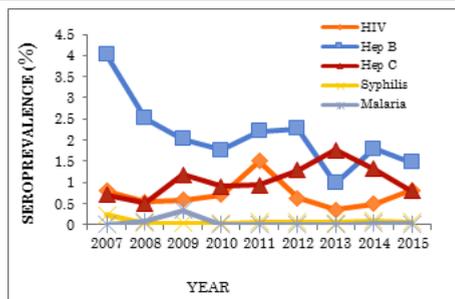
Prevalence of HBsAg in our blood donor population was 2.11 % which was contrary to the findings of other studies.<sup>14,16,17</sup> Studies by Chaudhary et al (1.93%) in western UP, Naskar et al (1.75%) in northern India, and Zameer et al (2.9%) in Pakistan showed similar findings when compared to the present study.<sup>12,18,19</sup> There was declining trend in the seroprevalence of HBV across the years in the present study (Figure 3).Detection of the IgM class of antibodies to the hepatitis B core antigen (Anti HBc – IgM) as an adjuvant marker can be used to confirm recent infection of HBV so that the higher prevalence of HBsAg among blood donors can be reduced.



**Figure 1: Trends of gender wise distribution of healthy donors (2007-2015)**



**Figure 2: Trends of voluntary and replacement donors (2007-2015)**



**Figure 3: Trends in seroprevalence of TTIs in blood donors (2007-2015)**

In our study the prevalence rate of HCV was observed to be 1.04 %. Similar result was seen in the study of Chaudhary et al (1.02 %) while Kaure et al (1.75%) and Zameer et al (3.85%) showed higher seroprevalence of HCV compared to the present study.<sup>12,13,19</sup> This variation in the HCV seroprevalence in different studies in India could be due to the use of different ELISA test kits having different sensitivities and specificities. Prevalence of syphilis in the present study (0.07 %) was similar to the study conducted by Leena et al and Chaudhary et al<sup>12,16</sup> in contrast to the studies conducted by Mehta et al (0.5%) and Kaure et al (0.67 %) which showed a higher seroprevalence of Syphilis. The low prevalence of syphilis in the blood donor population in various studies could be attributed to the concomitant use of antibiotics in a high proportion of transfusion recipients, allied with poor survival of *Treponema pallidum* during refrigerated storage of blood product.<sup>20</sup>

In the present study, the prevalence of malaria was found to be 0.04 %. Pailoor et al have reported a seroprevalence of 0.01 % for Malaria.<sup>21</sup> Zero seroprevalence was reported by Gupta et al, Sabharwal et al, Giri et al and Mythreyee et al.<sup>6,14,22,23</sup> This low prevalence and zero seroprevalence in few studies may be due to the fact that infection with malarial parasite results in development of fever and weakness. Because of the prominent signs and symptoms majority of the infected persons will not visit the blood donation camp/centre and even if they come, will be readily excluded by medical fitness examination and counseling.<sup>24</sup>

With the advent of Nucleic Acid Amplification Techniques (NAT), the risk of TTI in the western countries has decreased. In a study conducted by Mishra K K et al,<sup>25</sup> 79532 seronegative donations were tested by NAT leading to 51 positive samples. Though the NAT is highly specific and has benefits but its cost is high especially for developing countries like India. The greatest threat to the safety of the blood supply is the donation of blood by seronegative donors during the infectious window period when the donors are undergoing seroconversion. Such people represent new or incident infections. Although new techniques of testing will bring us closer to the goal of zero risk, it is unlikely that any test or combination of tests will be 100 percent effective in detecting window-period infections. It is also important to recognize that new, direct viral-detection tests will supplement existing screening assays rather than completely replace them.<sup>26</sup> Currently no technology exists to completely detect all window period donations. No matter how sensitive NAT becomes, we will never be able to completely close the exposure-to-seroconversion window period. The general public and media might believe that with the advancement in testing technologies zero risk blood products are currently available. This generalization is far from reality as judged by our current experience with new testing methodologies.<sup>27</sup>

## CONCLUSION

The study exhibits that most of the donors were voluntary with male preponderance. The prevalence of transfusion transmissible infections is low but result throws some insight into the prevalence of hepatitis B & hepatitis C in community keeping the fact in mind that there is no proper surveillance of these diseases in India. There are instances of considerable risk of TTI with the existing serological tests, which are carried out on the donors blood. Therefore, need exists to implement more specific test viz. NAT to eliminate all probable TTIs completely and cost effectively. Continuous improvement and implementation of strict donor selection criteria, sensitive screening tests and establishment of strict guidelines for blood transfusion can go a long way in reducing the risk of acquiring transfusion transmissible

infections. Other factors such as public awareness, vaccination of the entire population, strict vigilance of paid donors, educational and motivational programs could help in decreasing the infections.

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