

Original Research Article

A COMPARISON OF TWO HIV ANTIBODY ELISAs WITH A COMBINED ANTIGEN-ANTIBODY ELISA FOR THE OCCURANCE OF FALSE RESULTS IN A HOSPITAL-BASED BLOOD BANK IN NORTH CENTRAL NIGERIA.

ABSTRACT:

Background: Global strategies with targets for making safe blood universally availability by 2020 and the elimination of HIV transmission by 2030 have been set. This action throws a burden of care on resource=limited settings (RLS) like hospital-based blood banks to deploy appropriate strategies towards meeting these set targets.

Aims and Objectives: To assess false positive and false negative test results obtained with two third generation HIV antibody screening tests (Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA) in a hospital-based blood bank in North central Nigeria and to appraise implications of findings on blood safety and availability.

Materials and methods: This was a cross sectional hospital-based study carried out on the serum of four hundred and forty blood donors predominantly males and family donors/family replacement donors to evaluated the proportion of false negative (FN) and false positive (FP) test results obtained with Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA that are commonly used to safeguard blood donations against TT-HIV in Nigeria. These assays were compared with Genscreen ®PLUS HIV Ag- Ab ELISA (a combined HIV antigen-antibody ELISA or 4th Generation ELISA).

Results: False negative (FN) tests results were recorded as 60.98% and 46.34% for Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 respectively related to the sensitivities (39.02% and 53.50%) and specificities (100% and 99.50%) of Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 respectively. The proportion FP test results were found to be 0 and 4.88 percent for Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 respectively.

Conclusion: The Genscreen ®PLUS HIV Ag-Ab ELISA demonstrated superior ability in discriminating FP and FN HIV donors when compared with the two third generation antibody ELISAS. Deployment of these antibody assays could potentially compromise the quality of

31 blood sourced, encourage wastages and wrongful discard of blood units or disqualification of
32 blood donors as well as deny this RLS from achieving globally set targets.

33 **Recommendation:** While NAAT is the ideal test for securing all hospital-based blood
34 transfusions from TT-HIV but yet to be implemented in Nigeria, the Genscreen ®PLUS HIV
35 Ag-Ab ELISA demonstrated in this study to report less false negative and false positive test
36 results than the third generation ELISAS should be deployed in hospital-based transfusions to
37 ensure safety and blood availability.

38 **Key Words:** Antibody ELISA, Combined Ag-Ab ELISA; False Positive; False Negative;
39 Transfusion-transmissible=HIV; Nigeria;

40 **Introduction:**

41 Laboratory testing for human immunodeficiency virus (HIV) has been introduced since
42 1980s for individual patient-based diagnosis as well as high-risk and low-risk population-
43 based screening either as Enzyme – Linked Immuno-sorbent Assay (ELISA) or non-ELISA-
44 based techniques. (1)

45 Screening targets specific parts of HIV including its gene sequence, gene products or
46 measures the hosts' antibodies and are associated with varying quality parameters including
47 the proportions of false positive and false negative rates, sensitivity and specificities which
48 bear consequences on patients, care givers and society.

49 The HIV Nucleic acid amplification test (NAAT) currently deployed in resource endowed
50 settings (RES) but not universally available to resource limited settings (RLS) because of its
51 expensive, technically demanding and logistic challenging nature detects the infectious
52 particles or antigens even before antibodies are produced allowing for earlier detection of
53 primary HIV infection in high risk groups and narrows the diagnostic window and residual
54 risk of transfusing an infectious blood by over 50 percent. (2)(3)

55 The HIV antibody-based tests either as rapid Diagnostic Tests (HIV-RDT) or manual plate
56 Enzyme Immuno Assays (EIA) are the traditional methods utilized in securing blood
57 donations in RLS. The HIV-RDT defined as those tests that can be completed in less than 30
58 minutes and do not require instrumentation and can be read visually (4) have particularly
59 assumed popularity and patronage as a major initiative in protecting blood recipients from
60 TT-HIV in RLS.

61 The World Health Organization (WHO) has recommended that, donated blood should be
62 screened for HIV using a highly sensitive and specific anti-HIV-1 anti-HIV-2 immunoassay
63 or a combined HIV antigen-antibody immunoassay (EIA/CLIA) that is capable of detecting
64 subtypes specific to the country or region and in its absence, a highly sensitive and specific
65 anti-HIV-1 anti-HIV-2 rapid assay could be used in laboratories with small throughput,
66 remote areas or emergency situations. (5)

67 Quintessentially, NAAT is desirable but not compulsorily recommended for safeguarding
68 blood supplies and in its place different methodologies are usually deployed in different
69 regions of the world dependent on the local hospital or national recommendation which often
70 specifies that such test must identify all possible HIV infections in that setting.

71 Hospital-based HIV testing for blood transfusion is only aimed at “screening” to identify
72 blood donors or blood units testing HIV seronegative so as to be channeled towards
73 transfusion while those that test seropositive are given little consideration and the action often
74 require a referral to a treatment centre wherever it exists for diagnosis. In the case of an
75 infectious blood unit detected, it is discarded with implicating financial and man-hour
76 wastages.

77 The interpretation of all antibody-based HIV screening test requires some form of conversion
78 from a contentious measurement scale to a discontinuous scale as positive or negative test
79 result. When measured against standards, test sensitivity, specificity, positive and negative
80 predictive values usually differ and no single test has both 100% sensitivity and 100%
81 specificity nor 100% positive and 100% negative predictive values. (1)

82 HIV antibody assays deployed for blood safety and availability programmes are ideally
83 expected to be extremely sensitive and able to detect all known HIV subtypes tested without
84 having to record false negative results and be absolutely specific to minimize false positive
85 tests (6)

86 However, discrepancies in test methodologies usually arise from the proportion of false
87 positive and false negative test results which bears implications to patients, practitioners and
88 government. In order to improve efficiency, most blood transfusion centres screening for HIV
89 set up their cut off value at high sensitivity to minimize the number of false negative results
90 and defer blood donors with positive test results to other clinicians for repeat diagnostic
91 testing. (1)

92 In realization that, even the best methods for HIV screening are capable of producing false
93 positive and false negative results, Constantine and Zink (7) advised on careful and
94 appropriate selection of HIV tests. A false negative test result is observed where a potential
95 blood donor is identified as being HIV sero-negative when in fact such donor has the
96 infection when tested on a gold standard test or method. On the other hand, a false positive
97 test result is observed where a potential blood donor is screened as being HIV sero-negative
98 when indeed he or she does have HIV infection as tested with by a gold standard test or
99 method.

100 In many RLS of Africa, the organization of hospital-based transfusion centres is peculiar;
101 hospitals are generally “stand alone” entities relying on their lean financial budgets to run the
102 reputedly high-cost services associated with blood transfusion. Their responsibilities revolve
103 around all the key aspects of blood transfusion including blood donor recruitment, blood
104 collection, screening for transfusion transmissible infections, processing into components and
105 products as well as cross-matching and clinical utilization for transfusion in individual
106 centres or hospitals. In this setting, the logistics for donor assessment and counselling is often
107 weak paving way for unprofessionalism and paucity of safe blood donors who are truly
108 voluntary, altruistic and non-remunerated. (8) Such deviances potentially compromises
109 quality practices giving rise to unchecked high false positive testing of blood donors,
110 unnecessary donor deferrals and stigmatization. Many researchers including Philips et al (9)
111 have submitted on the importance of evaluating HIV screening tests with all specimen types
112 in the population of intending use before widespread application. (1)

113 As the global target of ensuring a zero HIV transmission by 2030 (10) gets close at hand,
114 RLS must brace up to achieve set target.

115 Therefore, giving the non-availability of NAAT and continued deployment of HIV antibody
116 tests to secure blood transfusion against TT-HIV viz a viz the need for routine validation of
117 these assays in our environment, we sought to assess false positive and false negative test
118 results obtained with two third generation HIV antibody screening test in comparison with a
119 combined antigen-antibody test (fourth generation assay) in a hospital-based blood bank in
120 North central Nigeria and appraised implications of our findings on blood safety and
121 availability in this RLS.

122 **METHODOLOGY:**

This cross sectional study validated false negative and false positive rates of two HIV antibody test assays (Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA) used to safeguard blood donations against TT-HIV in a hospital-based transfusion unit of Jos University Teaching Hospital(JUTH), North Central Nigeria. Evaluated assays were compared with GENSCREEN®PLUS HIV Ag- Ab ELISA (combined HIV antigen-antibody ELISA or 4th Generation ELISA or Enhanced ELISA) considering reports that, 4th generation ELISAs are similar in performances NAAT.(3)

All ethical standards were adhered to and ethical approval was obtained from the ethical committee of the institution.

Four hundred and forty (440) blood donors of both sexes aged between 18 and 55 years, who presented and met the inclusion criteria i.e. fulfilled the conditions to donate blood in Nigeria and consented to participate in this study were enrolled between May and August 2008. Those who did not meet the minimum criteria to donate blood and or declined to give informed consent were excluded. A validated questionnaire was administered by trained research assistants to identify donors' bio-data and their relevant characteristics.

Ten (10) milliliters of venous blood was collected from ante-cubital vein of all the blood donors using a large bore needle to avoid haemolysis and under aseptic conditions. Haemostasis was secured and the collected blood emptied into a clean evacuated tube without an anticoagulant. The process of serum extraction and storage was carried out using standard methods (11)(12). The serum collected was screened for HIV antibodies using Determine™ HIV 1/2 manufactured by Abbott Japan Co. Ltd, Minato-Ku, Tokyo-Japan and thereafter, tested with Dia Pro HIV 1/2/0 EIA and Genscreen®Plus HIV Ag- Ab ELISA manufactured by diagnostic Bioprobes Sx/Italy and BIO-RAD laboratories, 3 Bd Raymond Poincaré, Marnes La Couquette-France respectively. All reagents were sourced from commercial vendors within the country and a cold chain was maintained in the transport, delivery and storage of the reagents until its eventual utilization for testing. All procedures were carried out following the manufacturers' recommendations strictly.

Statistical Analysis: The combined HIV antigen-antibody ELISA Genscreen®Plus HIV Ag- Ab ELISA) was used to validate the two HIV antibody testing methods for False-Negative (FN) , false positive (FP) , negative predictive value (NPV), positive predictive value (PPV) together with the variation of sensitivity, specificity and risk ratios were calculated using the Graph Pad Prism 5 Statistical Package. A p-value ≤ 0.05 was taken as level of significance for interpretation of data using Fishers Exact Test.

157 **RESULTS:**

158 Table 1: False Negative, False Positive and some Relevant Laboratory quality considerations
 159 of Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 HIV-antibody assays as compared
 160 with Genscreen ®PLUS HIV Ag-Ab ELISA among blood donors.

Parameter	Determine™ HIV 1/2/0 vs Genscreen ®PLUS HIV Ag-Ab ELISA	HIV Dia Pro HIV 1/2/0 vs Genscreen ®PLUS HIV Ag- Ab ELISA
Total number of blood donors	440	440
True Positive	16	22
False Positive	25	2
True Negative	399	397
False Negative	0	19
Sensitivity	39.02%	53.50%
Specificity	100%	99.50%
Proportion of False Negative	60.98%	46.34%
Proportion of False positive	0	4.88%
Positive predictive Value	100%	99.5%
Negative Predictive Value	94.1%	95.4%
Relative Risk	16.96 (95% CI 11.59-24.81)	20.07 (95% CI 12.73-31.65)
Odds Ratio	517 (95% CI 30.13- 8871)	229.8 (95% CI 50.3-1050),
P<0.05	< 0.0001	< 0.0001

Statistical Significance	Yes	Yes
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161 KEY: CI- Confidence interval.

162 **DISCUSSION:**

163 Hospital-based transfusion centres in RLS can reduce the proportion of false negative testing
164 by deploying appropriate HIV testing methods to scale up their provision of safe blood and
165 by identifying truly infectious blood donors or blood units thereby ensuring availability of
166 blood donors and avoid unnecessary discard of donated blood units through proactive
167 assessments of assays used in this setting.

168 This study evaluating proportions of false negative and false positive test results observed
169 with two third generation HIV assays [(Determine™ HIV 1/2/0; a HIV-RDT and HIV Dia
170 Pro HIV 1/2/0; a manual plate-based EIA)] in comparison with Genscreen®PLUS HIV Ag-
171 Ab ELISA (Fourth generation ELISA) has found that, 60.98% and 46.34% false negative
172 (FN) tests results were recorded for Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0
173 respectively. The high false negative rates relate to the sensitivities (39.02% and 53.50%) and
174 specificities (100% and 99.50%) of Determine™ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0
175 respectively reported. (Table1)

176 While Mbaya D (13) reported an evaluation of Determine RDT by WHO wherein false
177 positive and false negative rates were low resulting in a reported sensitivity and specificity of
178 100% 99.6% respectively, thereby grouping it as an acceptable test method falling within the
179 acceptable clinical sensitivity $\geq 99\%$ for RDT and 100% for EIAs and a clinical specificity
180 of $\geq 98\%$ for RDT and EIAs (12), our findings in this study were different for the two assays
181 used for safety and availability of blood in this setting (12) The high proportion of FN rate
182 arise from the low sensitivity of the two assays in comparison with the Fourth generation
183 ELISA These findings show statistically significant relationship ($p < 0.001$) and suggest these
184 two assays inefficient in preventing TT-HIV infections when deployed for blood safety
185 interventions in RLS like our hospital-based blood transfusion centre. Generally, other
186 researchers have also reported on FN test results arising from deploying commercially
187 available assays.(14), (15) (16)(17), (18), (19),(20)

188 Even though FN test results are expected to be low among blood donors, a low risk group for
189 transfusion-transmissible infection (TTIs) coupled with the rigid pre donation screening
190 procuress usually put in place to defer those with identifiable risks, our findings are high.
191 Reports in many parts of Africa have shown false negative test results. In Ethiopia, Dessie et

al (14) in a related hospital-based study compared HIV antibody tests (Determine) with a combined antigen antibody HIV assay, also reported a high proportion of FN and a low sensitivity of the RDT. In Ghana, the residual risk of TT-HIV despite it being tested for HIV was reported to be high warranting recommendation for urgent intervention by internal and external quality control bodies in a bid to scale up blood transfusion safety. (16) In another study at a national blood centre in Abidjan, Cote d'Ivoire, amongst a safer population of blood donors and with trained personnel and equipment's, Saravit et al (15) estimated that, 6-12% of the total infected units, would result from false negative test results. (15) Reports in South African hospital-based transfusion practice are rare probably because of the functional South African Blood Transfusion Service that has successfully implemented NAAT in their transfusion system generally. However, surveillance in other settings suggest FN HIV antibody test results with some assays in settings like STI clinics. Quintessentially, it has been opinioned by some workers that, for a valid decision making process regarding the ideal time to test for HIV with some assays, the use of a table of probabilities of falsely-negative HIV test results in the pre- and post-test HIV counselling be adopted suggesting the probability of a false-negative result to be 0.01 at 80 days' post-exposure for third-generation tests and at 42 days for fourth-generation tests. (21) False-negative test results occur in the pre-seroconversion phase during primary HIV infection (diagnostic window when low antibody titres are below detectable cut-off levels of the assay). Other conditions including genetic variability (not well represented by the antigen profile contained in the assay) and atypical seroconversions, delayed or absent immune response in the very early or advanced stages of infection and laboratory reporting errors and problems inherent to the assay with respect to its format and design. (6) Besides FN HIV antibody test results have been reported in patients on antiretroviral therapy.

This study also found the proportion of false positive (FP) test to be 0 and 4.88 percent for DetermineTM HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 respectively; whereas DetermineTM HIV 1/2/0 did not record any false positive test result, HIV Dia Pro HIV 1/2/0 EIA gave a proportion approximating 5 percent. Rahman et al(22) also recorded a similar insignificant HIV false positive test result (especially with that obtained with the RDT in our study) amongst the Pakistan population. However, other workers have observed on a contrary for instance that; HIV RDTs may use a restricted target antigen range making them more susceptible than other immunoassays like western blot and line immune assay (LIA) to produce high false positive test result. (23),(24) Relatedly, in a Ghanaian study evaluating the

diagnostic accuracy of five hospital-based blood bank testing facilities that used rapid immunochromatographic assays (RIA) in screening blood donors/blood units in the absence of a standardized screening procedure for blood bank testing facilities in the country, the mean false positive was 11.1% and values as high as 28.0% reported in one centre. (17) False positive test results have been reported due factors including difference in constituent reagents, antigens, testing formants and personal operator errors, cross reactivity of HIV-1 and Hepatitis B virus, vaccination for influenza flu and the presence of HLA antibodies amongst others. (22) While some authors have reported on the causes of FP RDT(23), the cause of this varied FP test result is not clear. It may have been influenced by the specificity of the EIA compared with the RDT.

Minimizing FP HIV test results in hospital-based blood transfusion systems or centres is important in ensuring prudent management of blood supplies by averting unnecessary deferral of blood donors or wastages and higher costs arising from discarding tainted units of scarce blood sourced in this LRS. Besides, the fact that blood donation may be wasted because it is labelled sero-positive when in fact the blood donor or unit is negative; donors may develop apathy and loss of confidence in the services offered in that health facility especially if it is a protracted occurrence. Rahman et al(22) has also highlighted on some implications of high false positive test results to include psychosocial issues at the time of donation, shortage of blood supply especially if less common blood groups like Rhesus Negative) are involved, loss of blood donor pool for the hospital, and exhaust already meagre resources available to the hospital-based transfusion centre. (22) In a comprehensive review of handicaps impeding quality attainment including the provision of safe and available blood supplies in hospital-based transfusion centres in Africa, factors such as high cost of blood services amidst lean budgets, high dependence on external funding, paucity of voluntary non-remunerated blood donors, poor coordination of transfusion services with low operational quality systems have been reported. (8) The cumulative effect of these factors breeds FP results and contributes to an overall negative impact on the blood supplies of the country. Generally, concerns of compromised blood safety and availability abound in most African countries like Nigeria with weakened nationally coordinated Blood Transfusion services poor reagents/assay sourcing, storage, transportation, discrepancy in technical procedures and interpretation of HIV test results, poorly regulated quality testing supervision and oversight have bridged differing levels of transfusion quality in different countries even within the same country, state, province or region. Weak detection of HIV in blood donors or donations

due to false positive testing of donors leads to unnecessary deferrals or wastages of blood units and reduces blood availability in hospital settings.

The negative predictive value (NPV) of 94.1% and 95.9% for DetermineTM HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 respectively found in this study is low. A high NPV > 99% indicates a very high chance that, a negative result obtained with the assay is truly HIV-uninfected and this is the expectation for a screening test deployed in blood donation screening. The findings of a low NPV < 99% in our study, suggest that, the deployment of these two tests in our population of blood donors is likely to result in lower detection rates and such donors even though screened negative have potentials for being false and HIV infected. In overcoming this, implies deploying further test algorithms(25) either as single or parallel testing strategies that are diagnostically effective but more costly. Such practice risks adding preventable cost to the already resource limited and financially constrained hospital-based transfusion system. considering that such costs are ultimately transferred to the blood recipient giving the absence of health insurance policies in place, Such false testing in RLS breeds increased morbidity and mortality amongst health care seekers in hospital-based services.

The positive predictive value (PPV) in our study has been found to be 100% and 91.67% for Determine and Dia Pro HIV 1 /2/ 0 respectively. A positive predictive value is the proportion of blood donors who test positive and who actually have the disease by comparison with the gold standard. Other workers have reported varying PPV for different commercially available HIV assays in different populations.(26)(27)The findings in our study suggest Determine demonstrating itself as an excellent assay with a high PPV that correctly identifies all Positive donors or units for HIV while Dia Pro is weak with a low PPV and capable of deferring or allowing wastages of about 83/1000 blood donors arising from positive testing. In our population where the total donor population is less than 10/1000 and resources are generally scarce, HIV tests with high values of PPV may be counterproductive for an effective management of a hospital-based transfusion service. This finding of low PPV of Dia Pro HIV 1 /2 /0 is a significant concern on the impact this may have on recruitment, nurturing and retention of blood donors in dare efforts to change this predominantly family donor population to VNRBD that will guarantee safe and available blood supplies by 2020. Considering also that, Dia Pro HIV 1 /2 /0 is also a manual plate ELISA technique where the cost of testing is comparable to Genscreen ®PLUS HIV Ag-Ab ELISA, it may add no value in its being deployed for HIV screening in hospital-based settings. While the high PPV for DetermineTM HIV 1/2/0 may suggest its usefulness in diagnostic and surveillance studies or

initiatives, its utilization in blood donor or donation screening in a high risk population masquerading as low risk group and where safety and availability of blood is a priority is not supported by our findings

Ensuring blood availability through improved practices has become a topical public health initiative globally that is targeted at scaling up the total number of safe blood units collected annually in order to meet set target of unpaid donor population by 2020.(28) A recent review of blood donor deferral periods for men who have sex with men (MSM) from an earlier recommendation of lifetime deferral to a deferral of 12 months since the last sexual contact with another man based on justification that, an HIV infection acquired at least one year earlier should be readily detected by the blood screening tests routinely performed on donated blood samples before they are released for use, and the observation that Australia's decision to revise its policy from lifetime deferral to 12- month deferral for MSM led to no detected change in the safety of the blood supply.(29) (30)(31) With this recommendation coming into effect, a vast majority of MSM excluded under this policy earlier due to perceived risk of HIV transmission through blood donation can now be availed the opportunity to exercising their civic activity and contribute towards improving the current blood donation rates. (31) Even at this, there are emerging suggestions for the FDA to further review downward from 12 months to approximately 2-3 weeks and to accept donations without deferral from low-risk MSM who meet specific behavior-based criteria and their blood screened with the more sensitive NAAT testing in order to reduce the risk of window-period transmission for continued blood safety and the fairness of the blood donation policy. (31) Relatedly, there are also situations where blood donors are seronegative but have NAAT positive results or have negative NAAT even though they have been repeatedly tested seropositive or reactive with screening test for antibody, but negative or indeterminate HIV-1 Western blot results. Such donors are usually permanently deferred from blood donation but in this new trend of revision aimed at improving donor availability, evolving reentry criteria are being put in place to reduce the number permanently deferred because of such NAAT result. (32),(33)

There are also revised recommendations for determining eligibility of donors of human tissues, cells and those who have received human derived clotting factors.(31)

Hospital-based transfusion centres must not be left behind in improving blood availability. In Africa, although it is almost three decades since member nations resolved to promote the development of national blood services based on voluntary non-remunerated donation of blood, to enact effective legislation governing the operation of blood services, and to make

other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products, including monitoring the reagents deployed for preventing TT-HIV, (34) only few countries have achieved 100% voluntary unpaid blood donation which is the cornerstone of safe blood supply and availability through the development of their National Blood Transfusion Services (NBTS). Much of the challenges mitigating the establishment of NBTS hinge on high costs of services in general. In this instance, while some blood transfusion practitioners and managers attempt to consider costs and quality of life in developing practices (35) , many others priorities cost effectiveness consideration without an adequate concurrent appraisal of their impacts on the quality of life saved and the overall blood safety and availability program. Yet, there is an unresolved debate on whether adopting cost-effectiveness or quality of life-saved approaches should form the pillar of consideration in HIV care. (1)

False negative and FP test results arising from HIV test assays create difficulties in correctly associating quality of life saved in different HIV risk groups that present as donors as a comparison with the laboratory cost of equipment, reagents and personnel associated with these tests. Giving this scenario, the prevalent but often financially constrained hospital-based transfusion services adopt cost saving rather than quality of life saved considerations in adopting screening test to be deployed for safeguarding transfusion against TT-HIV in RLS. Quintessentially, the findings of FP, FN, NPV and PPV rates obtained with these two assays suggest that, HIV-antibody tests show enormous compromise to the quality of life saved and even impinges on costs with attendant wastages from wrongful discard of blood units or disqualification of blood donors.

Recent comparative reports from experiences of developed countries particularly in Europe and America seem to question the economy of adopting NAAT testing in their blood transfusion system as no statistically significant relationship was found between NAAT and prevention of TT-HIV thereby failing to justify the continued utilization of NAAT in screening for TT-HIV in their truly low risk population of blood donors while finding more applicability and significance of NAAT testing in screening blood donors or units in RLS for TT-HIV(2).

CONCLUSION:

While NAAT is the ideal test for securing all hospital-based blood transfusions in RLS from TT-HIV, it is yet to be implemented in in Nigeria. However, considering the low performance for these two third generation assays generally with respect to the proportion of

false negative test ($p < 0.0001$) when compared with Genscreen ®PLUS HIV Ag-Ab ELISA as demonstrated in this study, third generation ELISAS appear inadequate in securing blood recipients from TT-HIV. The positive predictive value of these two third generation HIV antibody assays fall short of providing blood availability in hospital-based settings.

RECOMMENDATIONS:

In providing safe blood to meet the health needs of deserving patients, the NBTS should be supported to deploy only the combined HIV antigen-antibody ELISA for all blood donors and donations in order to avert TT-HIV, improve safety and availability of blood in RLS as obtainable in resource endowed settings. Further studies on the prevalent subtypes amongst blood donors in our population and the factors responsible for our findings is recommended.

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