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Prevalence of hepatitis B virus infections among blood donors in Federal Capital Territory, Abuja, Nigeria

Ezeonu, C. M., Garba, S. A., Adabara, N. U., and Kuta, F. A.

Department of Microbiology, School of Life Sciences, Federal University of Technology, Minna, Nigeria
Correspondence to: scholajane@yahoo.com

Abstract

Background: Transfusion of hepatitis B virus (HBV) infected blood represents a major but avoidable means of HBV transmission, which unfortunately still account for millions of global HBV infections annually.
Method: This study determined the prevalence of HBV infection among 550 blood donors aged 18 to 60 years from selected hospitals and blood transfusion centres within the Federal Capital Territory, Nigeria, using hepatitis B surface antigen (HBsAg) rapid diagnostic test (RDT) kit and Enzyme linked Immuno-sorbent Assay (ELISA). Representative positive and negative samples for RDT and ELISA were tested by both conventional and real-time polymerase chain reaction (PCR) assay
Results: Forty nine (8.9%) and 14 (2.8%) out of the 550 blood donors tested positive for HBsAg with the RDT and ELISA respectively. Replacement donors had higher prevalence rate of the HBV infection than voluntary donors. The highest prevalence of HBV infection was recorded among the 30–39 year age group. The difference in the rate of infection between the males and the females was not statistically significant (p>0.05). A perfect agreement between RDT and PCR and fair agreement between ELISA and PCR were observed.
Conclusion: This study report a high prevalence of hepatitis B virus infections among blood donors in Abuja, Nigeria which underscores the need for proper screening of blood for transfusion to completely eliminate the incidence of transfusion transmitted HBV infections.

Key words: Blood, Malaria, Hepatitis, Rapid, Immuno-sorbent, Polymerase

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Prévalence de l'infection par le virus de l'hépatite B chez les donneurs de sang dans le Territoire de la capitale fédérale, Abuja, Nigéria

Ezeonu, C. M., Garba, S. A., Adabara, N. U., and Kuta, F. A.

Département de microbiologie, École des sciences de la vie, Université fédérale de technologie de Minna, Nigéria
Correspondance à: scholajane@yahoo.com

Abstrait

Contexte: La transfusion de sang infecté par le virus de l'hépatite B (VHB) représente un moyen important mais évitable de transmission du VHB, qui représente malheureusement toujours des millions d'infections mondiales au VHB chaque année.
Méthode: Cette étude a déterminé la prévalence de l'infection à VHB chez 550 donneurs de sang âgés de 18 à 60 ans de certains hôpitaux et centres de transfusion sanguine situés dans le Territoire de la capitale fédérale, au Nigéria, à l'aide du kit de test de diagnostic rapide (TDR) de l'antigène de l'hépatite B (HBsAg) et Essai immuno-sorbant lié à une enzyme (ELISA). Des échantillons positifs et négatifs représentatifs pour les TDR et ELISA ont été testés à la fois par le test de réaction en chaîne par polymérase (PCR) classique et en temps réel
Résultats: Quarante-neuf (8,9%) et 14 (2,8%) des 550 donneurs de sang ont été testés positifs pour HBsAg avec le TDR et le test ELISA, respectivement. Le taux de prévalence de l'infection à VHB était plus élevé chez les donneurs de remplacement que chez les donneurs volontaires. La prévalence la plus élevée d'infection par le VHB a été enregistrée dans le groupe d'âge des 30 à 39 ans. La différence de taux d'infection entre les hommes et les femmes n'était pas statistiquement significative ($p > 0,05$). Un accord parfait entre TDR et PCR et un accord juste entre ELISA et PCR ont
Conclusion: Cette étude fait état d'une prévalence élevée d'infections par le virus de l'hépatite B chez les donneurs de sang à Abuja, au Nigéria, ce qui souligne la nécessité d'un dépistage approprié du sang par transfusion afin d'éliminer

Mots-clés: sang, paludisme, hépatite, rapide, immuno-sorbant, polymérase

Introduction:

About 2 billion people worldwide have been infected with Hepatitis B Virus (HBV). An estimated 360 million people remain chronically infected with 2 million deaths annually (1). Hepatitis B viral infections are caused by the HBV; an envelope virus containing a partially double stranded circular DNA genome and classified within the family hepadnaviridae (2). HBV infects the liver, thereby impairing liver functions as the virus replicates within the hepatocytes during acute and chronic phases of HBV infections (3). According to the Centre for Disease Control and Prevention (CDC), HBV is present in the blood, blood products and body fluids such as vaginal secretions, semen and in low concentrations in the saliva of the carriers (4).

Among the various routes of transmission of HBV infection, blood transfusion transmission represents a deliberate process of transmission that can be avoided even with the slightest vigilance (5). In 2001, WHO estimated that transfusion of unsafe blood alone accounted for 8-16 million hepatitis B virus infections annually. Although, the incidence of transfusion transmitted hepatitis B has been gradually controlled within the intervening period, the available records show that HBV remains yet the viral infection with the greatest risk of transmission through blood transfusion especially in developing countries. An obviously high variability in the prevalence of HBV is seen across the countries, with higher incidence and prevalence observed in developing nations such as 1.6%–7.7% in Brazil, 19.6% in Egypt and 2-10% across India (6). In Nigeria, the pooled prevalence of HBV is reported to be about 13.6% (7).

Even though there are routine tests for demonstrating the presence or otherwise of this infection, the greatest risk are blood donations made in the infectious window period, which is the time between development of infectious viraemia and/or reactivity to routine serological or nucleic acid technology (NAT) based screening tests (8). The safety of blood can be guaranteed by application of assay technologies with high specificity and sensitivity so as to be able to identify all true positive blood units and true negative blood units (9). Screening of blood donors is a critical issue as the outcome of the test if flawed for whatever reason can result in serious consequences

for either the blood service or the blood donor. False positive result can lead to a larger number of blood donors being deferred, while a false negative testing may jeopardize blood safety (10).

In Nigeria, the prevalence of HBV infection has been speculated to vary with regard to the screening method used with prevalence rates varying from 12.3% by enzyme linked immunosorbent assay, 17.5% by immuno-chromatography and 13.6% by HBV DNA polymerase chain reaction (11). It is therefore necessary to monitor the safety of blood supply and the effectiveness of the presently employed screening procedures since pregnant women and children are the major recipient. The aim of this study was to determine the prevalence of Hepatitis B Virus among blood donors and to compare the sensitivity of HBV detection methods employed in the study area.

Materials and methods:

Study area

The study areas are blood bank units of Asokoro, Maitama, Wuse District Hospital; National Blood Transfusion Services; Federal Medical Centre Jabi, Karishi and Nyanya General Hospital, all in the Federal Capital Territory (FCT), Abuja, Nigeria.

Study design

The study is a descriptive cross sectional survey of blood donors which include voluntary, family/replacement donors, and commercial/paid donors which are not recorded.

Ethical clearance

The study was approved by the Health Research Ethics Committee of the Federal Capital Territory, Abuja and other ethics body of the chosen blood bank centres where applicable.

Study population

There were a total of 550 subjects comprising 521 (94.7%) males and 29 (5.3%) females who came to the blood bank units of the hospitals to donate blood. Sixty-three (11.5%) out of the 550 were voluntary donors while 487 (88.5%) were family replacement donors. No commercial/paid donors participated in the study. Participation in the study was based on informed consent while demographic data about subjects were collected through a structured questionnaire.

Inclusion criteria

All the subjects satisfied the qualifying criteria of age between 18 - 60 years, body weight of above 50 kg depending on the body mass index (BMI), haemoglobin requirement of more than 12.5 gm/dl and absence of significant medical or surgical history. All donors were offered pre and post donation counseling**.**

Exclusion criteria

Donors who did not meet the conditions spelt out in the inclusion criteria as well as those who did not consent to participate in the study, lactating mothers, pregnant or menstruating women, donors who did not meet the haemoglobin requirements, those who have donated more than the prescribed 3 times in the last 12 months and other requirements were excluded from participation in the study.

Samples collection and analysis

Five milli-liters of whole blood were obtained via venipuncture from the donors using 5 ml syringe (12). To ensure confidentiality of the donors, numbers were used. Two milli-liters of these were placed in ethylene diamine tetra acetic acid (EDTA) bottle for haematological screening of HBsAg. The remaining 3mls were dispensed into a red top vaccutainer tube, then allowed to clot naturally at room temperature, centrifuged at 3000rpm for 5minutes to obtain the serum and was pipetted out of the vaccutainer tube which was used for immunological analysis of HBsAg.

Rapid Diagnostic Test for HBsAg detection

Twenty five micro liters of serum

was added to the specimen well of the RDTs with the aid of pipette. The serum reacted with the particle coated with monoclonal anti-HBsAg. The mixture then migrates upward along the membrane by capillary action and reacts with polyclonal anti-HBsAg, which are pre-coated on the test region. After 15 minutes, invisibility of the control line indicated invalid result. The presence of two distinct lines in both the control and test regions indicated a positive result while one red line in the control region is a negative result. Strips used were from ACON® on the instructions of the manufacturers.

Enzyme Linked Immuno Sorbent Assay (ELISA) for HBV antibody detection

ELISA assay (ADALTIS, S. r, I Milano, Italy) was used to reconfirm blood samples that yielded negative results from RDTs screening tests to quantify the absence of anti-bodies to HBsAg. The procedure was carried out according to the manufacturer's instructions. First, 20 µL of assay diluent was added into each well except the blank, and 100 µL of positive control, negative control and specimen were added into their respective wells except the blank. The plates were covered and incubated for 60 minutes at 37ºC. After incubation, plate cover were discarded and 50 µL conjugate was added into each well (except the blank) and mix by tapping the plate gently. Each plate was covered and incubated for 30 minutes at 37ºC. Following incubation, plate cover was discarded and each well was soaked for 30-60 seconds before washing for 5 times with diluted washing buffer. After the final cycle of washing, the plate was turned down on a blotting paper and gently tapped to remove any remainders.

To each well of the plate, including the blank, 50 µL of substrate solution "A" and 50 µL of substrate solution "B", were added. The plate was incubated at 37ºC for 30 minutes without exposure to light. The enzymatic reactions that occurred between the substrate solutions and the conjugate produced blue colour in positive control and HBsAg positive sample wells. 50 µL of stop solution was added into each well and mixed gently. Intensive yellow colour developed in positive control and HBsAg positive sample wells. Plate reader was calibrated with the blank well and the absorbance read at 450 nm. The cut of value was calculated and result evaluated by reading the absorbance within 10 minutes after stopping the reaction.

Polymerase chain reaction (PCR) assays for HBV DNA

Three RDT positive HBsAg samples, and two positive and seven negative ELISA samples were subjected to both conventional PCR (BIONEER, USA) and real time PCR (DAAN Gene, Biotechnology, China) assays, at the DNA LABS Limited, Q5 Danja, off Katuru Road, Kaduna State, Nigeria, according to the manufacturer's instructions.

DNA extraction

DNA was extracted from 100 µL serum sample using DAAN Gene DNA kit (cat.♯ DA-451, China) as follows; 50 µl of Proteinase K was pipetted into the bottom of a 1.5 mL centrifuge tube. 200 µL of fluid sample was added to the tube, and 200 µL of virus lysing solution was then added and mixed by pulse-vortexing for 15 seconds. The resulting mixture was incubated at 72ºC for 10 min followed by a short spin down. 250 µL of ethanol (96-100 %) was added to the sample, mixed by vortexing and briefly centrifuged to remove drops from the inside of the tube lid. The mixture was applied carefully to the spin column (in a 2mL collection tube) without wetting the rim. The cap was closed and column in the collection tube was centrifuged at 12,000 rpm for 1 min.

The Mini spin column was placed in a clean 2 mL collection tube, and the tube containing the filtrate discarded. 500 µL of inhibitor removal and 500 µL of desalting solution (twice) were added to spin column without wetting the rim and centrifuged at 12,000 rpm for 1 min at room temperature and the spin column was replaced in a clean 2 mL collection tube. Filtrate was discarded in each step. Finally, the spin column was placed at room temperature in a clean centrifuge tube, 50 µL elution buffers was added to

the column and centrifuged at 14000 rpm for 3 minutes. The filtrate in this step resembles the isolated DNA.

Conventional PCR assay

Conventional PCR was performed using Bioneer AccuPower PCR PreMix a ready-to-use PCR reagent, which consist of lyophilized mix of; thermostable enzyme, dNTPs, reaction buffer, stabilizer, tracking dye and PCR product purification. A water/primer mix was prepared in a 0.5 mL Eppendorf tube on ice consisting of 2 µL of each primer (forward and reverse) and 280 µL of ultra-pure water. One strip of 6 Bioneer Premix tubes was labeled 1 to 6 including the positive and negative control and 16 µL of the water/primer mix was added to each of the 6 tubes with 2 µL of sample. These were placed in thin walled tubes inserted in the programmed PCR thermal cycler (Biometra's T Gradient).

The amplification reaction started with 3 min at 95°C for 1 cycle, followed by 30 seconds at 94°C, 45 seconds at 45°C, 1 minute at 72°C for 35 cycles, followed by final extension at 72°C for 7 minutes, and then soaked for 1 minute at 20°C. The primer pair, HepBP1: 5'-TCA CCA TAT TCT TGG GAA CAA GA-3' and HepBS1-2: 5'-CGA ACC ACT GAA CAA ATG GC-3', were used. The PCR products were electrophoresed on 3% agarose gels and DNA was visualized by ultraviolet trans-illuminator. Bands were compared by size with the presence of 350 bp DNA ladder fragment indicating a positive result.

Real Time PCR assay

Real Time PCR was performed using ABI Prism 7500 (Applied Biosystem, USA). All positive controls, negative controls and samples were tested in duplicates. 27 µL HBV-PCR and 3 µl Taq enzyme for each sample were properly mixed. A filter tip was used to add 20 µL supernatant of extracted DNA, HBV negative quality control product, HBV strong positive quality control product, HBV critical positive quality control product, and positive quantitative reference, into the HBV reaction tube. The tube was centrifuged at 8,000 rpm for several seconds and samples were transferred to PCR amplification detection region using the cyclic conditions, temperatures and channels as follows; In stage 1 with ABI Prism 7500 instrument setup, detection channels used are FAM, VIC and ROX at 93^{o}C for 2 minutes of 1 cycle. In stage 2 with Light cycler 4800 setup, detection channels used are FAM and VIC at 93^{o}C for 45 minutes and 55^{o}C for 60 seconds of 10 cycles. In stage 3 with DA7600 instrument setup, detection channels used are FAM and HEX at 93^{o}C for 30 seconds and 55^{o}C for 45 seconds, of 30 cycles

Statistical analysis:

Data generated were analyzed using the Statistical Package for the Social Sciences (SPSS) version 20.0 and Chi-square (X^2) test was used to measure significant relationship between different sociodemographic characteristics among blood donors at 95% confidence level.

Results:

Prevalence of hepatitis B virus infections

Out of the 550 blood samples obtained from the blood donors, 49 (8.9%) were positive for HBsAg with the RDTs while 14 (2.8%) were positive with ELISA. The age range of the donor is 18 to 60 years, with the majority of the donors (335) aged between 30 and 39 years, which also has the highest prevalence of HBV infections (Table 1). Both males and female donors tested positive for HBV (Table 2), with higher rates observed among the male subjects, 47 (9.0%) with RDT and 14 (2.9%) with ELISA compared to female subjects, 2 (6.8%) with RDT and none (0%) with ELISA. From the result of the RDT, replacement donors had a significantly higher rate of infection than voluntary donors (p = 0.008) (Table 3). DNA analyses of 12 samples (3 positive with RDT, 2 positive with ELISA and 7 negative with ELISA) were carried out by PCR (both real time and conventional PCR) as shown in Figures 1, 2 and 3. The samples were randomly selected upon screening them for HBsAg with RDT and confirmation with ELISA.

Table 1: Age group distribution of donors with HBV infections

Age group (years)	Number Examined	Number infected (RDT) (%)	Number infected (ELISA) (%)
< 20	1	0 (0.0)	0 (0.0)
20 – 29	83	8 (9.6)	1 (1.3)
30 – 39	335	31 (9.3)	11 (3.6)
≥ 40	131	10 (7.6)	2 (1.6)
Total	550	49	14
X^2		0.464	2.017
p value		0.927	0.569

Table 2: Gender distribution of hepatitis B virus infection among blood donors

Gender	RDT		X^2	*p* value	ELISA		X^2	*p* value
	No examined	No positive (%)			Number examined	No positive (%)		
Male	521	47 (9)	0.003138	0.9553	473	14 (2.9)	0.5180	0.4717
Female	29	2 (6.8)			17	0		
Total	550	49 (8.9)			490	14 (2.8)		

Table 3: Prevalence of hepatitis B virus infection among blood donor types

Types of Blood Donors	RDTs (%)		ELISA (%)	
	Number examined	Number infected	Number examined	Number infected
Voluntary	63	0 (0.0)	63	2 (3.2)
Family/Replacement	487	60 (13.6)	427	12 (2.7)
Commercial	0	0 (0.0)	0	0 (0.0)
X^2	6.959		0.043	
p value	0.008**		0.835	

The identification codes for the 12 samples are stated besides the Figures. Three (100%) positive samples from RDTs were positive with PCR. Also, 2 (22.2%) positive and 7 (77.8%) negative samples with ELISA were negative with real time PCR. In Figure 1, the curves in the graph represent positive samples with different viral load values of HBV DNA in the samples upon confirmation with real time PCR, while absence of values and curves in Figure 2 showed negative samples. In Figure 3, conventional PCR also confirmed the 2 positive and 1 negative ELISA samples as negative with marker at 350 bp DNA ladder. Tables 4, 5 and 6 show the sensitivity, specificity and accuracy of RDTs, ELISA and real time PCR methods of HBV detection used in this study.

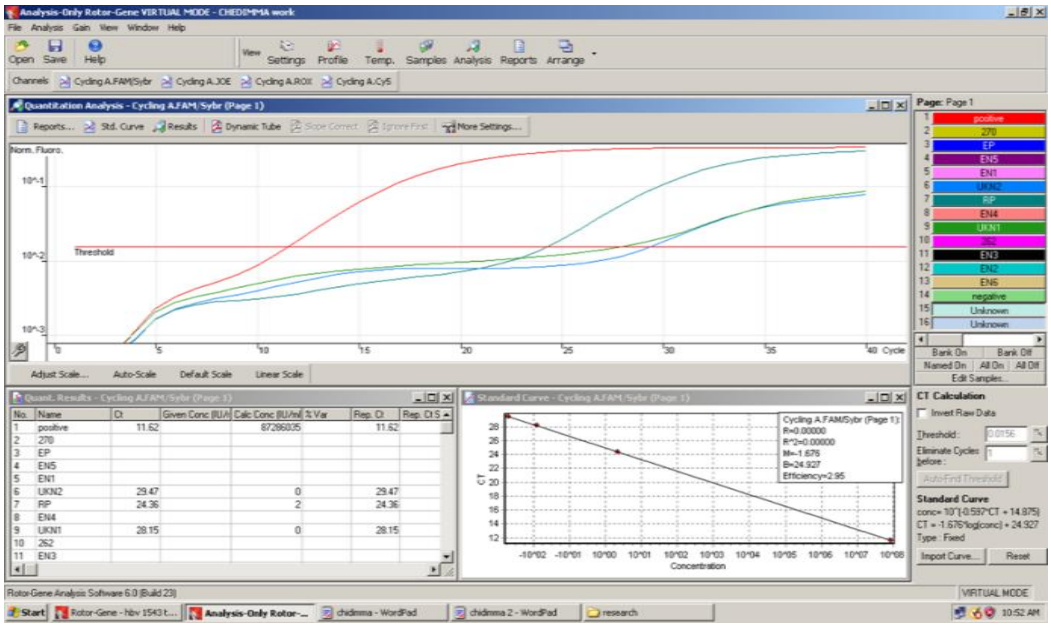

Fig 1: Amplification of extracted DNA from 3 positive RDTs, 2 positive ELISA and 7 negative ELISA samples using rt PCR. The curves on the graphs with the values on the table signify positive HBV samples from positive control and positive RDTs samples

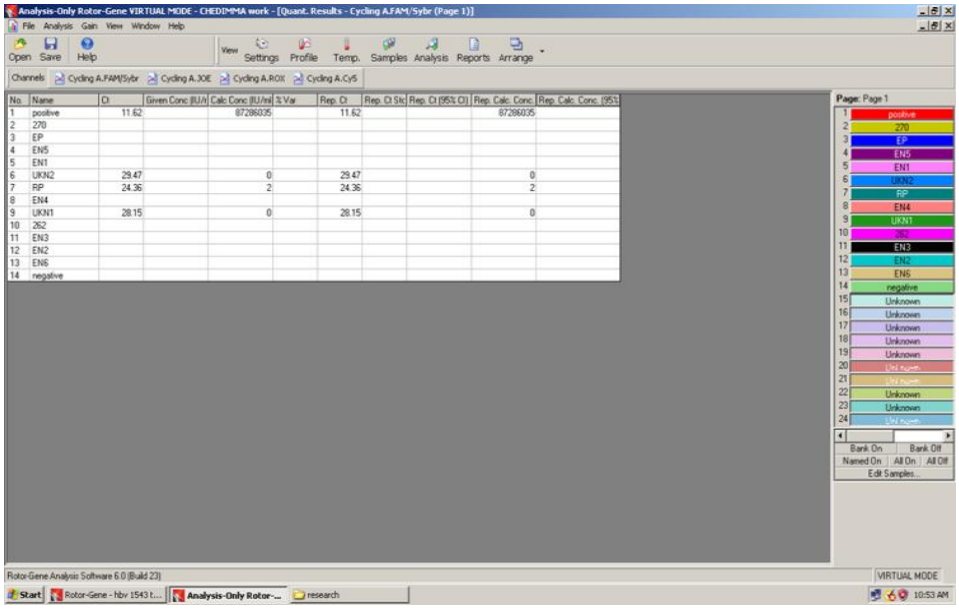

Fig 2: Amplification of extracted DNA from 3 positive RDTs, 2 positive ELISA and 7 negative ELISA samples using real-time PCR. The absence of curves on the amplified graphs with absence of values on some of the columns signifies that the 2 positive and 7 negative samples from ELISA tested negative after using real- time PCR

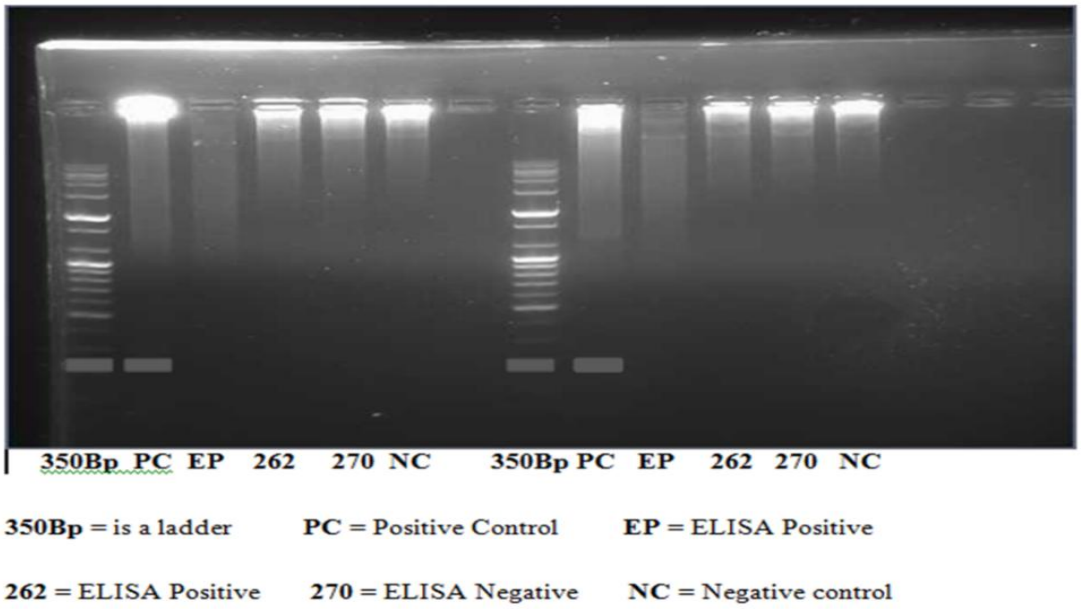

Fig 3: Agarose electrophoresis use to reconfirm 2 positive and 1 negative ELISA samples that were found to be negative using rt PCR

Table 4: Detection rate of HBV by RDT and ELISA tests

		ELISA		Total (%)	Kappa
		No reactive (%)	No non-reactive (%)		
RDT	Reactive	3 (100.0)	0 (0.0)	3 (100.0)	0.304*
	Non-reactive	2 (22.2)	7 (77.8)	9 (100.0)	
Total		5 (41.7)	7 (58.3)	12 (100.0)	

* = there's agreement between the two test methods. The two test methods will agree on 304 out of 550 samples

Table 5: Detection rate of HBV using ELISA and RT PCR

		ELISA		Total (%)	Kappa
		No reactive (%)	No non-reactive (%)		
RT PCR	Reactive	3 (100.0)	0 (0.0)	3 (100.0)	0.304
	Non-reactive	2 (22.2)	7 (77.8)	9 (100.0)	
	Total	5 (41.7)	7 (58.3)	12 (100.0)	

* = there's agreement between the two test methods. The two test methods will agree on 304 out of 550 samples

Table 6: Detection rate of HBV using RDT and PCR

		PCR		Total (%)	Kappa
		No reactive (%)	No non-reactive (%)		
RDT	Reactive	3 (100.0)	0 (0.0)	3 (100.0)	1.000*
	Non-reactive	0 (0.0)	9 (100.0)	9 (100.0)	
Total		3 (25.0)	9 (75.0)	12 (100.0)	

HBV infections and sociodemographic characteristics of blood donors

The prevalence of HBV infection estimated by RDTs and ELISA methods in relation to marital status was higher with 16.7% rate in divorced/separated donors (with RDTs), and 5.0% in singles (with ELISA) but this relationship is not statistically significant (p>0.05). In relation to occupational status, farmers had a higher prevalence of HBV infection with 17.0% but this was also not statistically significant (p>0.05). For educational status, the infection rate was higher in those with primary level education with 100% rate.

Analysis by risk factors in Table 7 shows association of HBV infections with factors such as tattooing, cauterization, blood transfusion, scarification, lack of vaccination, unprotected sex, multiple sex partners, anal sex, intravenous drug use, and injuries from sharp objects, and others.

Discussion:

According to the WHO criteria, the prevalence rate of 8.9% for HBsAg among blood donors in the Federal capital Territory, Abuja, Nigeria reported in our study is high (13). This rate is higher than 1.1% reported in Port-Harcourt (14), 2.4% in Yola (15), 4.2% in Zaria (16) and 5.9% in Ibadan (17). But our rate is lower than 20% reported in Benue State (18) and 17.5% in Abuja by Agbesor et al. (19). In Burkina Faso, a high prevalence rate of 17.3% was reported (20), 11.2% in Cameroon (21) but low rate of 2.48% was reported in Northern Karnataka, India (22). Although it is difficult to explain the differences in the rate reported in our study and those of others, the variations observed may be related to the differential knowledge about hepatitis risk factors, mode of transmission, and information or lack of it on how to make a diagnosis of hepatitis B virus infections in health centres.

The majority of donors (88.5%) tested in this study were family replacement donors rather than voluntary non-remunerated donors (11.5%). The number of voluntary blood donors has continued to decline over the years in Nigeria and the net result is that commercial and family replacement donors persist. Family replacement donors accounted for a significant number of HBV infection compared to voluntary non-remunerated donors. This observation is consistent with the WHO suggestion (23) that the safest source of blood is voluntary non-remunerated donors. This is because replacement donors have long been regarded as higher risk based upon the assumption that friends or relatives are more likely to deny or ignore risk factors that invite further inquiry, removing the protection afforded by risk-screening questionnaires in favor or

coercion to donate. Furthermore, where there is urgent need to procure donors, family members may pay donors for their services thereby compounding transfusion risk.

The associated risky behaviours of the blood donors positively correlated with the rate of HBV infection among the blood donors. This was obvious in the case of people who admitted to having incomplete or no HBV immunization history. The prevalence rate of HBV was significantly high among the donors who are divorcee (30%). This may be attributed to exhibition of risky sexual behaviours that put them at risk of infection. The age group 20 – 29 years, which is the group with highest infection rate (by RDT) in this study, is the sexually active and mostly independent adult group which incidentally constitutes the work force of the population. Appropriate agencies of the Federal Government of Nigeria and Non-governmental Organizations (NGO) need to redress by re-launching infection control programmes to curtail the spread of HBV infections. This should be aimed at changing high-risk behaviours, which are usually denied, among the youths.

Table 7: Infection rate of HBV on social demographic characteristics of donors

Social demographic characteristics		**No examined**	**RDTs reactive**	**ELISA reactive**
Marital Status	Single	99	8 (4.8)	8 (5.0)
	Married	183	35 (11.1)	5 (1.8)
	Divorced	7	3 (30.0)	0 (0.0)
	Undisclosed	26	3 (5.3)	1 (1.9)
X^2			11.734	4.476
p value			0.008	0.214
Occupation	Civil Servant	130	20 (8.2)	7 (3.1)
	Business	78	14 (10.3)	2 (1.6)
	Student	27	4 (8.5)	1 (2.3)
	Farmer	36	8 (17.0)	3 (7.3)
	Others	44	3 (3.9)	1 (1.4)
X^2			6.664	4.431
p value			0.155	0.351
Level of Education	Primary	1	1 (100.0)	0 (0.0)
	Secondary	95	16	2
	Tertiary	196	30	12
	Others	23	2	0
X^2			10.749	3.465
p value			0.013	0.325
Immunization against HBV	Yes	188	0 (0.0)	11 (2.8)
	No	127	49 (8.9)	3 (2.6)
X^2			122.578	0.24
P-value			0.000	8.76
Exposed to any risk	Surgery	37	14 (23.7)	0 (0.0)
	Blood Transfusion	82	10 (7.1)	0 (0.0)
	Cauterization	45	3 (4.8)	4 (6.6)
	Scarification	37	16 (35.6)	0 (0.0)
	Tattooing	101	5 (2.5)	8 (4.1)
	None	13	1 (2.4)	2 (5.0)
X^2			69.576	11.156
p value			0.000	0.048
Risky Sexual Behavior				
Unprotected sex		41	5 (7.9)	1 (1.7)
Multiple sexual partners		12	2 (15.4)	1 (9.1)
Anal sex		16	4 (14.8)	1 (4.3)
Sexually transmitted diseases		19	4 (12.9)	1 (3.7)
None		227	34 (8.2)	10 (2.6)
X^2			2.793	2.212
p value			0.593	0.697

In this study, PCR test achieved 100% sensitivity, and this extremely high sensitivity score was not at the expense of specificity, which also had a perfect performance. The sensitivity of a test is the probability that the test will produce a true positive result when used in an infected population while specificity is the probability that a test will produce a true negative result when used in a non-infected population. Based on the predictive values, RDTs test achieved 100% Positive Predictive Value (PPV), while Negative Predictive Value (PPV) dropped to 81%. PPV refer to the probability that a person is infected with HBV when a positive test result is observed while NPV is the probability that a person is not infected when the test result is negative. Generally, in this study, ELISA test failed to diagnose NPV of PCR negative samples.

The best detection method that will be suitable in screening blood donors for the purpose of eradicating HBV transfusion infections was statistically calculated using kappa (as shown in Tables 4, 5 and 6). Kappa is a measure of agreement that tells the extent to which two methods or raters will agree with each other beyond what might be expected by chance alone (Cohen, 1960). Landis and Koch (1977) went further in interpreting the results of kappa values from 0-1 as follows; poor agreement = 0.20 or less, fair = 0.20 to 0.40, moderate = 0.40 to 0.60, good = 0.60 to 0.80 and perfect = 0.80 to 1.00. The kappa results reported in this study indicated a significant fair agreement, showing that both RDTs and ELISA, and ELISA and PCR methods will agree on 304/550 (k=0.304). Also RDTs and PCR agree on 550/550 (k=1.000), indicating a perfect agreement between the two test methods as reported in Table 6.

Similarly, Kappa can be related to diagnostic likelihood ratios which are not yet commonly reported in peer-reviewed literature, but they can be a valuable tool for comparing the accuracy of several tests to the gold standard. The positive diagnostic likelihood ratio (PDLR) represents the odds ratio that a positive test result will be observed in an infected population compared to the odds that the same result will be observed among a non-infected population. The negative diagnostic likelihood ratio (NDLR) which represents the odds ratio that a negative test result will be observed in non-infected population compared to the odds that the same result will be observed among an infected population.

Although there are false negative samples observed in this study, the false positive rate was minimal. Providing a safe blood for the recipients still remains a major priority, especially in identifying donors at risk of spreading transmissible transfusion infections (TTIs) due to window period. New techniques of testing for HBV will result to zero risk and unnecessary deferral of donors with the introduction of nucleic acid amplification techniques (NAAT), in combination with other methods despite its cost.

Conclusively, this study recorded a higher prevalence rate of hepatitis B infection among blood donors in the Federal Capital Territory, Abuja, Nigeria. No voluntary donor was predisposed to hepatitis B infection with a higher significant difference at p = 0.008. In comparing the sensitivity of HBV detection methods namely, RTDs, ELISA and PCR, a fair agreement was observed between RDTs and ELISA and also between ELISA and PCR. A perfect agreement was observed between RDT and PCR.

It is recommended that upgrade of blood bank centres with modern advanced technology such as NAAT, in combination with other methods, should be employed. Encouraging 100% voluntary blood donation will reduce TTIs. Compulsory universal vaccination against HBV should be introduced in Nigeria (especially vaccination of neonates at birth in case of positive mothers) and the appropriate agencies of the Federal Government of Nigeria in conjunction with Non-Governmental Organizations (NGO) need to redress by re-launching infection control programmes to curtail the spread of HBV infections, with inclusion of HBV

testing and treatment in the list of laboratory tests covered by the National Health Insurance Scheme (NHIS) in the country.

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