



Original Article

Blood Transfusion Service and Hospital Blood Rotation: The Implications on Transfusion Safety in Nigeria

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ABSTRACT

Blood donation is not readily an altruistic sacrifice in sub-Saharan Africa where microbial infections, maternal haemorrhages, malaria and other tropical diseases that frequently require blood transfusion are daily diagnoses. Blood transfusion safety is hindered by the combined prevailing high rate of Transfusion-Transmissible Infections (TTIs) and poor screening techniques. This study determined the rate of Enzyme-Linked Immuno-Sorbent Assay (ELISA) positive reactions to transfusion-transmissible infections in rapid diagnostic test negative family replacement blood units, compared to the first time voluntarily donated blood. We studied records of blood units collected in a tertiary hospital from donors who scaled pre-donation Rapid diagnostic test (RDT) screening for the human immunodeficiency virus, hepatitis B and hepatitis C viruses and syphilis and rescreened by ELISA techniques at the National Blood Transfusion Service Centre in Jos, along with units from first-time voluntary blood donors. A total of 19562 blood units; 5945 (30.39%) rapid diagnostic tests negative from a linkage hospital and 13617 (69.61%) from first time voluntary donors were screened by ELISA methods for HIV, HBV, HCV, and syphilis. The overall TTIs detected by ELISA was 16.08%, significantly lower among pre-donation rapid screened family replacement blood donors [495(8.32%)] compared to 2651 (19.47%) among first-time voluntary donors; P=0.0001. Fifty-seven (0.96%) HIV, 166 (2.79%) HBV, 137 (2.31%) HCV and 137 (2.31%) syphilis were still detected respectively by ELISA in the pre-screened negative family replacement blood units. The outcome of ELISA screenings of blood collected from first-time volunteer donors were; 143 (1.05%) HIV, 1,486 (10.91%) HBV, 683 (5.02%) HCV, and 339 (2.49%) syphilis. Blood for transfusion should be screened negative at least with ELISA.

Keywords: *Blood, Screening, ELISA, Rapid Diagnostic Test, Transfusion.*

INTRODUCTION

The responsibility of the National Blood Transfusion Service is to provide sufficient quality blood in a timely manner, safe from the viral hepatitis (hepatitis B and C viruses), syphilis and the human immunodeficiency virus (HIV) for transfusion in Nigeria. Blood sourced from volunteers directly or from family replacement donors through

hospital blood collections are subjected to screening routinely using ELISA technology, at the National Blood Transfusion Service for the four infectious agents. The blood rotation programme of the National Blood Transfusion Service Centre (NBTS) Jos Centre ensures the transfer of blood units from

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hospitals within and around the north central region of Nigeria to the zonal blood service centre for screening, while only ELISA screened negative units are returned to these hospitals for transfusion. Most hospitals in sub-Saharan Africa including Nigeria and its north central region still utilize the rapid diagnostic test (RDT) kits in the hospitals to screen and transfuse blood. These four transfusion transmissible infections have been documented at varying frequencies among blood donors using the outcome of screening with rapid diagnostic test (RTD) kits, ELISA kit and nucleic acid test (NAT).

Buseri et al (2009) reported a high 18.6% sero-prevalence of hepatitis B virus, followed by Hepatitis C virus, HIV and syphilis (1.1%) infections among blood donors in Osogbo, South West Nigeria.¹ Largely paid blood donors in Lagos, the cosmopolitan and most populous city of Nigeria, had a prevalence of 9.80% HIV, 1.37% HBV, 1.10% syphilis and 0.84% HCV.² Ejele and other co-workers (2005), using rapid diagnostic test kits, documented low rate of human immunodeficiency, hepatitis B and hepatitis C viruses among their largely male commercial and replacement donors.³ Nwogoh *et al* (2011), working in South-South Nigeria demonstrated higher prevailing rates of viral TTIs among their commercial donors compared to replacement blood donors.⁴ In the South-East Nigeria, Okocha and others (2015) recorded an equal prevalence of 2.0% for hepatitis B and hepatitis C. They further observed varying sensitivity and rates of HIV positivity by using different test methods, the most sensitive being anti P24 antibody test.⁵ Amiwero and partners (2013) working in the central region of Nigeria, reported 14.1% HBV, 3.9% HCV and 1.0% HIV among their blood donors in Bida.⁶

Research reports from studies outside Nigeria show study populations that are predominantly volunteer blood donors. Hepatitis and syphilis constituted the high TTIs rates in a Ghanaian study out come on blood borne infectious diseases.⁷

Major transfusion transmissible infections were rampant among Cameroonian blood donors in 2003, still reflected in 2013.^{8,9} A 2011 A study report from Eritrea documented a 79.0% voluntary blood donor population with TTIs rate less than a digit except for hepatitis B that was detected in 2.58%.¹⁰ Ethiopian studies however recorded high TTIs rates in Wolaitasodo university referral hospital and among blood donors at Hawassa blood bank centre, both in southern Ethiopia.^{11,12} While HCV and HBV were detected in about 4% and 1% among Egyptian blood donors, HIV and syphilis were at less than single digit prevalence.¹³ At the Namibian Blood

Transfusion Service, nucleic acid test (NAT) yielded a low rate of 1.3% overall transfusion transmissible infections rate among their blood donations. The highest prevalence was recorded against HBV marker while the least was HCV.¹⁴

Trends in the prevalence of transfusion transmissible infections among blood donors in Albania was 7.4% overall with hepatitis B virus leading in donor infection.¹⁵ Institutional retrospective study of TTIs among a predominantly voluntary blood donors in Adaman and Nicobar islands of India demonstrated and overall 2.18% infections also leads by hepatitis B and C viruses.¹⁶ A study in the Sub-Malayan rural tertiary health care centre documented a low TTIs rate with hepatitis B accounting for nearly half of infections.¹⁷ The prevalence of TTIs in West China is put at 2.67% with observed decreasing trend among donors with increasing donations while increasing with donor age and low education level.¹⁸ Shreiber et al (1996) described the risk of transfusion of transfusion transmitted viral infections, as high as 1/63000 transfusion for HBV and as low as 1/641000 for the human T-lymphotropic virus.¹⁹ The implementation of a structured blood safety policy in South Africa saw a remarkable reduction in the prevalence of HIV from 0.17% in 1999 to 2000, to 0.08% between 2001 and 2002.²⁰

The National Blood Transfusion Service, considering the peculiarities in Nigeria, should lead in the development of an attainable, implementable and sustainable policy for blood safety in the country. This is critical now with the concluded withdrawal of funding support by the Centre for Disease Control (CDC), hitherto supporting blood safety in Nigeria and implementation of ELISA testing for blood transfusion. There is scanty information on the ELISA reactions of donated blood that scaled hospital rapid screening tests, and hence declared fit for transfusion at that level.

Aim and Objectives

This study sought to determine the TTIs status of donated blood units declared 'safe' after RDT screening s. The study was to enable us make recommendations for a sustainable blood screening protocol that guarantees safety from TTIs.

MATERIALS AND METHODS

This was a retrospective study of blood units collected in a hospital where pre-donation transfusion transmissible infections screening are carried out. Records of blood units

collected in a tertiary hospital from donors who scaled pre-donation Rapid diagnostic test (RDT), strips screening for the human immunodeficiency virus (Determine), hepatitis B virus (Skytech) hepatitis C virus (Agary) and syphilis (Skytech) and rescreened at the National blood Transfusion Service Centre in Jos were studied along with units from first-time voluntary blood donors who donated Voluntarily directly to the National blood Transfusion Service in Jos, Nigeria. ELISA methods used to screen donated blood at the National Blood Service Centre for each TTIs were; Genscreen HIV Ag-Ab, Bio-Rad, France and Monolisa HBs Ag, Bio-Rad, France for HIV and HBV respectively. HCV–Ab and Syphilis ELISA screenings were by DIAPRO kits produced in Italy. The outcome of ELISA screening for units pre rapid diagnostic tests screened negative for TTIs was compared to that of units collected from first-time volunteer donors and also screened with ELISA. Data was analysed using epi info 2010 version, P-value less than 0.05 was considered significant. The ethical clearance for this work was obtained from the ethics committee of the North Central Zonal Centre, Jos, of the National Blood Transfusion Service,

RESULTS

A total of 19562 blood units; 5945 (30.39%) rapid diagnostic tests negative from a linkage hospital and 13617 (69.61%) from first time voluntary donors were screened by ELISA methods for HIV P24 antigen and antibody, HBsAg, HCV antibody and syphilis antibody. The overall (crude) TTIs prevalence, detected by ELISA, was 16.08%, significantly lower among pre-donation rapid screened family replacement blood donors [495(8.32%)] compared to 2651(19.47%) among first-time voluntary donors; P=0.0001. Fifty-seven (0.96%) HIV, 166 (2.79%) HBV, 137 (2.31%) HCV and 137 (2.31%) syphilis were still detected respectively by ELISA in the 5,945 pre-screened negative blood units received from the linkage hospital (table 1). On the other hand the outcome of ELISA screenings of blood collected from 13,617 first-time volunteer donors without pre-donation RDT screening were; 143 (1.05%) HIV, 1,486 (10.91%) HBV, 683 (5.02%) HCV and 339 (2.49%) syphilis. The rate of ELISA positive reactions for HIV and syphilis among RDT pre-screened family replacement blood units and first time voluntary donors was not significant, P=0.55 and 0.43 respectively (table 1). The rate of ELISA positive reactions for HBV and HCV among pre-screened units

was significantly lower than among first-time voluntary blood donors, P=0.0001 in both cases (table 1)

Table 1: TTIs ELISA screening outcome of pre-donation RDTs screened negative family replacement and first-time voluntarily donated blood units at the National Blood Transfusion Service in Jos

TTIs	RDT Neg. FR Blood Units		First-Time Volunteer Blood Units		P value
	Pos (%)	Neg (%)	Pos (%)	Neg (%)	
HIV	57 (0.96)	5888 (99.04)	143 (1.05)	13474 (98.95)	0.55
Syphilis	137 (2.31)	5808 (97.69)	339 (2.40)	13278 (97.60)	0.43
HBV	166 (2.79)	5779 (97.21)	1486 (10.91)	12131 (89.09)	0.0001
HCV	137 (2.31)	5808 (99.04)	683 (5.02)	12934 (94.98)	0.0001
Total	495 (8.32)	5450 (91.78)	2651 (19.47)	10966 (81.53)	0.0001

Keys: TTIs; transfusion transmissible infections, HIV; human immunodeficiency virus, HBV; hepatitis B virus, HCV; hepatitis C virus

DISCUSSION

The crude TTIs rate (16.08%) for all blood units in this work is similar to, but lowers than was earlier described in 2013.²¹ This may suggest increased awareness on the need for self-deferral for intending voluntary blood donors who are at risk of contracting and transmitting the TTIs. Sustained donor education may reduce TTIs risk exposure and further narrow down the infection rate among existing and future genuine family replacement donors and altruistic blood givers. Transfusion of blood after a negative RDTs screening, as is obtainable in most health care centres in Nigeria, carries an unacceptable risk of infecting about 8% of recipients with TTIs. The blood service must intensify efforts at complementing health care by meeting both availability and quality in blood transfusion.

Hepatitis B virus among pre-donation screened family replacement blood donors in the linkage hospital when subjected to ELISA is lower than among our first-time voluntary blood donors tested over the same period. The prevalence of 10.91% HBV in the first-time volunteer donors is lower than 14.1% among largely non volunteer blood givers in Bida Nigeria.⁶ Pre-donation HBV screening missed (2.79%), Enzyme-linked Immuno-sorbent Assay (ELISA) detectable infection in presumed safe and subsequently bled donors. This finding concurs with Wu et al (2016) who observed that a simple rapid test card method could miss positive samples with low viral load and low antibody to core antigen or both.²² On the other hand; false positive HBV surface antigen tests could occur in peripheral blood progenitor donors who received granulocyte colony stimulating factors and also in post hepatitis B vaccination.^{23,24} Positive HBsAg in blood units from donors

screened negative with RDT kits before donation in our study does not only confirm the superior safety with ELISA technique but calls for mandatory HBV ELISA screening of blood for transfusion even when the donors are non-reactive at RDT. Where and when possible, we agree with Kuhns and colleagues (2006) who recommended the combination of nucleic acid amplification test (NAAT), hepatitis B core antibody and HBsAg for blood donor testing to attain best practice.²⁵ The high prevalence of Hepatitis B among blood donors in our setting calls for a local cost effective protocol that will achieve process contamination risk reduction at ELISA and NAT of donor blood. We therefore posit that all blood units in areas with high prevalence of HBV infection like ours should be subjected to RDT screening and only non-reacting unit's further screen with ELISA.

While HCV antibody ELISA test detected 5.02% evidence of infection among first-time voluntary donors, it was positive in 2.31% of blood units thought to be safe from hepatitis C contamination based on RDT negative test in our linkage site. The rate of HCV in presumed safe donors in our study is similar to the prevalence documented among blood donors in south-east Nigeria.⁵ In healthy blood donors, negative HCV serologic tests by sensitive enzyme immunoassays require confirmation by molecular diagnostic test such as HCV RNA-polymerase chain reaction which may detect infection in the diagnostic window period prior to seroconversion.²⁶ Maniez-Montreuil and others (2000) however recommended immunoblot and genome amplification tests for confirmation of positive and dubious HCV enzyme immunoassay result and PCR to distinguish between serological sequel and disease chronicity.²⁷ The close rates of ELISA reaction in both RDT pre-donation screened units and that from first-time voluntary donors implies that RDT screening may not save significant cost of HCV testing in blood donor while RDT without ELISA would lead to infection of blood recipients with serologic reactive units having probably low antibody titre. There may be no cost advantage in preliminary pre-donation screening for hepatitis C viral antibody.

The utilization of pre-donation RDTs for HIV and syphilis screenings of blood donors in the linkage hospital did not significantly reduce ELISA reactivity lower than recorded among our first-time voluntary donors (Table 1). The low HIV and syphilis infection rates among the two categories of donors in our study are similar to the low TTIs rates among a predominantly voluntary blood donors screened in Eritrea but

lower than the report from Southern Ethiopia.^{10,11} The transmission of HIV is most efficient through the transfusion of blood and blood products a situation, not only prevalent in Africa due to high blood therapy requirements, further compounded by poor blood donor or blood unit testing.²⁸ RDTs are poor tools for disease diagnosis and blood screening as significant false negative and positive reactions are common with great consequences in blood transfusion.²⁹ False positive result implies probable blood unit losses occurring at hospitals screening with RDTs while false negative screening outcome would lead to transfusion acquired infections of blood recipients. Zakari (2017) recently confirmed the reliability of HIV ELISA screening when he recorded no NAT positive outcome in over one thousand blood units earlier screened negative with the fourth generation ELISA.³⁰ Our findings therefore, further forewarn against the practice of transfusing blood units declared safe after rapid test screening for TTIs.

CONCLUSION

Markers of TTIs were detected by ELISA in blood received from FR donors who were, RDTs pre-screened negative for the infections, in this study. It is further concluded that blood unit declared safe after RDTs testing is unsafe for transfusion until it is subjected to at least ELISA testing for the TTIs. Transfusion of RDTs screened negative blood units is an unacceptable practice with risk for the transmission of serious transfusion acquired infections. There is likely a cost benefit for pre ELISA RDTs testing of hepatitis B infection in blood transfusion. Prevention and elimination of HIV and other transfusion transmissible infections may elude Nigeria and other similar settings unless a revolution in transfusion practice, backed by strong policy and legislation, which prohibits the use of RDTs only for pre-transfusion blood testing, is instituted.

RECOMMENDATION

We recommend an urgent enforceable legislation which would provide for a coordinated blood service that will ensure safety in blood transfusion in Nigeria. Blood unit for transfusion must be screened and certified free from the TTIs recommended for mandatory screening. RDTs should be used only as initial screening for HBV with all non-reactive units subjected to ELISA testing. We recommend a wider study to assess the blood safety practices at a national level. The introduction of

NAT testing in the blood service will not only provide the capacity to differentiate between true and false positive ELISA reactions but also identify cases with acute infections.

LIMITATIONS

The study only addressed the family replacement units in only a single linkage hospital partnering with the national blood transfusion service. Lack of funding prevented us from including NAT testing for the TTIs, which would have assess false positive and true positive units that reacted by ELISA.

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Conflict of interest

None declared

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