ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF NURSING AND MIDWIFERY

PREVALENCE AND ASSOCIATED FACTORS OF HEPATITIS B VIRUS INFECTION AMONG PREGNANT WOMEN ATTENDING ANTENATAL CARE CLINIC AT ADIGRAT GENERAL HOSPITAL TIGRAY, ETHIOPIA, 2019

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A THESIS PROPOSAL SUBMITTED TO SCHOOL OF GRADUATE STUDIES, ADDISABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE, SCHOOL OF NURSING AND MIDWIFERY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR DEGREE OF MASTER SCIENCE IN MATERNITY AND REPRODUCTIVE HEALTH NURSING.

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Full title of the thesis	**Prevalence and Associated Factors of Hepatitis B Virus Infection among Pregnant Women Attending Antenatal Care Clinic at Adigrat General Hospital, Tigray, Ethiopia**
Duration of project	The study will be conducted between March 1/2019 and April 30/2019.
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Approval sheet

ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES SCHOOL OF NURSNG AND MIDWIFERY

I, the undersigned MSc student, declare that I have submitted my original work on a title Prevalence and Associated Factors of Hepatitis B Virus Infection among Pregnant Women Attending Antenatal Care Clinic at Adigrat General Hospital, Tigray, Ethiopia for the examination.

Submitted by: Hailay kinfe

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This thesis proposal work has been submitted for examination with my approval as an advisor.

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ABBREVIATIONS AND ACRONYMS

HBV = Hepatitis B Virus

HBeAg= Hepatitis B envelope antigen

HBsAg = Hepatitis B Surface Antigen

HCsAg=hepatitis B Surface Antigen

HCV = Hepatitis C Virus

HIV = Human Immunodeficiency Virus

WHO= World Health Organization

STI=Sexually Transmitted Disease

DNA=Deoxyribo Nucleic Acid

CHB=Chronic Hepatitis B

HCC=Hepatocellular Carcinoma

CBC=Complete Blood Count

ANC=Antenatal Care

CI=Confidence Interval

OR=Odds Ratio

AOR=Adjusted odds ratio

MTCT=mother to Child Transmit ion

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SUMMARY

Background: Hepatitis B virus (HBV) is a serious cause of liver disease affecting millions of people throughout the world. When HBV is acquired during pregnancy, prenatal transmission can occur to the fetus.

Objective: This study is aimed at determining the prevalence and associated factors of HBV infection among pregnant women attending Antenatal Clinic (ANC) for routine pregnancy check-up of Adigrat General Hospital, Tigray Ethiopia.

Method: A hospital based cross-sectional study design will be conducted on 350 pregnant women visiting ANC between March 1/2019 and April 30/2019. Data regarding socio-demographic associated factors, hospital associated factors and risky cultural and behavioral factors will be gathered using questionnaire. Cards of the participant pregnant women will be checked for the presence of HPV. Data will be analyzed using SPSS version 20.

Work plan and budget: the study will be performed within 8 months, and the total cost of this study will be covered 25,146.00 ETB.

CHAPTER 1: INTRODUCTION

1.1. Background

Immunologic changes of pregnancy may induce a state of increased susceptibility to certain intracellular pathogens including viruses, intracellular bacteria and parasites. In relation to this viral infections in pregnancy are a major cause of morbidity and mortality for both mother and fetus(1). Hepatitis B is a common, serious disease caused by the hepatitis B virus (HBV), a partially double-stranded DNA virus of the Hepadnaviridae family. Four major serotypes (adw, ayw, adr and ayr) and nine minor subtypes have been serologically identified at the hepatitis B surface antigen (HBsAg) level. The complete sequencing of DNA from HBV isolates worldwide has led to the identification of eight genotypes (from A to H)(2).

HBV is highly contagious and relatively easy to be transmitted from one infected individual to another. It can be transmitted by transfusion of blood, infected blood and blood products, urine, semen, sweat, saliva, tears, breast milk, vaginal secretions and pathological effusions. The virus can be transmitted prenatally from HBV -infected mother to the newborn, and it is the most common mode of HBV infection transmission responsible for approximately one third of chronic HBV infections(3). Even though HBV has been detected in saliva, tears, breast milk, sweat, and urine, there is minimal evidence of transmission through exposure to these fluids where no blood is present, and breastfeeding has not been shown to increase risk of infection(4).

Chronic hepatitis B (CHB) in pregnancy is an important and pervasive issue with unique challenges. However, for pregnant women with chronic hepatitis B virus (HBV) infection, unlike the general population, many special problems need to be considered, such as the influence of HBV infection on the mother and fetus, influence of pregnancy on HBV replication, effects of antiviral treatment on maternal and neonatal outcomes, immunization of newborns and the possible flare of hepatitis after delivery(5).Globally Vertical transmission of HBV from infected mothers to their fetuses or newborns, either in utero or per partum remains a major source of continuing the reservoir of chronically infected individuals. Universal screening for HBV infection during pregnancy has been

recommended for many years, and identification of pregnant women with chronic HBV infection through universal screening has had a major impact in decreasing the risk of neonatal infection(6).

Based on the mechanisms of MTCT of HBV, several strategies have already been invited for the prevention of HBV infection during perinatal period, and HBV vaccination has been adopted in the national immunization program in many countries. In addition to neonatal immune-prophylaxis, treating with antiviral agents such as tenofovir or telbivudine during pregnancy beginning at 28–32 weeks of gestation may be safe and effective in preventing MTCT(6,33). HBV vaccine and HBV immunoglobulin can be administered within 12 hours of birth to all newborns of HBsAg-positive mothers or those with unknown or undocumented HBsAg status, regardless of whether maternal antiviral therapy has been given during the pregnancy and women with HBV infection be encouraged to breast-feed as long as the infant receives imunoprophylaxis at birth (HBV vaccination and hepatitis B immunoglobulin). Pregnant women with HBV infection suggest HBV viral load testing in the third trimester and if viral load is >6-8 log 10 copies/mL, HBV-targeted maternal antiviral therapy should be considered for the purpose of decreasing the risk of intrauterine fetal infection, tenofovir is a first-line agent(6).

1.2. Statement of the problem

Since the development of the Hepatitis B Virus vaccine in the 1980s, new cases have decreased, yet the disease remains a global health concern, especially due to high rates of mother-to-child transmission (MTCT) in many countries(6,34). In the previous year's different studies reported that, in developing countries and areas with high or intermediate endemicity where the most common route of infection is still vertical transmission from mother to child, and the rate of transmission increases if the mother is HBsAg positive. Furthermore, HBV infection does pose a risk not only to the mother and her newborn but also the sexual partners and health workers as well, and horizontal transmission between children, particularly siblings (2).

Mothers with extremely abnormal liver function complications are susceptible to postpartum hemorrhage, puerperal infection, low body weight infants, fetal distress, premature birth, fetal death and neonatal asphyxia. Vigorous metabolism and increased nutrient consumption are a series of physiological changes occur during pregnancy and, these changes promote to the metabolic needs of the mother as well as the needs of the growing fetus, abundant sex hormone produced by the mother needs to be metabolized and inactivated in the liver, metabolism and detoxification in the fetus also depend on the mother's liver, which correlates with aggravation of pre-existing liver diseases and exacerbation of liver damage. Even though HBV infection during pregnancy can often be tolerated, severe hepatitis and hepatic failure induced by perinatal hepatic flare reactions still occur, and can have an unfavorable outcome(5).

Globally, perinatal HBV transmission accounts for an estimated 21% of HBV related deaths, while regionally it ranges from 13% in the Eastern Mediterranean region to 26% in the Western Pacific region (2). Worldwide From the HBV infected peoples 50% of them have acquired their infection in the perinatal or neonatal period, the younger they are when infected with HBV, the higher the risk of developing CHB(5). Africa has the second largest number of chronic carriers after Asia and is considered as a region of high endemicity, despite the fact that the exact burden of hepatitis B in Africa is difficult to

assess due to inaccurate records and under-reporting, it is estimated that between 70 and 95% of the adult population show evidence of past exposure to HBV infection.(7).

In Africa studies conducted on prevalence of HBV infection among pregnant study subjects ranges from 1.6% to13.8% (8-14). Similarly, in Ethiopia hepatitis B virus is becoming an emerging public health concern. Recent systematic review of all types of viral hepatitis in Ethiopia concluded that the prevalence of HBV among the population is 7.4%(15) . This finding placed Ethiopia under the region of intermediate endemicity according to WHO regions for HBV, low > 2%, an intermediate 2%–7% and high ≥ 8% population prevalence of chronic HBV infection(16).Another current study on Hepatitis B virus infection among pregnant women in Ethiopia a systematic review and Meta-analysis shows that the pooled prevalence of HBV infection in Ethiopia among pregnant women is 4.7%(17).

The rate of HBV transmission from infected mother to the newborn is not well studied in Ethiopia. One study conducted in Addis Ababa revealed that 75% of newborns born from HBV infected women were positive with hepatitis B surface antigen(HBsAg) in 2012(19).In Ethiopia some institution based studies; the HBsAg prevalence rate among pregnant women varies between 3.5% and 8.4% (18, 20-26). More over the magnitude of HBV infection among pregnant mothers is still high in the northern part of Ethiopia particularly in Tigray as few studies indicated in 2015 at Mekelle 8.1%(35), and 5.5% in 2018among pregnant women attending antenatal care clinic in the health facilities of Tigray, Northern Ethiopia (27).

Over all HBV infection is the major global public health problem spreading rapidly in the developing countries including Ethiopia. Hence, screening antenatal women for hepatitis B surface antigen can give a reliable prevalence of the disease in a population and provide an avenue for preventing mother to child transmission of the virus, and also this study will generate data on HBV infection and associated factors following the fact that absence of data on HBV for researchers and policy makers. To the best of my knowledge, an epidemiological report of this type is scarce and quite inadequate in the region, particularly at Adigrat zone there is no published previous similar study, thus this study is aimed at

investigating the sero-prevalence and the possible risk factors of HBV among pregnant women attending antenatal care clinic at Adigrat General Hospital Tigray, Ethiopia.

CHAPTER 2: LITERATUREREVIEW

2.1. Prevalence of HBV infection

Hepatitis B virus infection occurs all over the world. In high endemic areas, like central Asian republics, Southeast Asia, Sub-Saharan Africa and the Amazon basin, the HBV carrier rate is over 8%. In low endemic regions, like the United States, Northern Europe, Australia and parts of South America, HBsAg prevalence is less than 2%. The Middle East, some Eastern European countries and the Mediterranean basin are considered areas of intermediate endemicity with a carrier rate between 2% and 8%(2).

Transmission of HBV from carrier mothers to their babies can occur during the perinatal period, and appears to be the most important factor in determining the prevalence of the infection in high endemicity areas, particularly in China and Southeast Asia. Epidemiological studies on HBV intrauterine infection in China showed that intrauterine infection occurs in 3.7-9.9% pregnant women with positive HBsAg and in Asia 9.8-17.39% with positive HBsAg/HBeAg(5, 2). In Africa also some institution based sero-prevalence studies of HBV among pregnant study subject in Egypt, Kenya, Tanzania, Kano Nigeria, Ghana, Sudan, and Solomon Islands revealed that the prevalence of HBsAg as 1.6%, 3.8%, 3.9%, 7,9%, 9.5%, 11%, 13.8% respectively(8-14). Similarly, in Ethiopia some institution based studies on sero-prevalence of HBsAg among pregnant women at Deder hospital, Dawro zone, Bahir Dar, Arba Minch, Dessie, Yirgalem, South Ethiopia and DreDawa, have shown the overall prevalence of HBV infection among pregnant mothers who attend ANC is 6.9%, 3.5 %, 3.8%, 4.3%, 4.9%, 7.2%, 7.8%, and8.4% respectively(18, 20-26).

2.2. Factors associated with HBV infection among pregnant women

In this study different literatures were reviewed to perceive factors that are associated with prevalence of HBV infection among pregnant women.

2.2.1. Socio- demographic and economic factors

Factors like age, educational level, marital status, gravidity, occupation and income, were considered in most studies to see its association with HBV infection as follows. According to the age of the pregnant mothers some literatures in different parts of the world revealed different findings considering having significance relationship with sero-positivity of HBV infection. A study conducted in Turkey shown that, the sero-prevalence of HBsAg was significantly associated with early age ($p = 0.027$)(3).

In Africa study conducted among pregnant mothers, in Sudan(13), Nigeria (11) ,Egypt (8),Ghana(12)and Tanzania(10)revealed that, age were not significantly associated with positive Hepatitis B infection rates. In Kenya(9),early age were significantly associated with HBsAg positivity (11-15 years) at first sexual encounter (χ^2 =8.185 df1 $p<0.01$), in Solomon Islands(14), the highest age-specific prevalence were in the age group of 30-34(22%) revealed that, the increased rates with increasing age may reflect ongoing new infections through sexual contact or other routes including health services. In Ethiopia also some institutional based studies among pregnant women attending antenatal clinic revealed that, age has no statistically significant with incidence of HBV infection across different age groups as shown by a study done at Arba Minche(22), Dawro(20), Yirgalem(24), Dre Dawa(26), BahiDarcity(21), South Ethiopia (25), Deder(18) and Dessie (23) with the highest age-specific prevalence in the age group of (25-29, 25-30, 25-30, <21, 26-30, 20-29, 18-30) respectively.

Regarding educational status of the pregnant mother most studies in different parts of the world revealed that, those with lower level of education has relatively higher risk of HBV infection compared to those with high level of education. A meta-analysis study done in Iran among pregnant women shown that, the risk of developing an HBV infection was significantly associated with illiteracy ($p = 0.013$)(28). Whereas a study conducted in Ghana among pregnant mothers revealed that, HBV infection was not associated with educational status of the pregnant mothers ($P>0.05$)(12). Also study done among pregnant women attending antenatal clinic in Honiara Solomon Islands, 2015 revealed that, there was no statistically significant difference in HBsAg prevalence by education (14).In

Ethiopia institutional based studies among pregnant mother attend antenatal clinic shows that, at Dessie Referral Hospital the prevalence of HBV infections were significantly higher among pregnant mothers who had no formal education (AOR 31.6; 95% CI 4.5-225, P = 0.001)(23). But At Deder hospital, Arba Minch Hospital, Yirgalem Hospital and Dre Dawa public hospitals, educational level were not significantly associated with HBsAg sero-positivity (18, 22, 24, 26).

Regarding marital status of the pregnant women some literature in different countries shown that marital status has not been considered as predisposing factors for HBV for example , a study conducted in Tanzania revealed that , there were no significant differences in marital status of the mothers(10).Similarly a study done in Ghana shown that there was no significant statistical association between HBsAg positivity and marital status (2=0.4, P>0.05), however, the highest prevalence of 3.5% (2/57) was found amongst the unmarried women(12).In Ethiopia institutional based studies conducted among pregnant mothers attend ANC, at Deder hospital, Arbaminch hospital and Yirgalem Hospital, revealed that marital status of the mother was not significantly associated with sero-positivity of HBV(18, 22, 24).But another facility based cross-sectional study at Dre Dawa shown that being single pregnant mothers (p-0.002), was factors significantly associated with HBV infection(26).

Inflation to the gravidity of the pregnant women some literatures revealed that, there were no direct association between gravidity of the mother and risks of acquiring HBV infection. For example a cross-sectional study carried out among pregnant women attending antenatal clinics at a tertiary hospital in Dar es Salaam Tanzania indicated that when premigravidea and multigravida compared against the risk of infection with hepatitis B infection, there was no statistically significant relationship between the two groups, however Ninety-six (31.0%) women were primigravidae(10).Similarly another study in Ghana also revealed that, Study of HBsAg sero-positivity in different gravidae among the pregnant women revealed that, there was no significant statistical differences between samples screened and gravida with HBsAg positivity (2=3.0, P>0.05), however, the highest prevalence of 3.7% (2/54) was found amongst HBsAg positive mothers in their first time pregnancy(12).Egypt Also shown that However 91.42% of cases were

multigravida, there was no significant difference between gravidity and risk of HBV infection(8). In Ethiopia some institution based studies conducted at Deder hospital, Arbaminch hospital and Yirgalem hospital similarly shows that, there was no association between parity and risks of HBV(18, 22, 24).

Regarding the occupation of pregnant women a study conducted in Iran shown, no significant relationship was observed between HBV infection and occupation ($p = 0.37$)(28). Similarly studies conducted in Kenya(9), Nigeria(11) , Ghana(12), Deder hospital(18),Yirgalem hospital(24), and Arbaminch hospital(22) shown that, there was no statistically significant association between occupation and risk of HBV infection.

2.2.2. Hospital associated factors

Concerning hospitalization history, some literatures shown that, history of hospitalization was significantly associated with HBV infection. A study done in Saudi among pregnant mothers revealed that, women with history of hospitalization showed a significant association with anti- HBV sero-positivity (Pvalue0.050)(30), and a study conduct among pregnant women in Egypt revealed that, hospital admission was a factor for acquiring HBV infection (P-value 0.000)(8).

Related to hospital associated factors blood transfusion was directly accountable for the transmission of most of microbial disease, some studies revealed significant association with incidence of HBV and blood transfusion. A study conducted among pregnant mothers in Turkey shown that, a significant association was observed between HBV infection and history of blood transfusion (AOR = 9.51, 95% CI = 1.92-46.80, p = 0.006)(3).Similarly systematic reviews and meta-analysis of HBV among pregnant Iranian women revealed that, the risk of developing HBV infection was significantly associated with blood transfusion ($p < 0.001$)(28).Another study done in Ethiopia Prevalence of Hepatitis B Virus and Associated Factors among Pregnant Mothers Attending Antenatal Care in Public Health Facilities, Dire Dawa also shown that, history of blood transfusion (p-0.008) was significantly associated with HBV infection(26).Whereas studies conducted among pregnant mothers in Tanzania shows, including blood transfusion none of the assessed associated factors were significantly related to HBV infection, and in Ghana revealed

that, HBV infection was not associated with any of the risk factors including blood transfusion(P>0.05)(10, 12).

Another hospital associated factors minor or major surgery and dental extraction are common practice that can be responsible for transmission of most of microbial infections. Regarding surgical procedure a study done to find Prevalence of Hepatitis B Virus infection among Egyptian Pregnant Women - A Single Center Study revealed that, surgeries were the risk factors for acquiring HBV infection (P-value= 0.011)(8). Similarly another study conducted in Lagos Nigeria among pregnant women shows, there were statistically significant differences in the sero-prevalence of HBsAg recorded among respondents with previous surgery (odd ratio [OR] - 2.97; 95% confidence interval (CI-1.08-16.67;P = 0.046(31). A study conducted to determine the prevalence of HBV infection and associated risk factors among pregnant women at selected facilities of Tigray revealed that, a statistical association of HBV infection was seen on participants those who had undergone surgical procedures ($P = 0.022$)(27).whereas another study conducted in Iran among pregnant women states that, no significant relationship was observed between HBV infection and history of surgery ($p = 0.32$)(28). Similarly study done in Saudi among pregnant women shows, history of surgery did not prove significant association with HBV(30).

In relation to dental procedure and HBV infection study conducted in Saudi among pregnant women revealed that Dental histories did not prove significant association with HBV(30). Another study done in Ghana also identified the HBV was not associated with any of the risk factors including dental procedure (P>0.05)(13). But a study done in Nigeria revealed Sero-prevalence of HBsAg amongst parturient were more in pregnant women, with history of dental procedures (34.0%) and tooth extraction as a risk for maternal infection of HBV(32).

2.2.3. Risky socio cultural and behavioral factors

HBV can found in various body fluids and has the ability to transmit through exchange/sharing infectious materials between different individuals, for the use of different Socio-cultural practices that exist today like tattooing, ear/ nose piercing. Having multiple

sexual partners is also a risk factor for HBV infection. Parenteral or percutaneous routes of HBV transmission, such as needle stick injury and mucus membrane splash in healthcare setting, as well as tattooing, piercing, sharing razors or toothbrushes, are also important in spreading the virus (3).

Concerning practice of tattooing, study in Iran shows no significant relationship was observed between HBV infection and tattooing ($p = 0.69$)(28). Whereas study in Nigeria shown that, tattooing was significant risk factors for HBV infection(11). Also in Turkey history of tattooing (AOR = 13.64, 95% CI = 2.52-73.76, p = 0.002) was significantly associated with the risk of HBV infection(3).Similarly in Ethiopia an intuitional based study done among pregnant mothers at Bahir Dar revealed that body tattooing (AOR = 5.7, 95% CI, 1.24-26.50) was significantly associated with HBV infection(21).

Regarding ear/nose piercing and risk of HBV among pregnant women a study conducted in Kano Nigeria shown history ear piercing was not significant risk factors for HBV infection(11). Whereas at Dre Dawa having nose/ear pierce (p-0.018), was significantly associated with HBV infection(26), at Dessie hospital in multivariate analysis, the prevalence of HBV infections were significantly higher among nose piercing (AOR18.1; 95%CI 2.9-114, P= 0.002)(23) and at Deder hospital nose piercing (AOR9.1;95%CI:1.34±61.79), was significant predictor of HBV infection(18).

In relation to risky behavioral practice sexual behavior of the individual can determine the risk of HBV infection. Studies conducted among Ethiopian pregnant women in different areas shows multiple sexual partner was a risk factor for HBV infection. For instance at Dawro multiple sexual partner (AOR = 6.923; 95% CI 1.685–28.441) was significantly associated with hepatitis B virus surface antigen (HBsAg) infection(20). Similarly at Yirgalem hospital Women with history of multiple sexual partners were significantly associated with HBsAg positivity(26). Another studies done at Dessie hospital among pregnant women revealed that, in multivariate analysis, the prevalence of HBV infections were significantly higher among patients who had history of multiple sexual practices (AOR 13.5; 95% CI 2.3-78, P =0.004)(23), at Deder hospital multiple sexual partners were significantly associated with HBV infection(18) and in Tigray selected health facilities

shown that, statistical association of HBV infection with risk factors was seen on participants, who were making unprotected sexual practices with multiple partners ($P = 0.03$)(27).

Other risky behavioral factors that increase the occurrence of HBV infection among pregnant women is also history of abortion, for instance a study done in Iran indicated the risk of developing an HBV infection was significantly associated with abortion ($p = 0.001$)(28). Also study done in Kano Nigeria shown history of abortion was significant risk factors for HBV infection(11). Other study done in Deder hospital Ethiopia among pregnant women revealed that, history of abortion (AOR10.9; 95%CI: 2.2±53.9) was significant predictor of HBV infection(18). And at Dawro abortion history (AOR = 4.975; 95% CI 1.21–20.456), was significantly associated with hepatitis B virus surface antigen (HBsAg) infection(20).

2.3. Conceptual frame work

This conceptual frame work will design to show the association between HBV sero-status of pregnant women (dependent variable) and associated factors (independent variables). The single arrow illustrates the effect of one variable to the other towards the direction of the arrow and the bidirectional arrow describes the bilateral relationship of variables.

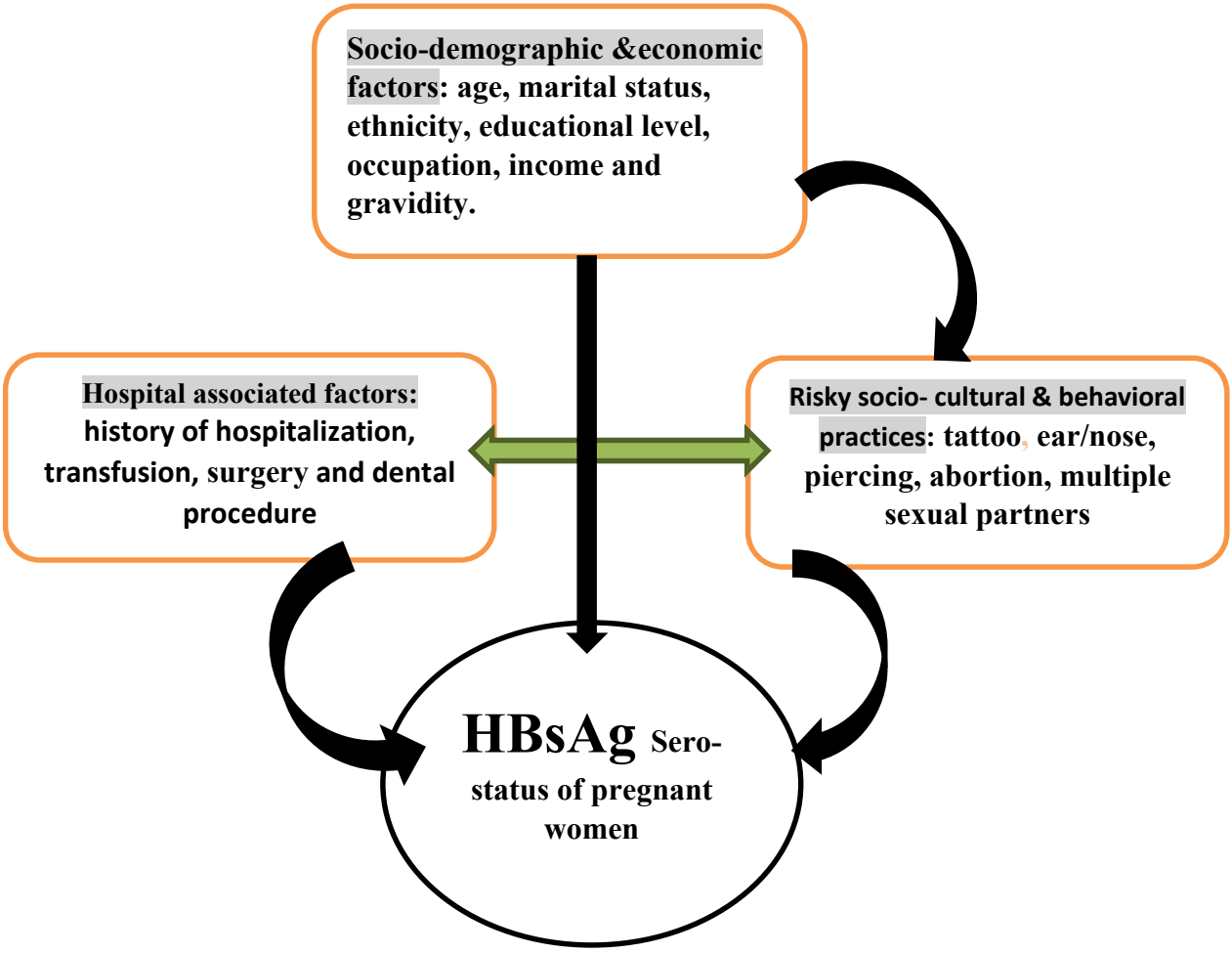

Figure 1: Conceptual frame work showing the relationship between the dependent variable and independent variables (adopted from SahiluA.and Hailay A., Sero-Prevalence of HBSAg and factors among Pregnant women in Ethiopia, 2014)

2.4. Significance of the study

The previous studies indicated that hepatitis B infection among pregnant women raise public health concern, and the magnitude of the problem is still high in many parts of Ethiopia including Northern Region(35). Different reports showed that the associated factors with HBV infections varied from region to region. Thus, determining the prevalence and associated factors with HBV infection among pregnant mothers attend ANC clinic in different geographical setting is paramount to design appropriate preventive measures, and the prevalence of HBV infection among antenatal population may give some indication on prevalence in the general population. Therefore, screening antenatal women for HBsAg can give hint to estimate prevalence of the disease in a population and provide an opportunity for preventing mother to child transmission of the virus.

Prevention of HBV infection is a public health priority, especially for those groups at major risk of becoming chronic carriers(2).It is obvious that the introduction of routine hepatitis B screening among pregnant women and its prevention control requires updated data on the magnitude of HBV, also HBV infected pregnant women are at risk of infecting their babies with a consequence of developing fulminate HBV infection. Therefore this study will provide valuable information on the magnitude and associated factors on HBV and helps to draw possible recommendation for prevention and control purposes for:-

1. Ministry of health Policy makers and stake holders
2. Health workers
3. For researchers

CHAPTER 3: OBJECTIVES

3.1. General objective

To determine the prevalence of HBV infection and associated factors among pregnant women attending antenatal clinic (ANC) at Adigrat General Hospital, Tigray, Ethiopia, 2019.

3.2. Specific objectives

To determine the prevalence of HBsAg among pregnant women attending at Adigrat General Hospital ANC clinic,

To determine factors associated with HBsAg among pregnant women attending at Adigrat General Hospital ANC clinic.

CHAPTER 4: METHODS AND MATERIALS

4.1. Study setting and period

Tigray Regional state is one of nine regions of the Federal democratic Republic of Ethiopia, located in the Northern Ethiopia bordering Eritrea and Sudan, locally bordering with Afar and Amara. The region has 6 zones and 47 Woredas. The study will be conducted at Adigrat General Hospital located in the Eastern zone of Tigray127km from Mekelle, the capital city of Tigray and 900 km from the capital city of Ethiopia, Addis Ababa. Adigrat is the capital city of Eastern zone of Tigray, and the total population is 86,100 according to 2015 the population of regions of Ethiopia. Regarding health facilities, the town has one General hospital and one health center. The hospital serves inpatient and outpatient health care services including ANC for routine pregnancy check-up services that include the assessment of pre-existing health conditions (screening for anemia, syphilis, HIV, hepatitis virus), vaccination, nutrition counseling, micronutrient supplementation and early detection of pregnancy related complications. However, routine HBV screening is strictly performed the prevalence and associated factors of the infection are not determined still. The ANC clinic serves 300 to 350 pregnant mothers per month. The study will conduct between Mar 1/2019 and Apr 30/2019.

4.2. Study design and sample size determination

An institutional based cross-sectional study design will be conducted among pregnant mothers who attend ANC clinic at Adigrat General Hospital. Sample size was calculated based on single population proportion formula by taking 8.4% the highest prevalence of HBV infection from previous study(26), desired precision of 3%, a 95% confidence level and 10% non- response rate. Finally:-

$$n = \frac{Z^2 P(1-P)}{d^2}$$ Where, n= sample size,

P (Prevalence) =8.4%=0.084 and (1-P) =0.916

d=margin of error=0.03,

Z= confidence interval (95%) = 1.96

$$n = \frac{(1.96)^2 \times 0.084 \times 0.916}{(0.03)^2} = 328$$

Since our source population is less than 10,000, which are 650 we can use the correction formula.

$$nf = \frac{n}{1+\frac{n}{N}} = 218$$ where, nf= sample size final

And 10% non-response rate is 22. **Hence** the total calculated sample size is **240**.

4.3. Population

4.3.1. Source population

All pregnant women attending ANC clinic at Adigrat health facilities.

4.3.2. Study population

The study populations will be all pregnant women attending ANC at Adigrat General Hospital during the study period.

4.3.3. Inclusion criteria

Pregnant women attending ANC in Adigrat General Hospital during data collection period.
Willing to participate in the study
Reside in Adigrat catchment area for at least 6months

4.3.4. Exclusion criteria

Pregnant women who come for the second time during the study period will be excluded.

4.4. Study variables

4.4.1. Dependent variable

HBsAg sero-status

4.4.2. Independent variables

Age, Blood transfusion, History of dental procedure, Ear/nose piercing, Educational level, Risky sexual behaviour, Tattooing, Occupation, Marital status, Income level, Gravidity, History of dental procedure, History of surgical procedure and Abortion.

4.5. Operational definition

Hepatitis B virus: -refers a potentially life-threatening liver infection caused by the hepatitis B virus (HBV).

Prevalence of hepatitis B virus:-refers to the prevalence of hepatitis B virus among pregnant mothers attending at the ANC clinic of Adigrat General Hospital.

History of hospitalization: -refers to the previous history of hospital admission of the study subject for any disease in the past.

Blood transfusion history: - refers to the transfusion history of the study subject for any problem.

History of dental procedures: -refers to any surgical procedures in the study subject in the past

History of surgical procedures: -refers to any surgical procedures minor or major practiced on the study subject in the past.

Risky Socio cultural factors: -refers to some of the social and cultural activities that were practiced by the study subject and able to serve as a means of exchange of body fluids and germs between individuals for example ear or nose piercing, contact with family member during visiting and caring of the sick in the past.

Risky behavioral factors: -refers to some of the behavioral malpractice of the subjects that exposed them to the risk of acquiring HBV infection from different source like abortion in the past.

4.6. Sampling technique

Systematic random sampling technique will be used to identify the study subjects and 650 pregnant women have attended to the Adigrat General hospital ANC clinic in two months as reported, and the sampling interval was calculated by using a formula, k=N/n which is, K=3, and the initial sample will be selected using lottery method. Therefore, every 3rd mother attending the clinic will be enrolled in the study until the calculated sample size will be achieved within the length of data collection period.

4.7. Data collection procedure

The data will be collected by face to face interview using structured questioner, and a questioner will be given to collect information on socio-demographic information, risky socio-cultural and behavioural practice and hospital associated factors. The data collectors will be those who are senior BSc midwife and had experience on data collection procedure. The questionnaire is standard and it has been adopted from similar study done in Somali Ethiopia(29).

To ensure consistency, the English version of the questionnaire will be translated to local language Tigrigna and then back to English by language experts. After brief explanation about the aim of the study the participants will invite to take part in the study voluntarily. As screening of HBsAg, HCsAg, CBC, syphilis and others are strict routinely practiced in Adigrat General Hospital, the institution has its own laboratory to investigate the above including HBsAg for all pregnant mothers without any payment. So HBV sero-status of the women can be easily addressed from their card, even for those who first visit pregnant mothers by waiting until the laboratory result has processed, because the laboratory results are strictly attached to the cards of the pregnant mother.

4.8. Data quality assurance

Prior to the actual data collection, pre-testing will be done on 5% of the total study subjects and have similar characteristics at Adigrat health facilities which will not be included in the analysis of the actual study and based on findings necessary amendments will be made. In order to achieve good data quality data collectors will be recruited based on their

profession and qualification for that reason senior BSC Midwifery will be involved in the data collection moreover ability to speak the local language and previous experience of data collection will be considered. Before the data collection begins, orientation will be provided to the data collectors on objectives of the study, steps and approach for interviewing. Vague points and other problems encountered about the questionnaire will be explained and clarified prior to the data collection. During the time of data collection firm supervision will be undertaken by the investigator and supervisors to ensure good quality of data and appropriateness. At the end of each data collection date the questionnaire will be crosschecked daily by the supervisors and the principal investigator and problems faced will be discussed over night with data collectors and the supervisors.

Regarding quality and specification of the test kits currently different brands of rapid HBsAg test kits are commercially available, with high sensitivity and specificity. The laboratory of Adigrat general hospital have NOVA cassette style HBsAg rapid test strip used for the detection of hepatitis B surface antigen (HBsAg).The test has sensitivity and specificity of approximately 99.7% and 99.3%, respectively.

4.9. Data Analysis

After checking for completeness and consistency of the collected information, the data will be cleaned, coded and entered in to Epi-Data version 3.1 and transfer to SPSS version 20 for analysis. Descriptive statistical analysis will be used to determine the socio-demographic and clinical characteristics of study participants and prevalence of HBV. Association between possible risk factors and prevalence of HBV infection will be determined using bivariate and multivariate logistic regression analysis. Odds ratio (OR), AOR and 95% CI will be used as a measure of strength of association. All explanatory variables with P-value $\leq$ 0.2 in the bivariate analysis will be included in multivariate logistic regression model. P-value less than 0.05 in multivariate analysis will be considered as statistical significance.

4.10. Ethical consideration

Ethical clearance will be obtained from Addis Ababa University IRB and permission from respective authorities and written consent of respondents' by explaining the objective of the study before the data collection. To get full co-operation, respondents will be reassured about the confidentiality of their response. They will also be ensured their voluntarily participation and right to take part or terminate at any time they wanted. The research assistants will be trained by the principal investigators on how to keep the confidentiality and anonymity of the responses of the respondents in all aspect.

4.11. Plan for dissemination of findings

The final result of this study will be presented to Addis Ababa University College of Health science post Graduate and disseminated to AAU library, Adigrat General Hospital, Tigray Health Bureau and other concerned governmental and nongovernmental organization; in addition, effort will be made to publish on local or international journal.

CHAPTER 5: PLAN OF ACTIVITES

Table 1: Work plan (planned through time line) is a plan to determine the weekly and monthly activities that we will do in our study starting from topic selection to submission of research thesis.

S.no	Activities	Responsible Person	Period							
			Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
1	Topic selection	PI								
2	Topic defense	PI								
3	Proposal writing	PI, advisory								
4	Proposal defense	PI								
5	Correction & submission of proposal	PI								
6	Training of data collectors' supervisors &pre-testing	PI, DC &SP								
7	Data collection	PI, DC &SP								
8	Data entry & analysis	PI								
9	Thesis report writing	PI &advisory								
10	Submission of first draft & Mock defense	PI								
11	Submission of first final paper	PI								
12	Thesis defense	PI								
13	Final thesis submission	PI								

CHAPTER 6: BUDGET PLAN

Table 2: Budget break down for the expense of the whole research

Item			Number	Expense for one	Total expense
Stationery		Paper	1500	0.50	750
		Pen	6	7	42
		Pencil	6	3	18
Personnel	Transport		40x	10	800
	Data collector		4	80 birr per day	12800
	Supervisors		1	120 birr per day	4800
	Translators		2	200	400
Training	Data collectors	Transport	4	10birr	80
		Tea break	4	200	200
		Lunch	4	60	240
		Daily fee	4	200	800
	Supervisors	Transport	1	10	20
		Tea break	1	100	100
		Lunch	1	60	60
		Daily fee	1	250	250
Print			1500	1 birr	1500
Contingency 10%	2,286 ETB birr				
Total	**25,146 ETB birr**				

CHAPTER 7: REFERENCES

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CHAPTER 8: APPENDIXES

APPENDIX I: Questioner English

Information on consent form

My name is Hailay kinfe Maternity and RH student at Addis Ababa University, currently undertaking a research on Prevalence and Associated Factors of Hepatitis B virus infection among Pregnant Women attending Antenatal Care Clinic at Adigrat General Hospital Tigray, Ethiopia. The main purpose of this research study is to determine the prevalence of HBV infection and associated factors among pregnant women at Antenatal Clinic of Adigrat General Hospital.

Procedures to be followed: Participation in this study requires, I ask you some questions which I will record the answers in the questionnaire. You have the right to refuse to participate in this study. You will receive the same care whether you agree to join the study or not and your decision will not change the care you will receive from the facility today/later or that you will get from any other facility at any other time. Participation is voluntary and you may ask questions related to the study at any time. You may refuse to respond to any question and you may also stop the interview at any time without any consequences to the services you receive from this health facility or any other organization now or in the future.

Discomfort and risks: Some of the questions you will be asked may make you uncomfortable. As such, you may refuse to answer these questions if you choose. The interview may add approximately half an hour to the time you wait before/after you receive your routine services. **Benefits**: You may receive no monetary benefit from this study. However, knowledge gained from this study may help in the management of infectious diseases in the future. There is no cost to you for enrolling in the study.

Confidentiality: The interview will be conducted in private and your name will not be recorded in the questionnaire. The questionnaire will be kept in a locked cabinet for safe keeping.

Contact information: If you have any questions feel free to contact the principal investigator hailay kinfe on 0923630556 or the Addis Ababa University Ethical Review Committee on_____.

Participant's statement: The above information regarding my participation in the study is clear to me. I have been given a chance to ask any questions and my questions have been answered to my satisfaction. My participation in the study is entirely voluntary. I understand that my records will be kept private and I can leave the study at any time. I understand that I will receive the same care whether I decide to participate in the study or not and my decision will not change the care I receive from the health facility today or that I will get from any other facility at any other time.

Name of participant_____

Signature/thumbprint_____ Date _____

Investigators statement: I, the undersigned have explained to the volunteer in a language she understands the procedures to be followed in the study and any risks/benefits that may be involved.

Name of interviewer_____

Interviewer signature_____ Date _____

Questionnaire for client exit

STUDY TITTLE: Prevalence and Associated Factors of Hepatitis B virus infection among Pregnant Women attending Antenatal Care Clinic at Adigrat General Hospital Tigray, Ethiopia.

Questionnaire number …… Name of interviewer …… Date …….. Service delivery point ……..

Introduction Hello my name is Hailay Kinfe from Addis Ababa University School of nursing and midwifery and I am interested to know the Prevalence and Associated Factors of Hepatitis B virus infection among Pregnant Women attending Antenatal Care Clinic at Adigrat General Hospital. The information you will give is very important and thus your cooperation and sincerity will be highly appreciated. I assure you the information shall be held with utmost confidentiality.

Thank you in advance

Instruction for data collectors

Interview pregnant women, who come for ANC, encircle the response of the respondents for multiple choice questions and for short answers write on the space provided.

Code № _____		**HBV sero-status**_____	
Part I. Socio-demographic and economic characteristics of the respondent.			
№	Question	Response category code	Skip to
100	Date of interview	_____	
101	What is your age in years?	_____years	
102	Ethnicity	Kunama…….……..1 Erob…….…….....2 Amhara…….……...3 Afar ……..……..4 Tigrie...……....5 Others…….....6	
103	What is your Marital status?	Single …….……...…...1 Cohabited…….…….2 Married …….....3 Divorced…….……..4	
104	What is your Educational level?	Cannot read and write…….1 Read and write (informal)…….2 Elementary (1-6) ……3 Junior (7-8) ……4 High school (9-12) …….……5 Above grade 12…….6	
105	What is your Main occupation?	Petty trader…….……...1 House wife…….…….....2 Non –employee…….……..…3 Formal employee……. …… 4	

		Others……..... 5	
106	What is your monthly income?	Cash (in Birr)/month _____	
107	Have you ever had any pregnancy before?	YES……1 NO……2 →	201
108	If yes on question 107, how many pregnancies have you had? Enter in Number	_____	
109	How many live births have you had? Enter №	Number _____	
Part II. Questionnaire related to hospital associated factors			
201	Have you ever been admitted in Hospital or clinics in the last 6 months?	YES……..1 NO……2 →	204
202	Have you ever had dental procedure in hospital or clinics	YES……...1 NO……..…2	
203	Have you ever been operated for surgical problem in Hospital?	YES……1 NO……...2	

Part III. Questionnaire related to risky socio cultural and behavioral factors			
301	Have you ever experienced abortion?	YES……...1 NO……2 ⟶ No response ……...……3 ⟶	 303 303
302	If yes in question 301 How many times in number?	_____	
303	Have you ever had tattoo on your body	YES……1 NO……..2	
304	Have you ever had ear piercing	YES……1 NO……...2	
305	Have you ever had nose piercing	YES……1 NO……...2	
306	Does your husband have another wife?	YES……1 NO……..…2 ⟶	 308
307	If yes on question 306 how many?	One ……1 Two……2 More than two……3	
308	Have you had official marriage before current husband?	YES……1 NO……...…2	

Card Review: -after the interview cards of the participants will be reviewed to identify either the sero-prevalence of the participants is positive or negative.

APPENDIX II: Tigrigna

ናይ ስምምዕነት ሓበሬታ ቅጥዒ

ሸመይ ሃይላይ ክንፈ ይብሃል:: ኣብ ኣዲስ ኣበባ ዩኒቨርሲቲ ናይ ካልኣይ ዲግሪ ተምሃራይ እየ:: ሐዚ ኣብ ኢትዮጵያ ዝርከብ ኣጠቓላሊ ሆስፒታል ኣዲግራት ብዛዕባ ሕማም ፀላም ከብዲ /ሄፕታይተስ ቢ/ ቫይረስ ኢንፌክሽንን ተዛመድቲ ምክንያታትን መፅናዕቲ ክገብር እየ:: ዋና ዕላማ ናይዚ መፅናዕቲ ኻዓ በዝሒ ሄፕታይተስ ቢ ቫይረስ ኢንፌክሽንን ተዛመድቲ ምክንያታትን ንምፍላጥ እዩ::

ከይዲ ናይዚ ተሳትፎ ከም ዝስዕብ ይኸውን

ነዚ ተሳትፎ ዘድልይዎ ነገራት ኣነ ዝተወሰነ ሕቶ ይሓተክን:: ነቲ ዝመለስክንኣ መልሲ መሊሰ ይምዝግቦ:: ናይ ዘይምስታፈ መሰልክን ሕልው እዩ:: ዋላ ኣብቲ መፅናዕቲ እንተዘትተሳተፍክን ምስ ማንም ማዕረ ኣገልግሎት ኢኽን እትረኽቦ:: ኣብዚ መፅናዕቲ ዘይምስታፍክን ንትረኽብዞ ኣገልግሎት ኣብ ኩሉ እዋንን ቦታን ለውጢ ኣየምፅእልክንን:: ተሳትፎኽን ብድሌት እዩ:: ዘይተረደዛክን ሕቶ ክትሕታ መሰልክን እዩ:: ኣብ ከይዲ እቲ ሕቶን መልስን ደስ ዘይብለክን ዛዕባ እንተሊኡ ኣብ ማንም እዋን ናይ ምግዳፍ መሰልክን ሕልው እዩ::

ኣብ ከይዲ ሕቶን መልስን ኣቋሪፅክን ስለ ዝወፃኽን ምንም ዓይነት ናይ ኣገልግሎት ምቅናስ ዋላ ንቀፃሊ ኣየምፅን::

ግዴታታትን ጉድኣታትን

ሓደ ሓደ ናይቶ እትሕተትኦም ሕቶታት ደስ ዘይብሉኽን ነገራት ክህልው ይኽእሉ እዮም:: ስለዚ ደስ ዘይብሉኽን ሕቶታት ምሕላፍ ትኽእላ ኢኽን::

ካብቲ ነገልግሎት ዝመፃኽናሉ ግዘ ኣስታት ሰላሳ ደቂቃ ክወስደልክን ይኽእል እዩ::

ጥቅሚ

ኣብዚ መፅናዕቲ ምስታፍ ትርፊ የብሉን:: ኮይኑ ግና ካብኡ ዝተረኽበ ፍልጠት ንቀፃሊ ካብ ተመሓላለፍቲ ሕማማት መፍትሒ ክርከብ ይኽእል እዩ።

ስለ ዓርሰ እምነት

እቲ መፅናዕቲ ዝካየድ ብግሊ እዩ። ስምክን ኣይፃሓፍን። እንደገና እቲ ዉፅኢት ተቆሊፉ እዩ ዝቅመጥ።

ናይ ሓበሬታ ኣድራሻ

ምንም ዓይነት ሕቶ እንድሕር ክትሓታ ደሊኽን ብ 0923630556 ናብ ናተይ ስልኪ ቁፅሪ ወይ ኣዲስ ኣበባ ዩኒቨርስቲ ክትድውላ ትኽእላ ኢኽን።

ናይ ተሳተፍቲ ሓሳብ

ልዕል ኢሉ ዝተገለፀ ሓሳብ ንዓይ ግልፂ እዩ። ሐጂ ዝኾነ ዓይነት ሕቶ ንኽሕተትን ክምልስን ድልውቲ እየ። እዚ ድማ ብድልየተይ ምኻኑ ከረጋግፅ ይደሊ። ኣብዚ ናይ ቃል ሕቶ ምስታፈይን ዘይምስታፈይን ዋላሓንቲ ለውጢ ኣብ ዝረኽቦ ዛገልግሎት ክምዘየምፅእ ተረዲአ ኣለኹ ዋላ ንቀፃሊ።

ናይ ተሳተፍቲ ሽም_____

ፊርማ_____ ዕለት_____

ናይ መፅናዕቲ መካየዲ ሓሳብ

ንዝኾነ ዓይነት ችግር ኣነ ተመራቂ ተምሃራይ ተሓታቲ ምኻነይ ከረጋግፀልክን ይፈቱ።

ናይ ሓታቲ ሽም_____

ናይ ሓታቲ ፊርማ_____ ዕለት_____

ሓበሬታ :- ናብ ቅድሚ ወሊድ ክትትል ዝመፃ ኣዴታት ሕቶ ምስ ሓተትኩም ነቲ ምረፅ ኣኽብብሉ ነቲ ዳሽ ምላእ ድማ ምልእዎ።

መለለዪ ቁፅሪ	ናይ ሄፓታይተስ ቢ ውፅኢት_____

ቀዳማይክፋል: ናይ ተሳተፍቲ ማሕበራውን ቁጠባውን ባህርያት

ተ.ቁ	ዓይነት ሕቶ	ናይ ተሓተቲ ሚስጥራዊ መልሲ	ናብ ዝቅፅል ሕቶ ሕለፍ
100	ናይ ቃል ሕቶ ዝተውሃበሉ መዓልቲ	ዕለት……	
101	ዕድመኺ ክንደይ እዩ ?	ብዓመት……	
102	ብሄር	ኩናማ……1 ኢሮብ……2 አምሓራ……3 ዓፋር……4 ትግራይ……5 ካሊእ_____	
103	ኩነታት መርዓ ?	ዘይተመርዓወት……1 ዘይተመርዓወት ግን ሓቢሮም ዝነብሩ…..2 ዝተመርዓወት……3 ዝተፋትሐት……4	
104	ደረጃ ትምህርቲ	ምንባብን ምፅሓፍን ዘይትክእል….1 ምፅሓፍን ምንባብን ትኽእል……2 ክሳብ ሻድሻይ ክፍሊ……3 ክሳብ ሻምናይ ክፍሊ……4 ክሳብ ዓሰርተ ክልተ ክፍሊ……5 ልዕሊ ዓሰርተ ክልተ ክፍሊ……6	
105	ስሩዕ ስራሕ	ነጋዲት……1 ሰራሕተኛ ገዛ……2 ዘይተከፋሊት……3 ተኸፋሊት……4 ኻሊእ_____	
106	ወርሓዊ ኣታዊ	ብ ጥረ ገንዘብ_____	
107	ቅድሚ ሐዚ ጥንሲ ኣጋጢሙ ይፈልጥ ዶ ?	እወ……1 ኣይፈልጥን……2 →	201
108	እንድሕር ናይ ሕቶ ቁፅሪ 107 መልሲ እወ ኾይኑ ክንደይ ግዜ ኣጋጢሙ ብቁፅሪ ይግለፁ	ቁፅሪ……	

109	ክንደይ ሂወት ዘለዎመ ቆልዑ ወሊድኪ ትፈልጢ?	ቁፅሪ.....	
ካልኣይ ክፋል÷ ምስ ሆስፒታል ዝተዛመዱ ምኽንያታት ዝምልከት ሕቶ			
201	ቅድሚ ሽድሽተ ወርሒ ኣብ ሆስፒታል ወይ ኣብጢዕና ጣብያ ሓሚምኪ ደቂስኪ ትፈልጢ ዶ?	እወ.....1 ኣይፈልጥን.....2 →	204
202	ቅድሚ ሐዚ ናይ ስኒ ሕክምና ገይርኪ ትፈልጢ ዶ?	እወ.....1 ኣይፈልጥን.....2	
203	ኣብ ሆስፒታል ናይ መጥባሕቲ ሕክምና ገይርኪ ትፈልጢ ዶ ?	እወ.....1 ኣይፈልጥን.....2	
ሳልሳይ ክፋል፡ ምስ ሓደጋ ካብ ዘጋፅሑ ማሕበራውን ባህላውን ልምድታት ዝዛመዱ ኩነታት ዝምልከት ሕቶ			
301	ጥንሲ ኣነፂልኪ /ኣውሪድኪ ትፈልጢ ዶ ?	እወ.....1 → ኣይፈልጥን.....2 303 መልሲ የለን.....3 → 303	
302	እንድሕር መልሲ ሕቶቁ ፅሪ 301 እወ ኾይኑ ክንደይ ግዜ ብቁፅሪ ኣቀምጥ?	ቁፅሪ.....	
303	ንቅሳት ተነቂስኪ ትፈልጢ ዶ ?	እወ.....1 ኣይፈልጥን.....2	
304	እዝኒኺ ተበሲፅኺ/ተሰቁርኪ ትፈልጢ ዶ?	እወ.....1 ኣይፈልጥን.....2	
305	ኣፍንጫኺ ተበሲፅኺ/ተሰቁርኪ ትፈልጢ ዶ?	እወ.....1 ኣየፈልጥን.....2	
306	ባዓልገዛኺ ካሊእ ሰበይቲ ኣላቶ ድያ ?	እወ.....1 የብሉን.....2	308
307	እንድሕር ናይ ሕቶ ቁፅሪ 306 መልሲ እወ ኾይኑ ክንደይ?	ሓደ.....1 ክልተ.....2 ካብ ክልተ ንላዕሊ.....3	
308	ቅድሚ ሐዚ ሰብ ዝፈልጦ መርዓ ገይርኪ ነይርኪ ዶ?	እወ.....1 ኣይገበርኩን.....2	