

## Original Research Article

### Screening for hepatitis B virus among HIV infected women seeking for Antiretroviral Therapy at National Institute for Pharmaceutical Research and Development (NIPRD), Abuja, Nigeria.

#### ABSTRACT

**Background:** Hepatitis B virus (HBV) infection is endemic and well documented in different locations of Nigeria among different sub-groups. Information regarding the prevalence of HBV in HIV infected women is scarce especially in Abuja, the capital city of Nigeria. **Aim:** This study aimed at determining the prevalence of Hepatitis B surface antigen (HBsAg) among HIV infected women seeking for antiretroviral therapy (ART) at the National Institute for Pharmaceutical Research and Development (NIPRD), Abuja, Nigeria. **Materials and Methods:** A health facility-based cross-sectional study was carried out in our laboratory from May, 2017 to March, 2019 among 1,386 recruited HIV infected women that were screened for HBsAg. Positive samples were confirmed using ELISA. Their socio-demographic data were collected using a questionnaire and written informed consent was obtained prior to study. Data were analyzed using frequency distribution table and SPSS (version 20.0). **Results:** Out of the 1,386 HIV infected women tested, 114 were seropositive for HBV infection giving an infection prevalence of 8.2%. The highest prevalence (2.2%) was observed at age group 25 – 29 years and followed by (1.7%) at age groups of 20 – 24 and 35 – 39 years. **Conclusion:** This present finding confirms high endemic of HBV infection. We recommend that HIV infected women should be routinely screened for HBV as part of ART commencement requirement.

**Keywords:** Cross-sectional, Prevalence, Hepatitis B virus, Antiretroviral Therapy, Questionnaire, Nigeria

#### 1.0 INTRODUCTION

The national prevalence of HIV was estimated to be 1.8% in 1991, to 4.5% in 1996, 5.8% in 2001, 5.0% in 2003 and 4.4% in 2005. However, the national prevalence seemed to stabilize between 2005 and 2010 as shown by the reported prevalence 4.4% (2005), 4.6% (2008), and 4.1% (2010), which ranged from 1.0% in Kebbi State to 12.7% in Benue State [1]. Based on the overall national prevalence of 4.1% obtained in 2010, it is estimated that 3.1million people in Nigeria are living with HIV/AIDS in 2010 and about 1.5 million require ARV drugs [2]. The national prevalence was further reduced in 2014 to 3.0% which implied that over 3.4 million Nigerians are currently infected with the virus and about 2.5 million needs ART [3].

Hepatitis B virus (HBV) causes hepatitis B infection. It is transmitted through sexual intercourse, newborns of infected mothers during childbirth, breastfeeding, and through

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41 | the placenta during childbirth, and also by exchange of saliva or other mucosal fluids  
42 | during kissing with an infected person [4]. The virus is an enveloped DNA virus that  
43 | infects the human liver that causes inflammation, hepatocellular necrosis and other liver  
44 | challenges. Potentially, this virus is referring as life-threatening cause of liver diseases  
45 | worldwide that can either be acute or chronic and it may range from symptomless  
46 | infection or mild disease to symptomatic or greatly fulminant inflammation [5]. The acute  
47 | or chronic viral hepatitis B infection is usually a self-limiting disease known with  
48 | hepatocellular necrosis and mild inflammation with a case mortality rate between 0.5 to  
49 | 1% [6].

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50 | Some studies depict increasing access to antiretroviral therapy (ART) and therefore  
51 | burden of viral hepatitis infection in resource limited settings is expected to raise as is  
52 | now the case in Europe and North America [7,8]. It is therefore, of great concern if this  
53 | is not addressed, viral hepatitis related challenge may hinder the success of ART  
54 | programs in developing countries [8]. Understanding the prevalence and disease  
55 | characteristics of HBV coinfection with HIV is thus significant [9]. Guidelines for the  
56 | clinical management of HIV patients recommends screening for viral hepatitis but  
57 | unfortunately this is not a standard practice in Nigeria, as it is not included in the  
58 | recommended package of baseline commencement laboratory tests.

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59 |  
60 | In 2018, World Health Organization (WHO) reported an estimated 257million people  
61 | **were**are living with HBV infection (as defined by hepatitis B surface antigen reactive)  
62 | [10]. In the developed countries, chronic HBV co-infection are found among estimated  
63 | 30% of HIV-positive persons, with only non or approximately 1% being co-infected with  
64 | HIV and HBV [11]. Some studies carried out across Nigeria have shown **difference**  
65 | prevalence **frequencies** of HIV/HBV co-infection from 9.2% to as high as 70.5%  
66 | [12,13,14,15]. The seroprevalence of HBV infection is very high in the developing  
67 | countries of sub-Saharan Africa and South East Asia where about 8 - 10% are chronic  
68 | infectious carriers; and these same geographic regions have over two-thirds of the  
69 | worldwide HIV burden [16,17].

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70 | HBV infections occur more frequently among HIV infected patients due to the shared  
71 | routes of transmission and further worsens the outcome for the mother and the infant  
72 | with a more rapid clinical and immunological progression [18,19]. Although, most  
73 | perinatal and horizontal transmission of HBV occur in areas of greater endemicity as  
74 | most infections are acquired in the first 5 years of life around Asia and Africa geographic  
75 | regions and estimated 25% of infected children will die of HBV related chronic liver  
76 | disease in adulthood [20,21].

Comment [DK6]: This sentence is overloaded.  
Re-write!

77 | The clinical presentation of non-specificity and the chronic course **that** makes the early  
78 | diagnosis of HBV difficult [20,21]. Thus, there may **therefore** be a silent or latent  
79 | epidemic of HBV among women Living with HIV/AIDS which still remains unclear and  
80 | thereby no intervention plan to scrub such menace.

81 | Although different studies on prevalence of HBV infection in Nigeria have been  
82 | previously carried out in different parts of the country, **but**, there is paucity of published  
83 | data on the prevalence of hepatitis B virus amongst HIV infected women in Abuja, the

84 capital city of Nigeria. Therefore, it is of great significant to investigate the proportion  
85 and frequency of HBV co-infection among HIV infected women attending care at the  
86 National Institute for Pharmaceutical Research and Development (NIPRD) Abuja in  
87 order to understand and **profound interventions aimed at management, prevention, care**  
88 **and treatment** in view of its growing public health importance. Thereby, providing a  
89 window of opportunity for patient education and behavioral modification by counselling  
90 and improved management of HBV co-infection in HIV infected women to achieve better  
91 outcome and ART usages. Hence, this **present** study **is aim to** investigated on the  
92 prevalence of HBV among HIV infected women in Abuja commencing care and  
93 management on ART.

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## 94 2.0 MATERIALS AND METHODS

### 95 2.1 Study area and design

96 The cross-sectional study was carried out at the National Institute for Pharmaceutical  
97 Research and Development (NIPRD) Abuja from May 2017 to March 2019 among HIV  
98 infected women on their first visit to our health facility seeking for antiretroviral therapy  
99 (ART) commencement.

100 Abuja is the Federal Capital City of Nigeria. The city is lying between latitude 8.25°N  
101 and 9.20°E of the equator and longitude 6.45°N and 7.39°E of Greenwich Meridian  
102 and located at the centre of the country with a landmass of approximately 7,315 km<sup>2</sup>, of  
103 which the actual city occupies 275.3 km<sup>2</sup>. It is found inat the Savannah area with  
104 moderate climatic weather conditions. The capital city is located at the north of the  
105 confluence of the River Niger and Benue River [22].

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106 National Institute for Pharmaceutical Research and Development (The NIPRD.)  
107 Abuja is one of the HIV care and treatment centre, the highest medical research and  
108 referral institution in Nigeria charged with the responsibility to conduct research oninto  
109 diseases of public health significant. Although, with the Federal Government of Nigeria  
110 programme in 2002 on ART commencement. It was selected principally to provide the  
111 research backup and referral centre serving a large population in the heart of Abuja and  
112 its environs for the national HIV programme implementations. Presently, the facility  
113 provides free comprehensive care, treatment and support for over 6,646 HIV patients.  
114 Patients are recruited into the HIV treatment programme following HIV confirmations or  
115 a referral from the HIV Counseling and Testing Centre (HCT), Virology laboratory of  
116 NIPRD, Abuja or transfer from other government recognized HIV treatment centres in  
117 the country.

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### 118 2.2 Study populations

119 The study populations s included d all HIV infected women seeking to commence ART  
120 treatment, who agreed and signed an informed consent to participate in the study. A  
121 total of 1, 386 HIV infected women were recruited in our laboratory, Human Virology unit  
122 of Microbiology and Biotechnology Department, NIPRD, Abuja for the study.

### 123 2.3 Selection Criteria

#### 124 2.3.1 Inclusion criterion

125 HIV infected women seeking for ART commencement in NIPRD facility during the  
126 period of data collection (May 2017 to March 2019) and consented to participate in the  
127 study were included.

### 128 2.3.2 Exclusion criterion

129 HIV infected women who did not consent to participate in the study were excluded.

## 130 2.4 Research Questionnaire

131 A well-researched structured self-administered questionnaire was designed to achieved  
132 the desire objective of the study and was used to collect baseline socio-  
133 demographic characteristics of all patients who consented. The questionnaire before  
134 the study was pre-tested on a total of 25 HIV infected woman in our health facility,  
135 with the necessary modification and corrections made following after the pre-test  
136 results.

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137 The socio-demographic variants include age, present place of stay, educational status,  
138 occupational status, marital status, ever tested for HBV, history of previous blood  
139 transfusion, alcoholism and phone numbers.

## 140 2.5 Samples collection

141 A total of 1,386 blood samples were collected from HIV infected women seeking for  
142 ART commencement. About five millilitres (5mL) of venous blood were carefully drawn  
143 from the veins of each patient into a well labeled Ethylene Diethyl Tetracetic Acid (K2  
144 EDTA) tube for CD4+ count and haematological assay as required for ART  
145 commencement baseline parameters. After the assay, the blood samples were  
146 centrifuged at 4,000 revolutions per minutes (rpm) for 10 minutes in order to obtain a  
147 clear supernatant plasma. The plasma was aliquoted into cryovials and stored in the -  
148 40°C freezer until ready for serological screenings for HBV.

## 149 2.6 Serological screening

150 All the plasma samples were screened for HBV infection based on the  
151 immunochromatographic technique (ICT). Serological diagnosis was carried out using  
152 Rapid diagnostic tests (RDTs), for HBV infection the SD BIOLINE (Standard Diagnostic  
153 (SD) Inc., Korea) one step HBV test kit was used for detection of HBV infection. The  
154 immunochromatographic rapid test is a qualitative detection of antibodies specific to  
155 HBV in blood with a sensitivity of 100% and specificity of 99.4%. The screening was  
156 carried out according to manufacturer's instructions found on the standard operation  
157 procedure insert.

158 The sero-positive samples to HBsAg detected by RDTs screening were further  
159 confirmed by another rapid ELISA according to manufacturer's specifications.

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## 160 2.7 Data analysis

161 The data were analyzed using frequency distribution table and figure. Each entry in the  
162 table contains the frequency or count of the occurrences of values within a particular

163 | group or interval, and in this way, the table and figure summarizes the distribution of  
164 | values in the sample or variable. Statistical package for social science SPSS (version  
165 | 20.0), (Chicago, Illinois) was used in other statistical analysis. Data like patients socio-  
166 | demographic characteristics was summarized using simple frequency tables. Level of  
167 | significance was determined at  $P < 0.05$  at 95% Confidence interval.

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### 168 | 3.0 RESULTS

169 | A total number of 1,386 HIV infected women were included in this study with age  
170 | ranged from 15 to 44 years (mean age of 37.0) that came for care at NIPRD ART clinic.  
171 | Out of the total number of women recruited and screened for HBV infection, 114 (8.2%)  
172 | tested positive while 1,272 (91.8%) tested negative for HBV infection. The highest  
173 | prevalence of 2.2% was observed in seen at age group 25 – 29 age group, followed by  
174 | 1.7% amongst age groups 20 – 24 and 35 – 39. The lowest prevalence of 0.4% was  
175 | observed in at age group of 15 – 19 age group years. The age group 25 - 29 years  
176 | were most represented age group (39.8%) and also had the highest HBV infection  
177 | (2.2%). There was no concurrent infection of HIV and hepatitis B infection observed in  
178 | this present study. The age distribution and HBV results of screened study patients are  
179 | shown in Figure 1.

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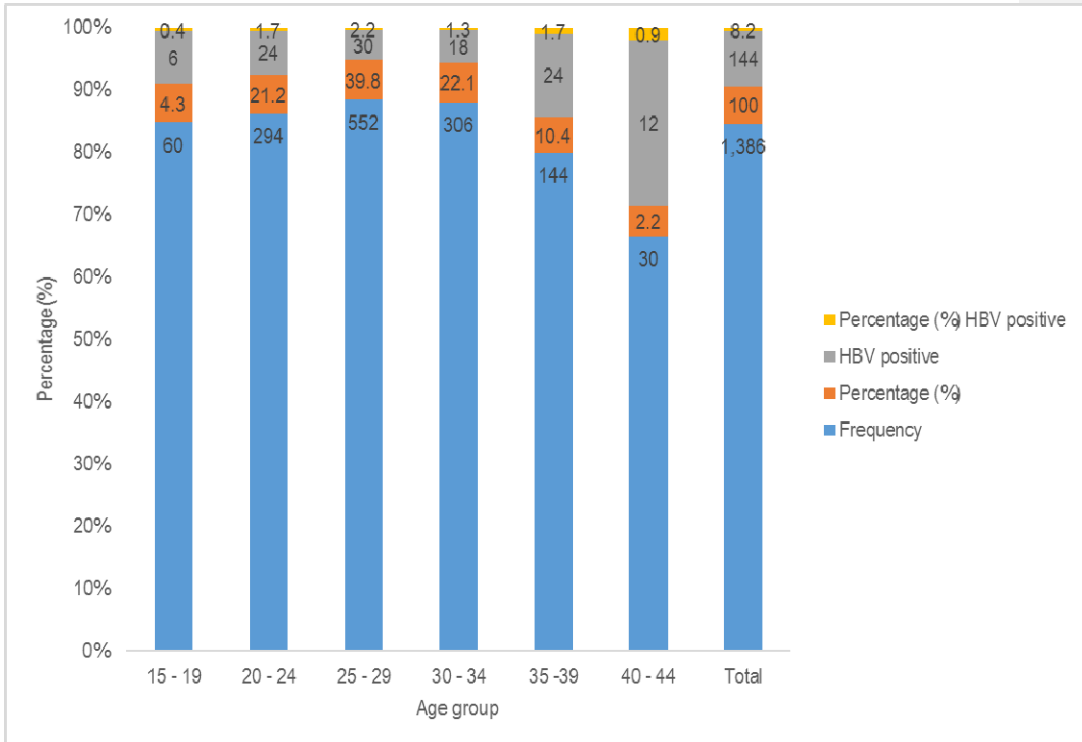
#### 180 | 3.1 Socio-demographic characteristics of the 1,386 HIV infected women in 181 | NIPRD, Abuja.

182 | Table 1: depicts the socio-demographic characteristics of the study participants. It was  
183 | observed that the prevalence of HBV varied according to age and marital status of the  
184 | women in the NIPRD ART clinic. Of the 1,386 patients, 941 (67.9%) were married, 151  
185 | (11%) were not married, 42 (3%) were divorcees or separated while 252 (18.2%)  
186 | were widowers. The study recorded more rural settler's patients than urban settlers  
187 | (65% vs 35%). Only 11% of the subjects had no formal education. Majority of the  
188 | women (50.1%) had secondary level of education and closely followed by primary  
189 | education (23.5%). Also, majority of the women were unemployed (43.5%). The blood  
190 | transfusion and alcohol consumption were only observed among 8.9% and 10.6%  
191 | respectively.

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193

194 **Figure 1: Age distribution and HBV results of the study patients (n = 1,386) at**

195 **NIPRD, Abuja.**

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197

198 **Table 1: Socio-demographic characteristics of HIV infected women studied (n = 1,386) in**  
199 **NIPRD, Abuja.**

200

Characteristics	Frequency	Percentage (%)
Educational status		
No formal education	153	11
Primary	326	23.5
Sec. school	694	50.1
Tertiary	213	15.4
Marital status		
Single	151	10.9
Married	941	67.9
Widowed	252	18.2
Divorced	42	3
Occupational status		
Civil servant	223	16.1
Self employed	430	31
Unemployed	603	43.5
Student	130	9.4
Residence		
Rural	901	65
Urban	485	35
Blood transfusion		
Yes	123	8.9
No	1,263	91.1
Alcohol consumption		
Yes	147	10.6
No	1,239	89.4

201 Note: No Patients have evidence of been previously screened for HBV infection.

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#### 204 4.0 DISCUSSION

205 The major objective of the study was to determine the hepatitis B prevalence rate in HIV  
206 infected women seeking care and treatment **on ART** between May 2017 to March 2018,  
207 and also to evaluate the endemicity of HBV among HIV infected women in NIPRD,  
208 Abuja. The viral hepatitis infection classification of high endemicity as defined by WHO  
209 is HBsAg greater than 7% in an adult population [23]. The prevalence of HBV positivity  
210 **8.2% among HIV infected women in this present study depicts that Abuja and its**  
211 **environs in the central region like other parts of Nigeria is endemic for this viral infection.**

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212 The rapid HBsAg antibody testing for HBV infection was used in this study, which are  
213 useful and powerful tool for screening infections at the point of care and treatment. This  
214 testing easily **identify/identifies** individuals infected with these viruses so as to proffer  
215 quick preventive services, additional investigations, care and treatment immediately.  
216 The screened individuals are therefore, are notified of their infection results or status,  
217 allowed to **make/take** informed decisions about their health care and other alternatives  
218 for treatment, **able to be give health talks on how** to take steps to limit hepatitis  
219 associated infection prognosis, for example, **as regards** vaccinations against HBV,  
220 alcohol consumptions, and have a reduced risk of transmission to others [24]. The  
221 sensitivity and specificity of rapid testing has been queried by some researchers [25]. It  
222 also remains unconfirmed whether HIV serostatus affects test effectiveness [25].  
223 **Although,** other researchers [26] concluded that HBsAg rapid diagnostic test is among  
224 accurate assay for screening for HBV infection in HIV infected persons in a Sub-  
225 Saharan Africa setting.

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226 Liver related disease **continued to remains a significant changer of health** in persons  
227 infected with HIV [27]. The negative effects of HIV infection with prognosis of HBV  
228 infection is well documented with high rates of higher hepatitis viral load, viral  
229 persistence and a more rapid prognosis to liver related challenges like cancer, fibrosis  
230 and hepato-cellular carcinoma in co-infected persons [7]. Unfortunately, in **the** most  
231 developing countries like Nigeria where screening for HBV is not **a** routine at the  
232 commencement assessment of HIV positive persons. In this study, none of study  
233 participants have evidence of been previously screened for HBV infection.

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234 The finding from this **present** study with prevalence rate of 8.2% for HBV infection  
235 among women in Abuja, although, much higher prevalence of 11 to 20% was observed  
236 by other researchers in Nigeria [28,29], Malawi [30] and Senegal [31] among HIV  
237 infected adults. This is unlikely to reflect the HBV burden in HIV patients. There are no  
238 recent publications or studies that have authenticated these findings. This prevalence in  
239 this study was higher than the 2.9%, 2.5% and 1.53% observed among women in Port  
240 Harcourt, South-south Nigeria [32], Iran [33] and amongst Afghan women attending  
241 government maternity hospitals in Kabul [34] respectively.

Comment [DK25]: See DK24

Comment [DK26]: A bit confusing. Present every idea/point separately.

Comment [DK27]: Any possible reasons/factors???

242 This observed prevalence of 8.2% in this study, is however lower than the 11.0%  
243 observed by [35], among women in Makurdi, North-Central Nigeria. It is also lower  
244 than the 11.6% observed by [36] and 12.6% observed by [37] among women in  
245 Maiduguri, North-Eastern Nigeria, and a rural community in North-Central Nigeria,  
246 respectively. **This was again,** lower than the 13.8% observed by Roingard and his co-  
247 researchers among Senegalese women in Dakar [38]. Finally, the observed prevalence

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248 | was also lower than the 63.3% observed by Imade and co-workers in Jos, North-  
249 | Central Nigeria amongst Nigerian women [16]. These observed variations in the  
250 | prevalence of HBV in women may be due to differences in lack of awareness, low  
251 | socioeconomic conditions, an unhygienic environment, cultural practices, sexual  
252 | behaviour and practices, differences in the geographical distribution among the regions  
253 | and variations in the test methods used and employed to detect Hepatitis B viral  
254 | infection as reported from literature.

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Comment [DK30]: Where do these factors apply? Be clear!

255 | One of the sociodemographic characteristics considered in this study was age of the  
256 | patients. The findings from this study showed that high prevalence (2.2%) of HBV  
257 | infection was observed in the 25 – 29 years' age group followed by the 20 – 24 and the  
258 | 30 – 34 years' age groups. This is concordant with the highest HBV infection  
259 | prevalence rate observed in the 25–29 years' age group in a comparable study in  
260 | Ibadan, Nigeria [39]. This may be so due to the fact that this age range falls within the  
261 | sexually active and fertile age group and hence are more at high risk of having a sexual  
262 | contact with an infected person [40]. This may be better explanation of the high  
263 | prevalence of HBV infection at this age group. Majority of the women (50.1%) tested  
264 | had secondary education. This may be because this study was hospital-based in a rural  
265 | area of Abuja i.e Idu, Karmo, Tashe, Gwawa, Jiwa, Zauda, Saburi, Dei- Dei etc.

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266 | Finally, there were some limitations in this present study. The diagnosis and  
267 | qualification of HBV co-infections was based on the detection of HBsAg antibodies by  
268 | use of rapid test kit and confirmation by another rapid ELISA. None of molecular  
269 | technique testing was conducted and absence of HCV RNA has been described in  
270 | 10 to 50% of anti HCV antibody positive persons in some related studies [41]. Data on  
271 | some known high risk factors for acquiring hepatitis, particularly sexual history and  
272 | practices, was lacking in part of data collected. The observations/findings in this study  
273 | cannot be generalised as they only insight the prevalence among HIV infected women  
274 | in our region as compared with studies in other parts of the country.

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## 275 | 5.0 CONCLUSION

276 | This study revealed a high prevalence of HBV infection amongst women, which  
277 | compares well with the findings reported by the World Health Organization that HBV  
278 | infection is highly endemic in Nigeria and developing countries. This support our  
279 | aim/objective of finding out the prevalence of HBV infection among HIV infected women  
280 | in our HIV management, care and treatment Hospital at NIPRD, Abuja.

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281 | It is therefore, recommended that HBV screening should be part of guidelines on routine  
282 | clinical investigations care services to be provided for all HIV infected women except  
283 | where a woman has already been reported to be HBV positive as it can influence  
284 | management. Health talks and education on prevention, awareness, risk, care and  
285 | management of the infection and widespread coverage of the HBV immunization of the  
286 | population should be encouraged.

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## 287 | CONFLICT OF INTEREST

288 | The authors confirm that this manuscript content has no conflict of interest.

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**CONSENT**

The patients were enrolled after they were sufficiently counseled on the objectives, risk and importance of the study. Written consents were obtained and all relevant confidentiality was kept throughout and after the study period.

Only the principal investigator held the results of blood samples tested. The patients were informed of their HBV test results as desired and the test results were delivered to individuals in a sealed form. The patients found positive were further counseled and linked to care in addition to the HIV treatments at the institute research clinic (NIPRD).

**ETHICAL APPROVAL**

Ethical clearance and approval for the study was obtained from the Institutional Review Board (IRB) of National Institute for Pharmaceutical Research and Development (NIPRD), Abuja in accordance with the code of ethics for biomedical research involving human subjects. The confidentiality, anonymity and privacy of all participants were guaranteed at all levels of this study. Written consent was given by participant.

The patients were recruited after they were sufficiently counseled on the objectives, risk and importance of the study. It is only the principal investigator held the results of blood samples tested for the virus. The patients were individually and privately informed of their HBV test results as desired and the test results were delivered in a sealed form. The patients found positive were further counseled and linked to care in addition to the HIV treatments at the institute research clinic (NIPRD).

**Comment [DK37]:** Move to materials and methods.

**Comment [DK38]:** See DK37.

UNDER PREVIEW

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