

## Donor Notification: Improve Response Rate by New Method of Registration

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### Abstract

**Introduction:** Screening test for transfusion transmitted infections (TTIs) like HIV, Hepatitis B, Hepatitis C, malaria and syphilis are mandatory in India. Along with this, mandatory testing for safe blood, transfusion services have also started to inform the TTI reactive donors. But post donation notification and follow-up poses a challenge, majorly due to lack of awareness about this among public. Our primary aim of the study to study the comparison of response rate of donor notification using various forms of communication along with that we also analysed the prevalence of TTIs among blood donors and concordance between various methods of testing.

**Material and Methods:** In this retrospective study from March 2015 to December 2017, total of 46,213 donors were included. TTI testing was performed using ELISA (Enzyme linked immuno-sorbent assay) and ID- NAT (Individual donor- Nucleic acid testing). Two methods like telephone, letter or both were used for notification of the reactive donors.

**Results:** Out of 46,213 donors, 1248 were found reactive for TTI (HIV- 127, HBV-772, HCV-277, Syphilis- 72). Out of total reactive donors 1026(82.2%) were found reactive by both methods ELISA and NAT testing, while 176(14.10%) were only ELISA and 46 (3.68%) were only NAT reactive. Response rate to letter, telephone and both was 22.18%, 55.02% and 70% respectively.

**Conclusion:** It is recommended to link donor's government verified identity card with blood bank registration process, in order, to get their correct address and mobile number. This will be helpful to contact donors for notification and reduce problems associated with incorrect address.

**Keywords:** Transfusion Transmitted Infection, Donor Notification, Identity Card, Donor Screening,

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### I. Introduction

Blood transfusion services (BTS) strive to provide safe blood, free from pathogens to all the recipients. This is ensured by stringent donor identification and screening of blood for transfusion transmitted infections (TTI)<sup>1</sup>. In the present world, there is a diminishing risk of getting infected by transfusion of blood products and this has been made possible by strict quality controls and testing at each level possible. With the advent of nucleic acid testing(NAT), it is even possible to identify donors in the window period. The importance of identifying donors in the window period is highlighted by the fact that prevalence of TTI is higher in chronically transfused patients compared to general population<sup>2</sup>. But, NAT testing is limited in resource poor settings due to high cost, infrastructure and lack of expertise<sup>3</sup>. In a middle-income country like India, donor counseling and notification assumes paramount importance.

One of the objectives of action plan for blood safety is awareness program for donor information, education and motivation to ensure adequate availability of safe blood. Under this aegis, blood donor is notified regarding his sero-reactive status<sup>4</sup>. Notification of donor is beneficial for both the donor and BTS. Donor is benefitted by early diagnosis and treatment and blood bank is able to reduce TTI reactive donor. Despite being a key step in blood safety, donor notification and response is an arduous task, especially in resource-limited settings. In this study, we aim to study donor response rate to notification of sero-reactive status and propose a new method of registration to improve the donor response rate.

### II. Materials And Methods

#### Study type and setting:

This was retrospective cross-sectional observation study done over a two-and-a-half-year period, from March 2015 to December 2017. The study was conducted on blood donors in Department of Transfusion Medicine in a tertiary care center in India.

**Study Population:**

A total of 46213 donors were included in the study. Blood donors were selected after proper medical examination and detail questioners as per departmental standard operating procedure (SOP). An informed consent was taken from donors for testing of their blood for transfusion transmitted infections (TTIs) like HIV1/2, Hepatitis B, hepatitis C, malaria and syphilis. Consent also taken if the test results is reported reacted they wouldby notifies either by letter or telephonic.

**Test Methodology:**

TTI testing were carried out by taking 8 ml sample in two EDTA vials (4ml in each). Donors were screened by ELISA using 4th generation ELISA test kits for HIV-1/2, 3rd generation ELISA test for HBsAG and HCV infections, and rapid immunochromatographic test for syphilis. All donations were also screened individually using the ProcleixUltrioplusassay (Hemogenemics), a multiplex NAT assay for the detection of hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) RNA, and human immunodeficiency virus-1 (HIV-1) RNA. If initial NAT result was positive, sample was retested again in triplicate. If any of these three tests were positive, sample was drawn from plasma bag and tested in triplicate. Discriminatory NAT was run if any test from plasma bag came positive.

**Notification process:**

If the results of either serology and/or NAT were found to be positive, blood unit was discarded as per hospital standard operating protocols and donor was notified of his/her status either by telephone, by letter or by both.

Donors who were from the same state resident they were contacted by telephone. If a donor could not be contacted first time, they were called again after 7days. If the donor did not responded even on second phone call, final (third) phone call was made after another 7 days. If donor could not have contacted after three trials by telephone then postal letter send to their registered address.

Donor who were from another state resident they were contacted by postal letter.

**Counselling session:**

Donors, who responded, were counselled by trained counsellor or by trained physician through one to one counselling. Donor identity was verified by government approved identity proof like driving licence, PAN card or Aadhar card etc.

After proper counselling donors referred to appropriate care centre i.e. ICTC for HIV positive, Liver clinic for hepatitis and STD clinic for donors with syphilis. Data was collated from counselling register and analysed by Microsoft excel 2016.

**Ethical approval and consent of the participants**

This study is approved by institutional ethical committee (IEC) and participants consent wasexcused by IEC due to retrospective nature of the study.

**III. Results**

In this two and a half year study period, 46213 donors were evaluated. Among this, 6148 Voluntary donors and 40065were replacement donors. Demographic details are given in Table 1.

	Number	%
Gender		
Male	44298	95.85
Female	1915	4.14
Total	46213	
Age group		
18-25	15,100	32.67
26-40	26863	58.2
41-65	4,250	9.19
Total	46213	
Donation type		
Voluntary	6148	13.30
Replacement	40065	86.69
Total	46213	

**Table 1:** To show demographic details of donors.

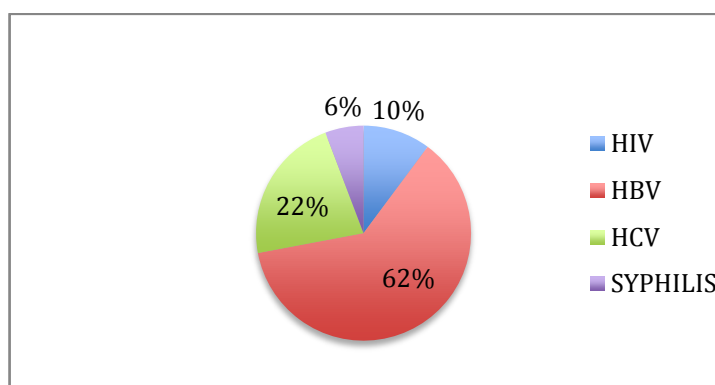
1248 donors were found to be reactive for TTI's. Among these, 1233 were replacement donors and 15 were voluntary donors. The prevalence of various TTI's is HIV - 0.27%, HBV- 1.67%, HCV - 0.59% and syphilis - 0.15% (Table 2, Figure 1).For HIV, HBV and HCV concordant serology was present in 2.22%. 0.38% were positive for ELISA only and 0.09% were positive for NAT only. (Table 3).

TTI	N=	Percentage Of Reactive Donors
HIV	127	0.27
HBV	772	1.67
HCV	277	0.59
SYPHILIS	72	0.15
Total	1248	2.70

**Table 2:** To show sero-prevalence of various TTI's in our study population.

Testing Method	Reactive Donors	%
ELISA & NAT	1026	2.22
ELISA ONLY	176	0.38
NAT ONLY	46	0.09
Total	1248	2.70

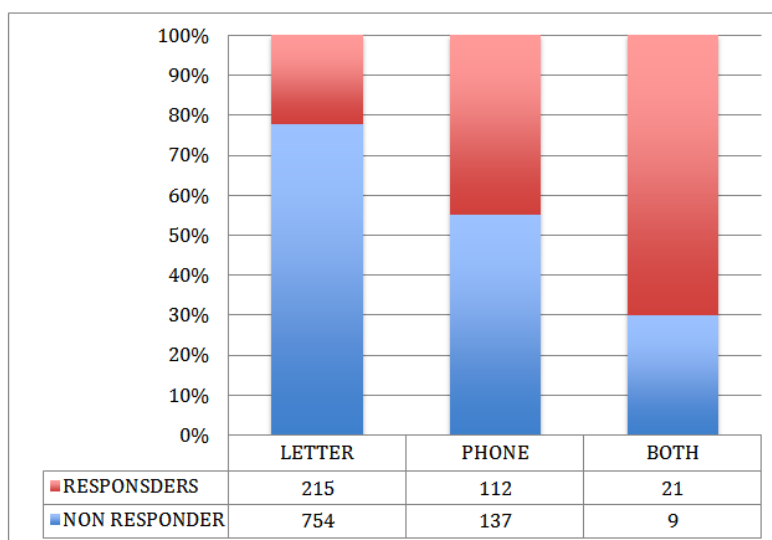
**Table 3:** To show reactivity for TTI by various methods of detection



**Figure 1:** To show Percentage of donor reactivity for various TTI

All the reactive donors were informed regarding the status either by letter, telephone or both. 77.66% (n=969) were notified by letter only, 19.95% (n=249) were notified only by telephone and 2.4% (n=30) were notified by both letter and phone.

373 donors(29.88%) responded to notification. Response rate to various methods of notification was letter – 22.18%, telephone – 55.02% and both- 70%. Response rate to phone and letter was significantly better compared to letter alone (p value <0.001). Response rate for voluantry donors was 66.66% and replacement donors was 25.59%. 3% (n=37) of sero-reactive donors did not receive their letter due to incorrect address.



**Figure 2:** To show response rate to various method of communication

#### IV. Discussion

With over 7.05 million blood units collected every year, BTS aims to ensure that the blood supplied to patient is safe and free from pathogens<sup>5</sup>. In the present world, with continuous and concerted efforts, there has been a declining trend in the transmission of TTI's, through blood and blood products. In the present study, the prevalence of various TTIs is HIV is 0.27%, HBV is 1.67%, HCV is 0.59% and syphilis is 0.15% ,this is comparable to national incidence for 2016-17 and previous studies<sup>5,6,7,8</sup>(Table 4). Also, it is notable that prevalence of TTI's has decreased in India<sup>7</sup>.

	TOTAL	HIV	HBSAG	HCV	VDRL
NACO <sup>5</sup>	1000000	0.14%	0.86%	0.34%	0.15%
Chaurasia et al, 2014 <sup>6</sup>	1,13,014	0.27%	1.38%	0.54%	0.32%
Chandra et al, 2014 <sup>7</sup>	11977	0.08%	0.24%	0.00%	0.01%
Puroshattam et al, 2012 <sup>14</sup>	5661	0.07%	1.09%	0.74%	0.07%
<b>Present study, 2017</b>	<b>46213</b>	<b>0.27%</b>	<b>1.67%</b>	<b>0.59%</b>	<b>0.15%</b>

**Table 4:** To show the sero-prevalence of Various TTI in present study and comparison with other study.

National guidelines entails that adequate efforts should be made by blood bank staff to contact donor regarding initial sero-reactive status<sup>4</sup>. In this regard, donors are contacted by various means. Previous studies have shown that less than half of the contacted donors respond to blood banks (Table 5), which is similar to western countries<sup>6,9,10,11,12</sup>. Reasons for poor response rate could be incorrect contact details, lack of awareness among donors regarding TTI's. Another reason is that patients come from far flung areas and find it difficult to return to the institute, often they do not respond to the notification. Chaudhary et al in their study have demonstrated that only 51% of donors are aware about post-donation notification of TTI's<sup>13</sup>. In this regard, donor counseling plays a major role. Donor counselling should include nature and use of blood, eligibility for donation, common TTI's, modes of transmission, window period and possibility of abnormal test. Also, the donor is given option of withdrawal and self deferral<sup>4</sup>. In a large volume centre, with limited resources, it is often difficult to ensure adequate counselling. This is also a major reason for poor response rates. This is strengthened by the fact response rate for a voluntary donation centre is better than other centres, where counselling services are adequate<sup>10</sup>. Also, donors responded better when notified by multiple means like letter, telephone and majority prefer being contacted over phone.

Study	Total Donors	Reactive Donors	Responders
Patel et al, 2012 <sup>9</sup>	20865	391 (1.87%)	236(23.3%)
Aggarwal N, 2014 <sup>10</sup>	48386	416(0.87%)	249(59.8%)
Arora S et al, 2015 <sup>11</sup>	15322	464(3.02%)	225(48.49%)
Chaurasia et al, 2014 <sup>6</sup>	113014	2838 (2.51%)	662(23.3%)
<b>Present study, 2017</b>	<b>46213</b>	<b>1248(2.70%)</b>	<b>373(29.88%)</b>

**Table 5:** To show the response rate of various donors to notification in present study comparison to other studies.

Another hurdle in donor notification noticed in this study, was the lack of correct address/phone number of donors. This has also been noted by Kotwal et al, who were unable to contact 50.6% of donors<sup>11</sup>. In this regard, we propose that aadhar card/ government authorised valid identity card should be made mandatory for donor registration. By making a social identity card/ government verified valid identity card mandatory for donation, we are able to ensure that correct address is entered in the records. As donor notification and education is the foundation for safe blood practices, a government approved valid address proof ( ideally aadhar card) will go a long way in sorting out the problem of incorrect addresses.

Though the prevalence of TTI is lower than ever before, but we must strive to achieve zero rate of transmission. In a resource limited country like India, where NAT facilities cannot be offered everywhere, the onus lies on the tertiary centres to notify and identify the reactive donors especially those in window period, so as to ensure safe blood. In the end, we recommend a government approved valid address proof as a part of donor entry, so the notification process could be improved.

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