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DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Assessment of Hepatitis B Viral Load level, Affordability, Knowledge, Attitudes, and Practices among Patients with Chronic Hepatitis B at St. Paul Hospital Millennium Medical College, Ethiopia

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This is to certify that the thesis prepared by Kassalem Dessie, entitled: Assessment of Hepatitis B Viral Load level, Affordability, Knowledge, Attitudes, and Practices among Patients with Chronic Hepatitis B at St. Paul Hospital Millennium Medical College, Ethiopia and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (clinical laboratory management and quality assurance) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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List of abbreviations / Acronyms

CHB	Chronic Hepatitis B
DNA	Deoxyribonucleic acid
IDI	In-Depth Interview
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCC	Hepato Cellular Carcinoma
HCV	Hepatitis C Virus
HIV	Human Immune Virus
IU/ml	International Unit per Milliliter
KAP	Knowledge Attitude and Practice
LIS	Laboratory Information System
PCR	Polymerase Chine Reaction
SPHMMC	St. Paul's Hospital Millennium Medical College
SPSS	Statistical Package For Social Science
VL	Viral Load
WHO	World Health Organization

Abstract

Background: Hepatitis B virus (HBV) is the main cause of liver infections that can result in chronic illness and liver cancer. This disease affects millions globally, with a particularly high burden in Africa, especially in Ethiopia. Access to HBV viral load testing is limited, making it challenging to diagnose and treat the disease. Despite being prevalent the viral load, affordability has not been well documented particularly in our country setup. Hence, this study aimed to assess HBV viral load quantification, affordability, knowledge, attitudes, and practices related to the disease among HBV-infected patients at St. Paul Hospital Millennium Medical College Ethiopia, in 2024.

Methods: A cross-sectional study was conducted at SPHMMC from January to April 2024, using both quantitative and qualitative data. The calculated sample size was 256, and a structured tool was used to evaluate patients' knowledge, attitudes, and practices (KAP). Affordability was assessed using household income and expenditure on HBV viral load (VL) tests. VL level with quality control was carried out using the Cobas 6800. Data completeness was ensured during collection, managed using SPSS version 25, and analyzed accordingly. Regression analysis was employed to evaluate the association of factors, with a p-value less than 0.05 considered significant. The Likert scale was used to measure KAP levels.

Result: There were 256 participants, 53.1% females. Males were more likely to have a high viral load compared to females (AOR = 2.49, 95% CI: 1.26, 4.92, p = 0.01). Individuals with co-infections were much more likely to have a high viral load (AOR = 8.38, 95% CI: 3.76, 12.29, p < 0.01). Half (50%) of the participants had good knowledge, 38.3% had a positive attitude, and 57.8% had good practices regarding HBV infection. Urban residents, higher-income earners, and individuals who tested viral load once within the previous month had lower odds of catastrophic expenditure (AOR = 0.11, 95% CI: 0.02, 0.60, p = 0.01), (AOR = 0.14, 95% CI: 0.05, 0.43, p <0.01), and (AOR = 0.01, 95% CI: 0.09, 0.17, p < 0.03), respectively.

Conclusion: The study highlights the importance of education and accessible testing for HBV, noting that males, co-infections, and alcohol consumption increase viral load. Financial barriers to accessing HBV viral load testing exist. Enhancements to HBV prevention via education, improved access, and behavioral interventions are needed.

Keywords: *Hepatitis B virus, viral load level, KAP, affordability, Ethiopia*

1. Introduction

1.1. Background

Hepatitis B virus (HBV) is a compact DNA virus with a viral envelope consisting of approximately 3200 base pairs(1). The virus replicates within the liver cells of humans, causing viral hepatitis. HBV remains the primary cause of viral hepatitis in less developed regions and is responsible for chronic liver disease, cirrhosis, and primary hepatocellular carcinoma. HBV and hepatitis C virus (HCV) are estimated to cause 80% of all cases of hepatocellular carcinoma (HCC), inducing cirrhosis and reducing life expectancy (2).

Hepatitis B can manifest as either a short-term acute infection or a prolonged, persistent condition. Chronic Hepatitis B (CHB) significantly raises the risk of mortality from cirrhosis and liver cancer (3). Around 296 million people are affected by Hepatitis B, resulting in an estimated 820,000 annual fatalities. Moreover, 25% of chronic Hepatitis B infections advance to develop liver cancer (4).

Africa has the second-highest prevalence of chronic HBV infection among all continents, affecting roughly 6.1% of its adult population (3). Sub-Saharan Africa bears a significant disease burden, with more than 60 million individuals living with HBV. Which is approximately 1 in 15 people (6.1%) in the region are infected with HB(5).

Ethiopia is one of the countries with a high disease burden, characterized by a notably high prevalence of hepatitis B. 35.8% of chronically ill patients in Ethiopia have tested positive for HBsAg(6).

The global impact of hepatitis B necessitates the precise and prompt identification of individuals with HBV infection and the application of treatment approaches rooted in well-established guidelines. Many hepatitis B patients do not exhibit noticeable symptoms in the initial stages, as distinct clinical signs tend to manifest in the later, often irreversible phases of the disease (7). Consequently, determining the infection's prognosis in terms of liver disease becomes extremely important. Early-stage deviations in specific laboratory parameters can serve as indicators of the potential development of fibrosis, cirrhosis, and ultimately hepatocellular carcinoma (HCC) (8).

In the context of identifying HBV infections, the measurement of HB viral load levels in the bloodstream plays a pivotal role in determining when to commence antiviral treatment and in assessing the treatment's effectiveness(9) . Evaluation of the relationship between the serum HBV viral load levels and hepatic pathology is a current hotspot in the diagnosis and treatment of CHB (10).

Hepatitis B presents a significant financial burden, and various obstacles complicate its efficient management, especially in regions with limited resources like Ethiopia. Challenges include difficulties in accessing, affording, and the extended waiting period for HBV viral load testing, which many hepatitis B patients encounter(11).

The advancement of HBV infection results from a combination of factors, encompassing the host's immune response, along with age, gender, viral genotypes, and environmental elements (7, 12). Based on statistical data, there are variations in how male and female patients respond to HBV infection, with males facing a higher likelihood of developing hepatocellular carcinoma (HCC) compared to females (13). This discrepancy could be attributed to the contrasting impacts of female sex hormones, namely estrogen (7). Furthermore, age appears to play a significant role in predicting the advancement of substantial fibrosis in patients and is also a crucial factor in the treatment of chronic hepatitis B (14, 15).

The level of HBV in patients can vary based on factors like pregnancy, organ transplantation, and HIV co-infection. During pregnancy, HBV DNA levels may fluctuate, but there isn't a consistent pattern. Organ transplant recipients receiving immunosuppressive medications can experience increased HBV replication and higher viral levels. In HIV-positive patients, co-infection often leads to higher HBV replication and more rapid liver disease progression, resulting in elevated HB viral level levels (16, 17).

In many developing nations, there is an ongoing requirement for an affordable method to measure the presence and level of HBV in the serum of individuals with chronic infections. The existing global systems for HBV DNA level are prohibitively costly for implementation in these regions(11). Testing HBsAg-positive persons for HBeAg or HBV load and then administering maternal antiviral prophylaxis if HBeAg-positive or high viral load is not a very effective way to prevent perinatal hepatitis B transmission(18).

Due to the low uptake of the HBV vaccine and the high probability of unintentional blood exposure, trainees in the health professions are extremely vulnerable to acquiring an HBV infection during their training (19).

In Ethiopia, the majority of the population including healthcare practitioners exhibit inadequate understanding, unfavorable perspectives, and inappropriate behavior when it comes to dealing with HBV infection(20).

Since the hepatitis B virus has many impacts on health and economic aspects the long-term effects and characteristics of the virus demand early detection and determination of the viral amount in their blood to have a good prognosis and treatment. Thus, this research will aim to explore various dimensions related to Hepatitis B viral load determination among HBV-infected patients at SPHMMC in Ethiopia. In addition to viral load determination, this study will investigate evaluate the affordability of diagnostic, and assess the Knowledge, Attitudes, and Practices of patients regarding of HBV infection.

1.2. Statement of the problem

Hepatitis B virus (HBV) poses a significant global health challenge, characterized by substantial disease burden, mortality rates, and economic implications(4). The virus affects over 6 million children under the age of 5 worldwide, with more than 2 billion people having been infected, and 248 million developing chronic infections(3). Cirrhosis or liver cancer claims the lives of 15% to 25% of those with chronic HBV infections, contributing to over 800,000 fatalities globally in 2017(21).

Advanced technologies for quantifying viral load exist worldwide, but the high cost of these instruments and a shortage of trained personnel pose significant challenges, especially in low- and middle-income nations. Access to these technologies is limited in such regions due to financial constraints and a scarcity of skilled individuals capable of operating the instruments. (22). In such regions, including Ethiopia, where HBV prevalence is 2 to 10 times higher than the global average, the scarcity of laboratories equipped for viral load determination exacerbates the challenge (23).

Diagnosis of HBV infection relies on serologic tests with limited sensitivity in predicting prognosis or disease severity(24). Advanced techniques for assessing viral load are crucial for treatment decisions, but constraints, especially in developing nations, hinder their widespread application(1). In Ethiopia, the impact of HBV infection is about 2 times higher than the average of globally, but there are not enough laboratories to quantify the viral load of the virus and the lack of comprehensive knowledge regarding HBV, load determination, associated factors influencing viral load, affordability of diagnostic tests, and the knowledge, attitudes, and practices of HBV-infected patients poses substantial challenges for healthcare providers and policymakers (6, 20). The management and prevention strategies rely heavily on accurate viral load measurements and understanding the socio-economic and behavioral determinants of the disease (6, 9, 25). Additionally, the affordability of diagnostic tests for viral load level is an important consideration, as limited resources may impede access to critical medical care (20).

This research aims to fill gaps in current literature by investigating aspects of Hepatitis B, such as viral load, affordability, knowledge, attitude, and practice among patients at SPHMMC, Ethiopia.

1.3. Significance of the study

HBV is a public health concern, with a significant impact on developing countries, including Ethiopia. This study had great importance in various aspects. Primarily, it helps to manage healthcare by monitoring disease progression and treatment efficacy through timely quantifying HBV load in infected patients. Secondly, it provides valuable epidemiological insights, offering knowledge on disease prevention, transmission and treatment, and factors influencing higher viral loads. Thirdly, the study's evaluation of the affordability of testing is crucial in resource-limited settings and can inform healthcare policies. Fourthly, understanding patients' knowledge, attitudes, and practices regarding Hepatitis B helps develop awareness campaigns and behavior interventions as part of the public health management.

In general, the study had local and global scope, providing valuable data for public health initiatives, patient care, and policy development, particularly in the context of Ethiopia's healthcare system and global efforts to combat HBV. Moreover, the findings of this study could serve as baseline data for further research by fellow researchers and policymakers.

2. Literature review

2.1. Hepatitis B viral load level

A study conducted in 2019 in China by Jing et al. to assess elements linked to disease advancement and viral replication in individuals with CHB infection reported that among the total of 478 HBsAg positive patients, the mean HBV viral load was $2.46x10^4$ international unit/ millimeter (IU/ML). Also, the report says that among male and female patients, males had more hepatitis B virus viral load and patients whose ages were less than 30 had more HBV viral load than the above age groups(8). Here is a study conducted in China in 2019 by Cheung W. et al, to assess and determine the best timing for quantifying hepatitis B virus DNA and the clinical indicators of a higher viral load during pregnancy. Reported as among the 352 hepatitis B virus-infected pregnant women whose gestational weeks are <22 gestational weeks having a range of 1 x 10^6 IU/ML to 1 x 10^8 IU/ML of HB viral load. This study also confirmed that there is a strong positive correlation between HB viral loads in pregnant women at different gestational ages (26).

An institutional based cross-sectional study which was conducted in China in 2002, by Lau GK et al, to identify high hepatitis B virus (HBV) viral load as the most significant risk factor for HBV reactivation in HBsAg-positive patients undergoing autologous hematopoietic cell transplantation. The report was among 37 HBsAg positive and hematopoietic stem cell transplanted individuals the median of HB viral load level was 800 pg/ml before transplantation but their HB viral load level was a median of 935pg/ml after transplantation which is due to the reactivation of HBV after transplantation and immune suppuration of patients by chemotherapy (27).

The study conducted in South Sulawesi, Indonesia at 2015 by Masita F. et al. to assess the effectiveness of quantitative HBsAg in predicting viral load in HBsAg-positive pregnant women. The report of the study was Out of 64 pregnant women which are positive for HBsAg had 31.62 to 5.2 x 10^7 IU/ml of Hepatitis B Virus viral load (28). In France there was a cross-sectional study which was conducted by Mayran C. et al in 2022 to assess hepatitis B virus viral load measurement using recombinase polymerase amplification paired with a lateral flow read-out. Among the 108 hepatitis B positive patients the mean hepatitis B virus viral load was 1.17 x 10^4 IU/ML(29).

In Nigeria in 2016 by Ireqbu et al reported as in the total 666 hepatitis B infected patients the mean HBV DNA was ranged from 20 IU/ML to 3.6×10^8 IU/ML. out of those 666 patients 9% (59) did not detected viral DNA, and 5.3% (36) patients had high hepatitis B viral load which is > 1.7×10^7 IU/ML and the remaining patients had between 20 IU/ML to 1.7×10^7 IU/ML. but majority 50.6% (337) patients had less than 2×10^3 IU/ML hepatitis B viral load(1). Another study conducted in Anambra State of this Nigeria in 2020 by Obiomah, C., et al, to "establish the correlation between HBV DNA level and standard hemato-serological parameters to devise a more economical diagnostic algorithm for managing Hepatitis B. Reported that of the total 264 hepatitis B infected individuals the median serum HBV DNA viral load in the cohort is approximately 422.50 IU/ml. The study also explored gender and sex-based differences in serum HBV DNA and HBsAg levels. However, the results indicated no significant differences in the median levels of these markers between male and female patients and also association between different age groups and hepatitis B viral load(25).

The prospective study that was conducted in Mozambique in 2016 by Wandeler G et al to quantify the HBV viral load in patients co-infected with HIV. The report was in the total of 156 HBsAg-positive HIV infected patients had HBV Median DNA level of 13,645 IU/mL (interquartile range 192–8,617,488). Among them 77 (49.4%) had high values (>20,000 IU/mL). Men were more likely to have high HBV DNA than women whereas the proportion of patients with high DNA was highest in patients with advanced WHO stage of HIV disease and low CD4 cell counts (30).

2.2. Knowledge, Attitudes, and Practices about Hepatitis B virus

A mixed study conducted in Thailand in 2021 by Bierhoff M. Et al for assessment of women's KAP who were migrants. The finding of the study was averagely 19.85% had knowledge about HBV 43% had practice 76 % of them had negative attitude about HBV infection (31).

A cross-sectional study design was conducted in Pakistan, 2023 to assess examining the impact of hepatitis-related knowledge, attitudes, and practices on the quality of life, with a focus on the moderating influence of internalized stigma among patients positive for hepatitis B virus. The result was majority of the study participants had good knowledge, attitude and practice on HBV. Unfortunately, specific numerical values for KAP were not provided (32).

In 2023 there was a cross-sectional study conducted in Jordan, 2023 by Nader A. et al to "assess the knowledge, attitudes, and practices toward HBV and its associated factors". The report was in 2223 participants, 40 % possessed high levels of attitudes and knowledge. Additionally, 63.9% of people practiced good HBV behavior (33).

A hospital-based cross-sectional descriptive study was conducted in Sudan, 2019 by Sanna M. et al to assess the "KAP towards HBV infection among nurse and midwifes". Their result was among the 110 respondents 58% had knowledge about HBV and 27 % of the respondents had poor practice about HBV prevention and transmission (34).

A cross-sectional study conducted in Gondar Ethiopia 2020 by Gebrecherkos T. et al for the "assessment of KAP towards HBV among pregnant Women attending antenatal care". The report was among the 354 total study participants 73.4% of them have inadequate knowledge. And only 18.9% were aware that HBV can be transmitted from mother to child during pregnancy. 47.7% of the participants seek treatment from traditional healers when they have symptoms of HBV, but less than half (43.8%) of the participants believe they will never contract the virus. only 28.5% of the participants thought that hepatitis B could lead to liver cancer, whereas the majority of respondents (85.87%) had never undergone an HBV screening (35). The other cross-sectional study conducted in Northwest Ethiopia in 2016 by Abdnur A. et al for the "assessment of KAP towards prevention of HBV among health students". The result was among the total 246 study participants 20% had not an adequate knowledge about HBV risk factors, prevention and mode of transmission and about 17% had negative attitude about HBV. 26.8 % of the participants had exposure to blood and body fluid (19).

An institutional based cross-sectional study conducted in Tibebe Gion specialized hospital Bahirdar Ethiopia to assess "Knowledge, Attitude, Practices, and Associated Factor towards Hepatitis B Virus Infection among Health Care Professionals" by Belete Et al., the report of the study was of 422 healthcare workers, revealed an average KAP score of 65.6%. The result suggests a need for additional training to enhance their healthcare domain knowledge. Conversely, greater work experience was associated with higher knowledge levels, emphasizing the value of practical experience in domain-specific knowledge acquisition. Attitudes among healthcare workers significantly impact their behavior, and the study found that degree holders

and specialists displayed more positive attitudes, with odds ratios of 2.49 and 9.78, respectively(20).

2.3. Affordability of HB viral load test

There was a study conducted in India by Hubert Darius et al**,** to assess the Measurement of hepatitis B virus DNA in plasma using a sensitive and cost-effective in-house real-time PCR assay. The report of this study was Current international systems to quantify HBV DNA are too expensive to be used in developing countries rather using in-house methods is cost effective rather using in-house real time PCR is cost infective for developing countries (36).

A study conducted in 2014 in USA by Fan l. et al to evaluate the cost-effectiveness of testing the VL in pregnant women who are HBV positive. The report was the current recommended technique for HB lad quantification is not cost-effective. The technique can loss $3 million per quality of adjusted life year (37).

A retrospective study was conducted in Uganda in 2011 by Juliana N. et al for analysis of the expenses associated with viral load testing from the viewpoint of healthcare providers. The study indicates the cost of HBV viral load is $12.09 and $ 11.32 to for the Abbot and Roche platforms respectively. Operating costs made up the largest portion of the cost per test in both platforms 35.9% for Roche and 33.6% for Abbott. The cost for both platform was not affordable for patients who pay in out of pocket (38).

3. Objectives

3.1. General objective

To assess Hepatitis B Viral load level, affordability, knowledge, attitude, and practice among patients with chronic Hepatitis B Infected at St. Paul Hospital Millennium Medical College, Ethiopia, 2024.

3.2. Specific objectives

- To determine the Hepatitis B viral load level among Hepatitis B infected patients at St. Paul Hospital Millennium Medical College, Ethiopia 2024.
- To assess the level of Knowledge, Attitudes, and Practices of Hepatitis B infected patients regarding Hepatitis B virus follow-up at St. Paul Hospital Millennium Medical College, Ethiopia, 2024.
- To determine the level of affordability of Hepatitis B viral load testing for Hepatitis B infected patients at St. Paul Hospital Millennium Medical College, Ethiopia, 2024.

4. Materials and methods

4.1. Study area

The study was conducted at SPHMMC which is located in Addis Ababa Ethiopia. The hospital has More than 2800 clinical, academic, administrative, and support staff members who work at the institution. The hospital teaches medical students and has been doing basic and applied research in addition to providing medical specialty services to patients who are referred from all over the nation. The College can accommodate more than 700 inpatient beds, but on a daily average, 1200 emergency and outpatient patients are seen *(SPHMMC).* The hospital has laboratory services such as hematology, clinical chemistry, serology and virology, parasitology, urinalysis, transplant laboratory, blood bank, maternity and child health laboratory, microbiology, and infertility laboratory. Each laboratory services use different advanced instruments and laboratory information systems including cobas6800. St. Paul's Hospital is selected for this study because it has the highest patient load of any other hospital in the country(39). Based on the Gastric Intestinal (GI) department of the hospital data more than 598 HBV-infected patients were following their treatment in the hospital.

4.2. Study design and period

An institutional-based cross-sectional study using both quantitative and qualitative data was conducted from January to April 2024 at SPHMMC.

4.3. Population

4.3.1. Source of population

- All hepatitis B virus infected individuals who are attending SPHMMC.
- All reported and documented results for hepatitis B viral load level during the study period.

4.3.2. Study population

The study population was all HB virus-infected individuals who have been laboratory requested for HB viral load test and had follow up and eligible reported and documented results for HBV viral load level for retrospective study at SPHMMC.

4.4. Inclusion and exclusion criteria

4.4.1 Inclusion criteria

- HBsAg positive patients who are 18 and above years old having the laboratory requests for hepatitis B viral load test during the study period and patients who were with informed consent and volunteers
- Those HBV positive clients who are on follow-up
- All reported and complete documented laboratory results for HBV viral load level were included in the study

4.4.2. Exclusion criteria

The exclusion criteria for the study were:

- Incomplete data (for HBV viral load baseline data and related information)
- Reports such as mislabeling, insufficient sample, wrong test tube, inappropriate sample,
- Duplicated tests
- lost follow up

4.5. Variables of the study

4.5.1. Dependent variables

- Hepatitis B viral load level
- Level of knowledge
- Level of attitude
- Level of practice
- Degree of affordability of Hepatitis B viral load test

4.5.2. Independent variables

- Age
- Gender
- Educational status
- Occupation
- Co infection with other pathogens or disease condition
- Alcohol consumption
- Smoking
- Economic status(income)

4.6. Sample size determination and sampling technique

4.6.1. Sample size determination

To assess the proportion of HBV infected patients' viral load, affordability and KAP among individuals at SPHMMC College in Ethiopia, the sample size was calculated by assuming a 50% prevalence rate due to the absence of specific literature. The determination of the required sample size was employed the single population proportion formula outlined below. Additionally, 10% of the sample size was allocated to account for potential non-respondent participants.

$$ni = \frac{Z^2 \alpha/2\ P\ (1-P)}{W^2}$$

ni = $(1.96)^2$ x 0.5(1-0.5)/ $(0.05)^2$ =384. However, since the source population for the study was 598, which was less than 10,000, the following correction formula was used.

nf $= ni/(1 + \frac{ni}{N})$ =384/ (1+384/598) =233. After considering its 10% the minimum sample size was 256

Where nf = corrected sample size

ni = uncorrected

N = total number of all the source population.

w = Margin of error between the sample and the population (w=5%)

p= estimated population proportion (50%)

Z α/2 = 95% confident interval from the normal table for a given value (1.96)

For the qualitative study part, data saturation was achieved after interviewing 25 participants. Saturation was determined when consecutive interviews no longer yielded new themes or insights relevant to the research questions. The participants included a diverse range of gender, age and residence ensuring a comprehensive understanding of the phenomenon under investigation.

4.6.2. Sampling technique

A simple random sampling technique was conducted to ensure a rigorous and unbiased selection of participants. Additionally, a purposive or consecutive sampling approach was utilized based on the sampling frame, ensuring the targeted inclusion of participants to meet specific criteria. This dual-sampling strategy aimed to enhance the study's precision and relevance by combining

the benefits of random selection with purposive selection, thereby optimizing the selection process for a more nuanced and insightful analysis.

4.7. Measurement and Data collection

4.7.1. Data collection procedure

The data collection process for this study was designed to comprehensively capture insights into HBV dynamics through a combination of retrospective and prospective methods. In the retrospective phase, baseline results for HBV viral load levels were meticulously extracted from existing documents and the laboratory information system. This data, spanning a specified timeframe, was offered valuable insights into patients' past viral load levels, contributing to a thorough understanding of the virus's trajectory.

In the prospective phase, data was collected in real time during the study period through two primary avenues. Firstly, patients' clinical histories were systematically recorded using a checklist, extracting pertinent information from their medical records and interviewing. Secondly, the level results of patients' HBV viral load were documented, providing a contemporaneous perspective on the virus's dynamics and allowing for a dynamic analysis of changes over time.

To complement the quantitative findings, qualitative data was gathered through structured questionnaires and facilitated in-depth interviews. The questionnaires, which incorporate written consent and cover socio-demographic variables, provided additional context to the numerical data. IDI was organized by selecting participants based on specific criteria, which was guided by trained moderators to explore participants' knowledge, attitudes and practices related to HB infection prevention and test affordability of VL. During IDI there was tap recording and then translation. Thematic analysis was applied to identify key patterns and themes emerging from the qualitative data, enriching the overall understanding of the study.

The questions to measure the KAP of participants about HBV infection included various items. Specifically, the questions assessing attitudes towards HBV infection were structured using a Likert scale format. Economic aspects was assessed through inquiries included in the structured questionnaires, specifically focusing on participants' total household income and expenditures

related to the HBV viral load test. This comprehensive approach aims to evaluate the affordability of the test.

To ensure inclusivity, individuals meeting the study's inclusion criteria were encouraged to independently complete all questionnaire sections. In cases where assistance was required, data collectors conduct interviews, employing a meticulous approach to ensure a comprehensive understanding of the factors under investigation. By integrating both retrospective and prospective data collection methods, coupled with a robust qualitative approach through IDI, this comprehensive procedure aims to provide a nuanced understanding of HBV dynamics, economic implications, and preventive measures, contributing to a holistic analysis of the study objectives.

4.8. Quality control and quality assurance

The study's reliability was ensured through meticulous quality control measures at every laboratory stage. Daily feedback and corrections from advisors ensured data collector proficiency. Regular checks ensured data completeness, accuracy, and clarity. A 5% pretest of the study population preceded actual data collection. Data collectors received thorough training for uniformity and accuracy. Cross-checks were conducted daily to verify checklist completeness and eliminate redundancy. Advisors closely monitored the data collection process to uphold data integrity and reliability. A comprehensive quality assurance framework, covering pre-analytical, analytical, and post-analytical stages, was strictly followed. Prior to data collection, the tool underwent pre-testing for accuracy and consistency

4.8.1 Pre-analytical data quality control

During the pre-analytical phase, Specimens were meticulously labeled with patients' names, Medical Record Numbers (MRNs), and dates to avoid any identification errors. Appropriate volume of blood was taken from the participants. Attention was given to check for hemolysis, clotting, and specimen contamination, and a waiting period of 10 to 15 minutes will be observed to stabilize the serum separate jell with the blood.

4.8.2. Analytical data quality control

During Analytical phase of quality control program routine checks of instruments and reagents, with control samples for cobass 6800 run at defined intervals for monitoring. Every day before the sample was run low; medium and high control reagent was used for Cobass6800 analyzer to maintain the reagents quality and preventive maintenance.

4.8.3. Post-analytical data quality control

In the post-analytical stage, results were diligently verified for accuracy before release, and correlations with clinical information were made to ensure relevance and consistency.

4.9. Data analysis and interpretation

Data entry, coding, cleaning, sorting, and analysis were conducted using SPSS version 25, robust statistical software. Thorough validation processes was implemented, checking for frequencies, accuracy, consistencies, missed values, and variable integrity.

To characterize the study population, frequencies, proportions, and summary statistics were employed, providing a comprehensive overview of relevant variables. Bivariate and multivariate logistic regression analyses were performed to assess the association of independent variables with the dependent variable. Statistical significance was determined with a p-value threshold of less than 0.05.

Evaluation of participants' knowledge, attitude, and practice was assessed based on mean, with scores above the mean considered indicative of good knowledge, attitude, and practice. Additionally, the affordability of VL test costs was assessed, by comparing the cost expense from participants' household income. Participant expense above 40% of their income for VL test was considered as catastrophe expenditure. This strategic approach ensures a meticulous examination of the study findings, employing both statistical rigor and practical benchmarks for meaningful interpretation.

4.10. Operational definition

I. **Affordability:** ability to pay HBV-infected patients for the level of HBV VL at SPHMMC (center of financial inclusion definition**).**
II. **Positive attitude:** when the study participants able to give above the mean for the given attitude item question (19).
III. **Negative attitude:** when the study participants give below the mean for the given attitude item question (19).
IV. **Good Knowledge:** when the study participants able to answer correctly above the mean of the questions in knowledge items (19).

V. **Poor knowledge:** when the study participants answer less than mean of the questions in knowledge items (19).

VI. **Lost follow up:** hepatitis B infected patients who terminate their treatment follow up (40).

VII. **Good practice:** when the study participants able to answer correctly above mean of the questions in practice items (19).

VIII. **Poor practice:** when the study participants will be answer less than the mean of the questions in knowledge items (19).

IX. **Catastrophe expenditure**: expense for medical issues more than 40% of household income

X. **Non-Catastrophe expenditure:** expense for medical issues less than 40% of household income

XI. **Low viral load :** HBV amount < 20,000 IU/ml (American Association for the Study of Liver Diseases (AASLD) Guidelines)

XII. **High viral load :** HBV amount >20,000 IU/ml (AASLD)

4.11. Ethical consideration

The study was conducted after ethical letter obtained from Research and Ethics Committee of medical Laboratory Sciences department, College of Health Sciences Addis Ababa University *(DRERC/746/24/MLS)* and institutional review board of SPHMMC *(PM23/1056).*

Informed written consent was taken from the participants before enrollment in the study. Then the objective of this study was explained to the study participants, and those willing to participate were included. To ensure confidentiality of data, study subjects were identified using codes and unauthorized persons were not able to access the collected data.

4.12. Result dissemination plan

The study findings will be shared with the Department of Medical Laboratory Science at Addis Ababa University and subsequently distributed to healthcare planners and individuals requiring the information as a fundamental reference for future investigations. Moreover, the results will be presented at national and international conferences and are scheduled for publication in respected journals.

5. Result

5.1. Socio demographic characteristics of the study participants

This study enrolled a total of 256 study participants who are on HBV treatment follow up from the selected hospital; of which 46.9% (120/256) of them were men, and 53.1% (136/256) of them were women. Participants' average age was 37.96 years, with a standard deviation of 10.4 years. Of the study participants, majority 31.3% (80/256) were between 33 to 40 years old. Regarding educational attainment, the largest percentage 30.1 % (77/256) had completed elementary school. Regarding residence, the majority identified as urban residence 59.8 (153/256). The distribution of household income (in Ethiopian Birr) reveals that a sizable fraction 33.2% (85/256) is in the 3000-5000 income range, (Table 1).

Table 1: socio-demographic of study participants at SPHMMC from Januarys to April, 2024

Variables		Number	Percent
Sex	Male	120	46.9
	Female	136	53.1
Age in year	18 - 24	16	6.3
	25 – 32	72	28.1
	33 – 40	80	31.3
	41 – 48	49	19.3
	49 – 56	29	11.3
	57 – 64	5	2.0
	>65	5	2.0
Residence	Urban	153	59.8
	Rural	103	40.2
educational status	Illiterate	31	12.1
	Primary school	77	30.1
	Secondary school	72	28.1
	Diploma	33	12.9
	Degree and above	43	16.8
Household income in ETB	<3000	81	31.6
	3000-5000	85	33.2
	5000-10000	52	20.3
	>10000	7	2.7
	Have no income	31	12.1

NB: ETB = Ethiopian birr

5.2. Viral Load Statistics of the participants

As indicated on table 2 the mean viral load is 1,066,019.6 IU/ml, indicating the average amount of virus present in the blood of the study participants. The standard deviation of 6,213,305.3 IU/ml suggests a high degree of variability in VL levels among individuals. The minimum recorded VL is 13.0 IU/ml, showing that some individuals have very low levels of the virus, while the maximum VL is 74,090,000.0 IU/ml, indicating extremely high viral presence. This wide range highlights significant differences in the VL experienced by different individuals within the study. (Table 2)

Table 2:- VL statics of participants at SPHMMC from January to April 2024

Mean VL	**Standard division**	**Minimum VL amount**	**Maximum VL amount**
1066019.6 IU/ml	6213305.3 IU/ml	13.0 IU/ml	74090000.0 IU/ml

5.3. Co-infections or Disease Conditions and pregnant of the study participants

Table three represents on co-infections or disease conditions observed among individuals co-infected with BHV in a study. The most common co-infections are HIV 13.9% (11/79), diabetes mellitus (DM) 12.7% (10/79), and dyspepsia 11.4% (11/79). Chronic kidney disease (CKD), hepatitis C virus (HCV) and chronic liver disease (CLD) each affect 6.3% (5/79) of the individuals, rheumatoid arthritis (RA), and tuberculosis (TB) each account for 5.1% (4/79). Conditions such as anemia, hypertension (HTN), and pneumonia are seen in 2.5% (2/79) of the cases. Less frequently occurring conditions, each with a prevalence of 1.3%, include allergic conjunctivitis, back bone fracture, Diethylstilbestrol (DES) exposure, impetigo, myomectomy scar, symptomatic cholelithiasis, and various other ailments. The data underscores a significant burden of multiple co-morbid conditions in individuals infected with BHV, highlighting the complexity of their health status. Regarding to pregnant out of 136 women 19.1% are pregnant women. (Table 3)

Table 3: Co-infections or Disease Conditions and pregnant of the study participants at SPHMMC from January to April, 2024.

Co-infection or disease condition and pregnancy	**number**	**Percent**
Pregnancy	26	19.1
Allergic Conjunctivitis	1	1.3
Anemia	2	2.5
Back Bone Fracture	1	1.3
Bleeding Dis Order	3	3.8
Chronic Kidney Disease (CKD)	5	6.3
Chronic Liver Disease (CLD)	5	6.3
Des (Diethylstilbestrol)	1	1.3
Diabetes Mellitus (DM)	10	12.7
Dyspepsia	9	11.4
Hepatitis C Virus	5	6.3
Human Immune Virus (HIV)	11	13.9
Hypertension	2	2.5
Impetigo	1	1.3
Mixed Blepharitis	3	3.8
Myomectomy Scare	1	1.3
P/Falciparum	2	2.5
Pneumonia	2	2.5
Rheumatoid Arthritis (RA)	4	5.1
Symptomatic Cholelithias	1	1.3
tuberculosis (TB)	5	6.3
Thrombocytopenia	4	5.1
Urinary Tract Infection (UTI)	3	3.8

5.4. HBV viral load level of the study participants

Based on American Association for the Study of Liver Diseases (AASLD) Guidelines patients' HBV viral load was categorized as low infectiousness (viral load) which is $< (2 \times 10^4$ IU/ml) and high infectiousness (high viral load) which is ($\geq 2 \times 10^4$ IU/ml. (Table 4)

The distribution of participants' VL levels was categorized by various demographic and behavioral factors, which are presented in Table 4. Among males, 56.7% (68/120) of individuals had a low VL level, while 43.3% (52/256) had a high VL. Among females, the majority 76.5% (104/136) had a low VL level with 23.53% (32/256) having a high VL. Participants younger than 38 years old had a low VL level in 71.3% (50/70) of cases, while the rest 28.6% (20/70) had a high VL level. Among those aged 38 or older, 65.6% (122/186) had a low VL level and 31.4%

(64/186) had a high VL. Among pregnant women, 65.4% (17/26) had a low VL level, while 34.6% (9/26) had a high VL. Among non-pregnant, the majority 79.1% (87/110) had a low VL level. Of those with co-infection, 36.7% (29/79) had a low VL level, whereas the majority 63.3% (50/79) had a high VL level. In contrast, among those without co-infection, the majority 75.4% (104/138) had a low VL level. Among alcohol drinkers, 48.0% (12/25) had a low VL level, while the majority of non-drinkers 69.3% (160/231) had a low VL. Regarding smoking, while the sample size for smokers is small, the majority of both smokers and non-smokers had a low VL level (Table 4).

Table 4: Distribution of HBV viral load level by different condition at SPHMMC from January to April 2024

Variables		**Low VL level (<2 x 10^4 IU/ml) N (%)**	**High VL level (≥2 x 10^4 IU/ml) N (%)**	**Total**
Gender	male	68(56.7)	52(43.3)	120
	female	104(76.5)	32(23.5)	136
Age in years	<38	50(71.4)	20(28.8)	70
	≥38	122(65.6)	64(34.4)	186
Pregnant	pregnant	17(65.4)	9(34.6)	26
	Non- pregnant	87(79.1)	23(20.9)	110
Co-infection	Co-infection	29(36.7)	50(63.3)	79
	Non-Co infection	104(75.4)	34(26.6)	138
Alcohol drinker	Alcohol drinker	12(48.0)	13(52.0)	25
	Non-alcohol drinker	160(69.3)	71(30.7)	231
Smoker	smoker	2(40.0)	3(60.0)	5
	Non- smoker	170(67.7)	81(32.3)	251

NB: VL= viral load, IU/ml= international unit / milliliter

5.5. Association of average HB viral load with different Factors

Various factors were considered and statistically analyzed to assess the level of HBV viral load associated with different conditions. Both COR and AOR, along with their 95% CI and corresponding p-values, were utilized. Gender showed a significant association with VL, with males being 2.49 times more likely to have a high VL level compared to females (COR = 2.49, 95% CI: 1.45, 4.25, p = <0.01; AOR = 2.49, 95% CI: 1.26, 4.92, p = 0.01). Age did not display a significant association with VL level; individuals under 38 years had a COR = 1.31, 95% CI: 0.72, 2.39, p = 0.38) compared to those aged 38 years or older. Pregnancy status also did not

exhibit a significant association with VL level; pregnant women had a COR = 0.50, 95% CI: 0.20, 1.27, p = 0.84 compared to non-pregnant women.

Co-infection is significantly associated with a higher VL level. Individuals with co-infections are much more likely to have a high VL level, with a COR =8.38, 95%CI: 3.76, 12.29, P=<0.01; AOR= 8.94, 95%CI: 4.65, 17.17, p = <0.01.

Alcohol consumption shows a borderline significant association with VL level. Alcohol drinkers have a COR= 2.01, 95%CI: 1.78, 4.94, p=0.04 but the association becomes non-significant after adjustment, with an AOR 1.49, 95%CI: 0.85, 3.12, p = 0.08**.** Smoking status does not show a significant association with VL level; smokers have a COR=0.32, 95% CI: 0.05, 1.94**,** p = 0.21 compared to non-smokers, (Table 5).

Table 5: Association of average HB viral load level with Factors at SPHMMC from January to April 2024.

Variables		**VL level**		**COR(95%CI)**	**P value**	**AOR(95%CI)**	**P value**
		low	**high**				
Gender	male	52(43.3)	68(56.7)	2.49(1.45,4.25)	<0.01*	2.49 (1.26,4.92)	0.01*
	female	32(23.5)	104(76.5)	1		1	
Age	<38 years	20(28.6)	50(71.4)	1.31(0.72,2.39)	0.38		
	≥38 years	64(34.44)	122(65.6)	1			
pregnant	pregnant	9(34.6)	17(65.4)	0.50 (0.20,1.27)	0.84		
	Non-pregnant	23(20.9)	87(79.1)	1		1	
Co-infection	Co-infected	50(63.3)	29(36.7)	8.38 (2.76,12.29)	<0.01*	8.94 (4.65,17.17)	<0.01*
	Non-Co infected	34(26.6)	104(75.4)	1		1	
Alcohol drinker	Alcohol drinker	13(52.0)	12(48.0)	2.01 (1.78,4.94)	0.04*	2.44 (0.89,6.68)	0.08
	Non-alcohol drinker	71(30.7)	160(69.3)	1		1	
Smoker	smoker	3(60.0)	2(40.0)	0.32 (0.05,1.94)	0.21		
	Non-smoker	81(32.3)	170(67.7)	1			

NB: VL= Viral load, 1= Reference, AOR adjusted odds ratio, COR=crude odds ratio, 95%CI= confidence interval, * = statically significant

5.6. Assessment of study participants knowledge level towards HBV

The knowledge of respondents about early detection, transmission, and prevention of HBV exhibited the quantity and proportion of participants who responded with "Yes," "No," or "Not sure" to several inquiries regarding HBV. Overall, there are differences in knowledge regarding several facets of HBV. There are noticeable gaps in understanding, especially when it comes to the route of transmission, even though a sizable number of respondents correctly identified that HBV can cause liver cancer or cirrhosis 26.6% (68/256) and can be transferred by unsafe sex 42.6% (109/256). For instance, only a small percentage 15.6% (40/256) of respondents correctly identified the possibility of HBV spreading by casual hand shaking or contacts with open wounds 20.7% (53/256). Likewise, there was a variable level of knowledge on laboratory testing 55.1% (141/256) and HBV post-exposure prophylaxis 5.9% (15/256), (Table 6).

Table 6:- Knowledge-based questions around HBV of the study participants at SPHMMC from January to April 2024

Knowledge question	**Yes N (%)**	**No N (%)**	**Not sure N (%)**
Can HBV lead to cirrhosis or liver cancer?	68(26.6)	99(38.7)	89(34.8)
Is hand shaking a casual way for HBV to spread?	40(15.6)	123(48.0)	93(36.3)
Can an open wound contact transmit HBV?	53(20.7)	108(42.2)	95(37.1)
Is it possible for contaminated blood or bodily fluids to spread HBV?	77(30.1)	90(35.2)	89(34.8)
Can unprotected sexual contact spread HBV?	109(42.6)	76(29.7)	71(27.7)
Is it possible for contaminated water to spread HBV?	72(28.1)	102(39.8)	82(32.1)
Is HIV 50–100 times less contagious than HBV?	19(7.4)	156(60.9)	81(31.6)
Are you aware of the post-exposure prophylaxis for HBV?	15(5.9)	147(57.4)	94(36.7)
Do you believe that HBV does lab testing?	141(55.1)	54(21.1)	61(23.8)

NB: - HBV= Hepatitis B virus

5.7. Assessment of the attitude level of patients towards HBV

A significant proportion agreed that all patients should be tested for HBV before receiving healthcare 48.4% (124/256) and that HBV viral suppression is effective 39.1% (100/256). However, there are concerning attitudes evident. For instance, a notable portion expressed

discomfort in taking care of people with HBV 56.3% (144/256), and there's a lack of confidence in post-exposure prophylaxis as a preventative measure 32.8% (84/256). Additionally, a considerable number expressed no concern about being infected with HBV 36.7% (94), which underscores a potential need for increased awareness and education regarding HBV risks and preventative measures, (Table 7).

Table 7:- Attitude-based questions on HBV of the study participants at SPHMMC from January to April 2024

Attitude-based questions	**Strongly agree N (%)**	**Agree N (%)**	**Disagree N (%)**	**Strongly disagree N (%)**	**Not sure N (%)**
No fear of having HBV infection	29(11.3)	94(36.7)	105(41.0)	14(5.5)	14(5.5)
Every patient should have an HBV test before receiving medical care.	34(13.3)	124(48.4)	64(25.0)	11(4.3)	23(9.0)
I find it uncomfortable to care for those who have HBV.	22(8.6)	47(18.4)	144(56.3)	25(9.8)	18(7.0)
Prophylactic measures after exposure can help avoid HBV infection.	30(11.7)	39(15.2)	84(32.8)	57(22.3)	46(18.0)
HBV viral suppression is effective	92(35.9)	100(39.1)	39(15.2)	8(3.1)	17(6.6)

5.8. Assessment of practice level towards HBV

The majority of participants 93.4% (239/256) stated that they have tested for HB viral load, suggesting a proactive strategy for tracking the status of HBV infection. On the other hand, 6.6% (17/256) of respondents said they had never tested for HBV before getting infected. A sizable percentage of participants 69.1% (177/256) admitted to encountering difficulties or impediments when trying to get or recommend HBV viral load testing. This research highlights some logistical or systemic problems that could impede the efficacy of HBV management techniques. Regarding workplace safety, 60.9% (156/256) of participants mentioned that they have been injured by a needle stick, underscoring the risks that come with working in the medical field.

On the other hand, 39.1% (100/256) said they had never had a needle stick injury. Responses on following safety procedures were evenly divided: 50.4% (129/256) of respondents confirmed

that sharps should be disposed of properly after usage or operation, whereas 49.6% (127/126) reported as they didn't, (Table 8).

Table 8:- Practice-based questions on HBV of the study participants at SPHMMC from January to April 2024

Practice-based questions	**Yes N (%)**	**No N (%)**
Have you ever tested HBV regularly before infected?	239(93.4)	17(6.6)
Are there any challenges or barriers you face in accessing or promoting Hepatitis B viral load testing?	177(69.1)	79(30.9)
Have you ever been injured by a needle stick?	156(60.9)	100(39.1)
After using or performing a procedure, do you dispose of sharps properly?	129(50.4)	127(49.6)

5.9. KAP level of study participants

Respondents' KAP about HBV differed noticeably from one another. Just 50% of participant's show high (above mean) understanding of HBV, compared to the rest 50% had poor knowledge (below mean). Regarding to attitude a sizable percentage of respondents (61.7%) had a negative opinions (below mean) about HBV, in contrast to the 38.3%, had positive attitudes (above the mean). In terms of practice about HBV the majority 57.8% had well (above the mean) to practice HBV well despite the general lack of thorough information and unfavorable attitudes, while 42.2% engage in poor practice (below the mean). (Figure 1)

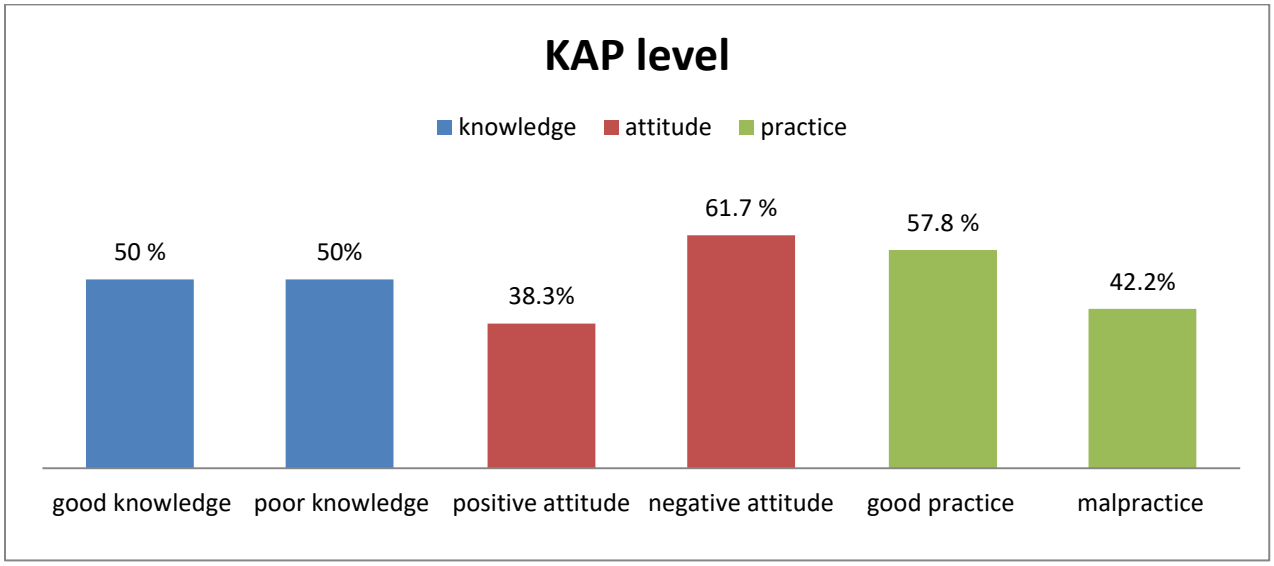

Figure 1-KAP levels of the respondents about HBV early detection, transmission, and prevention at SPHMMC from January to April 2024

5.10. Factors associated with KAP about HBV infection

Table 9 Provides detailed insights from a study investigating the relationships between demographic variables, with KAP accompanied by AOR, 95% CI, and corresponding p-values to gauge the significance of the associations.

In terms of gender, no significant disparity in knowledge was observed between males and females, as indicated by an AOR = 1.00, 95% CI: 0.61, 1.63, p = 1.00. However, while there was a slightly elevated proportion of negative attitudes among males, the difference was not statistically significant, with an AOR = 1.15, 95% CI: 0.69, 1.90, p = 0.35. Surprisingly, male exhibit significantly better practice compared to females, with an AOR of 1.72, 95% CI: 1.04, 2.83, p=0.03).

Regarding age, there was no significant difference in knowledge between age groups, with an AOR = 0.91, 95% CI: 0.35, 2.41, p = 0.85. However, younger individuals (<38 years) demonstrate significantly more positive attitudes, with an AOR = 1.73, 95% CI: 1.04, 2.88, p = 0.04. Practice remains consistent across age groups, with no significant difference noted.

Residence, whether urban or rural, does not yield significant differences in any domain. Urban residency showed a slightly elevated odds ratio for knowledge (AOR = 1.34, 95% CI: 0.81, 2.21, p = 0.25), but this difference was not statistically significant. Similarly, attitude and practice do not significantly differ based on residence.

Educational status significantly influences attitudes, with higher education correlating with more positive attitudes. Non-formal education individuals exhibit severely deficient knowledge (AOR = <0.01, 95% CI: 0.09, 27.98, p = 1.00), while those with diplomas display significantly better practice (AOR = 3.41, 95% CI: 1.17, 9.93, p = 0.03), though with some uncertainty due to wide confidence intervals. (Table 9)

Table 9:- Bivariate and multivariate analyses of factor associated with KAP towards HBV infections

Variables	**Good Knowledge**	**Poor Knowledge**	**AOR(95% CI)**	**P Value**	**Positive Attitude**	**Negative Attitude**	**AOR(95%CI)**	**P Value**	**Good Practice**	**Poor practice**	**AOR(95%CI)**	**P Value**
Gender												
Male	60(50.0)	60(50.0)	1.00(0.61, 1.63)	1.00	48(40.0)	72(60.0)	1.15(0.69, 1.90)	0.35	61(50.8)	59(49.2)	1.72(1.04, 2.83)	0.03*
Female	68(50.0)	68(50.0)	1		50(36.8)	86(63.2)	1		8(64.0)	49(36.0)	1	
Age												
<38 years	73 (52.5)	66(47.5)	0.91(0.35, 2.41)	0.85	55(36.9)	94(63.1)	1.73(1.04, 2.88)	0.04*	87(62.6)	52(37.4)	1.54(0.93, 2.53)	0.09
≥38 years	55 (47.0)	62(53.0)	1		53(45.3)	64(54.7)	1		61(52.1)	56(47.9)	1	
Residence												
Urban	81(52.9)	72(47.1)	1.34(0.81, 2.21)	0.25	54(35.3)	99(64.7)	0.73(0.44, 1.22)	0.81	89(58.2)	64(41.8)	1.04(0.63,1.72)	0.89
Rural	47(45.6)	56(54.7)	1		44(42.7)	59(57.8)	1		59(57.3)	44(42.7)	1	
Educational Status												
Non-formal education	3(9.7)	28(90.3)	0.09(0.01,27.98)	1.00	20(64.5)	11(35.5)	0.91(.341,2.45)	0.91	13(41.9)	18(58.1)	0.39(0.15,1.00)	0.05*
Primary School	37(48.1)	40(51.9)	0.22(0.05,.967)	0.05*	27(35.1)	50(64.9)	1.26(.566,2.82)	0.86	46(59.7)	31(40.3)	0.80(.37,1.73)	0.56
Secondary School	34(47.2)	38(52.8)	0.56(0.18,1.72)	<0.01*	27(37.5)	45(62.5)	1.05(0.45,2.42)	0.57	44(61.1)	28(38.9)	0.84(.38,1.85)	0.67
Diploma	20(60.6)	13(39.4)	0.33(0.06,1.33)	0.19	10(30.3)	23(69.7)	3.41(1.17,9.93)	0.025*	17(51.5)	16(48.5)	0.57(0.23,1.44)	0.23
Degree and Above	34(79.1)	9(20.9)	1		1(32.6)	29(67.4)	1		28(65.1)	15(34.9)	1	

5.11. Assessment of HBV viral load test affordability

The affordability of HBV quantification testing and financial difficulties were the main reasons for delayed testing in the diagnostic system. Specifically, 34.8% (89 / 256) underwent the HBV VL test once a month, while more than half, 53.5% (137 / 256), had the VL test twice in the past month. When it came to HBV quantitation testing, a large majority 78.1% (200/256) reported facing financial difficulties when undergoing the HBV VL test. Among them, 47.3% (121/256) admitted to postponing or skipping the VL test due to these financial concerns. The majority of respondents 93.4% (239) said that their financial situation was affected by the cost of HBV quantitation testing, and 89.1% considered the test to be expensive. When asked who pays for the test, 68.0% (174/256) of respondents said that they do, and 32.0% (82/256) mentioned that their family covers the cost, (Table 10).

Table 10:- Questions for the assessment of HBV viral load test affordability at SPHMMC from January to April 2024.

Questions	**Response**	**Number**	**Percent**
how often do you get HBV level tests in the last one month	Once	89	34.8
	Twice	137	53.5
Do you face any financial challenges when it comes to getting HBV level tests	Yes	200	78.1
	No	56	21.9
Who covers the cost of the test of HBV viral load?	Self	174	68.0
	Family	82	32.0
Have you ever delayed or skipped HBV level testing due to financial concerns	Yes	121	47.3
	No	135	52.7
Does the cost of HBV level testing influence you economically	Yes	239	93.4
	No	17	6.6
Do you think that the cost for hepatitis B virus level is coasty	Yes	228	89.1
	No	28	10.9

5.12. Factors Influencing Expenditure on HBV Viral Load Testing

Factors associated with catastrophic expenditure (≥40% of income) on HBV VL tests were examined to assess the affordability and challenges related to the cost of HBV diagnostic tests. It was found that urban residents were significantly less likely to experience catastrophic expenditure compared to rural residents (AOR = 0.11, 95% CI: 0.02, 0.60, p = 0.01), indicating that living in urban areas protects against high healthcare costs. The frequency of testing also

plays a role; individuals tested once a month face lower odds of catastrophic expenditure compared to those tested twice (AOR = 0.14, 95% CI: 0.05, 0.43, p = 0.01), suggesting that more frequent testing increases the financial burden. Additionally, participants with a monthly income over 10,001 ETB were significantly less likely to incur catastrophic expenses compared to those with no income (AOR = 0.01, 95% CI: 0.09, 0.17, p <0.01), highlighting the protective effect of higher income. Gender, age, educational status, and intermediate income levels did not show significant associations with catastrophic expenditure, (Table 11).

Table 11:- Factors Influencing Expenditure on HBV Viral Load Testing at SPHMMC from January to April 2024.

Variables		**Expense for HB VL**		**COR(95%CI)**	**P value**	**AOR(95%CI)**	**P value**
		Catastrophic expenditure (≥40%)	Non-Catastrophic expenditure (<40%)				
Gender	Male	106(46.3)	14(51.9)	0.80(0.36,1.77)	0.58		
	Female	123(53.7)	13(48.1)	1			
Age	<38	129(53.9)	10(58.8)	1.12(0.50,2.48)	0.788		
	≥38	110(46.1)	7(41.2)	1			
Residence	urban	128(55.9)	25(92.6)	0.10(0.02,.438)	0.002*	0.108(.019,.603)	0.01*
	Rural	101(44.1)	2(7.4)	1			
Educational status	Illiterate	29(12.8)	2(7.4)	26.196(.001,29.978)	0.998		
	Primary school	70(30.7)	7(25.9)	1.997(.451,4.336)	0.561		
	Secondary school	60(26.4)	12(44.5)	0.811(.880,2.345)	0.699		
	Diploma	31(13.6)	2(7.4)	5.189(.593,45.413)	0.137		
	Degree and above	37(16.3)	6(22.2)	1			
frequency of HBV VL tests in the	Once	70(30.6)	17(63.0)	0.259(0.11,0.59)	<0.01*	0.14(0.05,0.43)	<0.01*
	Twice	159(69.4)	10(37.0)	1			

Variables		Expense for HB VL		COR(95%CI)	P value	AOR(95%CI)	P value
		Catastrophic expenditure (≥40%)	Non-Catastrophic expenditure (<40%)				
past one month							
Monthly household income ETB	>3000	79(34.5)	2(7.4)	1.72(0.37,20.24)	0.33		
	3001-5000	77(33.6)	8(29.6)	0.66(0.13,3.31)	0.62		
	5001-10,000	43(18.8)	9(33.3)	0.33(0.07,1.64)	0.18		
	>10,001	1(0.4)	6(22.2)	0.01(0.09,0.15)	<0.01*	0.01(0.09,0.17)	<0.01*
	Have no income	29(12.7)	2(7.4)	1			

NB: - 1= Reference, AOR= adjusted odds ratio, COR=crude odds ratio, 95%CI= confidence interval, ETB = Ethiopian birr, * statically significant

5.13. A qualitative exploration of participants KAP and affordability for HB viral load

Through an in-depth interview analysis of qualitative data, this report provides on the KAP and affordability of HBV viral load level among HBV-infected individuals at SPHMMC

Knowledge about HBV laboratory tests, transmission, and prevention

Respondents exhibit a broad range of understanding when it comes to HBV laboratory tests, transmission routes, and preventive measures. While some display a solid grasp of HBV testing procedures and its transmission through blood contact and sharing sharp objects, others highlight preventive strategies like abstaining from unprotected sex and avoiding sharing sharp materials. However, a notable subset of respondents lacks in-depth knowledge about HBV, its laboratory testing methods, various modes of transmission, and the array of preventive measures available.

"***I only know there is a laboratory test for HBV but I don't know details about the test. I am not sure more about the transmission. But maybe the HBV transmitted by blood contact, by using sharp materials together with infected individuals and unprotected sex. Even if it is***

***difficult to protect ourselves from HBV, we can prevent it by abstaining from unprotected sex*.**"

Knowledge about HBV and practice about how acquired hepatitis B Virus

Responses from participants showcase a range of uncertainty regarding the acquisition of HBV. While some individuals confidently attribute their infection to specific instances such as blood contact, exposure to sharp objects, or sexual transmission, others express uncertainty about the exact mode of transmission. This variance in understanding underscores the complexity of HBV transmission and the need for comprehensive education on its various routes of acquisition.

"I don't remember how I got infected with HBV but it may be either by blood contact or exposure to sharp materials."

Attitudes' of participants about HBV and the importance of VL level

A notable lack of understanding is observed among respondents regarding HBV viral load level. While some individuals undergo regular tests, they do so without a full comprehension of the significance behind these assessments. This highlights a crucial gap in knowledge where individuals may be participating in testing without fully understanding the implications of their results. Bridging this gap through comprehensive education and communication about the importance of viral load level is essential to ensure informed decision-making and effective management of HBV infections.

"Even though I have HBV VL regularly, I don't understand anything about the viral load."

Some respondents exhibit diverse perceptions regarding the importance of monitoring HBV viral load. While some recognize its significance for guiding treatment decisions and preventing disease progression, others lack a detailed understanding of its importance. Particularly noteworthy is the recognition among respondents that monitoring viral load is crucial, especially for individuals with co-infections. This highlights the importance of tailored education and communication strategies to ensure all individuals affected by HBV understand the rationale behind viral load monitoring and its role in managing the infection effectively.

"***I believe that knowing the viral load of the virus in the blood has its own importance; specifically, I don't know what those important are."***

"Regularly knowing the VL in the body is important for individuals who have co infection"

About the affordability of Cost of HBV Viral Load Test

Many respondents express concerns about the prohibitively high cost of HBV viral load testing, which creates significant financial burdens, especially for individuals with low incomes. Frustration and concern are palpable among some respondents regarding the exorbitant costs, with many suggesting the urgent need for price reductions to enhance accessibility. Patients unanimously agree that the cost of HBV VL tests is excessively expensive, whether conducted in private or governmental laboratories. This widespread sentiment underscores the urgent need for policy interventions aimed at reducing costs and improving affordability to ensure equitable access to essential HBV testing services.

"I find the cost of the HBV VL test is too high for me to afford. On this occasion, I would like to remind the concerned party to reduce the price of HBV VL test".

"Even though the cost is lower relative to private institution it is too expensive for low income patients"

6. Discussion

6.1. HBV Viral load level

Quantifying the viral load of HBV is crucial for diagnosing and monitoring HBV infection and evaluating the effectiveness of treatment. This involves measuring the genetic material of HBV in the blood of infected individuals.

In this study conducted at SPHMMC, it was observed that a majority of HBV-infected individuals receiving treatment were females. Although the exact reason is not clear, a similar trend was noted in a previous study conducted in Mozambique and Zambia by Gilles W. et al (30). The higher prevalence of females in these studies may be attributed to greater healthcare engagement among women, particularly during routine pregnancy check-ups and follow-up visits. This increased medical interaction provides more opportunities for viral marker testing, resulting in higher detection rates among females. However, in other previous research conducted in Nigeria by Iregbu KC et al (1)and Chinwe O. et al(25) it was documented that males had higher rates of infection than females. This difference may be due to the increased financial resources available to males for undergoing tests compared to women.

The finding of the current study shows significant associations between viral load (degree of infectiousness) and gender. Males were more likely to have a high VL level compared to females with AOR =2.49 (95% CI: 1.26, 4.92, p = 0.01). This suggests that males are approximately 2.5 times more likely to have a high degree of infectiousness compared to females. On other similar studies conducted in Nigeria Iregbu KC. *Et al* (1) and conducted in china by Jing *et al* (8) reported with a similar finding. Even though high HB viral load in males need further study the possible difference may be estrogen hormone in females has a role to lowering the viral replication. The other possibility for the difference is behavioral factors such as alcohol consumption and smoking are more common among males than females. Those behaviors could an impact on HBV replication rates and disease progression. In contrast there was a study conducted in Nigeria by Chinwe O. Et al(25) indicated as there is no significant differences in the HB viral load between males and females.

In current study co-infection or had other disease condition had significantly associated with higher degree of infectiousness (high VL) with (AOR = 8.94, 95% CI: 4.65, 17.17, p < 0.01). This suggests that co-infected individuals were significantly more likely to have a high VL level

even after adjusting for other factors. Previous study conducted in Northeast Ethiopia found that individuals with co-infections had significantly higher viral loads. Specifically, those with a viral load exceeding 1000 copies/ml were 6.53 times more likely to be co-infected with HBV compared to those with undetectable viral loads (AOR = 6.53, 95% CI: 1.87, 22.72)(41). And the other study conducted in Ethiopia also highlighted the interactions between HBV and the host immune response, emphasizing that co-infections can complicate the clinical outcomes of HBV. This study stressed that HBV infection's progression and severity are influenced by various factors, including co-infections, which can lead to higher viral loads and increased risk of liver complications such as cirrhosis and HCC(42). This is because of Immunosuppression by co-infection with different illness(43).

In this study alcohol consumption showed a borderline significant association with the degree of infectiousness (COR = 2.01, 95% CI: 1.78, 4.94, p = 0.04), in line with other previous study conducted by Cargiulo T. showed similar finding.(44)

6.2. Knowledge attitude and practice towards of HBV infection

This study showed that 26.6% of the study participants can answer correctly as HBV can cause liver cancer and 42.6% of the respondent correctly answered as HBV can transmit by unprotected sex. For instance only 5.9% of the respondents answered correctly as the virus have post exposure prophylaxis and 20.7% were known that the virus can be transmitted with open wounds. More than half (55.1%) knew that the virus has a laboratory tests. This means study participants had moderate understanding as the virus has a laboratory test. The mean score knowledge of this study participants were 31% HBV infection. The study also showed halve (50%) hade knowledge of bellow the mean (poor knowledge) the other half (50) had above the mean knowledge (good knowledge). This result was lowest with the study conducted in Bahirdar, Ethiopia which was documented as 65.6% had good knowledge and 34.4% had poor knowledge (20), Northwest Ethiopia(80% and 20%) good and poor knowledge respectively(19), Khartoum Sudan 58% had knowledge about HBV (34). This difference may be due to difference in local health departments or NGOs in Bahir Dar and northwest Ethiopia might have more active or effective programs compared to those in Addis Ababa. And the study in sudan was conducted on health professionals who may have awareness on HBV. But the finding of this study was greater than a study conducted in Thailand whose report was only 19.85 % had good

knowledge (31). This is may be because of the study was done on migrant individuals which may have low information about medical issues due to language barrier and limited health educational resource.

Regarding to attitude of respondents about HBV infection in this study nearly half of the respondents (48.4%) agreed that all patients should be bested for HBV before receiving health care. 39.1 % were believe that HBV viral suppuration is important for understanding of current medical treatment. In addition 32.8% of the respondents had a lack of confident post-exposure prophylaxis as a preventative measure for hepatitis B virus. Over all based on this study the positive and negative attitude of the respondent about HBV infection were 38.3% and 61.7% respectively. This result was the lowest as compared with the studies conducted in Bahirdar, Ethiopia whose report was 40.3% and 59.7% of the participants had positive and negative attitude about HBV infection respectively(20), Gondar, Ethiopia (43.8% and 56.2%)(35) Had positive and negative attitude about HBV infection respectively (19), Jordan 40% and 60% had positive and negative attitude about HBV infection respectively (33). The difference may be local health departments in Bahir Dar might have more active or effective programs compared to those in Addis Ababa and pregnant women in Gondar are often more focused on potential risks to their unborn child, leading to a heightened sense of responsibility and concern about infections, about HBV. But this finding showed respondents had greater attitude about HBV than the study conducted in Northwest Ethiopia which was reported as 17% of the respondents had positive attitude and 83% had negative attitude on HBV infection and (19), the study conducted in Thailand (24% of the participant had positive attitude) (31). This may be due to HBV infected individuals often engage with support groups like healthcare providers and communities that offer positive attitude.

In terms of practice about HBV infection this study showed that the majority of participants (93.4%) were tested for HB viral load, suggesting a proactive strategy to tracking the status of HBV infection. On the other hand, 6.6% of respondents said they had never tested for HBV before get infected. A substantial percentage of participants (69.1%) admitted to encountering difficulties or impediments when trying to get or recommend HBV viral load testing. And also 60.9% of participants mentioned that they have been injured by a needle stick, underscoring the risks that come with working in the medical field. The overall practice of participants was 57.8%

and 42.2% good practice and poor practice respectively about HBV infection. This is lowest as compared the study conducted in Sudan (73% had good practice and the rests had poor practice about HBV (34) Jordan whose report was 63.9% had good practice and 36.1% had poor practice (33). This may be the differences, involving healthcare infrastructure, public health policies, education, economic conditions, and cultural factors in Ethiopian and Jordan and the study participants were health professionals for the study done in Sudan. But the good practice level of this study is greater than the study conducted in Bahirdar Ethiopia (34.8% had good practice on HBV),(20) Gondar Ethiopia (26.8% had good practice on HBV), %)(35) Northwest Ethiopia (30.9% had good practice on HBV) (19) and Thailand (43% had good practice on HBV) (31). This result difference may be due to the better practice of HBV management in Addis Ababa compared to Gondar and Bahirdar is due to superior healthcare infrastructure, greater access to healthcare services, more effective public health initiatives, higher levels of education and awareness. And the study conducted in Thailand was on migrants which may have low information about medical issues due to language barrier and limited health educational resource.

The qualitative findings on current study HBV knowledge and awareness reveal a varied understanding among respondents regarding HBV laboratory tests, transmission, and preventive measures. Some individuals display a solid grasp of HBV testing procedures and recognize transmission routes such as blood contact and sharing sharp objects, while others emphasize prevention strategies like abstaining from unprotected sex and not sharing sharp materials. However, a notable subset lacks detailed knowledge about HBV, including its testing methods, transmission, and preventive measures. Similar qualitative studies conducted in Uganda (45)found broad knowledge spectrums, significant stigma impacting employment and medical care access.in contrast a qualitative systemic review study conducted in UK found that immigrants had in adequate KAP on HBV infection(46). This is because migrants may have low information about medical issues due to language barrier and limited health educational resource.

6.3. HBV viral load test affordability

The study found that the majority of participants, 89.5% (229 / 256), experienced catastrophic expenditures on HB viral load tests, which means the costs were at least 40% of their household income based on WHO guidelines. The remaining 10.5% (27/256) had non-catastrophic expenses, falling below the 40% mark. This result is consistent with existing literature on

catastrophic health expenditures, especially in low- and middle-income countries, where specialized medical tests often impose significant economic burden. For example, one study demonstrated that high healthcare costs frequently lead to catastrophic spending and impoverishment (46, 47), while another study highlighted the vulnerability of households in countries with insufficient health insurance or public financing to such financial shocks (48). WHO reports further emphasize the risk of out-of-pocket health expenditures pushing households into poverty and limiting access to essential health services (49). The findings of this study underscore the urgent need for improved health financing policies to shield households from financial hardship and ensure fair access to essential healthcare services.

The finding on this study also showed participants who lived in urban (Addis Ababa) had significantly afford the cost of viral load test compared with residents in rural area (AOR = 0.11, 95%CI: 0.02, 0.60, p = 0.01). The study conducted in Ethiopia highlighted those significant urban-rural disparities in healthcare utilization and financial protection(47). In a similar manner, people whose monthly income is more than 10,001 ETB had significantly lower likelihood of experiencing catastrophic expenses (AOR = 0.01, 95%CI: 0.09, 0.17, p = <0.01). A study conducted before showed a strong association between higher income levels and reduced risk of catastrophic health expenditures. Higher income earners generally have greater financial resources to cover healthcare expenses, including diagnostic tests, thereby reducing their vulnerability to catastrophic spending (48, 49).

The qualitative finding of this study showed that many respondents express concerns about the prohibitively high cost of HBV viral load testing, which creates significant financial burdens, especially for individuals with low incomes.in line with a study in Southeast Asia also highlighted the financial burden of HBV viral load testing, with respondents emphasizing the need for policy measures to improve affordability(50). Conversely, a study in rural Latin America found that while cost was a concern, respondents prioritized barriers(51).

7. Strengths and Limitations of the study

The study demonstrates several strengths in its approach to understanding hepatitis B virus infection and its management. It adopts a comprehensive data collection strategy, encompassing various facets such as hepatitis B viral load measurements, demographic details, and insights into knowledge, attitudes, and practices related to HBV infection with a substantial sample size of 256 participants. However

The study lacks information regarding the specific drugs administered to patients, thereby potentially obscuring insights into treatment efficacy and outcomes. The other limitation was the study is cross-sectional design restricts the establishment of causality or temporal relationships between variables, warranting caution in drawing definitive conclusions.

8. Conclusion and recommendation

8.1. Conclusion

The study revealed several important findings about HBV transmission, prevention, and testing practices. It found that males are more likely to be highly infectious, especially when they also have co-infections and consume alcohol. However, there are still gaps in knowledge and attitudes about HBV transmission and prevention, so targeted educational efforts are needed. While most participants get regular HBV testing, some face barriers like cost and accessibility, especially in rural areas and for people with lower incomes. The study also showed that there are differences in knowledge and behavior based on demographics and education, emphasizing the need for tailored interventions to improve HBV awareness and testing across different populations.

8.2. Recommendation

It is imperative that healthcare authorities prioritize comprehensive interventions to improve awareness, prevention, and testing of HBV. This includes launching targeted educational campaigns to address knowledge gaps among demographic groups with lower awareness levels. Policymakers should support initiatives aimed at enhancing access to testing facilities, reducing costs, and increasing availability in rural areas. Simultaneously, public health organizations must coordinate efforts to develop interventions that target risky behaviors like alcohol consumption, thereby reducing the transmission risk. By combining education, improved accessibility to testing, and behavioral interventions, these collective actions can effectively combat HBV transmission and significantly improve public health outcomes.

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10. Annex

Annex I checklist form

Code no --------

	Response and value	remark
MRN		
Sex		
Age		
HB viral load amount	1st 2nd 3rd	
HBV therapy	Yes no	
Duration of therapy for HBV		
Infection by other pathogens Disease condign	Yes no	
If yes specify the pathogen or the disease		
Duration for chemotherapy		
Vaccination history for HBV		
Pregnant	Yes no	
Organ transplantation	Yes no	
Smoker	Yes no	
Alcohol consumption		

Annex II Questionnaire

English version questionnaire

Individual consent form

Information sheet

Good morning? / Good afternoon? My name is …….I am MSc student from Addis Ababa University. I am conducting a study about the Hepatitis B Virus viral load Level **.**You are selected by chance to participate in the study. I need to collect data about socio-demography; and some other questions I want to assure you that all of your answers will be strictly confidential. You have the right to participate or not, to stop the interview at any time or to skip any questions that you don't want to answer. Your participation is completely voluntary but your experiences could be very helpful to design better HBV prevention and treatment strategy for patients. The interview may take approximately half an hour to complete.

Do you have any questions?

Consent form

Purpose: The purpose of this research is to study Hepatitis B Virus viral load Level: Viral load determination, associated factors, affordability and KAP among Hepatitis B Infected Patients at St. Paul Hospital, Ethiopia

Benefits: There is no direct benefit from participating in this research but the results of the study are no doubt to be important for improvement of risk management related with HBV.

Risks: By participating in this research project, there will be no any risk faced to you

Incentives: There is no any payment to be gained by taking part in this research.

Confidentiality: Every piece of information will be kept confidentially. Information will be accessed by the research only and no wastage will be allowed.

Contact persons: If you want to know more information, have any question, you can contact me through the researchers address below.

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Socio-demographic data

Patient Code_____

number	Questions		
1	sex	• male	• female
2	Age		
3	Residence	• Urban	• rural
4	occupations	• Farmer • Housewife • Maid servant • Housewife • employee/private	• student • Daily laborer Unemployed • Other (specify)
5	Educational status	• Illiterate • Elementary school	• High school • Diploma • degree and above
6	income	• <3000/ month • 3000--5000/month	• 5000—10000/month • >10000
7	Marital status	• single • Madrid	• Unaired • separated

Knowledge-related questions about HBV viral load level, early detection, transmission, and prevention.

questions	Yes	no	Not sure
Can HBV cause liver cancer or cirrhosis?			
Can HBV spread by casual hand shaking?			
Can HBV spread by contact with open wound			
Can HBV transmitted by contaminated blood and bodyfluids			
Can HBV transmitted by unsafe sex?			
Can HBV transmitted with contaminated water?			
HBV is 50 to 100 times more infectious than HIV?			

questions	Yes	no	Not sure
What is HB viral load and its purpose?			
Do you think HBV has laboratory tests?			
Do you know HBV has postexposure prophylaxis?			

Attitude-related questions about HBV early detection, transmission, and prevention

Attitude-related questions	Strongly agree	Agree	Dis agree	Strongly diagree	Not sure
No concern of being infected with HBV					
All patients should be tested for HBV before receive health care					
I do not feel comfortable to take care of people with HBV					
Post exposure prophylactic can prevent from HBV infection					
HBV viral suppression is effective					

Practice-related questions about HBV early detection, transmission, and prevention

Practice questions	**yes**	**no**
Have you ever tested HB viral load?		
Are there any challenges or barriers you face in accessing or Promoting Hepatitis B viral load testing?		
Have you ever hand a needle stick injury		
Do you dispose of sharps properly after a procedure?		

Questions to assess the affordability HB viral load level test

questions	response	
how much is the total household income in a month		
how often do you get HBV level test		
Do you face any financial challenges when it comes to getting HBV level tests?	Yes	no

questions	response	
Who covers the cost of the test		
Have you ever had to pay out-of-pocket for HBV level testing	yes	no
If so, how much did it cost?		
Have you ever delayed or skipped HBV level testing due to financial concerns	yes	no
Does the cost of HBV level testing influence you economically	yes	no
Do you think that the cost for hepatitis B virus level is coasty	yes	no

IDI / interview clients guiding question

1. What you think about HBV early detection, transmission prevention?
2. How do you get hepatitis B virus?
3. What you think about HBV viral load level
4. What are your perceptions about the importance of regularly monitoring Hepatitis B viral load in patients?
5. What you think about the cost of HB viral load test?

Thank you very much for giving your precious time and your collaboration

Qustioner Amharic version

1. የመረጃ መስጫ ቅጽ

ስሜ_____ይባሊሌ፡፡የመጣሁት ከ አዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮላጅ የህክምና ሊቦራቶሪ ሳይንስ ትምህርት ቤት ሁሇተኛ ዱግሪ ተመራቂ ተማሪ ስሆን የሄፐታይተስ ቢ ቫይረስ መጠን፡ የቫይራሌ ጭነት አወሳሰን፣ አቅምና እውቀት፣ አመሇካከት እና ተግባርበተመሇከተ ሇሚሰራዉ ጥናት የመረጃ ሰብሳቢ ነኝ፡፡ የሄፐታይተስ ቪቫይረስ በአሇም አቀፍ ዯረጃ በስፋት ያሇ ችግር ሲሆን ብዙ ሚሉዮን በሊይ የሚሆኑ ሰዎችነ እያጠቃ የሚገኝ በሽታ ነው፡፡ የጥናቱ አሊማም የሄፐታይተስ ቢ ቫይረስ መጠን፡ የቫይራሌ ጭነት አወሳሰን፣ ተያያዥ ምክንያቶች፣ አቅምና እውቀት፣ አመሇካከት እና ተግባርበተመሇከተ ማወቅ ነው፡፡ክርሰዎ ጋራ ስሇ ሶሺዮ-ዱሞግራፊ መረጃ እና አንዳንድ ሊልች ጥያቄዎች እተይቀወታሇሁ ሉረጋግጥሌዎ የምፈሌገው ሁለም መሌሶችዎ በጥብቅ ሚስጥራዊ ይሆናለ። በማንኛውም ጊዜ ቃሇ መጠይቁን የማቆም ወይም መመሇስ የማትፈሌጉትን ማንኛውንም ጥያቄ የመዝሇሌ፣ የመሳተፍም ያሇመሳተፍ መብት አሌዎት። የእርስዎ ተሳትፎ ሙለ በሙለ በፈቃዯኝነት ነው ነገር ግን የእርስዎ ተሞክሮ ሇታካሚዎች የተሻሇ የሄፐታይተስ ቢ ቫይረስ መከሊከያ እና ህክምና ስትራቴጂ ሇመንዯፍ በጣም ጠቃሚ ሉሆን ይችሊሌ

ቃሇ ምሌሌሱና ምርመራው በግምት ግማሽ ሰአት ይፈጃሌ፡፡

2. የስምምነት መጠየቅያ ቅጽ

- ቃሇ ምሌሌስ ሇመስጠት ፈቃዯኛ ነዎት?

1. ፈቃዯኛ ነኝ _____ 2. ፈቃዯኛ አይዯሇሁም_____አመስግነህ/ሽ ቃሇ-መጠይቁን አቁም/ሚ

እባክዎትን ከዚህ በታች የተዘረዘሩ ነጥቦን በጥሞና ያንብቡ እና በመጨረሻ በተሰጠው ክፍት ቦታ ፈርማዎን ያኑሩ:: የሄፐታይተስ ቢ ቫይረስ መጠን፡ የቫይራሌ ጭነት አወሳሰን፣ ተያያዥ ምክንያቶች፣ አቅምና እውቀት፣ አመሇካከት እና ተግባርበተመሇከተ ሇማጥናት የሚካየዯውን ጥናት ዓሊማውን ተረዴቻሇሁ። የምሰጠው መረጃ ሇዚህ ጥናት ብቻ እንዯሚሌ አውቂያሇሁ። ሇጥናቱ የምሰጠው መረጃ እንዲሁም ውጤቱ እንዯሚያዝ ተረዴቻሇሁ። በጥናቱ በመሳተፌ የሚከፈሇኝ ክፍያንዯላ አውቂያሇሁ። ስሇዚህ ከሊይ የተጠቀሱትን ነጥቦች በመረዲት መረጃ ሇመስጠት ተስማምቻሇሁ።

ፊርማ _____ ቀን ____/____/____

በጠያቂው የሚፈረም፤ ከዚህ በሊይ የተመሇከተውን መረጃና ስምምነት መፈጸማችን አረጋግጣሇሁ ፊርማ----------

ኮድ_____

ቁጥር	ባሕርያት	
1	ጾታ	ወንድ ሴት
2	ዕድሜ	
3	መኖሪያ ቤት	ከተማ ገጠር
4	ሥራ	አርሶ አዮር የመንግሰት የቀን ሰራተኛ ነጋዴ ስራ የላቸው- የቤት ሰራተ የቤት እመቤት ተማሪ
5	የትምህርት ዮረጃ	• ማንበብና መጻፍ የማይችለ • አንዮኛ ዮረጅጃ ትመምህርት • ሁለተኛ ዮረጃ ትምህርት ዲፕልማ ቤት • ዲግሪ እና ከዚያ በሊይ
6	ገቢ	<3000/በወር 5000—10000/በወር 3000—5000/በወር >10000/በወር

ስለ ሄፓታይተስ ቢ.ቫይረስ ቅድመ ምርመራ፣ ስርጭት እና መከሊከሌ ከእውቀት ጋር የተያያዙ ጥያቄዎች።

ጥያቄ	አዎ	አይ	እርግጠኛ አይደለሁም
ሄፓታይተስ ቢ.ቫይረስ የጉበት ነቀርሳ ያስከትሊሌ			
ሄፓታይተስ ቢ.ቫይረስ እጅን በመጨባበጥ ይሰራጫሌ			
ሄፓታይተስ ቢ.ቫይረስ በቁሰሆ አማካኝነት ይሰራጫሌ			
ሄፓታይተስ ቢ.ቫይረስ በዮም እና የሰውነት ፈሳሽ አማካኝነት ይሰራጫሌ			
ሄፓታይተስ ቢ.ቫይረስ ዮህንነቱ ባሌተጠበቀ የግብረ ሥጋ ግንኙነት የሚተሊሆፍ ይመስሊችሌ			
ሄፓታይተስ ቢ.ቫይረስ በተበከሆ ውሃ ሉተሊሆፍ ይችሊሌ			
ሄፓታይተስ ቢ.ቫይረስ ከኤች አይ ቪ ከ 50 እስከ 100 እጥፍ ይበሌጥ መሰራጨት ይችሊሌ			
የሄፓታይተስ ቢ.ቫይረስ ድህረ ተጋሊጭነት መከሊያ እንዳሆው ያውቃለ			
የሄፓታይተስ ቢ.ቫይረስ የሊቦራቶሪ አለው			

ስሆ የሄፓታይተስ ቢ.ቫይረስ ቅድመ ምርመራ፣ ስርጭት እና መከሊከሌ ከአመሇካከት ጋር የተያያዙ ጥያቄዎች

ከአመሇካከት ጋር የተያያዙ ጥያቄዎች	በጣም እስማማሌሁ	እስማማሌሁ	አሌስማማም	በጣም አሌስማማም	እርግጠኛ አይዯሇሁም
በሄፓታይተስ ቢ.ቫይረስ ምንም ስጋት የሇኝም።					
ሁለም ታካሚዎች የጤና እንክብካቤ ከማግኘታቸው በፊት ሇሄፓታይተስ ቢ.ቫይረስ ምርመራ መዯረግ አሇባቸው					
የሄፓታይተስ ቢ.ቫይረስ ያሇባቸውን ሰዎች መንከባከብ ምቾት አይሰማኝም					
በሄፓታይተስ ቢ.ቫይረስ ከተጋሇጡ በኋሊ ፕሮፊሇቲክ ከ ሄፓታይተስ ቢ.ቫይረስ ኢንፌክሽን ሉከሊከሌ ይችሊሌ					
የሄፓታይተስ ቢ.ቫይረስ መጠንን ማውቅ ጥቅም አለው					

ስለ የሄፓታይተስ ቢ.ቫይረስ ቅድመ ምርመራ፣ ስርጭት እና መከሊከሌ ከሌምድ ጋር የተያያዙ ጥያቄዎች

ጥያቄ	አዎ	አይ
የሄፓታይተስ ቢ.ቫይረስ መጠን ምርመራ አድርገው ያውቃለ		
ሄፓታይተስ ቢ የቫይረስ መጠን ምርመራን ሇማግኘት ወይም የሚያጋጥሙዎት ተግዳሮቶች ወይም እንቅፋቶች አጋጥሞዎት ያውቃሌ		
መርፌ ወይንም ስሇታማ ነገር ቆርጦዎት ያውቃሌ		
ከተጠቀሙ በኋሊ ስሇታማ መሳሪያዎችን በትክክሌ እና በጥንቃቄ ያስወግዳለ		

የሄፓታይተስ ቢ.ቫይረስ መጠን ምርመራዎችን የዋጋ ተመጣጣኝነትን ሇመገምገም የሚያስችለ ጥያቄዎች

በአንድ ወር ውስጥ አጠቃሊይ የቤተሰብ ገቢ ምን ያህሌ ነው		
ምን ያህሌ ጊዜ የ የሄፓታይተስ ቢ.ቫይረስ መጠን ምርመራዎችን ያገኛለ		
የሄፓታይተስ ቢ.ቫይረስ መጠን ምርመራዎችን ሇማግኘት በሚዯረግበት ጊዜ ምንአይነት የገንዘብ ችግር ያጋጥምዎታሌ?		
የሄፓታይተስ ቢ.ቫይረስ የምርመራውን ወጪ የሚሸፍነው ማን ነው		
የሄፓታይተስ ቢ.ቫይረስ መጠን መሇኪያ ምርመራ ከኪስዎ መክፇሌ ነበረብዎ	አዎ	አይ

ከሆነስ ምን ያህሌ አስወጣ?		
በገንዘብ ጉዳዮች ምክንያት የየሄፓታይተስ ቢ.ቫይረስ መጠን መሆኪያ ምርመራ ዘግይተው ወይም አቋችጠው ያውቃለ	አዎ	አይ
የሄፓታይተስ ቢ.ቫይረስ መጠን መሆኪያ ምርመራ ዋጋ በኢኮኖሚ ሊይ ተጽዕኖ ያሳድራሌ	አዎ	አይ
የሄፓታይተስ ቢ.ቫይረስ መጠን መሆኪያ ምርመራ ዋጋው ውድ ነው ብለውያስባለ?	አዎ	አይ

ስለ **HBV** የቡድን ጥያቄዎች

1. ስለ ሄፓታይተስ ቢ.ቫይረስ ቅድመ ምርመራ ፣ ስርጭት መከሊከሌ ምን ያስባለ?
2. የ ሄፐታይተስ ቢ ቫይረስ እንዴት ያዘወት?
3. ስለ ሄፓታይተስ ቢ.ቫይረስ ጭነት መጠን ምን እንዯሚያስቡ እና ዋጋው ነው?
4. በታካሚዎች ሊይ የሄፐታይተስ ቢ ቫይረስ ጭነትን በየጊዜው መከታተሌ አስፈሊጊ ስሆመሆኑ ያሆዎት አመሆካከት ምንድን ነው?
5. ስሆ ሄፓታይተስ ቢ የቫይረስ መጠን ምርመራ ዋጋ ምን ያስባለ?

ውድ ጊዜዎትን ሰውተው ሊዯረጉሌኝ ትብብር ከሌብ እናመሰግናለን!

Annex III Measurement and laboratory Test

cobas®6800 is an in vitro nucleic acid amplification test for the quantitation of nucleic acid of the organism in human EDTA plasma or serum of HBV-infected individuals

Principle of cobas®6800

The cobas® 6800 procedure is an automated system that extracts and purifies nucleic acids from patient samples. It then uses PCR amplification and detection to determine the presence and quantity of nucleic acids. The system has different modules for sample handling and data management, with results categorized as target not detected, below the lower limit of quantitation, above the upper limit of quantitation, or within the linear range.

The process involves releasing viral nucleic acid, removing impurities, and purifying the nucleic acid. Target-specific amplification is achieved with specialized primers, while unwanted amp icons are eliminated during the first thermal cycling step. The system uses specific detection probes labeled with fluorescent dyes to detect both the HBV target and a control DNA (DNA- QS) simultaneously. During PCR amplification, the probes bind to the DNA target, leading to cleavage and the release of a fluorescent signal. This signal is detected and allows for the simultaneous identification of the amplified nucleic of the organism and the control control.

Test Procedure

cobas® HBV can be run with a minimum required sample volume of 650 µL. The test procedure is summarizes below:-

1. Fill reagents and consumables
2. Load racks with samples
3. Run the test
4. Review and export result
5. Unload consumables

Quality Control

- One negative control [(–) C] and two positive controls, a low positive control HBV L(+)C and a high positive control [HBV H(+)C] is processed with each batch.

- In the cobas® 6800 software and/or report, check for flags and their associated results to ensure the batch validity.
- The batch is valid if no flags appear for all three controls, which includes one negative control and two positive controls: HBV L (+)C, HBV H(+)C. The negative control result is displayed as (–) C and the low and high positive controls are displayed as HxV L(+)C and HxV H(+)C.

Invalidation of results is performed automatically by the cobas® 6800/8800 software based on negative and positive control failures.

Observation and Results

For a valid batch, check each individual sample for flags in the cobas® 6800/8800 software and/or report.

Annex V: Quantitative Nucleic Acid Amplification Test (NAAT)

HBV viral load testing is recommended for individuals with chronic hepatitis B infection, especially those undergoing antiviral treatment or being considered for treatment. Viral load testing can help monitor treatment efficacy, assess disease progression, and guide clinical management. The result of viral load level should be report in IU/ML. The specific viral load threshold value for initiating antiviral treatment is different as the clinical situation of the patient but WHO recommends as a cutoff value mare than 2, 0000 IU/ML consider for the initiating of treatment.

- 0 to 500 IU/ML as a harmless infectious trace
- 500 to 5,000 IU/ML as unlikely to ever cause harm or infect ,
- 5,000 to 250,000 IU/ML as low risk and infectious via a transfusion of blood to a wound
- 250,000 to 1 million IU/ML as medium risk infectious via transfusion and via sexual fluids,
- More than 1 million IU/ML as high risk. Infectious via transfusion and via sexual fluids

Annex VI: HBV treatment and viral load test Protocol Principle of the protocol

The overarching objective of WHO is to achieve the highest possible level of health for all people. These guidelines have been developed with this principle in mind and that of the United Nations Universal Declaration of Human Rights. People infected with viral hepatitis may come from vulnerable or marginalized groups with poor access to appropriate health care, and be subject to discrimination and stigma. It is therefore essential that these guidelines and the policies derived from them incorporate basic human rights, including the right to confidentiality and informed decision-making when considering whether to be screened and treated for HBV infection.

Phases of chronic hepatitis B

1. The immune-tolerant phase occurs most commonly in HBsAg-positive children and young adults infected in the perinatal or early childhood period. It usually persists into young adulthood and may last 10–30 years after perinatal infection. Typically, serum HBeAg is detectable, HBV DNA levels are high (usually more than 200 000 IU/mL), and alanine aminotransferase (ALT) levels may be normal or only minimally raised. There is minimal liver inflammation, no or slow progression to fibrosis, and low spontaneous HBeAg loss.

2. This is usually followed by an HBeAg-positive immune-active phase of active inflammatory disease. Serum ALT may be abnormal or fluctuate and is accompanied by variable decreases in HBV DNA levels. Symptoms of hepatitis may be present and there is more severe, histologically evident hepatitis and fibrosis. This phase may last from several weeks to years, and may result in successful seroconversion from an HBeAg-positive to an anti-HBe state. Seroconversion rates are higher in those with raised serum aminotransferases and those infected with genotypes D, A, F and (in Asia) B.

3. The non-replicative or inactive immune-control phase (previously called the inactive carrier phase) follows successful seroconversion from an HBeAg- positive to anti-HBe state, which occurs in approximately 10–15% of HBeAg-positive persons per year. Once HBeAg is cleared, the disease may remit, with minimal progression of fibrosis, and serum ALT levels

revert to normal with low or undetectable levels of HBV DNA (less than 2000 IU/ mL). HBeAg seroconversion at a young age, prior to the onset of significant liver disease, confers a good prognosis, with a substantially reduced risk of cirrhosis and liver cancer. However, active viral replication can reappear in a proportion of persons.

4. In addition to HBeAg-positive chronic hepatitis, HBeAg-negative (immune escape-mutant‖) active chronic hepatitis occurs in approximately 5–15% of HBeAg-negative, anti-HBe-positive persons in the inactive carrier state (8,25,26).

5. HBV reactivation may occur spontaneously or may be triggered by cancer chemotherapy and other immunosuppressive therapy, and may lead to fatal acute-on-chronic hepatitis, and pre-emptive nucleos(t)ide

Analogue (NA) therapy is therefore used. Occult HBV infection (defined as persistence of HBV DNA in the liver in persons in whom HBsAg is not detectable in the blood) may also be reactivated through prolonged chemo- or immunosuppressive therapy. Subjects with occult infection may also represent an important source of new infections in blood transfusion services in HBV-endemic LMICs where HBsAg is used as the sole marker of infection in donor populations. Persons who have cleared HBsAg and who are negative for HBV DNA but anti-HBc positive may reactivate if given potent immunosuppressive drugs.

HBV serological markers

Previous HBV infection is characterized by the presence of antibodies (anti-HBs and anti-HBc). Immunity to HBV infection after vaccination is characterized by the presence of only anti-HBs. CHB is defined as the persistence of HBsAg for more than 6 months. Recently, quantitative HBsAg level determination has been proposed to differentiate inactive HBsAg carriers from persons with active disease.

HBeAg: It also needs to be established whether the person is in the HBeAg- positive or HBeAg-negative phase of infection though both require lifelong monitoring, as the condition may change over time. In persons with CHB, a positive HBeAg result usually indicates the presence of active HBV replication and high infectivity. Spontaneous improvement may occur following HBeAg-

positive seroconversion (anti-HBe), with a decline in HBV replication, and normalization of ALT levels. This confers a good prognosis and does not require treatment. HBeAg can also be used to monitor treatment response, as HBeAg (anti-HBe) seroconversion in HBeAg-positive persons with a sustained undetectable HBV DNA viral load may be considered a potential stopping point of treatment. However, this is infrequent even with potent NA therapy. Some HBeAg- negative persons have active HBV replication but are positive for anti-HBe and do not produce HBeAg due to the presence of HBV variants or pre-core mutants.

Biological evaluation of HBV infection

Serum HBV DNA concentrations quantified by real-time polymerase chain reaction (PCR) correlate with disease and are used to differentiate active HBeAg-negative disease from inactive chronic infection, and for decisions to treat and subsequent monitoring. Serial measures over a few months or longer are preferable, but there remains a lack of consensus regarding the level below which HBV DNA concentrations are indicative of inactive‖ disease, or the threshold above which treatment should be initiated. HBV DNA concentrations are also used for optimal monitoring of response to antiviral therapy, and a rise may indicate the emergence of resistant variants. WHO standards are now available for expression of HBV DNA, concentrations Serum HBV DNA levels should be expressed in IU/mL to ensure comparability; values given as copies/mL can be converted to IU/mL by dividing by a factor of 5 to approximate the conversion used in the most commonly used assays (i.e. 10 000 copies/mL = 2000 IU/mL; 100 000 copies/mL = 20 000 IU/mL; 1 million copies/mL = 200 000 IU/mL). The same assay should be used in the same patient to evaluate the efficacy of antiviral therapy. Access to HBV DNA testing remains very poor in resource-limited settings. Every patient’s treatment shall evaluate every 2 to 8 weeks by considering their viral DNA level to evaluate their treatment outcome.

Declaration

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

Kassalem Dessie

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Date of submission: _____

This thesis has been submitted with our approval as advisors.

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Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.