**Original research article**

Assessment of Hepatitis B Vaccine Efficacy, Prevalence of Infection, and Risk Determinants Among Expectant Mothers At Antenatal Care in Abyei, South Sudan

**Abstract**

**Background:** The silent but deadly Hepatitis B virus (HBV) poses a threat to world health. Particularly in low and middle-income countries (LMICs), HBV is still underdiagnosed and not well controlled despite the availability of preventive measures like vaccines and antiviral medications. The study aimed to assess the effectiveness of the Hepatitis B Vaccine, Seroprevalence Of Hepatitis B, And Associated Risk Factors Among Pregnant Mothers At Antenatal Clinics In Abyei, South Sudan.

**Methods:** A hybrid type 1 implementation design was adopted in this study. In this study, both purposive and systematic random sampling were employed to recruit the study respondents. 382 prgenant mothers and 94 infants participated in the study. Mothers were tested for HBsAg and those positive were followed up. The infants born of positive mothers were tested after completing three-dose vaccination. Both chi-square and multilinear regression analyses were employed. A significance level was set at a p-value of less or equal to 0.05.

**Results:** The seroprevalence of HBV among expectant mothers was 19%. According to logistic regression analysis, respondents with a history of STIs had a 12 times higher chance of testing positive for Hepatitis B (A.O.R=12.848, p=0.0001) while pregnant women taking intravenous medication 2.3 times likely to test positive for Hepatitis B (p=0.004, A.O. R=2.3). Despite the availability of infants’ vaccination, vertical transmission of HBV from mother to child occurrence was 4.3%.

**Conclusion:** Infection with hepatitis B among pregnant women was 19%, which is a serious public health issue that needs immediate attention. This study emphasizes the need for focused interventions to reduce the risk factors of intravenous medication use and the presence of sexually transmitted infections (STIs), which are linked to increased risk.

**Keywords**: Infection, Hepatitis B, hybrid type 1, Vaccine

**Introduction**

A viral infection that targets the liver, hepatitis B can result in both acute and long-term illness(WHO, 2024). In addition, to contact with blood or other bodily fluids during intercourse with a partner who is infected, unsafe injections, or sharp object exposure, the virus is most frequently passed from mother to child during childbirth and early childhood. According to WHO estimates, 1.2 million new cases of hepatitis B infection occur annually, and 254 million people have a chronic infection as of 2022(2). Approximately 1.1 million people died from cirrhosis and hepatocellular carcinoma (primary liver cancer) as a result of hepatitis B in 2022. Safe, accessible, and effective vaccines can prevent hepatitis B(WHO, 2024).

Africa accounts for about 70% of all hepatitis B infections globally(3). Decades may pass after a person contracts the virus before they begin to show symptoms. With 4.5 million African children infected, the region is responsible for 70% of all Hepatitis B cases worldwide that occur in children under the age of five(4). This is especially concerning for the future. Compared to 40 countries in 2019, 33 countries now have a prevalence of more than 1% for Hepatitis B in children under the age of five(5).

With over 296 million cases worldwide, the hepatitis B virus (HBV) is a serious health concern that can cause serious illnesses like liver cancer and cirrhosis(6). An estimated 523,000 deaths in 2019 were attributed to liver cancer and cirrhosis caused by HBV(7). Inadequate diagnosis and underutilization of preventive measures continue to exist despite their availability, which exacerbates the public health issue. The WHO wants to eradicate viral hepatitis by 2030, but if current trends continue, estimates indicate that HBV mortality will increase by 39%(8).

HBV primarily affects low and middle-income countries (LMICs), especially those in Africa, where more than 60% of new cases and fatalities occur. There are currently 65 million infected individuals in Africa alone, and by 2030, that figure may rise to 80 million(9). Chronic HBV is a major health burden in Africa because it frequently results in serious complications like liver cirrhosis and cancer(10). WHO's recommendations for routine vaccinations and better access to testing and treatment are part of the fight against HBV, but obstacles like a lack of public awareness and a lack of adequate healthcare infrastructure impede progress(11).

Due to the fact that HBV is endemic in many regions of the continent and spreads through unsafe healthcare practices, sexual contact, and mother-to-child transmission, the burden of the virus is especially high in Africa(10). Many Africans lack access to effective vaccines or are not aware that they have hepatitis B(12). Liver cancer, which is mostly caused by HBV, is the third most common cause of cancer-related deaths in Africa(13). The region's HBV public health problem is made worse by the lack of adequate healthcare services and vaccination coverage.

With a high HBV prevalence of 10-15% and notable mortality rates, South Sudan is a prime example of the difficulties encountered by many African countries(1). Inadequate healthcare infrastructure, ongoing conflict, and limited resources hinder the nation's efforts to integrate HBV vaccination into national immunization programs and raise public awareness(14). Effective prevention and treatment strategies are desperately needed, as evidenced by the high rates of transmission from mother to child. Examining HBV seroprevalence and risk factors for hepatitis B transmission among expectant mothers visiting prenatal clinics in South Sudan's Abyei Area was the objective of this study.

**Materials and Methods**

**Study design**

A hybrid type 1 implementation design was adopted in this study. It allowed the researcher to evaluate the effectiveness of intervention in this case, the hepatitis B vaccination, and the contextual factors that influence it. This type of study design allowed the researcher to investigate both the prevalence (seroprevalence) of an outcome or exposure at a specific point in time (cross-sectional) and the development of that outcome or exposure over a defined period (cohort).

**Study area**

Geopolitically significant, Abyei is at the center of border disputes between the governments of Sudan and South Sudan. Abyei is strategically significant because it is situated on the border between the two countries. Its geographic coordinates, which range from latitudes 11.5° N to 10.5° N and longitudes 29.5° E to 27.5° E, define a specific area. Five primary health clinics in the Abyei region of South Sudan were chosen to participate in this study. In the Abyei region, providing health services is fraught with difficulties because the government and its partners only fund a small number of medical facilities to serve the populace. The region was chosen due to its proximity to northern Sudan and its status as a hub for individuals from various ethnic backgrounds.

**Study population**

The study population for this study comprised pregnant women attending antenatal care and their newborns in the Abyei Area, South Sudan. Specifically, the focus was on mothers residing in the southern and northern regions along the banks of River Kiir within the Abyei area.

**Sample size determination**

The sample size for this study was determined to be roughly 382 study participants using the Fisher formula.

**Sampling technique**

In this study, both purposive and systematic random sampling were employed to recruit the study respondents for this research. Abyei which was the study area was selected purposively. Health facilities where the study respondents were obtained were also selected purposively. Lastly, systematic random sampling was employed to select study respondents for this study from the chosen health facility.

**Data collection tools and procedures**

Structured Questionnaires were used to collect quantitative data on pregnant women seeking antenatal care in the selected facilities. Quantitative data collection focused on the prevalence of hepatitis B, Risk factors of hepatitis B among pregnant mothers**,** and effectiveness of the Hepatitis B vaccine. Blood samples were collected and analyzed for Hepatitis B surface antigen (HBsAg) using enzyme-linked immunosorbent assay (ELISA) Blood samples were tested for HBsAg, and positive and negative mothers were followed until delivery. Newborns received the Hepatitis B vaccine and were tested after six months to assess the vaccine's protective effectiveness.

**Statistical analysis**

Before being examined using the Statistical Package for the Social Sciences (SPSS) version 29.0, the quantitative data was carefully cleaned, arranged, and coded. To show how various research aspects relate to one another, descriptive statistics such as frequencies, percentages, means, and standard deviations were used. Inferential statistics were also performed, including multilinear regression analysis. A significance level was set at a p-value of less or equal to 0.05. A thorough grasp of the relationships between the variables in the research framework was made possible by this method, which also provided insights into possible trends, patterns, and causal relationships.

**Ethical consideration**

The Institutional Scientific, Research Ethical Review Committee (ISREC) at Mount Kenya University was consulted carefully before the study started. Furthermore, to support the study on behalf of the government, approval from the Abyei State/National Ministry of Health was required. Explicit informed consent was diligently obtained from each participant before participation in the study. It was made clear that participation in the study was completely voluntary and free from any kind of pressure or compulsion. Strict procedures were put in place to protect participant data, guaranteeing the integrity of their privacy and confidentiality. Any personal identifiers were carefully avoided in study documentation or publications, and all collected data was anonymized and stored securely to prevent unwanted access. At the same time, careful measures were taken to reduce any possible risks to the participants, guaranteeing that the study procedures were safe and did not cause them any unnecessary pain or injury. To prevent the spread of any infectious agents, strict infection control procedures were also strictly followed when drawing blood samples.

**Results**

**Socio-demographic characteristics of study participants**

Table 1 below provides the social demographic characteristics of the study respondents. A third (30.1%) of study participants were between the ages of 26 and 30, 24.9% were over 30, and 45% were between the ages of 15 and 25. Just 12.6% of respondents had completed secondary school, while more than half (52.1%) had never attended school. According to marital status, the majority of the mothers were in monogamous marriages (46.9%), polygamy was 43.7%, which was somewhat close to the study population's monogamous rate, and the lowest percentage of participants were unmarried (9.4%). Regarding employment status, only 36.4% of respondents were employed, while 53.1% of respondents were unemployed. In terms of income, a sizable fraction made over 20,000 South Sudanese pounds. In terms of gestational age, the majority of women (59.4%) were multipara, and all were in the third trimester. The majority of mothers (65.1%) have working husbands, while 34.9% have non-working husbands.

**Seroprevalence of Hepatitis B among Pregnant Mothers**

The seroprevalence among expectant mothers in Abyei, South Sudan, who seek prenatal care is shown in Figure 1. 81% of research participants (N=73) tested negative for viral hepatitis B, while 19% had a diagnosis.

**Risk factors associated with viral hepatitis B infection among pregnant mothers**

To determine the risk factors associated with hepatitis B infections, a chi-square test for independence was first carried out, Age of first sexual life χ2 (*6.1212 (1), p= 0.013)*, having an incident of STI χ2 (154.6550, (df=2), *p = 0.000)*, use of IV drugs χ2 (54.7617, (df=1*) p= 0.000)*, having a husband living with HBV χ2(42.545,7 (df=1) *p = 0.000),* and piercing nose or ear χ2 (*18.4305 (df=1) p= 0.000)* were significantly associated with Hepatitis B seroprevalence.

As provided in Table 2 below, According to logistic regression analysis, respondents with a history of STIs had a 12 times higher chance of testing positive for Hepatitis B than those without a history of STIs (A.O.R=12.848, p=0.0001). Another predictor of a positive hepatitis B test was intravenous medication use. If a pregnant woman takes intravenous medication, her chances of testing positive for Hepatitis B are 2.3 times higher. (p=0.004, A.O. R=2.3).

**Effectiveness of Hepatitis B vaccine alone in preventing mother-to-child transmission among pregnant mothers**

To determine the efficacy of the hepatitis B vaccine in preventing mother-to-child transmission among their infants, a cohort of 47 pregnant mothers' infants who tested positive were monitored. For comparison, a comparable percentage was compared to cases. Two children of cases (mothers with a hepatitis B diagnosis) tested positive among those who did. 2.044 was the risk ratio (C.I. 1.659-2.519). Fisher's exact p-value was 0.4946, indicating no statistical association.

The results of children who received all recommended vaccinations and the likelihood of testing positive for hepatitis B were monitored in this survey. Hepatitis seroprevalence and child vaccination status did not significantly correlate, as shown in Table 3 (RR: 0.719 (C.I. 0.179-2.893) Fisher's exact p = 0.5241). According to Table 3, all exposed infants are cases because the exposed group's risk of becoming a case is 1. About 48.9% of the infants in the unexposed group are cases, according to the risk of 0.489. The risk difference is 0.511, indicating a 51.1 percentage point absolute difference in risk between the exposed and unexposed groups.

From this study, the ratio of risk was 2.044. This indicates that the exposed group's risk of the outcome is roughly 2.044 times higher than the unexposed group's risk. Therefore, the risk of the outcome being measured is more than doubled when exposed to hepatitis B. Fraction attributable to the exposure (Attr. frac. ex.) This value of 0.511 means that exposure to Hepatitis B accounts for 51.1% of the risk in the exposed group. Attributable Population Fraction (Attr. frac. Pop) At 0.022, this value indicates that 2.2% of the population's overall risk (exposed and unexposed) can be attributed to belonging to the exposed group. Interval of 95% Confidence for the Risk Ratio The confidence interval's upper and lower bounds are 0.613 and 0.409, respectively. Due to the small sample size, especially of the exposed group (just two infants), there is a high degree of uncertainty surrounding the risk ratio estimate, as indicated by this wide confidence interval.

**Discussion**

A remarkable seroprevalence rate of 19% was found in this study, which highlights the high prevalence of viral hepatitis B among expectant mothers seeking antenatal care. Abyei is classified as a high endemic area for hepatitis B due to this remarkably high rate; regions with a prevalence of 8% or higher are classified as such, while those with a prevalence of 2% or less are classified as low endemic areas(3). A study conducted in Burkina Faso found that the seroprevalence rate among pregnant women was 19.1%, which is marginally higher than the prevalence found in Abyei(15). Similarly, research in Ethiopia showed seroprevalence rates between 7.7% and 8.5%, which was lower than the prevalence in Abyei(16,17). The significance of routine prenatal hepatitis B screening is emphasized by the World Health Organization. Finding pregnant women with high viral loads who require antiviral therapy to lower the risk of mother-to-child transmission depends on this screening(2). To prevent the disease in the following generation, it is also essential to guarantee that infants born to mothers who are positive for HBV have access to the hepatitis B vaccine.

From this study, respondents with a history of STIs had a 12 times higher chance of testing positive for Hepatitis B than those without a history of STIs.Individuals with a history of STIs often have multiple sexual partners, increasing their exposure to HBV through high-risk sexual behaviors. Behaviors such as inconsistent condom use, engaging in casual or transactional sex, and substance abuse increase the likelihood of acquiring STIs, including HBV. People with a history of one STI are more likely to have had similar exposures that also put them at risk for HBV. This study's findings are similar to a study conducted in Ethiopia assessing the seroprevalence of HBV infection and associated factors among women who were pregnant which showed that a history of sexually transmitted infection was a predictor of HBV infection(18) (Kampe et al., 2023). Another meta-analysis and systematic review revealed similar findings to this study showing that current and past sexually transmitted diseases were associated with HBV infection(19).

From this research, intravenous medication use raised the odds of hepatitis B by 2.3. The association between **intravenous (IV) medication use** and **hepatitis B (HBV)** is primarily related to the potential for exposure to contaminated needles, syringes, or IV drug equipment. HBV is highly infectious and can survive outside the body for up to 7 days. If intravenous medication or drugs are administered using contaminated needles or syringes, there is a significant risk of HBV transmission. Findings from this research were concurrent with those of two other studies carried out in Iran(20,21).

The findings showed that 2 children, or 4.26% of the cohort, tested positive for Hepatitis B out of 47 children born to HBV-positive mothers who were vaccinated. These results highlight how crucial it is to put in place all-encompassing vaccination plans that involve more than just giving the HBV vaccine. Interestingly, the study emphasizes how important it is to include other preventive measures like the zero-dose vaccine and the administration of Hepatitis B Immunoglobulin (HBIG). In contrast, research from China has produced conflicting findings about how well the HBV vaccine works to prevent MTCT. For instance, a study found that when vaccinated with the HBV vaccine either by itself or in conjunction with HBIG, 0% of children born to mothers who tested negative for HBV developed Hepatitis B(22). Infants born to mothers with HBV after vaccination had a 1.9% transmission rate, according to another study (23).

**Conclusion**

In conclusion, hepatitis B infection among pregnant women in Abyei, South Sudan, represents a significant public health challenge that requires urgent attention. This study highlights the heightened risk associated with the presence of sexually transmitted infections (STIs) and the use of intravenous medication, emphasizing the need for targeted interventions to mitigate these risk factors. Integrating hepatitis B preventive services into routine antenatal care, including screening, vaccination, and awareness programs, is crucial. This can be achieved by training healthcare professionals, ensuring necessary resources, and providing prophylactic services for infants born to HBV-positive mothers. Antiviral treatment should be made available for pregnant women with high viral loads to mitigate mother-to-child transmission risks.

Consent

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

Disclaimer (Artificial intelligence)

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Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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Details of the AI usage are given below:

1. Option 1

2.

3.

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**Tables**

**Table 1: Socio-demographic characteristics of study participants**

|  |  |  |  |
| --- | --- | --- | --- |
| Variables | Categories | Freq. | Percent  |
| Age of Respondents | 15-25 years | 172 | 45.0 |
| 26-30 years | 115 | 30.1 |
| >30 | 95 | 24.9 |
| Level of Education | Not been to school |  199 |  52.1 |
| Primary | 135 | 35.3 |
| Secondary | 48 | 12.6 |
| Employment status | Employed | 139 | 36.4 |
| Student | 40 | 10.5 |
| Unemployed | 203 | 53.1 |
| Level of income | 10,000-20,000 SSP | 51 | 34.7 |
| >20,000 SSP | 96 | 65.3 |
| Marital status | Monogamy | 179 | 46.9 |
| Polygamy | 167 | 43.7  |
| Unmarried | 36 | 9.4 |
| Gestational age  | third trimester | 382 | 100 |
| Parity  | Granmultipara >4 children | 96 | 25.1 |
| Multipara 2-4 children | 227 | 59.4 |
| Primipara 1 child | 59 | 15.5 |
| Husband/spouse's working status | Not working | 127 | 34.9 |
| Working | 137 | 65.1 |

**Table 2: Predictors of HBV**

|  |
| --- |
| **HBsAg result** |
| **Age of sexual life** | **Negative** | **Positive** | **Total** |
| 13-15 years | 173(56.4) | 54(72.0) | *6.1212 (df=1), p= 0.013* |
| 16 years and above | 134(43.7) | 21(28.0) |
| **Suffering from STI** |  |  |  |
| No | 263(85.7) | 10(13.3) | 154.6550, (df=2), *p =**0.000* |
| Yes | 44(14.3) | 65(86.7) |
| **Ever used by IV drugs** |  |  |  |
| **No** | 232(75.6) | 23(30.7) | 54.7617, (df=1) p= 0.000 |
| **Yes** | 75(24.4) | 52(33.3) |  |
| **Husband living with HBV** |  |  |  |
| **No** | 300(97.7) | 58(77.3) | 42.5457 (df=1) p = 0.000 |
| **Yes** | 7(2.3) | 17(22.7) |  |
| **Have you pierced your nose or ear** | No | Yes |  |
| **No** | 63(20.5) | 0(0.0) | 18.4305 (df=1) p= 0.000 |
| **Yes** | 244(79.5) | 75(100.0) |  |

**Table 3: Cohort Analysis of pregnant mothers who tested for Hep B and Child Hep B outcome.**

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Exposed** | **Unexposed** | **Total** |
| Cases  | 2 | 45 | 47 |
| Non-cases  | 0 | 47 | 47 |
| Total  | 2 | 92 | 94 |
| Risk  | 1 | 0.489 | 0.5 |
|   | **Point estimate [95% conf. interval]** |
|   |   | **Lower** | **Upper** |
| Risk difference  | 0.511 | 0.409 | 0.613 |
| Risk ratio  | 2.044 | 1.659 | 2.519 |
| Attr. frac. ex. | 0.511 | 0.397 | 0.603 |
| Attr. frac. Pop | 0.022 |   |   |
|  *1-sided Fisher's exact p = 0.2473* |   |
|  *2-sided Fisher's exact p = 0.4946* |   |

**Figures**

**Figure 1: Seroprevalence of Hepatitis B among pregnant mothers**