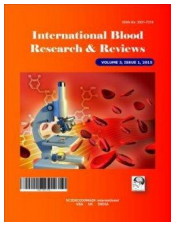

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Laboratory Accuracy of Some Human Immunodeficiency Virus Screening Methods in a Nigerian Blood Bank: Is it time for Universal Adoption of Enzyme-linked Immuno-Sorbent Assay Methodologies as the Minimum Testing Paradigm?

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Authors' contributions

This work was carried out in collaboration between all authors. Author OJA conceptualized, carried the research, and produced the manuscript for scientific publication. Author GSS reviewed the work and provided statistical analysis. Author EJO provided statistical analysis. Author OJH analyzed the samples, and reviewed literature. Author MTP reviewed the methodology and analyzed the study for scientific publication. Author OAM analyzed the laboratory methods and revised the manuscript for a scientific publication. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To compare the prevalence rates, relevant indices of laboratory accuracy and proportion of false negative test results for some WHO recommended methodologies used for HIV screening amongst blood donor sata hospital-based blood bank in Nigeria.
Study Design: A cross-sectional.
Place and Duration: Blood bank unit of Jos University Teaching Hospital (JUTH) and the Nigerian National Blood Transfusion Service (NBTS) North Central Zonal Office, Jos between May and August 2008.
Methodology: Four hundred and forty blood donors (379 males and 61 females; aged 18-55 years) predominantly family replacement blood donors who met the minimum criteria to donate blood in Nigeria were included. Blood collection, serum processing, testing and interpretation of results were carried out using standard methods and manufacturers' instruction. Serum was tested with a rapid test (Determine™ HIV- 1/2) and an EIA [Dia Pro HIV 1/2/0 ELISA] method. The samples were further tested with a 4th generation ELISA [GENSCREEN®PLUS HIV Ag- Ab ELISA].
Results: The prevalence of HIV in blood donors differed with the test method and assay as follows; Determine TM HIV 1/ 2 (3.6%), Dia Pro HIV 1/2/0 ELISA (5.5%) and GENSCREEN®PLUS HIV Ag-Ab ELISA (9.3) respectively.
Determine TM HIV-1/ 2gave a sensitivity of 0.39 (95% CI 0.24-0.55), specificity 1.00,95% CI 0.99-1.00), false negative [FN] (61%), positive predictive value [PPV] 1.00 95% CI 0.79-1.00), and a negative predictive value [NPV] 0.94, 95% CI 0.91-0.96 when compared with GENSCREEN®PLUS HIV Ag-Ab ELISA method. P<0.001.
Dia Pro HIV 1/2/0 ELISA gave a sensitivity of 0.54, 95% CI.37-0.69, specificity 0.995, 95% CI 0.99-1.00, FN(46.3%), PPV (0.9295% CI 0.73-0.99 and a NPV (0.95, 95% CI0.93-0.97) when compared with GENSCREEN®PLUS HIV Ag-Ab ELISA method. P<0.001.
Determine TM HIV 1/2 had a sensitivity of 0.67 95% CI 0.45-0.84, specificity of 1.00; 95% CI 0.99-1.00, FN (33.3%), PPV (1.00 95% CI 0.79-1.00 and a NPV 0.98, 95% CI 0.96-0.99 when compared with Dia Pro HIV 1/2/0 ELISA method. P<0.001.
Conclusion: The prevalence of HIV in blood donors is method dependent with GENSCREEN®PLUS HIV Ag-Ab ELISA higher than Dia Pro HIV 1/2/0 and Determine TM HIV 1/ 2. Dia Pro HIV 1/2/0 is more accurate and has fewer FN test results than Determine TM HIV 1/ 2. There is a need to discourage rapid testing as a major testing algorithm amongst hospital-based blood banks. Instead, ELISA methods should be adopted as the minimum testing paradigm. However, further testing with Nucleic Acid Amplification Testing (NAT) is recommended to validate reliability of this study.

Keywords: Blood donors; HIV infection; prevalence; hospital-based blood bank; laboratory accuracy; blood transfusion; Nigeria.

1. INTRODUCTION

Adequate interception of Human Immunodeficiency Virus (HIV) contaminated blood donations through responsible and responsive testing is feasible and remains the most cost-effective HIV prevention strategy required to protect blood supplies against HIV infection [1]. Unfortunately, inadequate screening for transfusion transmissible HIV (TT-HIV) continues to plague many resource-poor settings like some hospital-based blood banks in Nigeria [2].

The various testing methods currently available for screening blood donations target different parts of the virus ranging from gene sequence, gene products or measure the hosts' immune response against the virus with respect to the antibodies produced either as an Enzyme–Linked Immuno-sorbent Assay (ELISA) or non-ELISA based methodology [3]. The HIV Nucleic Acid Amplification Testing (NAT) for instance, has emerged a superior testing technology for virus detection and in safeguarding blood supplies. Understandably, NAT is used in developed economies to safeguard donor blood and tissues from HIV contamination thereby reducing the risk of TT-HIV remarkably in many countries like Germany, France and USA. [2,4]. However, NAT is expensive, technically demanding with enormous logistic challenges and not universally available to safeguard blood supplies in many resource-poor settings and particularly where there is a lack of political will

and commitment on the part of their leaders. Similarly, the enzyme immunoassays (EIA) which have undergone quality improvement from first generation to fourth generation by utilizing recombinant antigens and synthetic peptides as well as the antigen-antibody sandwich technology making it very usefully in securing blood donations against HIV infections. Even though ELISA methods are universally available to increase the sensitivity of HIV detection in a cost effective manner, the challenges of erratic power supply, paucity of skilled manpower and strict quality control measures required limits its usage. Yet, some resource-poor countries have demonstrated that, its application is achievable and have even gone a step further in developing indigenous ELISAs with sensitivity to HIV strains inherent in their localities [5]. The development of rapid HIV antibody serologic test methods for emergency diagnosis and surveillance, have emerged in popularity in protecting blood supplies especially in resource-poor settings because of its ease of performance, visually read results and in not requiring any sophisticated equipment's or other ancillary challenges associated with ELISA testing methods [6]. In many countries like Nigeria, rapid tests are convenient and acceptable for HIV screening of blood donations against HIV infection at hospital-based blood transfusion services [7]. The World Health Organization (WHO) has also recommended that, the screening for HIV in donated blood should be performed using a highly sensitive and specific anti-HIV-1 anti-HIV-2 immunoassay or a combined HIV antigen-antibody immunoassay (EIA/CLIA) capable of detecting subtypes specific to the country or region. In its absence, a highly sensitive and specific anti-HIV-1 anti-HIV-2 rapid assay could be used in laboratories with small throughput, remote areas or emergency situations [8]. This recommendation is probably in a bid to get all donations test HIV-negative before transfusion worldwide irrespective of the financial strength of the nation. However, it is imperative that, tests employed for screening in a particular area should detect the prevalent strains of the virus. Therefore, irrespective of which methodology is employed, accurate testing to eliminate false negative screening remains a top priority since, blood recipients of false negative blood donations have more than 95% risk of acquiring TT-HIV infection [9]. Many potential causes of false-negative HIV screening of blood donation may exist including; the diagnostic window in the pre-seroconversion phase, genetic variability, atypical seroconversions, a delayed or absent immune response in the very early or advanced stages of infection and laboratory reporting errors. Studies however, indicate that, about 90% of false-negative results are observed in the pre-seroconversion phase during primary HIV infection (i.e. diagnostic window) [10]. There are indications that, in many of resource-poor settings of Africa, TT-HIV resulting from inadequate blood screening accounts for the second largest mode of HIV transmission [1] Imperatively, increased application of appropriate HIV testing methods in blood donation is undoubtedly a panacea to universal access to prevention of TT-HIV in blood supplies in resource-limited settings like the hospital based blood banks in Nigeria. This is more relevant now that the support for HIV activities to many resource-poor economies is dwindling. In recent past, many hospital-based blood banks in Nigeria benefited from foreign donor support agencies through the provision of rapid test kits for TT-HIV prevention (when available) and provided training of hospital staff on blood safety among other assistance. However, with the global economic crisis spreading wild, Nigeria has witnessed an unprecedented reduction in support for HIV prevention. This development has called for more prudent allocation and management of meagre resources in a truly cost-effective manner. Quintessentially, more strategies and measures to improve the effectiveness of the routine screening of blood donors and the safety of the blood components against HIV have to be individualized and localized as appropriate.

Therefore, we sought to evaluate two HIV screening methods (one rapid test and one ELISA method) in a population of Nigerian blood donors at a tertiary hospital-based blood bank with a view to accessing their laboratory accuracies in HIV detection as well as identify the presence or absence of false negative donations in this resource poor setting by using a combined HIV antigen-antibody ELISA (GENSCREEN®PLUS HIV Ag-Ab ELISA) used at the Nigerian National Blood Transfusion service (NBTS) and shown by Chatteriee et al. [11] to produce results concordant with individual donor nucleic acid testing (ID-NAT), for validation of the specimen. Furthermore the prevalence rate with the different assays was sought.

2. MATERIALS AND METHODS

The laboratory performances of one simple/rapid test (Determine™ HIV- 1/2) and one EIA [Dia Pro HIV 1/2/0 ELISA] methodologies were accessed

among 440 (379 males and 61 females) predominantly family replacements blood donors aged between 18 and 55 years at the blood bank unit of Jos University Teaching Hospital (JUTH) between May and August 2008. Blood donors who met the inclusion criteria i.e. fulfilled the conditions to donate blood in Nigeria, [12] and gave an informed written consent were consecutively enrolled, while those who did not meet the minimum criteria to donate blood and or declined to give an informed consent were excluded from the study. A questionnaire was administered by trained research assistants to identify donors' bio-data and their relevant characteristics. Ethical approval was obtained from the ethical committee of Jos University Teaching Hospital (JUTH) and all ethical standards were adhered to. Ten (10) milliliters of venous blood was collected from ante-cubital vein of all the blood donors using a large bore needle under aseptic conditions. Haemostasis was secured and the collected blood emptied into a clean evacuated tube without an anticoagulant. Care was taken to ensure that, all validation specimens were of adequate volume and of high quality by being properly collected and processed while also avoiding hemolysis and practices that would encourage fungal or bacterial contamination/growth. Freshly collected specimen were preferably tested within 24 hours of collection using Determine™ HIV- 1/2 while aliquot samples for ELISA testing were stored at -20°C and for periods not longer than one month and processed batched together. In general, the process of serum extraction and storage was carried out using the WHO recommended methods [13].

The serum collected was screened for HIV antibodies using Determine™ HIV 1/2 sourced from ABBOTT JAPAN CO. LTD, Minato-Ku, Tokyo-Japan. Thereafter, the sera were also serially tested at the Nigerian NBTS North Central Zonal Office, Jos with Dia Pro HIV 1/2/0 EIA sourced from diagnostic Bioprobes Sx/Italy and GENSCREEN®PLUS HIV Ag- Ab ELISA sourced from BIO-RAD laboratories, 3 Bd Raymond Poincaré, Marnes La Couquette-France. All procedures were carried out following the manufacturers' recommendations. The interpretation of the HIV Enzyme Immunoassay (EIA) sero-status as positive or negative was judged based on the manufacturer's instructions of recommended cut-off values and in line with the relevant controls included in the respective assays.

2.1 Statistical Analysis

Analysis of proportions of false negative results, sensitivity, specificity, positive and Negative predictive values as well as comparison of variables was carried out 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.

3. RESULTS

This study found that, Determine™ HIV 1/2 test method gave a sensitivity of 39.02%, specificity (100%), proportion of False Negative (61%), PPV (100%), and a NPV (94.1%) when compared with GENSCREEN®PLUS HIV Ag-Ab ELISA method. (Table 2).

On the other hand, Dia Pro HIV 1/2/0 ELISA gave a sensitivity of 53.5%, specificity (99.5%), proportion of False Negative (46.3%), PPV (99.5%), and a NPV (95.4%) when compared with GENSCREEN®PLUS HIV Ag-Ab ELISA method (Table 2).

Similarly, the Determine TM HIV 1/2 test method had a sensitivity of 67%, specificity (100%), proportion of False Negative (33.3%), PPV(100%), and a NPV(98%) when compared with Dia Pro HIV 1/2/0 ELISA method. Dia Pro HIV 1/2/0 Positive (Table 2).

The prevalence of HIV amongst blood donors was different depending on the screening method employed. (Table 1).

Table 1. Prevalence of HIV among blood donors-using three different methods

	Positive	Negative	Prevalence (%)
Determine™ HIV- 1/ 2	16	424	3.6
Dia Pro HIV 1/2/0	24	416	5.5
GENSCREEN®PLUS HIV AG-AB ELISA	41	399	9.3

Table 2. A comparison of relevant indices of laboratory accuracy and proportion of false negative results for the two screening methods in different combinations amongst blood donors

	Determine™ HIV-1/ 2versus HIV Dia Pro HIV 1/2/0	Determine™ HIV- 1/ 2versus genscreen ®PLUS HIV Ag-Ab ELISA	HIV Dia Pro HIV1/2/0 versus genscreen ®PLUS HIV Ag-Ab ELISA
p-value	<0.001	<0.001	<0.001
Alpha value	<0.05	<0.05	<0.05
Statistical significance	Yes	Yes	Yes
Sensitivity	0.67	0.39	0.54
95% CI	0.45-0.84	0.24-0.55	0.37-0.69
Specificity	1.00	1.00	0.995
95% CI	0.99-1.00	0.991-1.00	0.999
PPV	1.00	1.00	0.92
95% CI	0.79-1.00	0.79-1.00	0.73-0.99
NPV	0.98	0.94	0.95
95% CI	0.96-0.99	0.91-0.96	0.93-0.97
Relative risk	53	16.98	20.7
95% CI	27-105	11.59-2481	12.73-3165
Odds ratio	1617	517	229.8
95% CI	89-29241	30.13-8871	50.3-1050
Proportion of false negative (%)	33.3	61	46.3

KEY PPV=Positive Predictive Value; NPV=Negative Predictive Value; CI=Confidence Interval

4. DISCUSSION

Since the laboratory accuracy of a HIV screening test method can be described in terms of the degree to which people with and those without HIV infection are correctly categorized(i.e. sensitivity and the specificity), [14] and in view of the WHO recommendation that a sensitivity of ≥99% and a specificity of ≥98% is required for accurate HIV testing methods, [15] the findings in our study show an overall low laboratory performance of Determine™ HIV- 1/2 (Rapid Test) and Dia Pro HIV 1/2/0 ELISA (3rd Generation ELISA) over GENSCREEN®PLUS HIV Ag- Ab ELISA. (4th Generation ELISA). Similarly, the proportion of false negative test results were higher with Determine™ HIV- 1/ 2andDia Pro HIV 1/2/0 ELISA when compared with GENSCREEN®PLUS HIV Ag- Ab ELISA. (Table 2) Also, the proportion of false negative test results with Determine™ HIV- 1/2 were more when compared with Dia Pro HIV 1/2/0 ELISA. These findings suggest an overall low performance of Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA compared to GENSCREEN®PLUS HIV Ag- Ab ELISA amongst blood donors in a hospital-based blood bank; an implication of ELISA superiority over Rapid test method (Table 2).

Generally, even though studies evaluating HIV screening kits/methods in the context of blood donations screening at hospital-based blood banks in Nigeria to the knowledge of the authors are scarce, Determine™ HIV- 1/2 tests was validated and recommended for HIV diagnosis by the Federal Ministry of Health in Nigeria [7,16]. Additionally, this validation recommended serial testing rather than parallel testing as a tool to improving accuracy and cost effectiveness in HIV diagnosis. It also recommended rapid testing for securing blood donations against HIV infection [16]. A serial HIV testing algorithm requires testing to be carried out on all specimens using a single assay and those found to be positive are then retested with a second assay. In the serial algorithm, discordant results are considered indeterminate and retesting with a third, tiebreaker test may be required [17]. Understandably, this approach differs in the blood bank whose desire is to provide safe blood rather than make diagnosis. For instance, while a single result of HIV screening test carried out on a blood donation may suffice in deciding whether a blood unit or component for transfusion is to be release or not, (even though an initial reactive result may be repeated) a single test alone is not sufficient to determine infection or subsequent action and often involves additional testing over a period of time either to pursue the diagnosis or follow up or monitor disease progression [8,18]. Therefore, the application of serial testing method in the hospital-based blood bank may

have no economic gains but rather add unnecessary costs to procuring a unit of blood for transfusion. Besides, it may promote waste of man-hours in waiting by potential blood donors. This act is capable of deterring many of these donors who are predominantly family replacements from becoming voluntary non-remunerated blood donors through education and mobilization as this is desirable if Nigeria must achieve the WHO target of 100% voluntary blood donation by 2020.

While some studies have documented that some rapid tests performs comparably to standard ELISA and western blot in patients with established HIV infection as well as in cohorts of newly infected patients tested at regular intervals during the seroconversion period,(14) others have reported on the low sensitivity of Determine HIV -1/2. [18-20]. Some studies have also reported that, certain types of rapid HIV tests are producing false-negative results [21]. A study conducted by the South African government revealed rapid HIV testing sensitivities that averaged 68.7% in Cape Town's local clinics and thus, failed to detect HIV in nearly one third of patients who had the virus [22]. In another study [23], of nine hundred ninety-four participants who had either negative or discordant rapid test results, eleven (1.1%) had acute HIV infection and an additional twenty (2.0%) had chronic HIV infection (false negative rapid test). A large South African study proved that the actual sensitivity of HIV test kits used outside of the laboratory was on average 93.5% and even with additional training and quality control improvement increased to only 95.1% [24]. While in Cameroon, the same rapid testing algorithm that produced a specificity of 98.8% had a sensitivity of 94.7%, resulting in 6 out of every 100 people receiving a negative diagnosis when they are in fact HIV-positive (15). False negatives are a threat not only to public health prevention strategy but also to the health and well-being of the individual. A false negative result, despite being incorrect in some cases, may prevent patients from seeking out other testing opportunities, taking the necessary precautions to prevent the transmission of HIV and receiving the timely care and treatment that they require [25]. In spite of these, the Nigerian government in 2011 carried out another evaluation of HIV kits [16] and excluded Determine and the ELISA based HIV assays including Dia Pro HIV1/2/0.Yet, there are concerns of sub-standard test kits circulating in the Nigerian market [18].

The prevalence of HIV amongst blood donorsin our study showed marked differences depending on the accuracy of a test method. (Table 1). In Nigeria, whereas the NBTS will logically report the prevalence based on the combined antigen-antibody test assays employed in screening at their few regional centres nationwide, studies at many hospital-based blood banks will utilize what is available and acceptable i.e. rapid test or antibody ELISA. These discrepant results may be utilized for planning, budgeting, intervention, funding, prevention and blood bank management erroneously and may not truly reflect the situation nationally. The HIV prevalence of blood donors in blood banks ought to be lower when compared with the general population, commercial sex workers, drivers, etc. by virtue of the strict adherence to deferral criterion in this setting. Therefore, a high prevalence rate detected with GENSCREEN®PLUS HIV Ag- Ab ELISA may signify a weak deferral system in which, high risk donors erroneously skip being deferred either because of insufficient tool for deferral of blood donors or insincerity of blood donors in truthfully reporting high risk behaviours before blood donation only to be detected by a more sensitive test. Therefore, for a true representation of blood safety activities in the country, national figures from the different geopolitical zones must be harmonized with a single testing methodology. This will allow for prudent management of lean blood bank budgets, aid evaluation and implementation of pre-donation screening questionnaires/interventions to intercept or defer high risk donors who knowingly or unknowingly may taint blood supplies. It will also help preserve unnecessary HIV screening and prevent donations in the window period, enable adequate planning and budgetary allocation for blood safety drives. Besides, it will help the country effectively monitor disease progression, incidence and development of resistance to treatment where applicable in a cost-effective manner. These are only achievable through adoption of appropriate methodology like ELISA testing method for HIV screening at hospital-based blood banks in Nigeria pending the universal application of NAT testing of blood supplies. In a survey of blood transfusion practice in Nigeria, [26] it was reported that, even though many hospital-based blood banks have ELISA plates and readers capable of being used for HIV screening, many lack requisite trained personnel's to effectively put them to use. With the emergence of HIV treatment in most hospitals, some hospitals now have access to function an alternate power supply which hitherto

was a major impediment. Therefore, there is an urgent need to step down training from the NBTS, non-governmental organizations (NGO) and other hospitals and philanthropist with requisite knowledge on ELISA techniques in order to put these machines and equipment's into use for the overall health and safety of the country's blood supplies. When this is done, support for blood safety by partner NGOs will shift from supply of rapid kits to ELISA reagents in various hospitals. Beyond this, blood banks in immediate localities could also collaborate financially and technically in order to provide safe blood for their hospitals and communities in a cost-effective manner for the overall interest of the nation.

5. CONCLUSION

This study has shown that, the prevalence of HIV in blood donors in a Nigerian Hospital-based blood bank is largely method dependent and ELISAs perform better than Rapid test method. Even amongst ELISAs, the GENSCREEN®PLUS HIV Ag-Ab ELISA (4th generation) showed a higher prevalence than Dia Pro HIV1/2/0 (3rd Generation ELISA). Also, ELISA methodology showed more statistically significant indices of laboratory accuracy when compared with rapid tests. Therefore, the continued employment of rapid test to secure blood donations against HIV should be reconsidered instead; the Nigerian government should strive to establish NAT testing in the country. In the interim, the 4th generation ELISAs should be adopted as the minimum testing paradigm in order to secure blood donations against HIV infection at hospital-based blood banks.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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