

## PREVAILING FACTORS; AN EVALUATION OF ANNUAL BUDGETARY ALLOCATION FOR HEPATITIS B VIRUS (HBV) IN NIGERIA

Temitope Blessing Awoyinka <sup>1</sup>, Eniola Olaitan Kolawole <sup>2,3\*</sup>, Augustine Seun Ofeh <sup>4</sup>, Stephen Ebuka Ebuka <sup>5</sup>, Sodiq Abiola Abolade <sup>6</sup>, Bartholomew Onyekachi Okolo <sup>7</sup> and Eunice Temitope Ayeni <sup>8</sup>

<sup>1</sup>University of Ibadan, Department of Biochemistry, Ibadan, Oyo State, Nigeria

<sup>2</sup>Ahmadu Bello University, Department of Microbiology, Zaria, Kaduna State, Nigeria

<sup>3</sup>Taraba State University, Department of Applied Parasitology, Jalingo, Nigeria

<sup>4</sup>Delta State University, Department of Microbiology, Abraka, Delta State, Nigeria

<sup>5</sup>University of Nigeria, Department of Medical Laboratory Science, Nsukka, Enugu State Nigeria

<sup>6</sup>Olabisi Onabanjo University, Department of Microbiology, Ago-Iwoye, Ogun state, Nigeria

<sup>7</sup>University of Nigeria, Department of Biochemistry, Nsukka, Enugu State, Nigeria

<sup>8</sup>Federal University of Technology Akure, Department of Biochemistry, Ondo State, Nigeria

\*Corresponding author: [olaitankola34@gmail.com](mailto:olaitankola34@gmail.com)

### ABSTRACT

Hepatitis B virus is the main contributor to acute and chronic liver diseases. It is an infectious disease that over two billion people are thought to have been exposed to and about 340 million of them are chronic carriers. This virus can be contracted through an infected person's blood or body fluid, small open wounds, or mucosal surfaces. A review of the literature through PubMed, Google Scholar, clinicaltrials.gov, WHO, and ResearchGate was conducted to retrieve the primary studies published between 2015 and 2022. A model of Nigeria's Budget allocation to the health sector from 2012 to 2022 was used to estimate the yearly budget allocation to health sectors in Nigeria yearly. About nine in ten Nigerians who live with chronic Hepatitis B virus are unaware of their infection status due to a lack of resources and low budget allocation and exclusion of HBV in financing strategy development. The 2012 to 2022 model breakdown showed that only US\$ 6.44 was budgeted for every Nigerian's medical care for one year, making it almost impossible for an average Nigerian to get a proper hepatitis screening and diagnosis. However, the Nigerian Government has been able to make a move to begin the production of hepatitis vaccines to eradicate the burden of the disease. Despite the availability of reliable vaccines and treatment options, Nigeria is still saddled with treatment and management even though there are well-structured National Strategic plans.

**Keywords:** Budget Allocation, Hepatitis B, Nigerian Government, Financing Strategy

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### 1. INTRODUCTION

The Hepadnavirus family, which comprises the small, confined human hepatitis B virus (HBV), is composed of circular, partly double-stranded viruses that replicate through reverse transcription (Wu and Chang 2015). The covalently closed circular DNA (cccDNA), which serves as the transcriptional template for the pre-genomic ribonucleic acid (RNA) and messenger RNA (mRNA) for the hepatitis B surface antigen (HBsAg) and hepatitis B antigen/core antigen (HBeAg/HBcAg), is delivered by the virus particles into the hepatocyte nucleus during infection. HBcAg, which is required for virus maturation and release, controls RNA encapsidation, DNA synthesis, and the transfer of partly double-stranded DNA into the nucleus to help replenish cccDNA (Lewellyn and Leob 2011).

When HBV enters the hepatocyte via the sodium-taurocholate co-transporting polypeptide (NTCP) receptor, it is uncoated in the cytoplasm. The host RNA polymerase II uses the covalently closed circular (ccc) form of the core particles' DNA genomes, which is converted into this form in the nucleus (Yang et al. 2014). This enzyme's five major RNA transcripts include two genomic and three subgenomic RNA transcripts. Pregenomic RNA (pgRNA) is translated into the viral polymerase and the core protein in the cytoplasm, whereas subgenomic RNA is translated into the three envelope proteins and the X protein. During the assembly of nucleocapsids, viral polymerase and a single genomic RNA molecule are integrated into the expanding viral core (Lewellyn and Leob 2011). Once viral RNA has been encapsidated, reverse transcription can begin. Sequential DNA synthesis produces the two viral strands. The viral polymerase's ribonuclease H (RNase H) action transforms the

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encapsidated RNA template into the initial DNA strand, commonly referred to as the "minus strand." The first DNA strand is then used as a template to produce the second DNA strand (Saitta et al. 2015). There are two conceivable outcomes for the HBV DNA genome-containing core particle: it may either be reimported into the nucleus to make more cccDNA or it might be coated in L, M, and S surface antigens and expelled from the cell. Antiviral drugs target or may target each of these procedures as well as interactions between the virus and host cellular pathways (Yang et al. 2014).

The hepatitis B virus is what causes both acute and chronic hepatitis B in humans (HBV). In countries with high HBV prevalence, infection normally occurs early in life, resulting in lifelong chronic infection and carriage of the virus as opposed to infection later in life, which usually causes an acute, self-limiting illness followed by viral clearance or, in rare cases, fulminant cases and liver failure. The presence of serum hepatitis B surface antigen (HBsAg; the viral glycoprotein) after six months of infection denotes a chronic hepatitis B infection (Yuen et al. 2018). A serious public health concern is chronic HBV infection. Chronic HBV infection can lead to the evolution of liver fibrosis and cirrhosis, which may cause decompensated (symptomatic) liver damage and/or the emergence of hepatocellular carcinoma (HCC) in HBV carriers (Gourari et al. 2019). Episodes of brief, high-grade liver inflammation and fibrogenic process activation are also possible. Another mechanism producing HCC is HBV infection, which also has additional carcinogenic potential after integrating into the host genome (Yuen et al. 2018).

## 2. Mode of Infection of Hepatitis B Virus (HBV)

Through mucosal or percutaneous contact with infected blood and other bodily fluids like saliva, vaginal, menstrual, and seminal secretions, the hepatitis B virus is transmitted to humans (Mast 1996). HBV can be transmitted sexually, especially among unvaccinated people who have intercourse with infected partners or sex workers. During surgical, medical, or dental procedures, the virus can also be spread by using sharp instruments, such as razor blades, needles, or objects contaminated with infected blood or fluid. It can also be spread by getting involved in certain behaviors, such as getting tattoos, abusing intravenous and percutaneous drugs, using improperly sterilized syringes and needles, getting body piercings, and using acupuncture and acupuncture needles (Mast 1996).

Children born to hepatitis B-positive mothers, people who have had sex with an infected person, those who have had multiple sexual partners, homosexual men, individuals who abuse injection drugs, those who have had domestic contact with an infected person, hemodialysis patients, people who live in facilities for the developmentally disabled, and traveler so are all at risk of contracting the virus (CDC 2016).

## 3. Prevalence of Hepatitis B Virus in Various States in Nigeria

In the University of Nigeria Teaching Hospital, Ituku, 140 children between the ages of 18 months and 15 years had a 4.3% prevalence rate of HBV (Uleanya and Obidike 2015). Children aged 1 to 5 years had the lowest prevalence (2%), and it was noted that there had been a progressive decline as an outcome of hepatitis B vaccination. Pregnant women (n=1032) were screened between 2000 and 2004 at a clinic at Braithwaite Memorial Hospital in Port Harcourt, Nigeria (Obi et al. 2006). Out of these, women between the ages of 21 and 45 had a frequency of 61%, while those between the ages of 21 and 25 had the lowest prevalence at 1.75%. In contrast to a greater frequency of 25.9% among HIV patients, he reported 14.3% HBsAg seropositivity.

According to Anaele et al. (2021), the age range between 21 and 30 years has had the highest prevalence rate of HBV among patients diagnosed in Imo state (56%), while the age group 0 to 10 years has had the lowest prevalence rate (8%). In the Enugu metropolitan area, Ike et al. (2022) reported on the distribution of HBV and associated factors in certain risk groups. Out of 518 individuals sampled between 2013 and 2015, 45 tested positive for HBsAg, resulting in an 8.7% prevalence and 16 HIV patients out of those sampled had the greatest prevalence of HBV (25.5%), which was followed by 20 blood donors (8.6%). Furthermore, he noted that 25 males (10.2%) have a larger incidence than 20 girls (7.3%). A report by Akinniyi et al. (2021) showed the prevalence of HBsAg to be 8.7%, anti-HBs prevalence was 10%, while HBeAg was 2.7%, anti-HBe 6.0%, and anti-HBc 6.7%. Higher HBsAg, HBeAg, and anti-HBc prevalence were observed among the male participants with 13.9%, 5.6%, and 13.9%, respectively, while the female participants had more anti-HBs and anti-HBe of 1.8% and 6.1%, respectively. Age group 51-60 years had the highest prevalence of HBsAg (17.7%), HBeAg (11.8%), and anti-HBe (11.8%) while the age group 31-40 years had the highest prevalence of anti-HBs (14.8%) and anti-HBe (9.8%).

Belo (2000) identified the incidence of HBV indicators among surgeons in 3 main hospitals in Lagos, 167 blood samples from the surgeon were taken, while 193 blood samples from the office personnel served as the control group. Compared to the control group, which had a prevalence of 15%, the surgeons had a higher rate of HBV surface antigen (HBsAg) at 25.7% (P=0.01).

Luka et al. (2008) conducted a seroprevalence study of HBV infection in Zaria. Ten of the 120 serum samples were examined for seropositivity. The 30-34 age group had the highest frequency (18.2%), which had been preceded by the 25-29 age group. The 20-24 age group had the lowest prevalence (6.3%). Blood samples from 113 individuals were analyzed by Pennap et al. (2010) in Keffi (a northern community in Nigeria). Out of the 113 analyzed samples, 15 (13.2%) people were positive for HBV and HCV. 9.5% of females and 24.1% of males had HBsAg, according to gender-related prevalence data. The largest age-related prevalence was seen in the age range of 1 to 40 years (13.8%), while the prevalence for those over 40 years old was 11.5%.

The incidence of HBV sero-markers in female sex workers in Enugu State, Nigeria, was reported by Aniche et al. (2002). Out of 200 participants, 81 (41%) had at least one sero-marker that was positive, 44 (22%) had signs of a natural illness, and 38 (19%) had signs of a vaccine allergy. The study with a high exposure rate found intermediate prevalence. According to a paper by Magaji et al. (2020), five healthcare facilities in Jos, Nigeria, had a significant frequency of HBV infection among pregnant women. Among these five facilities, 241 samples out of 3238 tested positive for HBsAg, representing a prevalence of 7.4%. The highest prevalence rate of HBsAg was found to be 19.2% in the age range of 21 to 40 years, according to Omote et al. (2018) cross-sectional and prospective study among patients at a tertiary healthcare center in Jalingo, Taraba state. Out of 513 samples tested, the gender-based prevalence was also higher in men (14.7% vs. 9% for women).

According to a report by Aba and Aminu (2016), 31 (3.9%) of the 800 pregnant women evaluated in Kaduna had HBsAg-positive results. Women between the ages of 21 and 25 had the highest prevalence ( $P=0.968$ ). The women with the highest seroprevalence of HBsAg were those who were in their second trimester ( $P=0.938$ ), had a tertiary education ( $P=0.972$ ), and had husbands who were involved in polygamous partnerships ( $P=0.944$ ). Adegbesan-Omilabu et al. (2015) cross-sectional research of 150 pregnant women at an antenatal clinic in Lagos State revealed that 11 (7.3%) of them came back positive for HBsAg, 4 (36.4%) of those 11 women tested positive for HBsAg. In Sokoto, Northwestern Nigeria, Augustine et al. (2014) investigated the prevalence of transfusion-transmissible hepatitis B infection among blood donors. He investigated the incidence of HBV infection among 150 blood donors between the ages of 18 and 65, 133 of whom were men and 17 of whom were women. Based on gender and ABO blood group, 8 blood group O donors had a considerably greater prevalence of HBV (57.2%) than blood groups A, B, and AB donors 3 (25.4%) and (7.1%). In terms of age-related, younger donors (18-28 years old) were found to have the highest prevalence (71.43%).

According to Ajuwon et al. (2021), the final analyses of 47 studies involving 21,702 participants revealed a pooled prevalence of 9.5%. Sub-group analyses revealed the highest HBV prevalence in rural settings (10.7%). The Northwest region had the highest prevalence (12.1%) among Nigeria's six geopolitical zones/regions. The estimate of total variation between studies indicated substantial heterogeneity. However, the statistical test for Egger's regression showed no evidence of publication bias ( $P=0.879$ ). Furthermore, Fasola et al. (2022) examined 274 participants, out of this 15 (5.5%) were HBsAg-positive by RDT and 36 (13.1%) by ELISA, while 133 (48.5%) were anti-HBc positive. Out of 232 HBsAg-negative donors, 107 (46.1%) were anti-HBc positive. Of the 107 HBsAg-negative but anti-HBc-positive samples, only one (0.93%) was HBV DNA-positive. The HBV DNA-positive donor was HBsAg-negative by both RDT and ELISA tests. The Median (and interquartile range) age of the patients was 31.0 (25.5-39.0) years, with males constituting 107 (64.8%) as reported by Ahmad et al. (2019). A majority (83.6%) of the samples were HBV-DNA-positive with 82.6% of the HBV-DNA-positive samples being mixed genotype infections. Irrespective of the mode of occurrence, five HBV genotypes were identified with HBV/E (97.1%) being the most predominant, followed by HBV/B (82.6%), HBV/A (24.6%), then HBV/C (17.4%), while HBV/D (0.7%) was the least prevalent.

#### 4. Diagnosis of HBV Infection

The patient's medical history, physical examination, determination of the extent of liver disease, and interpretation of various hepatitis markers, including HBsAg, HB core antigen (HBcAg), HBeAg, HB surface antibody (anti-HBs/HBsAb), HB core antibody (anti-HBc), anti-HBc IgM, and HB e antibody (anti-HBe), with a focus on the detection of HBV infection, are the first steps in diagnosing this infection (WHO 2017). High levels of the enzymes alanine aminotransferase (ALT) and aspartate aminotransferase (AST), as well as the finding of HBsAg and IgM antibodies against the hepatitis B core antigen, can all be used to identify HBV infection (anti-HBc IgM). Through AST/ALT normalization, HBsAg loss, and seroconversion to HBsAg, 90–95% of immunocompetent people who acquire HBV in adulthood will spontaneously remove the virus and build immunity to HBV reinfection. Without seroconversion to anti-HBs, the HBV infection causes permanent HBsAg persistence in infants or early children.

Based on the detection of HBsAg in serum for more than six months, chronic HBV infection is diagnosed (Sarin 2016; EASL 2017; Terrault 2018). The interaction between the host immune system and viral replication

regulates the natural development of chronic HBV infection. Even after being clear of HBsAg, many patients will continue to test positive for HBV DNA, and they do so for a considerable amount of time.

## 5. Treatment of HBV

Therapy and prevention are primarily carried out to prevent the advancement of liver disorders to the health state known as cirrhosis, hepatocellular cancer, liver transplantation, and death. The improvement of the patient's quality of life and survival is the main purpose of treatment (Terrault 2018). Normalizing liver enzyme levels and correcting the histologic inflammatory response to necrotic cell death are brought about by eliminating HBV replication. Even in patients with cirrhosis, the progression of fibrosis can be stopped if viral suppression is maintained. According to a study by Marcellin et al. (2013), paired liver biopsy results showed that 348 patients had an 87% fibrosis regression rate and that 96 patients with cirrhosis had a 71% fibrosis regression rate. The long-term inhibition of viruses also lowers the risk of hepatocarcinogenesis (Liaw 2004). There are five nucleotide analogues (NUC) that have been approved for the treatment of HBV: lamivudine (LAM), telbivudine (ETV), entecavir (ETV), adefovir (ADV), and tenofovir (TDF) (Lok 2016). Conventional or Peg IFN-(IFN- $\alpha$ ) immunomodulators or NUCs like LAM adefovirdipivoxil, ETV, TDF, or telbivudine are suggested as viable treatment alternatives for CHB patients (Manzoor 2015).

## 6. Federal Government Budget Allocation for HBV

Nigeria is one of the nations with one of the greatest burdens of hepatitis in the world, with estimates indicating that there are 2.5 million cases of infection. The Federal Ministry of Health (FMOH) in Nigeria is cognizant of the urgent need to expand access to diagnosis and treatment to reduce morbidity and death associated with the disease's effects, like in other countries with a high prevalence of hepatitis. Nigeria has one of the highest rates of HBV infection in Africa (>8%) (Kramvis 2007). Almost 90% of Nigerians with chronic HBV are unaware of their infection status and are absent from data on global public health due to a lack of financing, political will, and knowledge of the issue (WHO 2018).

### 6.1. Budgetary Allocation to Specifically Tackle HBV, Especially in Vaccine Production

Many civil society organizations included in the technical working group (TWG) expressed concerns and lobbied for the inclusion of HBV in the development of the financial plan. This is a genuine concern given that the prevalence of HBsAg in Nigeria is 11% and that HBV services are typically expensive and exclusively offered in the private sector. The official program was launched in 2015, and a five-year National Strategic Plan (NSP) and clinical guidelines were released in 2016, however, Nigeria's federal and state governments have not yet obtained the funding required to accomplish program objectives.

Given that there is a limited amount of domestic funding available, the HCV program must compete with other health goals for that funding, and strong evidence of the benefits of focusing on HCV is required. It is more challenging for Nigeria to obtain adequate funding for HCV since the federal and state governments have different financial responsibilities for health services. Because the provision of health services across Nigeria's 36 separate states is mostly managed by independent state ministries of health, agreement on programming and financing strategies requires a lot of cooperation between the federal and state governments.

The budget for the year 2022, which carries 4.93% (\$35.63 million in the budget) of the total yearly allocation for the previous five years, has the highest of all; the budget for the year 2012, with 5.95% budget, had the highest for the previous ten years, according to a study of the budget allocated for the health sector in Nigeria annually over the past ten years. Budget trends from 2012 to 2022 (Fig. 1) have the following values, which equate to 5.5, 5.95, 4.4, 5.5, 4.23, 4.16, 3.9, 4.75, 4.16, 4.526 and 4.93%, respectively (Otaru and Nwaosu 2015; Chukwuma 2020; Adebowale-Tambe and Kanabe 2021; Kazeem 2021). At their gathering in Abuja in April 2001, the African Union (AU) members committed to devoting at least 15% of their annual budgets to enhancing the healthcare system. However, a breakdown of the proposed \$35.631 million appropriation bill for 2021 that President Muhammadu Buhari presented to a joint session of the National Assembly showed that, despite the ongoing COVID-19 challenge and the threat of a new pandemic, only 4.526% (or roughly US\$1.287 billion) was allotted to health.

Only US\$6.44, \$0.54, and \$0.018 were allotted in the projected budget to pay for each Nigerian's medical costs over the course of a year, a month, and a day, respectively. Two hundred million Nigerians divided by US\$1,287,368,884, the sum suggested in the 2021 appropriation bill for capital and recurring expenses, equals US\$6.44. It is nearly hard for the average Nigerian to receive a good hepatitis screening, diagnosis, and out-of-pocket payment because a viral load test for hepatitis costs 53 US\$ (20,000 naira), and a 12-week cause treatment to cure chronic HCV infection costs roughly 200 to 300 US\$. Due to all of these, some households will become

even more impoverished because of rising catastrophic and out-of-pocket medical costs. The infrastructure and tools needed for healthcare delivery systems will also be impacted.

The primary causes of the country's resources running out are the recent COVID-19 outbreak, which has brought the global economy to a standstill, and rising insecurity in many parts of the country. Because oil is the primary source of government funding, the decline in oil prices caused by the epidemic has further reduced government cash generation (FMoH 2020). A convincing clinical and financial reason for HCV eradication is required to begin making the case for committing financial resources to eliminate programming. The country's annual budget prevents it from relying on itself for treatment; as a result, it needs to supplement through other health financing methods, including loans and grants from organizations like the World Bank, the Global Fund, and the United States President's Emergency Preparedness Fund for AIDS Relief, among others, while also considering donations (Chukwuma 2020).

According to the World Health Organization's (WHO) Global Health Sector Strategy (GHSS), Nigeria, the disease must be eradicated by the year 2030 to reduce out-of-pocket costs for the treatment of hepatitis (Yasir et al. 2018). Dr Osagie Ehanire, the Minister of Health declared in the Guardian newspaper published on Jul. 25, 2022, that Nigeria is to begin the production of hepatitis vaccines to eradicate the burden of the disease in the country (Onyedika-Ugoeze and Nzor 2022).

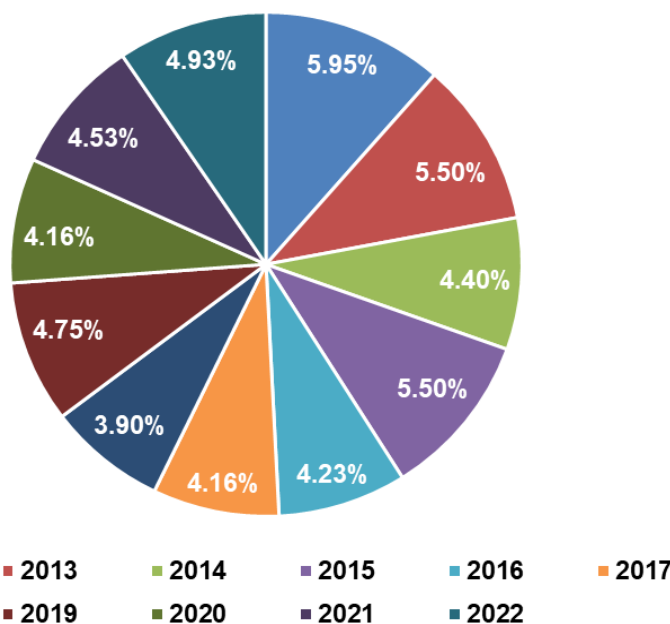


Fig. 1: Nigeria's Budget allocation to the health sector from 2012-2022.

### 6.2. The Effectiveness of Financial Inventions

Hepatitis C patients in Lafiya, Nasarawa state, now have access to affordable treatment thanks to the Clinton Health Access Initiative's (CHAI) initiative and partnership with the government. The program provides low-cost HCV RNA for US\$35 per month and generic DAAs for US\$80 per month. CHAI has been successful in negotiating cheaper rates for HCV diagnostics in various health facilities across Nigeria, including those in Lagos, Abuja, and Kwara, enabling patients to get HCV RNA tests.

In Nigeria, more than 80% of on-demand creation, testing, and linkage to patient care are carried out by civil society organizations and patient advocacy groups. The African Regional Board Member gave 120 doses of DAAs to the Centre for Initiative and Development (CFID) and other Nigerian civil society organizations at the African Hepatitis Summit in Kampala, Uganda, in June 2019.

In Nigeria, routine childhood vaccination schedules have included the pentavalent (DTP-HepB-Hib) vaccine and the hepatitis B birth dose since 2004. Dr Walter Kazadi Mulombo, WHO Country Representative, claims that Nigeria has been able to reduce the number of childhood hepatitis B infections globally as a result of its implementation. According to Dr Walter Kazadi Mulombo (WHO 2017), universal precaution has been governed since 2007. The nation started screening all donated and transfused blood and blood products in 2005 for HBV and HCV.

Overall, testing and treatment for HBV and HCV infection are good uses of healthcare resources at the current level of implementation. According to WHO recommendations, HBV therapy is lifelong and still necessitates

yearly HBV DNA screening. As a result, intervention rarely results in cost savings for healthcare (Tordrup et al. 2020). For HCV, the course of treatment is shorter and results in a single test show that more than 90% of patients have been cured. Therefore, the intervention may result in cost savings for the healthcare system. In conclusion, testing and treatment for hepatitis are both cost-effective for HBV and, in some cases, even cost-saving for HCV at the current activity level.

### 6.3. Consequences of budget allocation to HBV prevalence

The rise in tropical parasitic diseases in Nigeria and other African nations, according to Professor Egwuyenga (Guardian paper 2022), is primarily a result of inadequate budgetary provision, misplaced priorities, and a lack of political will, as he noted in his keynote address at the 46th annual conference of parasitology and public health (PPSN). He voiced alarm over the anticipated 17% global increase in non-communicable disease (NCD) fatalities over the next 10 years, with a staggering 27% increase in the African Region. He explained that this corresponds to 28 million more fatalities from illnesses like cardiovascular disease, cancer, diabetes, and chronic respiratory diseases and that they are anticipated to surpass the total number of deaths from infectious, maternal, perinatal, and nutrition-related illnesses. In comparison to other African countries, Nigeria has completely failed to guarantee that 15% of its annual financial budget goes toward health. The incapacity of the government and politicians, notably the National Assembly, to establish the correct priorities hinders Nigeria's commitment to providing adequate funding for health and disease control programs. The absence of political will to sustainably fund health and disease control is more proof of this.

More than half of the US\$1,008,083,800 Nigeria intended to spend on health in 2020, he said, "went to the National Assembly, meaning that for every US\$0.0043 spent on Nigerians' health care, US\$0.0022 went to the National Assembly (The Guardian paper 2022).

## 7. Conclusion

Hepatitis B is one of the major contributors to acute and chronic liver disease globally. It's a silent killer and dreaded attributed to asymptomatic presentations in people. It's transmitted widely through blood, sperm, body fluids, and mother to child and is highly prevalent in Africa, especially in Nigeria being hyperendemic. Despite the availability of extremely safe, effective, and reliable vaccines and treatment options, Nigeria is still saddled with treatment and management and not prevention, even though there are well-structured National Strategic plans. One of the very core reasons has been the lack of funding and the high poverty level. Annual Nigeria budgetary analysis of the health sector shows it is inadequate and limited. With the high cost of laboratory testing, treatment, and management for Hepatitis B, the high Prevalence of Hepatitis, and low health outcomes are consequent upon limited allocation. The Overall effects of limited funding to the health sector to fight hepatitis are shared limited funds to other greater or similar infectious diseases, lack of adequate HBV vaccine and coverage, high mortality in the low-income population owing to high dependency on Government-funded health care system, low Human capital development index; overdependency on private laboratories and hospital for diagnosis due to inefficient public counterpart will impact GDP and overall well-being negatively.

### ORCID

Temitope B. Awoyinka <https://orcid.org/0000-0003-1165-5961>  
Eniola O. Kolawole <https://orcid.org/0000-0003-4919-1883>  
Augustine S. Ofeh <https://orcid.org/0000-0003-3255-2582>  
Stephen E. Ebuka <https://orcid.org/0000-0002-2844-0660>  
Sodiq A. Abolade <https://orcid.org/0000-0002-6954-612X>  
Bartholomew O. Okolo <https://orcid.org/0000-0003-2276-1428>  
Eunice T. Ayeni <https://orcid.org/0000-0002-9365-0322>

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