

Original Article

A study on screening of blood donors for seroprevalence of transfusion transmitted infections at Transfusion Medicine department of Armed Forces Institute of Pathology (AFIP), Dhaka.

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ABSTRACT: Safe blood transfusion (SBT) is a challenge in the arena of Transfusion Medicine. Each transfusion carries a risk of transmitting blood-borne pathogens. The present study was therefore aimed to elucidate the prevalence of transfusion transmitted infection (TTI) on routine screening of blood donors with their seroprevalence. A retrospective cross sectional study was done from June 2018 to December 2018 over 7875 donors at Transfusion Medicine Department of AFIP, Dhaka Cantonment. Total 41 were found reactive in the screening assays. The prevalence of HBV, HCV and HIV in our study population was 0.4%, 0.03% and 0.03% respectively. Every ICT reactive sample were re-tested by ELISA to confirm these positive cases. In ELISA among 37 HBV ICT positive samples 35 remain reactive. There was no positive case of Malaria and Syphilis. The study also revealed that HBsAg, Anti-HCV and Anti-HIV positive cases were more prevalent among young donors.

Keywords: TTI -Transfusion Transmitted Infections, ICT - Immunochromatographic Test, ELISA- Enzyme-Linked Immune sorbent Assay, NAT-Nucleic Acid Amplification Testing.

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INTRODUCTION

Blood transfusion is a significant life-saving intervention in the present era of patient management system. The establishment of systems to ensure screening of donated blood is a core component of every national blood program. As the blood and blood products are a potential source of infections and the necessity of transfusion is increasing day by day, transfusion transmissible infections (TTIs) have become a major threat to ensure safe transfusion. Every year more than 90 million units of blood are collected worldwide. Each transfusion carries a risk of

transmitting blood-borne pathogens. To improve blood transfusion safety, the World Health Organization (WHO) recommends an integrated strategy including establishment of well-organized blood transfusion services, prioritization of blood donation from voluntary non-remunerated donors, screening of donated blood for at least the five major transfusion-transmissible infections (TTIs) with quality-assured assays, rational use of blood and implementation of effective quality control systems¹.

Mandatory screening of donated blood for transfusion in Bangladesh began in 2000 after implementation of the Safe Blood Transfusion Programme (SBTP) at all hospital based blood transfusion centers. Testing began under the purview of the Safe Blood Transfusion Act 2002 which states that before transfusion, all blood and blood products must undergo testing for five transfusion transmissible infections (TTIs)².

MATERIALS AND METHOD

Study design

This was a retrospective cross-sectional study conducted in Armed Forces Institute of Pathology (AFIP), Dhaka cantonment, Dhaka during a period of 07 months from 1st June 2018 to 31th December 2018. A total 7875 (seven thousands eight hundred seventy five) cases were selected by convenience sampling method after fulfillment of selection criteria. Inclusion criteria was age: 18 to 60 years, weight: not

Specimen collection

The donors with informed consent and fulfilling the criteria of a standard donor, blood was collected with all aseptic precaution. Samples were collected in prelabeled pilot tube and then serum was separated from clotted blood. A screening algorithm sets out a sequence of steps in the blood screening process to be followed in each facility to determine the suitability of each unit of donated blood and its components for

less than 45 kgs, temperature: below 99.5°F, pulse: 60-100 beat/min, blood pressure: systolic 100-180 mmHg and diastolic 60-100 mmHg, Haemoglobin level: male ≥ 12.5 g/dl, female ≥ 11.5 g/dl, no puncture site, scar mark on arms or forearms indicative of professional donors or intravenous drug users and should be free from respiratory diseases, skin diseases specially at the site of phlebotomy and TTIs. Exclusion criteria were included like malnourished, below 18-year old, weight <50 kg, anaemic person, had a history of jaundice, malaria, asthma, immune compromised i.e diabetic patient, hypertension, heart disease, pregnant and lactating women, engaged in high risk behavior (i.e. unsafe sexual, exposure, drug abuse), had past history of HBV, HCV, HIV I & II, syphilis or were apparently unhealthy or malnourished, travelling history in the endemic area, history of live vaccination (measles, mumps) within last 12 months and donation interval shall be 3-4 months.

clinical or manufacturing use. It specifies the actual tests to be used and, based on each test result, directs the user to the next step. A screening algorithm should be developed for each TTI. The algorithm is determined by the specific infection marker for screening. Once an algorithm has been defined, this will guide the procurement of the specific test kits, reagents and laboratory testing systems required.

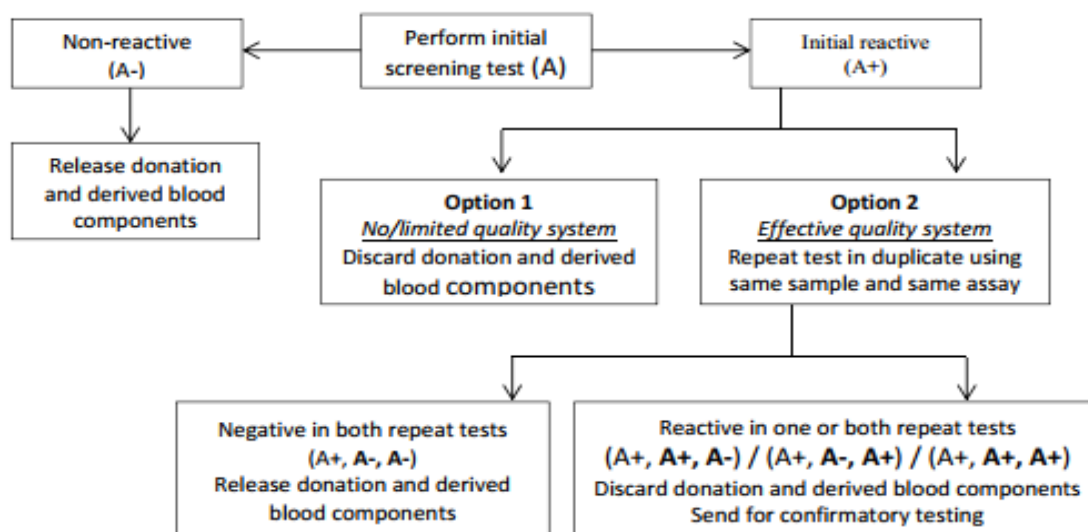


Figure1. Algorithm for Blood Screening2

Pre-and post-donation screening of blood donors

Testing began under the purview of the Safe Blood Transfusion Act 2002 which states that before transfusion, all blood and blood products must undergo testing for five transfusion transmissible infections (TTIs), i.e. Hepatitis B, Hepatitis C, syphilis, malaria and HIV. With globalization and the ability of pathogens to evolve rapidly, continuous

redefining of testing standards and laboratory techniques is paramount for maintaining a safe blood supply.

Detection of HBsAg (qDetect™ Test Kit), Anti-HCV (ABON™ Rapid Test Device) and Anti-HIV 1/2 (ABON™ Rapid Test Device) were done by latex agglutination ICT and reconfirmed by ELISA. Sera were also tested for presence of treponemal antibodies

using rapid plasma reagin (RPR) test with IMMUTREP CARBON ANTIGEN (OD031/OD041). Malaria was screened with Malaria Pf/Pv Antigen (MAL Pf/Pv) Test Kit. Positive specimens were confirmed by microscopic examination. All test were performed in accordance with the instruction of reagent manufacturer. Other necessary laboratory information was collected after completion of test from the donor register book in Transfusion Medicine Department of AFIP.

Performance characteristics of test method

ICT

Sensitivity: >99.53% (99.53%-100.0%)*

Specificity: 99.78% (99.36%-99.95%)*

Accuracy: 99-85% (99.56%-99.97%)*

*95% Confidence Interval

ELISA

The ELISA is a widely used application for detecting and quantifying protein and antigen from various samples. Target specific ELISA Kits are available from a variety of manufacturers (Murex HBsAg Version 3, Murex anti-HCV Version 4.0, EIAgen). The overall sensitivity and specificity of ELISA were 95% and 99.5% respectively.

Procedure of collecting data

Data were collected from donor register book in Transfusion Medicine Department of AFIP from June 2018 to December 2018 and were reviewed. Finally total 7875 donors were included for the study.

Data analysis

After completion data were checked, verified, edited, and coded. The data were analyzed with the help of statistics.

Statistical Analysis

Data have been analyzed by SPSS (Statistical Package for the Social Sciences), results have been compiled in chart and diagram and conclusion were drawn.

Ethical consideration

Ethics committees of AFIP had an important role to play and ensuring the ethical standard and scientific merit of study. The following measures were taken during my study.

1. Quality and integrity of the study.
2. Informed consent from donors.
3. Confidentiality and anonymity of personal history.
4. Voluntarily participation of donors.
5. Avoidance of any harm to the participants.
6. Independency and impartiality during data collection.

RESULTS

Type of donors

In Transfusion Medicine department of AFIP no professional donor had taken part in donation system. In Bangladesh, more than 600 thousands units of blood are collected each year but the majority of these donors are replacement donors, specially family members or close friends of the patient with the intention to help in emergency situations. The relative outnumbered of armed forces personnel was due to regular donation program in armed forces organization.

Table1. Type of the donors (n=7875)

Donors	No	Total
Armed Forces Personnel	2620 (33.27%)	n=7875
Civilians	5255 (66.73%)	

In table1 showing that out of n=7875 donors, Armed Forces Personnel was 2620(33%) and majority was civilians 5255(67%).

Gender distribution of donors

The safe blood is a critical component. The safest donors are found among people who donate their blood voluntarily mainly out of altruism and are self-aware of their unsuitability to serve as a blood donor.

WHO estimates that blood donation by at least 01% of the population is needed to meet the demand. Female blood donor participation is a key issue in this contest. A substantial inequality has emerged between the proportion of male and female donors. The lower proportion of female donors could be attributed to high deferral rates due to anaemia and low body weight as also low motivation levels. Moreover a multiparous woman is not a suitable donor.

Table2. Sex distribution of donors (n=7875)

Sex	No
Male	7579 (96.24%)
Female	296 (3.76%)
Total	7875

Table2 showing that among 7875 donors majority was male donor 7579(96%) and female donor was only 296(4%).

Age preference for blood donation

Demographic changes have a direct impact on the transfusion demand. Blood donors must be at least 18

years old for blood donation with a view to give consent. The outnumbered of donors within 18-27 years is due to increased number of population belonging to this age group.

Table3. Age distribution of donors (n=7875)

Age in years	No
18-27	4226 (53.66%)
28-37	2829 (35.92%)
38-47	686 (8.71%)
48-57	134 (1.70%)
total	7875

Table3 revealed that out of 7875 donors majority was 4226(53.66%) within 18-27 years old age. Least age prevalence of the donors was 134(1.70%) of 48-57 years old age.

Seroprevalence of TTIs

Transfusion of blood and its components is life saving as well as it has life threatening hazards. With every unit of blood there is a 1% chance of transfusion associated problems including transfusion transmitted diseases. Bangladesh maintains a very low prevalence (<1%) of TTI markers. Almost 98% of public centers

use rapid assays for screening. Blood screening programme start in Bangladesh in 2000 at all hospital based blood transfusion centers. The objective of screening is to detect markers of infection, and prevent the release of infected blood and blood components for clinical use. The assay selected for screening should be highly sensitive and specific. The aim is to detect all possibly infected donations while minimizing wastage due to false positive results. Reactive donations that are confirmed positive, or in which results are indeterminate, should be discarded using methods in accordance with standard safety precautions.

Table4. Sero positivity among the donor by ICT (n=7875)

Screening test	No
HBsAg	37 (0.4%)
Anti-HCV	2 (0.03%)
Anti-HIV	2 (0.02%)
Malaria	-
Syphilis	-
Total	41 (0.52%)

Table4 showed that among 7875 donors 41 samples were reactive in ICT method of testing. Among them HBsAg, anti-HCV and anti-HIV were 37, 2 and 2

positive cases respectively. There were no positive cases of malaria and syphilis.

Table5. Sero positivity among the donor by ELISA (n=7875)

Screening test	ICT positive	ELISA positive
HBsAg	37 (0.46%)	35 (0.4%)
Anti-HCV	2 (0.03%)	2 (0.03%)
Anti-HIV	2 (0.02%)	2 (0.03%)
Malaria	-	-
Syphilis	-	-
Total	41 (0.52%)	39 (0.5%)

Table- V showing out of 7875 donors, positive cases of HBsAg, anti-HCV and anti-HIV were 35(0.4%), 2(0.03%) and 2(0.03%) respectively

Types of assays for reactive cases

The assays commonly in use are designed to detect antibodies, antigens or the nucleic acid of the infectious agent. However, not all assays are suitable in all situations; each has its limitations which need to be understood and taken into

consideration when making a selection. The main types of assay used for blood screening are:

- Immunoassays (IAS)
- Enzyme immunoassays (EIAs)
- Chemiluminescence immunoassays (CLIAs)
- Rapid/simple single-use assays (rapid tests)
- Nucleic acid amplification technology (NAT) assays.

Each assay should be validated in its place of use to assure that the performance is as expected according to the results of evaluation.

Table6. Distribution of reactive cases in ELISA (n=39)

Screening test	Armed Forces Personnel	Civilians	Total
HBsAg	4 (10.26%)	31 (79.49%)	35 (89.74%)
Anti-HCV	-	2 (5.13%)	2 (5.13%)
Anti-HIV	1 (2.56%)	1 (2.56%)	2 (5.13%)
Malaria	-	-	-
Syphilis	-	-	-

Table6 revealed that among 39 seropositive donors, in ELISA majority was civilians 34(87%), HBsAg positive 31(79.49%), anti-HCV 2(5.13%), anti-HIV 1(2.56%) and Armed Forces Personnel was 5(12.92%), HBsAg positive 4(10.26%), anti-HIV positive 1(2.56%) respectively.

Seroprevalence with age-variation

This study did not find any association between TTIs Seroprevalence and blood transfusion history. Recent implementation of high quality screening assays, coupled with stringent pre-donation screening and enhanced haemovigilance may have influence in decrease transfusion risk observed earlier. Meanwhile, previous exposure of high risk sex still harbor the TTIs burden observed among young blood donors.

Table7. Sero positivity in different age group (n=39)

Age in years	Positive cases	HBsAg	Anti-HCV	Anti-HIV
18-27	25	23(58.97%)	1(2.56%)	1(2.56%)
28-37	09	08(20.51%)	1(2.56%)	
38-47	04	03(7.69%)	-	01(2.56%)
48-57	01	01(2.56%)	-	-
Total (n=39)	39 (0.5%)	35(89.74%)	02 (5.13%)	02 (5.13%)

Table7 showing out of 39 reactive donors, 25 positive cases belongs to 18-27 years age group having HBsAg 23(58.97%), Anti-HCV 1(2.56%) and Anti-HIV 1(2.56%) positivity respectively; 09 positive cases belongs to 28-37 years age group having HBsAg

08(20.51%), Anti-HCV 1(2.56%) positivity respectively; 38-47 years age group have 4 positive cases among them HBsAg 03(7.69%), Anti-HCV 1(2.56%); 48-57 years age group have 1 positive cases of HBsAg 1(2.56%) respectively.

DISCUSSION

According to the WHO, safe blood is a universal right. A national program is a crucial requirement in the process of procuring safe blood which must include proper donor selection, recruitment, retention and education³.

This study comprises of total 7875 samples of donor came to AFIP for routine screening. Out of 7875 samples, 41 samples were reactive in ICT method of testing. Among them HBsAg, anti-HCV and anti-HIV were 37, 2 and 2 positive cases respectively. There was no reactive cases of malaria and syphilis. Every ICT reactive sample were re-tested by ELISA to confirm these positive cases. In ELISA among 37 HBV ICT positive sample 35 become reactive and 2 sample become negative for HBsAg and anti-HCV, anti-HIV both positive sample remain reactive. Among 39 reactive donors all of them were male. No female donors were screening positive.

Hilda Fernandes, Prema Fancy D'souza and Pushpa Maria D'souza showed in Indian Society of Haematology & Transfusion Medicine in 2010 among 9599 donors for the prevalence of TTI over a period of 2 years, out of these 97.5% were male donors and 2.5% were female donors. Prevalence of TTI in total donors was 0.6%. Prevalence of hepatitis B was highest (0.34%) followed by syphilis (0.11%),

HIV&HCV (0.06%) and malaria (0.01%)⁴. In our study male donor were 96% and female donor were 4% which is consistent with their study. In our study TTI prevalence was 0.5% and hepatitis B was highest (0.4%) followed by HCV and HIV (0.03%) but syphilis and malaria was 0.0%. So our present study is almost similar to their study except the prevalence of malaria and syphilis.

Henshaw Uchechi Okoroiwu, Ifeyinwa Maryann Okafor et al. Showed in their study that out of the 24,979 screened prospective donors in the 2005–2016 study period, 3739 (14.96%) were infected with at least one infective agent. The overall prevalence of HBV, HCV, syphilis and HIV were 4.1%, 3.6%, 3.1% and 4.2%, respectively. The study showed male dominated donor pool (98.7%) with higher prevalence (4.2%) of transfusion-transmissible infections than in female donors (0.0%)⁵. In our set up male donor also constituted majority (96.24%) with higher prevalence of TTI in male than in female donor (0.0%). In our study TTI prevalence was 0.5% and hepatitis B was highest followed by HCV and HIV (0.03%) but syphilis and malaria was 0.0% which is much lower prevalence rate than their prevalence. So their TTI prevalence was not consistent with our study. Comparison of TTI prevalence with other similar studies showing in the table below:

Table8. Comparison of TTIs prevalence with other similar studies

Study	Sample size	Sero prevalence	HBsAg	Anti-HCV	Anti-HIV	Malaria	Syphilis
Hilda Fernandes, Prema Fancy D'souza et al. ⁴	9599	0.6%.	0.34%	0.06%	0.06%	0.01%	0.11%
Henshaw Uchechi Okoroiwu et al. ⁵	24,979	14.96%	4.2%	3.6%	4.2%	-	3.1%
Mohammed Alaidarous et al. ⁶	3028	1.2%	0.46%	0.66%	0.07%	-	-
Present study	7875	0.5%	0.4%	0.03%	0.03%	-	-

Mohammed Alaidarous et al showed in their study in Saudi Arabia that out of the 3028 blood samples, 10 (0.33%) reacted to HBsAg; 12 (0.40%) reacted to HCV antigens; 4 (0.13%) reacted to HIV Ab/Ag combinations; 6 (0.20%); 297 (9.81%) reacted to HBcAbs and 236 (7.80%) reacted to HBsAbs. Additionally, NATs showed that 14 (0.46%) reacted to NAT-HBV; 20 (0.66%) samples were reacted to NAT-HCV and 2 (0.07%) samples reacted to NAT-HIV. 16 (0.53%) were reacted to syphilis. No sample was positive for malaria. Their study results indicated that NATs are more effective than serology tests for detecting TTIs. Moreover, correlations between sex distribution of TTI prevalence with other similar studies:

standard serology tests and NATs indicated that using NATs could improve test sensitivities and decrease residual risks of TTIs and ensure safe blood transfusions⁶. In our study out of 7875 samples, 41 samples were reactive in ICT method of testing. Every ICT reactive sample was re-tested by ELISA to confirm these positive cases. In ELISA among 37 HBV ICT positive sample 35 become reactive and 2 sample become negative for HBsAg and anti-HCV, anti-HIV both positive sample remain reactive. So in our study ELISAs are more effective than serology tests for detecting TTIs. The following table showing

Table9. Gender distribution of TTIs prevalence

Study	No of sample	Male donor	Female donor	TTI Prevalence in Male	TTI Prevalence in Female
Hilda Fernandes ,Prema Fancy D'souza et al. ⁴	9599	97.5%	2.5%	-	-
Henshaw Uchechi Okoroiwu et al. ⁵	24979	98.7%	1.3%	100%	0%
Present study	7875	96.24%	3.76%	100%	0%

There was no positive case of Syphilis, Malaria and HIV which was consistent with other local studies. Studies done in Pakistan, Israel and Iran found a rising trend of syphilis frequency in their population⁷. In another local study, 5.5% VDRL positive cases were found, most of them were young donors. This finding is also not consistent with our study finding⁸.

In our study majority of the donors were 4226 (53.66%) age between 18 and 27 years old. In our study most of the donors are male and within young age group. Other studies have similar age distribution⁹. Selection of this population group may underestimate the actual prevalence because around 50% of our population is female. In our study male donors recorded the highest prevalence of TTIs and no female donor were found reactive for TTIs. This finding is similar to the report of Okocha et al. Zaheer et al. attributed this to the view that women are confined to home settings, and therefore, are comparatively less exposed to the risks factors associated with transfusion transmissible infections as compared to males^{10,11}.

CONCLUSION

Our study reveals that a significant number of donors are positive for TTIs who are a potential source of transfusion related infections. It justifies the necessity of stringent screening of blood donors to prevent the transfusion transmissible infections. Bangladesh is a low-resource well populated country with many limitations in the system of providing healthcare. Standard practices should be in place to include appropriate testing, careful selection of donors, screening and compatibility testing, storage of donations and issue of blood units for either routine or emergency use. The implementation of Standard Operating Procedures (SOPs) for the processes involved in blood screening is also an effective tool in improving the safety of the blood supply. For future up gradation of transfusion department and to justify emergency demands of right blood components in a right time for right person, all the information of recipients should be documented and saved.

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