

# Understanding Trends of Transfusion-Transmissible Infections Among Voluntary Blood Donors



## Medical Science

**KEYWORDS :** Transfusion Transmitted Infections (TTI), Seroprevalence, Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), malaria.

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### ABSTRACT

**Context:** Complications arising out of improperly tested/screened blood units before transfusion are included as integral part of preventive medical mistakes. This retrospective study will show the epidemiological burden of voluntary blood donors carrying communicable diseases and transfusion transmitted diseases.

**Aims:** The aim of this project is to observe the incidence of Syphilis, Hepatitis, HIV and malaria among voluntary blood donors in a blood bank.

**Settings and Design:** This was a retrospective observational study conducted from 10th July 2013 till 10th July 2016.

**The equipment's used:** Blood was collected from satellite bag in 3 ml plain sterile vial and 2 ml in ethylene diamine tetra acetic acid (EDTA) vial. For the test procedures, we have a separate air conditioned laboratory equipped with all the necessities like ELISA reader, ELISA washer, Incubator, multichannel and variable micropipettes etc. as per guidelines of Food and Drug Administration, Government of India. The blood unit was discarded as per guidelines of NACO whenever the pilot donor samples were found positive for any TTI.

**Methods and Material:** Data was accumulated and analysed from blood bank records, pertaining to all voluntary donors who were screened for various TTIs using respective immunological methods. Then the tabulated seropositive donors were correlated with relevant epidemiological profiles

**Statistical analysis used:** Descriptive statistics like mean, median, mode, percentage and proportion were used. **Results:** The epidemiological burden of infected blood collected amongst 4179 voluntary blood donors is of 1.9%. No donor has seropositivity for more than one infection in the study. The concurrent rates for seropositivity were highest for HbsAg (1.22%) followed by HCV (0.26), VDRL (0.23%), HIV (0.21) and Malaria (0%) in descending order. **Conclusions:** From the results it is concluded that the society still faces a big problem as HbsAg infection still continues to prevail and has high incidence of the disease in the general population. Seropositivity of HIV was found to be low in western and eastern Indian compared to northern and southern Indian. Implementation of strict selection criteria of donors as per guidelines laid down for blood banks in gazette notification of Government of India should be followed strictly

### INTRODUCTION:

A blood donation occurs when a person voluntarily has his blood drawn and used for transfusions and made into biopharmaceutical medications by a process called fractionation (separation of whole-blood components). Voluntary blood donors, donate blood when requested by BTS, when requested by a colleague, friend or family member, who donates blood on his own initiative, or a soldier who volunteers to give blood when requested to do so. In order to prevent an ineligible donor from donating again, every donor must be checked against a permanent record of previously deferred donors<sup>1</sup>. The AABB, formerly known as the American Association of Blood Banks, was established in 1947. As outlined in AABB standards, blood collection facilities must confirm donor identity and link the donor to existing donor records<sup>2</sup>. Obtaining an accurate medical history of donor is essential. It is a well-known fact that transfusion of blood and blood components as a specialized modality of patient management has been saving millions of lives worldwide each year. Amongst undesirable complication arising out of transfusion of blood and blood products transmission of certain infection like HIV, Hepatitis B and C are most significant for the long term detrimental side effect. Meticulous pretransfusion testing and screening particularly for transfusion transmissible infections (TTI) is the need of the hour<sup>3</sup>. The Indian subcontinent is classified as an intermediate Hepatitis B Virus (HBV) endemic (HBsAg carriage 2-7%) zone and has the second largest global pool of chronic HBV infections<sup>4</sup>. The risk of transfusion transmission of these viruses may be alarming due to high seroprevalence of HIV, anti-HCV, and HBsAg (0.5%, 0.4%, and 1.4%, respectively) among blood donors<sup>5</sup>. Blood is one of the major sources of transmission of hepatitis B, hepatitis C, syphilis, and many other diseases<sup>6-8</sup>. It is mandatory to test each donor's blood for syphilis by a Venereal Disease Reference Laboratory (VDRL), and for HBsAg, anti-HCV. Vector-borne malaria is a major public health problem in

India; however, the malaria endemic city is quite variable across the country<sup>9</sup>. In India, strategies adopted to prevent occurrence of TTM are: a) mandatory deferral of donors with history of fever (presumably malaria) in the last 3 months and b) to test donated blood for presence of malaria infection<sup>10</sup>. However, prevalence of markers for malaria in blood donors and incidence of TTM in patients is scantily reported, though significant risk is highlighted by frequent case reports<sup>11-14</sup>. The aim of this study is to estimate the seroprevalence of transfusion transmitted infections among voluntary blood donors at P.D.V.V.P.F's Medical hospital, Ahmednagar. This knowledge might give us the idea of disease burden of the society and the basic epidemiology of these diseases in the rural community.

### AIM:

The aim of this project is to observe the incidence of Syphilis, Hepatitis, HIV and malaria among voluntary blood donors in P.D.V.V.P.F' medical college.

### OBJECTIVES:

1. The data generated will help the clinicians for judicious use of blood as well as awareness regarding the Transfusion transmitted infections and,
2. Show the epidemiological burden of voluntary blood donors carrying communicable diseases and transfusion transmitted diseases.

### MATERIALS AND METHODS:

**Type of study:** This was a retrospective observational study.

**Time period of study:** this study was conducted from 10<sup>th</sup> July 2013 till 10<sup>th</sup> July 2016.

**Study method:** In general, the diagnosis of HBV, HCV, HIV and syphilis is based on the presence of the corresponding antigens or antibodies in blood serum [26]. Blood was collected from satellite bag in 3 ml plain sterile vial

and 2 ml in ethylene diamine tetra acetic acid (EDTA) vial. For the test procedures, a separate air conditioned laboratory equipped with all the necessities like ELISA reader, ELISA washer, Incubator, multichannel and variable micropipettes etc. as per guidelines of Food and Drug Administration, Government of India was used. The blood unit was discarded as per guidelines of NACO whenever the pilot donor samples were found positive for any TTI. The data was pooled and analyzed using suitable statistical tests as and when required e.g.; percentage, proportion etc.

**The equipment's used:**

Hepatitis- the donor serum samples were analyzed to detect anti-HCV antibodies and HbsAg antibodies by ELISA.

Syphilis- the donor serum samples were tested by VDRL test.

HIV- the donor blood was tested for HIV 1 and 2 antibodies.

Malaria- examination for malaria parasite was done by thick and thin smear examination using standard methods<sup>14</sup>. A thick smear was drawn, stained with Giemsa stain, and observed under microscope in low power, high power, and then using oil immersion lens.

**Research question:**

1. What is the incidence of syphilis, hepatitis, HIV and malaria in voluntary blood donors?

**Research hypothesis:**

Complications arising out of improperly tested/screened blood units before transfusion are included as integral part of preventive medical mistakes. This retrospective study will show the epidemiological burden of voluntary blood donors carrying communicable diseases and transfusion transmitted diseases.

**Enrollment criteria:**

All the patients enrolled were fulfilling following inclusion and exclusion criteria.

**Inclusion criteria:**

1. The patients should have donated blood voluntarily from 10<sup>th</sup> July 2016 and 10<sup>th</sup> July 2013.
2. Their age should be above 18 year.
3. The patients should have fulfilled all criteria's for blood donation during blood donation.

**Exclusion criteria:**

1. Patients with history of chronic illness, heart disorders and kidney disorders.

**Following parameters were studied:**

**1. Serial number:**

**2. Hepatitis: this included**

- HBsAg reactive/ non-reactive.
- HCV reactive/ non-reactive.

**3. HIV: this included**

- HIV 1 antibody present/ antibody absent.
- HIV 2 antibody present/ antibody absent.

**3. Peripheral blood smear reports: this includes**

- Malarial parasite present/ absent.

**4. Syphilis: this includes**

- VDRL test reactive/ non-reactive.

**Sample size:** The sample size was of all the patients fulfilling the inclusion and exclusion criteria from 10<sup>th</sup> July 2016 till 10<sup>th</sup> July 2013. Three years retrospective sample size was **4179 voluntary donors**.

**Analysis plan:** Descriptive statistics like mean, median, mode, percentage and proportion were used.

**Amendment of protocol:** No change in the study procedure was effected without the mutual agreement of investigator, guide.

**Confidentiality:** The identity of candidate generated in the study was not disclosed. The data was made available only to the investigator involved in the study and to the regulatory authorities. Break in the confidentiality was not made.

**Implications:** This research will give insight on the level of positive cases of Hepatitis, syphilis and malaria encountered in voluntary donors in blood bank. As the cases are voluntary donors it will also indicate the level epidemiological burden of hepatitis, syphilis, malaria and typhoid in the society.

**FUNDING:**

This research did not receive any specific grant from any funding agency in the public, commercial or nonprofit organizations.

**RESULTS:**

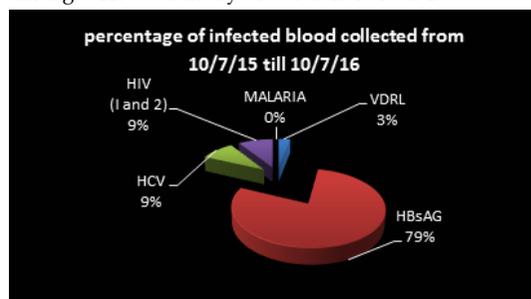
Total of 4179 voluntary blood donor samples were collected from 10<sup>th</sup> July 2013 till 10<sup>th</sup> July 2016.

YEAR	TOTAL TTI	HBsAg	HCV	SYPHILIS	HIV (1+2)	MALARIA
2013-2014	24 (0.57%)	12	3	7	2	0
2014-2015	24 (0.57%)	13	5	2	4	0
2015-2016	33 (0.78%)	26	3	1	3	0
<b>TOTAL SERO-PREVALENCE:</b>	<b>81/4179* (1.9%)</b>	<b>51/4179 (1.22%)</b>	<b>11/4179 (0.26%)</b>	<b>10/4179 (0.23%)</b>	<b>9/4179 (0.21%)</b>	<b>0 (0%)</b>

**TABLE NO 1. \*4179= TOTAL NUMBER OF VOLUNTARY BLOOD DONORS IN P.D.V.V.Fs MEDICAL COLLEGES BLOOD BANK FROM 2013-2016.**

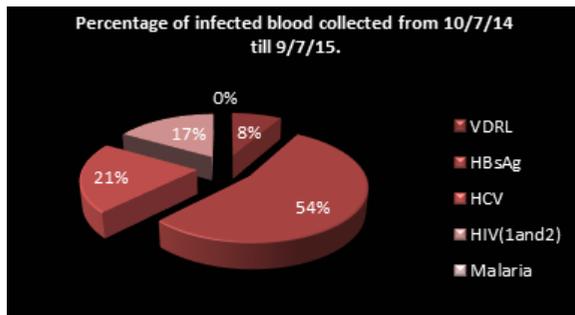
According to table no. 1 from 4179 voluntary blood donors 33 individuals had infected samples from 10<sup>th</sup> July 2015 till 10<sup>th</sup> July 2016, 24 individuals had infected samples from 10<sup>th</sup> July 2014 till 9<sup>th</sup> July 2015 and 24 individuals had infected samples from 10<sup>th</sup> July 2013 till 9<sup>th</sup> July 2014.

The epidemiological burden of infected blood collected amongst 4179 voluntary blood donors is of 1.9%.



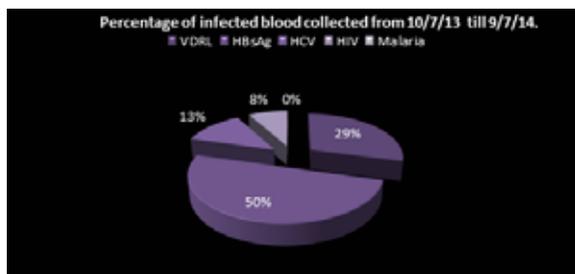
**GRAPH NO. 1**

Total number of infected blood collected from 10<sup>th</sup> July 2015 till 10<sup>th</sup> July 2016 was 33. According graph no 1 amongst 33 infected individual VDRL reactivity was seen in 1 individual (3%), HbsAg reactivity was seen amongst 26 individuals (78.7%), HCV reactivity was seen amongst 3 individuals (9%), HIV (1 and 2) positivity was seen in 3 individuals (9%) and malaria was not detected from any voluntary blood donor.



**GRAPH NO 2**

Total number of infected blood collected from 10/7/14 till 9/7/15 is of 24 individuals. From graph no 2 we infer that amongst 24 infected individuals 2 came positive for VDRL (8%), 13 came positive for HbsAg (54%), 5 came positive for HCV (21%), 4 came positive for HIV(1 and 2) (17%) and 0 individuals showed malaria parasites presence in the blood collected.



**GRAPH NO 3**

Total number of infected blood collected from 10/7/13 till 9/7/14 is of 24 individuals. Graph no 3 shows that amongst 24 individuals with infected blood 7 showed positivity in VDRL (29%), 12 showed positivity in HbsAg (50%), 3 showed positivity in HCV (13%), 2 showed positivity in HIV (8%) and nil amount of collected blood showed malarial parasites presence on checking in smear.

The epidemiological burden of voluntary blood donors carrying syphilis (29%) and hepatitis C (13%) was highest from 2013 till 2014, hepatitis B (79%) was highest from 2015 till 2016 and HIV (17%) was highest from 2014 till 2015.

In 4179 voluntary blood donors from 2013 till 2016 not a single individual was detected with malaria.

Maximum percentage of voluntary blood donors from 2013 till 2016 showed positivity for hepatitis B, i.e. 51 cases amongst 80 total infected cases.

**DISCUSSION:** Overall seropositivity of TTIs was found to be decreasing from 4.64 to 3.55% in a Gwalior based study [30]. In our study the overall seropositivity was found to be constant from 2013 till 2015 (0.57%), a sudden rise was noted from 2015 till 2016 (0.78%) (From table 1).

The Indian subcontinent is classified as an intermediate

Hepatitis B virus endemic zone (HbsAg carriage 2-7%) and has the second largest global pool of chronic HBV infection [4]. HBV is most commonly found in the “carrier stage” (prolonged stage of asymptomatic infection) due to its very low replicating capacity. This leads to extremely low viral loads which are usually missed by routine serology tests. Also the mutant strains and OBI (Occult Hepatitis B Infection) are very common in this infection, which are usually missed by routine serology [17]. Out of 350 million Hepatitis B chronic carriers worldwide 40 million arise in India [20]. The seroprevalence of HBV by Purushottam A. Giri et al. [44] was 1.09% from Loni, Ahmednagar, Maharashtra and almost similar findings were noted in our study (1.22%) as well as in other studies conducted by Chatteraj A et al. [40], Kaur et al [41], and Singh B et al. [42] while Hilda et al. [43] reported a low prevalence of 0.34%. Wide range of HBV seropositivity is also reported from different parts of India which ranges from 1.86 to 4% [31-35]. In our study seropositivity for syphilis is 0.17%. In other Indian subcontinent studies it is seen to be 0.01% [35], 0.85% [38] and 1.2% [39]

In India, there are about 12-13 million HCV carriers and modeling data predict that the burden of disease could soon increase substantially [18]. In a recent study done in Hisar, Haryana, the seroprevalence of anti-HCV antibodies was calculated to be 1 per cent [23]. In studies performed in northern Indian, western India (rajasthan) and north-east India(Darjeeling) the cumulative seroprevalence of HCV was 0.83% [24], 0.04% [25], 0.62% [26]. In our study the seroprevalence of HCV was 0.23% (from table 1), which is comparatively lesser than northern India, Darjeeling and Haryana, but it was found to be more than western Indian (Rajasthan).

In our study seropositivity for syphilis is 0.23%. In other Indian subcontinent studies it is seen to be 0.01% [35], 0.11% [45], 0.07% [46], 0.85% [38] and 1.2% [39].

Adult HIV prevalence -0.31% - 2009 [19]. The seropositivity for anti-HIV I and II was 3(0.1%) in a study conducted in northern India [24]. Amongst 22905 voluntary blood donors, in a study in Rajasthan, seropositivity for Human Immunodeficiency Virus (HIV) was 0.034% [25]. Prevalence of HIV in western part of India is 0.16% and it is same as study conducted in Northern Gujarat (0.16%) [29]. Low incidence of seropositivity for HIV was seen in our study 0.21% as compared to other studies 0.32% [36], 0.23%(2004) & 0.35%(2005) [37]. But it was found to be higher as compared to studies conducted in northern India, and northern Gujarat. Southern part of India has more prevalence of HIV than any other part (0.91%) [29].

According to latest data of National Vector Borne Disease Control Programme, 2010 had 13 states suffering with epidemics of malaria in which Maharashtra’s Ahmednagar district was also involved and in 2011 also Ahmednagar had an epidemic of malaria. But in our present study seroprevalence of malaria amongst 4179 voluntary blood donors was 0%. This drastic drop in malaria cases amongst voluntary blood donors might be due to timely diagnosis and treatment, increased public awareness, proper referral services and effective donor screening.

**Table no.: Comparison of transfusion transmitted infections: trends in different parts of India.**

place	Donor tested	HbsAg reactive	HCV reactive	VDRL reactive	HIV reactive	MP positive	References
Gwalior	67132	2360 (3.51%)	161 (0.24%)	114 (0.17%)	91 (0.13%)	21 (0.03%)	

Mangalore	9599	33(0.34%)	6(0.06%)	11(0.11%)	6(0.06%)	1(0.01)	42
Ludhiana	44064	290(0.66%)	483(1.09%)	373(0.85%)	37(0.08%)	-	37
Dehradun	6751	67(0.99%)	13(0.19%)	42(0.62%)	9(0.13%)	0(0.00)	39
Bhopal	5008	149(2.97%)	29(0.57%)	12(0.23%)	26(0.51%)	-	46
Luc-know	39060	497(1.27%)	90(0.23%)	111(0.28%)	170(0.44%)	-	47
New Delhi	28966	646(2.23%)	192(0.66%)	-	163(0.56%)	-	27

## CONCLUSION:

The epidemiological burden of infected blood collected amongst 4179 voluntary blood donors is of 1.9%. No donor has seropositivity for more than one infection in the study. The concurrent rates for seropositivity were highest for HbsAg (1.22%) followed by HCV (0.26), VDRL (0.23%), HIV (0.21) and Malaria (0%) in descending order. From the results it is concluded that the society still faces a big problem as HbsAg infection still continues to prevail and has high incidence of the disease in the general population. Seropositivity of HIV was found to be low in western and eastern Indian compared to northern and southern Indian. Implementation of strict selection criteria of donors as per guidelines laid down for blood banks in gazette notification of Government of India should be followed strictly. Although blood and blood products may never be completely risk-free of infectious substances, it is vital that the blood banking industry steer towards available stringent screening techniques such as NAT that will ensure added safety and reduce the residual risk of transfusion transmitted infections [16].

## SOLUTION:

World Health Organization (WHO) recommends integrated strategy to improve blood transfusion safety by

1. Well-organized blood transfusion services,
2. Prioritization of blood donation from voluntary non-remunerated donors,
3. Screening of donated blood for at least the four major transfusion transmissible infections (TTI) with quality assured system,
4. Rational use of blood and implementation of effective quality control systems [20].

## COMPETING INTERESTS:

Authors have declared that no competing interests exist.

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