

## SEROPREVALENCE OF INFECTIOUS DISEASES IN BLOOD DONORS BY ID-NAT IN A TERTIARY CARE CENTRE IN NORTHERN INDIA

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### ABSTRACT

This study was carried out to determine the prevalence of infectious diseases in blood donors by individual donor nucleic acid testing (ID-NAT). Safe blood transfusion practices can save people from being exposed to the risk of transfusion transmissible infections. Serum samples from voluntary and replacement donors were tested for infectious diseases like Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) by ID-NAT and the results were analysed statistically. Majority of the donors were in the 3rd decade of life, 15770 (59.6%); followed by in 4th decade of life, 5218 (19.7%). There were 24113 (91.1%) males as compared to 2354 (8.9%) female donors, with male-female ratio of 29.9:1. Replacement donations were 24583 (92.9%) and voluntary donations were 1884 (7.1%). The seroprevalence of HIV was 19 (0.07%), HCV was 173 (0.7%), HbsAg was 705 (2.6%) and 25570 (96.6%) donors were non reactive by ID-NAT. The sensitivity, specificity and diagnostic accuracy by ID-NAT was 99.2%, 96.7% and 99.8% respectively. ID-NAT is a very sensitive testing modality of infectious blood, which decreases the window period of infections, and thus enhances the safety of blood transfusion.

**KEYWORDS:** Blood Donors, Seroprevalence, Infectious Diseases, ID-NAT.

### INTRODUCTION

The goal of donor screening and testing practices in modern blood banking, is to ensure safe blood transfusion, free from transfusion-transmitted infections (TTIs). Technological advancements have led to the development of more sensitive methods, like individual donor nucleic acid testing (ID-NAT) to detect TTIs. Decrease in the window period by ID-NAT has minimised false-negative results and enhanced detection of asymptomatic carriers (1-2).

Professional donors, like drug addicts, homosexuals and commercial sex workers are a potent source of infection risk. A large number of blood transfusions are carried out every day to save innumerable lives. Though, safe blood transfusions carry an inherent risk of transmission of infective diseases. Risk of TTIs is more in cardiac patients receiving multiple transfusions and undergoing invasive surgeries.

Increase in the number of TTIs has been instrumental in the revolutionary changes and developments in both testing of blood units as well as transfusion protocols to improve blood safety. Drug and Cosmetics act of 1940 in India, has made mandatory testing of each donated unit of blood for infectious diseases like Human Immunodeficiency Virus (HIV), Hepatitis C

Virus (HCV), Hepatitis B Virus (HBV), malaria and syphilis (3). TTIs could pose a considerable burden on the health status and economics in a country like India. The need to enhance the blood safety by introducing better methods for testing of blood units cannot be over emphasized. With an estimated population of 1.21 billion, India has the world's third largest population suffering from HIV/AIDS, with an estimated prevalence of 0.31% in 2009 (4). The prevalence of hepatitis B in India is 2–10% amongst the general population.<sup>4</sup> Also cases of Hepatitis C is on the rise in India, with 12–13 million HCV carriers, leading to various chronic liver diseases, like hepatic cirrhosis and hepatocellular carcinoma (HCC) (5).

To ensure safe blood services in India, 100.0% voluntary donations with effective screening tests is the need of the hour. Even after being seronegative the blood transfusions are still at risk of transmitting infections. To reduce the residual risk, sensitive screening tests like nucleic acid testing (NAT) should be performed in blood banks for detecting infectious diseases. NAT has increased the possibility of detecting window period infections and reduced the residual risk of TTIs. Though NAT testing is not yet mandatory in India, but few centers have started this technique for screening infectious diseases in donors

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to enhance blood safety (6). The present study aims to determine the sero-prevalence of infectious diseases like HIV, HBV and HCV in blood donors by ID-NAT.

# MATERIAL AND METHODS

All voluntary and replacement blood donors coming to Jawaharlal Nehru Medical College Hospital Blood and Component Bank from January, 2019 to January, 2020 were screened with strict donor selection criteria and after taking detailed history and thorough clinical examination.

Serum samples of all donors were tested for anti HIV 1 and 2 antibody, anti HCV antibody and HBsAg by ID-NAT (Porcleix® Panther® System). All internal quality control measures were followed daily using both positive and negative controls supplied by the manufacturers.

Statistical Package for the Social Sciences (SPSS Inc., Chicago, Illinois, USA, version 17.0) was employed for Statistical analysis of the results obtained by windows software program and Chi-Square Tests. p value of less than 0.05 was considered to be statistically significant.

# OBSERVATIONS

The present study was carried out on blood donors at the Blood and Component Bank of Jawaharlal Nehru Medical College and Hospital, AMU, Aligarh from January 2019 to January 2020, after ethical clearance from the hospital ethics committee. The total number of whole blood donations during the period was 26467 in number.

Majority of the blood donors were in the third decade of life, 15770 (59.5%); followed by in the fourth decade of life, 5218 (19.7%) cases (Table 1).

AGE ( years )	NO. OF DONORS	PERCENTAGE
10-20	2647	10.0
21-30	15770	59.6
31-40	5218	19.7
41-50	2612	9.8
>50	220	0.9
<b>TOTAL</b>	<b>26467</b>	<b>100.0</b>

**Table 1: Distribution of Donors According to Age**

Males comprised 24113 donors (91.1%) and female donors were 2354 in number (8.9%), with male-female ratio of 29.9:1, with a statistically significant correlation ( $p < 0.001$ ). This is a very low percentage of female donors, considering the fact that women comprise about 48.0% of Indian population (Table 2).

GENDER	NO. OF DONORS	PERCENTAGE
MALES	24113	91.1
FEMALES	2354	8.9
<b>TOTAL</b>	<b>26467</b>	<b>100.0</b>

**Table 2: Distribution of Donors According to Gender**

Replacement blood donations comprised the major type of donation, with 24583 (92.9%) donations and voluntary donations comprised of 1884 (7.1%) donations. A statistically significant correlation was noted between the two types of donations with p value of less than 0.05 (Table 3).

TYPE OF DONATION	NO. OF DONORS	PERCENTAGE
REPLACEMENT	24583	92.9
VOLUNTARY	1884	7.1
<b>TOTAL</b>	<b>26467</b>	<b>100.0</b>

**Table 3: Distribution of Donors According to the type of Donation**

Most of the blood donors were non reactive by ID-NAT, 25570 (96.6%). HBsAg positivity was seen in 705 (2.6%) donors, followed by 173 (0.7%) HCV positive cases and 19 (0.07%) HIV seroprevalence in donors (Table 4).

INFECTIOUS DISEASE	NO. OF POSITIVE DONORS	PERCENTAGE
HIV	19	0.07
HCV	173	0.7
HBV	705	2.6
NON REACTIVE	25570	96.6
<b>TOTAL</b>	<b>26467</b>	<b>100.0</b>

**Table 4: Seroprevalence of HIV, HCV, HBsAg by ID-NAT**

The sensitivity, specificity and diagnostic accuracy of NAT in infectious disease screening of blood donors was 99.2%, 96.7% and 99.8% respectively in our study.

## DISCUSSION

There is a need for mandatory screening of infectious diseases in blood donors to minimise the potential risk of transfusion transmissible diseases (7). The prevalence of infection in blood donors can help in understanding the approximate prevalence of infection in the general population (8).

Our study showed male dominance (91.1%) with females constituting only 8.9% despite of females comprising 48.0% of Indian population. Several studies in Africa have also reported increased number of male blood donors, with 61.0% in Togo, 71.2% in Burkina Faso and 90.0% in Ghana (9-11). In a recent survey in Central and Western Africa, females comprised less than 30.0% of total blood donors (12-13).

The present study showed high percentage of replacement donors (92.9%) as compared to voluntary donors (7.1%). Our study is comparable to studies from North India by Awasthi et al and Singh et al who reported 85.2% and 82.4% replacement donors (14-15). Higher percentage of replacement donors has also been reported by Yadav et al from Central India (92.0%) (16). In our study we concluded that most of the replacement donors carry infections. Therefore, by increasing voluntary donations, risk of TTI's can be reduced.

HBV is a major global public health problem and World Health Organization recommendation emphasizes using a highly sensitive and specific HBsAg screening immunoassay test to minimize the risk of transfusion transmitted hepatitis B infection.

Approximately 30.0% of the world's population is infected with HBV infection, which is one of the leading causes of death due to HBV-related hepatocellular carcinoma in the world. India lies in an intermediate HBV endemicity zone and the number of HBV carriers in India is estimated to be 50 million.<sup>17</sup> The prevalence of HBV is 2.0- 8.0% in the general population and 1.0% to 2.0% in blood donors in India (17-19).

The seroprevalence of HCV infection among blood donors is 0.4-19.2% worldwide. The seroprevalence of HCV infection in voluntary blood donors in India is 0.12-2.5%, with an overall prevalence of less than 2.0% (1,6). HCV causes subclinical acute hepatitis which progresses gradually to chronic hepatitis in about 80.0% of the infected individuals (20). HCV infection predisposes to cirrhosis liver and primary hepatocellular carcinoma.

Parenteral transmission through blood transfusion and infected needles and syringes remain the most significant route of transmission for infectious diseases in our country. Infected blood transfusion is a potent source of transmission of the diseases like

HIV/AIDS, Hepatitis B and C, syphilis and malaria to the susceptible patient. In developed countries, numerous corrective measures have reduced the spread of infection through transfusion. In India, the scenario is slowly shifting with blood banks gradually introducing NAT to provide safe blood.

A highly sensitive NAT for blood-borne viruses has become essential for the safety of blood components. For more than 2 decades, the NAT screening of blood donations has become standard in developed countries (21-23). The purpose of introduction of NAT in blood banks is for providing additional layer of blood safety. NAT is a highly sensitive and specific screening test, which detects the viral nucleic acids by amplification of RNA and DNA. NAT allows early detection than other serological tests by decreasing the window period of HIV, HBV and HCV infections and increases the false reactive results (24-25).

A recent study from Punjab showed that implementation of NAT helped in preventing 129 patients from getting infected through blood transfusion as out of 32,978 samples, 43 sero nonreactive samples were detected positive by ID NAT.<sup>26</sup> The study concluded that universal application of NAT in blood banks for blood safety is needed for not only matching the international standards but also reducing the burden of the diseases in the society (26).

A retrospective analysis of 5 years of NAT implementation from AIIMS, New Delhi, concluded that NAT is an important screening test in prevention of transfusion transmitted infections (27). Another study from North India, ID-NAT screening detected a total of 156 samples positive (108 HBV, 46 HCV and 2 HIV), which reduced to 93 cases (57 HBV, 34 HCV and none HIV), when additional testing with chemiluminescence immunoassay was further employed on 35,722 seronegative donations (28).

Our study documents serious concerns regarding the HIV, HBV, and HCV infections among the blood donors and the safety of the blood transfusions in our country. The seroprevalence of HIV, HCV and HBsAg infections in our study was 0.07%, 0.7% and 2.6% respectively. Even low prevalence amounts to large number of infected people, considering the vast population of our country. The combined yield (seronegative/NAT reactive) for HIV-I, HCV and HBV has been reported as 0.065%, 0.034% and 0.038% respectively (29-31).

NAT has added an additional layer of safety to the donated blood by further narrowing the window period (32-33). Benefit of NAT as a second tier of testing has been demonstrated through detection of units termed "NAT" yield, which is serology



nonreactive, but NAT reactive. Individual donor NAT (ID-NAT) is a highly sensitive and specific test, which can detect low levels of viral DNA and RNA, with the ability to detect occult infections (34). NAT has been found to be more sensitive and specific than other serological antibody assays.

Studies show that NAT is not sensitive to detect infection in 0.5-1.0% of HBc-reactive and HBsAg-negative donors, which contains very low HBV DNA levels (35-36). This scenario where serology test shows positive result whereas NAT test demonstrates negative result is called as "seroyield." Now, the problem arises whether these seroreactive, but NAT nonreactive (seroyield) units are considered to be infectious or not. Implementation of viral specific serology testing along with NAT testing reduces viral transmitted infection rate to a great extent, but at the same time large number of discrepant results are observed between the serology and NAT. Thus larger controlled trials are required for evaluation of these types of "seroyield" cases (37).

NAT screening is arguably better than serological antibody screening as it narrows the window period of infectious diseases, thereby increases the seropositivity on individual donations. Thanks to the development of NAT technology, the safety of blood components has increased substantially. Since its introduction as a screening test, several hundred NAT-positive donations, so-called NAT yields, have been detected, thereby preventing transfusion-transmitted infections (38-40). Consequently the incremental cost-effectiveness of NAT is marginal since the safety benefits are immense in the prevention of transfusion transmitted diseases (41-42).

## CONCLUSIONS

The possibility of detecting window period infections can be increased and reduce the residual risk of TTIs, by using ID-NAT and thereby infectious donations can be reduced to the recipients.

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