

STRATEGIES TO PROMOTE THE PREVENTION OF HEPATITIS B VIRUS INFECTION AMONG PREGNANT WOMEN IN ETHIOPIA

Gebrekrstos Negash Gebru*

Mekelle, Tigray, Ethiopia.

*Corresponding Author

Gebrekrstos Negash Gebru

Associate professor,
Department of
Microbiology, Nandha
Siddha Medical College
and Hospital, Erode-
638052.

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Abstract: -

Background:

The hepatitis B virus (HBV) poses a significant global health threat, with 240–350 million chronic infections and 1.3 million deaths yearly. In Ethiopia, the prevalence of HBV among pregnant women was recorded to be between 2.3% to 7.8% from 2014 to 2018, indicating a widespread issue. Despite existing knowledge about risk factors, the high prevalence of HBV infection among pregnant women persists, and effective prevention strategies have yet to be determined. This study aims to develop and implement strategies to effectively prevent HBV transmission among pregnant women in Ethiopia.

Methods: The study was conducted in four healthcare facilities in the Tigray regional state of Ethiopia. It consisted of three phases: Phase 1 involved an integrative literature review to explore best practices in preventing HBV infection among pregnant women. Phase 2 focused on exploring the perceptions and views of pregnant women and healthcare workers regarding HBV prevention measures among pregnant women in Ethiopia. Phase 3 involved the development and validation of strategies to promote the prevention of HBV transmission among pregnant women in Ethiopia. The study included pregnant women receiving antenatal care services and healthcare workers providing these services. The sample size for each group was determined using the saturation principle. Data was collected through semi-structured interviews and focus group discussions. Field notes were taken during the interviews, and the interviews were audio recorded with participants' permission. Tesch's method of data analysis was used.

Results and Discussions:

According to a review of twelve studies, it is crucial to screen pregnant women for HBV infection during the first trimester to prevent mother-to-child transmission (MTCT) and identify infected partners. In areas with high HBV prevalence, most infections occur due to MTCT in early childhood. Based on our research, routine screening of pregnant women during each prenatal visit is a good strategy to break the cycle of HBV infection and decrease the impact of MTCT. Additionally, nine studies have reported that maternal antiviral prophylaxis and therapy for pregnant women infected with HBV are effective strategies to prevent disease transmission. Qualitative data collected from pregnant women and healthcare workers indicated a low level of knowledge, attitude, and practice regarding HBV prevention and control activities.

Conclusions: This comprehensive study delves into the perspectives of pregnant women and healthcare workers regarding HBV infection and its prevention strategies. Additionally, it explores the most effective practices for preventing HBV infection in pregnant women. These strategies have been rigorously validated using a SWOT analysis framework and through extensive consultative meetings with various stakeholders. Furthermore, the study recommends further qualitative research on the drivers of HBV infection.

Keywords: Hepatitis B virus, pregnant women, strategies, prevention, Ethiopia.

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1. Background Orientation of the Study

1.1 Introduction

This chapter provides an overview of the background information of the research including hepatitis B virus (HBV) prevalence among the general population as well as among pregnant women globally, in Sub Saharan Africa and in Ethiopia and the major challenges in the prevention of HBV infection among pregnant women. It also provides the overview of the research problem, purpose, objectives, and research questions that the study seeks to address. The chapter also details the significance of the study, key concepts and definitions, research paradigm and theoretical framework. The research design and methodology of the study including ethical considerations are also highlighted in this chapter. It also describes the scope and limitation of the study and the overall structure of the proposal.

1.2 Research Problem

1.2.1 Background of the research problem

Hepatitis is an inflammation of the liver, which is most commonly caused by five viral infections, namely hepatitis A virus, hepatitis B virus, hepatitis C virus, hepatitis D virus, and hepatitis E virus. Hepatitis A virus, hepatitis C virus, hepatitis D virus, and hepatitis E virus are Ribonucleic acid viruses (Dienstag 2018). Hepatitis B virus (HBV) is a double-stranded circular deoxyribonucleic acid genome within the family of Hepadnaviridae (Dienstag 2018). The HBV replicates like a retrovirus (Dienstag 2018) and is highly contagious due to its ability to be transmitted through horizontal and vertical routes (World Health Organization 2015:5). Among other health problems, HBV causes hepatocellular necrosis and inflammation, which are both potentially life-threatening liver diseases (Balogh, Victor, Asham, Burroughs, Boktour, Saharia, Li, Ghobrial & Monsour 2016:41; Eke, Eke & Okafor 2012:1-8; WHO 2014).

Globally, the HBV is responsible for 240–350 million chronic infections every year (WHO 2015). Hepatitis B viral -related cirrhosis and hepatocellular carcinoma cause 1.3 million deaths every year (Cowie, Carville & MacLachlan 2013:953–954). In 2015, the WHO estimated the global prevalence of HBV infection in the general population to be 3.5% and that between 5% and 10% of the adult population in Sub-Saharan Africa (SSA) and East Asia were chronically infected with HBV (WHO 2015). In SSA, about 60% of the population is exposed to HBV in its lifetime, and 8% has an active infection at any point in time (Howell, Lemoine & Thursz 2014:381-396). It is estimated that HBV infection accounts for 87890 deaths annually in SSA (WHO 2017), and it is endemic in Ethiopia with a prevalence of 7.4% among the general population (Belyhun, Maier, Mulu, Diro & Liebert 2016:761). Another systematic review conducted in Ethiopia showed that the pooled prevalence of HBV among the general population from 2010 to 2017 was 6% (Yazie & Tebeje 2019:917).

Several studies in the Asian region have indicated a high prevalence of HBV infection ranging from 3% to 11% among pregnant women. Choisy, Keomalaphet, Xaydalasouk, Quet, Latthaphasavang, and Buisson (2017:1-5) found that the prevalence of HBV infection during the period from 2008 through 2014 among pregnant women in Laos was 5.4%. Different studies conducted during the period from 2007 through

2017 in SSA have reported a pooled prevalence of HBV infection among pregnant women to be 11.2% in Cameroon (Bigna, Amougou, Asangbeh, Kenne, Noumegni, Ngo-Malabo & Noubiap 2017:4) and 13.6% in Nigeria for the period from 2000 to 2013 (Musa, Bussell, Borodo, Samaila & Femi 2015:163–172).

Different studies conducted from 2014 to 2018 in Ethiopia found HBV prevalence among pregnant women to range from 2.3% to 7.8% (Belyhun et al 2016:761; Desalegn, Wassie, Beyene, Mihret & Ebstie 2016:16; Deme, Edao, Jaya, Tisiano, Fano, Alegria, Reyes, Gorgolas & Ramos 2016:1032–1039; Kebede, Abateneh & Belay 2018:322; Molla, Munshea & Nibret 2015:204; Yohanes, Zerdo & Chufamo 2016:7; Umare, Seyoum, Gobena & Hailemariyam 2016; Chernet, Yesuf & Alagaw 2017:418; Zenebe, Mulu, Yimer & Abera 2014:118). In 2018, Kebede et al (2018:322) conducted a systematic review and estimated the pooled prevalence of HBV infection among pregnant women in Ethiopia at 4.7%. Studies also showed that the prevalence of HBV infection among pregnant women in Ethiopia varies across the regional states with relatively higher in Tigray regional state, northern Ethiopia which is 5.5% when compared with other regional states of the country such as Amhara regional state 4.5%, and Somalia regional state 3.7% (Araya, Niguse, Gebrekidan, Hailekiros, Berhe & Asmelash 2018:503-509; Kebede et al 2016:761).

The prevalence of HBV infection in SSA, including Ethiopia, is on the increase, with studies showing it to range from 3% to 13.6% (Buisson et al 2014; Musa et al 2015). The high prevalence of HBV infection reported by these studies and its health consequences demonstrate that this infection is a public health concern in Ethiopia that needs public, governmental, and non-governmental attention.

According to Gambarin-Galwan (2007:945-963), and Ahmed (2016:1-4), consequences of HBV infection during pregnancy is associated with a high risk of maternal complications ranging from premature labor to maternal death (Ahmed 2016; Gambarin-Gelwan 2007; National Institute for Health and Clinical Excellence 2008). In high and intermediate endemic areas, perinatal and early childhood transmissions are the main routes of HBV (WHO 2009:405-419). Early HBV infection transmission, especially mother to child transmission contributes to more than one –third of the chronic cases of HBV infection (Keane, Funk & Shimakawa 2016:1005-1017).

Major challenges of HBV elimination in Sub-Saharan Africa include curtailing MTCT through a full vaccination schedule. Accessibility and affordability of diagnostic assays also delay therapy (Spearman et al 2017:900–909). Screening for HBV surface antigen to all pregnant women and vaccination of their babies at birth dose have been recommended widely, yet it is not a routine practice in Ethiopian health care facilities (Chernet, Yesuf, & Alagaw 2017:418; Shiferaw, Letebo & Bane 2016:769; WHO 2015). Although the hepatitis B vaccine was introduced for 6 to 14-week-old children, there are currently no active programs administering the vaccine at birth. Studies show that administering HBV vaccination to 90% of new-borns within 24 hours from birth will protect 84% of global infection-related deaths. Shiferaw et al. (2016:7) indicate that the Ethiopian national health response to hepatitis infection is limited. The same study shows that healthcare workers often take no further action after diagnosing patients with

viral hepatitis mainly because of the absence of treatment guidelines (Shiferaw et al 2016:10). Furthermore, the WHO (2015) notes that in Ethiopia, there is no coordinated HBV vaccination program in place to prevent infection among the adult population.

The global recognition of the severity of the infection and attention given to HBV infection in most developing countries is suboptimal. A global commitment to combat the disease is still desired (Stanaway, Flaxman, Naghavi, Fitzmaurice, Vos, Abubakar, AbuRaddad, Asadi, Bhala, Cowie, Forouzanfour, Groeger, Hanafiah, Jacobsen, James, MacLachlan, Maledheh, Martin, Mokdad, Mokdad, Mray, Plass, Rana, Rein, Richardus, Sanabria, Saylan, Shahrzaz, So, Vlassov, Wederpass, Wiersma, Younis, Yu, El Sayed Zaki & Cooke 2013:1081–1088; WHO 2017).

In May 2016, WHO in line with the Sustainable Development Goals (SDG) has set targets of 90% reduction in new chronic cases and 65% reduction in mortality rates due to HBV infection by 2030. The WHO (2016:22) targets are dependent on providing treatment to 80% of eligible individuals with chronic HBV infections globally. Therefore, substantial public health efforts of HBV preventive and treatment strategies among pregnant women will be required to reach the WHO targets (Spearman et al:900–909). However, most countries in SSA, including Ethiopia do not have HBV vaccines for adults, which means that children who missed vaccination during childhood cannot be given the service as adults. In 2016, the United Nations Children's' Fund (2018) and WHO (2018) reported that only 74% of eligible children in SSA received all required three doses of HBV vaccine. Case finding, testing, care, and management of chronic hepatitis B patients is recommended at all levels of health care system including primary health care in countries with a prevalence of hepatitis B infection $\geq 2\%$ (HPA, 2011b). However, Shiferaw et al (2016:11) found a lack of clear guidance and strategies to enhance case finding, screening, diagnosis, and treatment of HBV-infected patients including pregnant women in Ethiopia. Therefore, the study aimed to develop strategies to promote the prevention of HBV infection among pregnant women in Ethiopia.

1.2.2 Statement of the Research Problem

Hepatitis B virus infection is a serious and growing public health problem in SSA including Ethiopia. Studies conducted in Ethiopia have found a high prevalence of HBV infection among pregnant women ranging from 2.3 % to 7.8 % (Araya et al 2018:503-509; Deme et al 2016:1032–1039; Kebede et al 2018:322; Zenebe et al 2014:118).

Pregnant women infected with HBV before or during pregnancy are vulnerable to a high risk of maternal complications, and maternal deaths (Ahmed 2016; Gambarin-Gelwan 2007). Without any prophylaxis women who are infected with HBV are likely to transmit the virus to their offspring at the time of delivery (Chang 2007:160–167). A study conducted in Ethiopia in 2012 showed that about 75% of newborns to HBV-infected women were positive with hepatitis B surface antigen (HBsAg) (Tegegne et al 2014:239). Babies infected with HBV at birth have a 90% chance of developing lifelong, chronic hepatitis which increases their risk of developing serious health problems such as liver cirrhosis and hepatocellular carcinoma by 25% with time (Trehanpati, Hissar, Shrivastav & Sarin 2013:700–710).

Despite the availability of a vaccine to prevent HBV infection, in Ethiopia, the pooled prevalence of HBV infection among pregnant women was estimated at 4.7% (Kebede et al 2018). Although the prevalence of HBV infection in Ethiopia is unacceptably high, Shiferaw et al (2016:3-4) found that attention given to its prevention among pregnant women within the national policy is lacking. Also, there are no appropriate strategies for the prevention of HBV infection in the Ethiopian health care system. Studies have also revealed that awareness about the magnitude of HBV infection, its prevention, and treatment among key stakeholders including policymakers, managers of health programs, health care providers, communities, and local and international development partners is low. Yet, the prevention of HBV infection requires a high degree of attention by those key stakeholders to develop an organized and adequately resourced response with well-articulated policies and effective strategies. However, there have been no sufficient actions to prevent infections of hepatitis B virus among pregnant women (WHO 2015).

This study was conducted in Tigray regional state, northern Ethiopia. Araya et al (2018:507) found that the prevalence of HBV among pregnant women in the Tigray regional state was 5.5%. As indicated above, Kebede et al (2018:761) estimated the pooled prevalence of HBV infection among pregnant women in Ethiopia to be 4.7%. This shows that the prevalence of HBV infection among pregnant women in Tigray regional state is relatively higher than the national prevalence. The reason for the relatively higher prevalence of HBV infection among pregnant women in Tigray regional state is not well understood, making the regional state an important study site for the current study.

Several studies have been conducted in Ethiopia to determine the prevalence of HBV among the general population and pregnant women as well as to identify the risk factors associated with infection (Belyhun et al 2016:761; Chernet et al 2017:418; Deme et al 2016:1032–1039; Desalegn et al 2016:16; Kebede et al 2018:322; Umare et al 2016; Yohanes et al 2016). However, there is limited information on effective strategies for the prevention of HBV infection transmission among pregnant women. Although knowledge of the perceptions and views of pregnant women and healthcare workers on the factors influencing the prevention of HBV infection among Ethiopian pregnant women is critical in designing and developing strategies for the prevention of HBV, it is not well understood. Evidence related to the programmatic, health system, and socio-cultural factors challenging the HBV infection prevention measures among pregnant women in Ethiopia is also lacking.

Therefore, the main objective of this study was to explore the views and perceptions of pregnant women attending- and healthcare workers providing- antenatal care services on the factors influencing prevention of HBV infection among pregnant women and develop strategies to promote the prevention of HBV infection among pregnant women in Ethiopia. This study will contribute to HBV infection elimination efforts of the Ethiopian Ministry of Health and partners mainly WHO by 2030. The results of this study also provided evidence-based recommendations for HBV infection prevention among pregnant women in settings that are similar to Ethiopia.

1.3 Purpose of the Study

The purpose of this study was to develop and validate strategies to promote the prevention of hepatitis B virus infection among pregnant women in Ethiopia. The strategies may help to promote the prevention of HBV infection among the general population and among pregnant women in similar settings.

1.4 Research Objectives

- To explore best practices in the prevention of hepatitis B virus infection among pregnant women.
- To explore perceptions and views of pregnant women regarding factors influencing the prevention of hepatitis B virus infection among pregnant women in Ethiopia.
- To explore perceptions of healthcare workers regarding factors influencing the prevention of hepatitis B virus infection among pregnant women in Ethiopia.
- To develop and validate strategies to promote the prevention of hepatitis B virus infection among pregnant women in Ethiopia.

1.5 Research Questions/Hypothesis

- What are the best practices in the prevention of hepatitis B virus infection among pregnant women?
- What are the perceptions and views of pregnant women regarding the factors influencing the prevention of hepatitis B virus infection among pregnant women in Ethiopia?
- What are the perceptions of healthcare workers regarding the factors influencing the prevention of hepatitis B virus infection among pregnant women in Ethiopia?
- What are the strategies that promote the prevention of hepatitis B virus infection among pregnant women in Ethiopia?
- How can those strategies be validated to assess their feasibility, acceptability, and practicability in the study area and other similar settings?

1.6 Significance of the Study

The significance of a study, which is also called the contribution of a study, is defined as the relevance of the research or the importance of the results of the study for various audiences or population groups that may benefit from the findings and recommendations of the study (Creswell 2014:249).

The global HBV prevalence at 3.5% as well as regional prevalence ranging from 5%-10% among the general population still remains high (Howell et al 2014:381-396, Choisy et al 2017:1-5, WHO 2017, Cowie et al 2013:953–954). The HBV infection rate among pregnant women in Ethiopia has also been reported high, which ranges from 2.3% to 7.8% (Choisy et al 2017:1-5, Kebede et al 2018:322; Molla et al 2015:204; Yohanes et al 2016:7; Umare et al 2016; Chernet et al 2017:418; Zenebe et al 2014:118). Several studies and reports from agencies, associations and groups have called for an organized global response with well-articulated policies and strategies to mitigate this high rate of infection (WHO 2016; Shiferaw et al 2016:3-4). The World Health Organization (WHO 2015) has proposed member states to develop a

comprehensive approach and effective strategies to guide viral hepatitis response activities. However, to date even though HBV is well recognized as a public health problem, the attention given to it by the Ethiopia Ministry of Health and its developmental partners is low, and the response to the infections in Ethiopia is limited and there are no tools, and systems necessary for an effective response at all levels of the Ethiopian healthcare system (Shiferaw et al 2016:769). Even though few qualitative studies conducted in SSA have highlighted the challenges faced by healthcare workers on HBV prevention activities, there are limited recent studies documenting the challenges and factors influencing the HBV prevention measures among pregnant women in Ethiopia. Similarly, there were no previous detail qualitative studies on perceptions and views of healthcare workers, clinicians working in ANC clinics and also the views and perceptions of pregnant women on the facilitators and barriers to HBV prevention measures in halting Hepatitis B virus infection in Ethiopia are not understood. The availability of the information on best practice to prevent hepatitis B in Ethiopia is also suboptimal.

For that reason, there are two primary driving forces to conduct this study in the area of HBV prevention measures among pregnant women. First, even though WHO targeted HBV elimination by 2030 (WHO 2016:22), the rate of infection among the general population and among pregnant women is still high (Molla et al 2015:204; Yohanes et al 2016:7; Umare et al 2016; Chernet et al 2017:418; Zenebe et al 2014:118). Second, there are limited studies on the factors influencing HBV infection prevention measures among pregnant women in the Ethiopian healthcare system.

This study therefore has the following contributions to: the health care system, policymakers, healthcare service providers, and the general public as well as to pregnant women to make choices or decisions based on well-articulated evidence. First, the study explored and documented the best practices on HBV infection prevention among pregnant women in resource limited settings. Second, the factors influencing HBV infection prevention measures in Ethiopia were explored from the healthcare workers' and pregnant women's perspectives. Third, the findings of this study will critically support for policy formulation; and used to develop strategies which could promote the HBV infection prevention measures. The findings would also help to: set priorities and improve health service delivery of Hepatitis B infection in the Ethiopian health care system.

Strategies have also been developed to integrate effective interventions that include comprehensive guidance, information and awareness-raising to prevent the HBV infection transmission to the newborns and family, and to integrate into existing maternal, reproductive and child health services and social welfare in the country, as well as, in other similar countries in the African region.

The strategies will contribute the WHO and Ethiopia Ministry of Health efforts in eliminating the HBV infection by 2030. Finally, it may also provide as baseline information for further robust follow-up studies.

1.7 Definition of Key Concepts

Prevention: The WHO (2019) defines prevention of infections and injuries at three levels: primary, secondary, and tertiary prevention. Primary prevention is an intervention designed to

prevent the occurrence of disease or injury and promote health. Secondary prevention is an intervention based on the earliest possible identification of disease so that it can be more readily treated or managed, and adverse sequela can be prevented. Tertiary prevention is an intervention concerned with the promotion of independent function and prevention of further disease-related deterioration (WHO 2019).

In the current study, the definition of prevention involved all three levels. That is, interventions geared towards preventing the occurrence of HBV and stop transmission of infection among pregnant women through strategies such as vaccination and promoting health as well as the early identification and prompt treatment of those who are already infected with hepatitis B virus infection to prevent adverse effects of the disease. The definition of prevention in this study also included the promotion of independent function and prevention of further hepatitis B disease-related deterioration.

Gaps in health service delivery: The gaps in health service delivery has been defined as disparities in healthcare access, health care needs, and medical care and treatment services provided in communities or population groups when comparing different populations that fall along with racial, ethnic, or socioeconomic lines or in different settings (Riley 2012:167-174). In this study, gaps are defined as the discrepancy between recommended best practices and health care services that are provided in the study settings.

Strategy: Sachin (2012) defines strategy as a “unique set of activities and operating structures that an organization puts in place to deliver value to its customers” (Sachin 2012). Borrowing from Sachin’s definition of strategy, strategy in the current study is defined as activities and standard operating procedures that the Ministry of Health or any other agency with legal authority puts in place to prevent HBV infection among pregnant women.

Pregnancy: Pregnancy is defined as the period from conception to the birth after the egg is fertilized and then implanted in the lining of the uterus (William & Sheil 2018). In this study, pregnancy is referred to as a woman who is in a state of carrying one or more embryo or fetus in her uterus, confirmed by positive pregnancy test results in a urine test, blood test or ultrasound detection of a fetal heartbeat.

Hepatitis B Virus: Harrison (2015:298-299) defines HBV as one of the hepadnaviruses (hepatotropic DNA viruses’ family) with a remarkably compact genomic structure. Dienstag (2018) also defines HBV as a double-stranded circular deoxyribonucleic acid (DNA) genome virus within the family of Hepadnaviridae. Harrison (2015)’s definition of HBV will be adopted in this current study.

Practice: This refers to how communities or group of people demonstrate their knowledge and attitude through their actions (Riley 2012:167-174). In this study, practice is operationally defined as the actual practice of the respondents in the prevention of the HBV infection.

Vertical transmission: This is the transmission of an infection caused by pathogens directly from the mother to an embryo, fetus, or baby during pregnancy via placenta or during childbirth. Vertical transmission of HBV is defined as positivity at 6–12 months of life of the hepatitis B surface antigen (HBsAg) or HBV-

DNA in an infant born to an infected mother (Borgia, Carleo, Gaeta & Gentile 2012:4677). In this current study, vertical transmission is the transmission of the HBV from a hepatitis B positive pregnant woman to her child during pregnancy via the placenta or labour.

Mother To Child Transmission: WHO (2015) defines mother to child transmission of Human Immunodeficiency Virus (HIV) infection, an infection similar to hepatitis B virus infection, as “transmission of the virus from infected mother to her child during pregnancy, labour, delivery or breastfeeding is called mother-to-child transmission” (WHO 2015:5). Borgia et al (2012:4677-4678) also define vertical transmission of HBV as “positivity at 6–12 months of life of the hepatitis B surface antigen (HBsAg) or of HBV-DNA in an infant born to an infected mother”. This current study defined mother to child transmission as the transmission of the hepatitis B virus from a hepatitis B positive pregnant woman to the fetus during pregnancy or to the infant at birth.

Vaccination: The US Centres for Disease Control and Prevention (CDC) defines vaccination as “the process of getting a vaccine into the body or the act of introducing a vaccine into the body to produce immunity to a specific disease”. CDC also defines vaccination as a procedure in which the system is exposed to an antigen, such as viruses, bacteria, inactivated toxin, or attenuated pathogen to elicit antigen-specific antibodies. Vaccination, in this study, is the administration of the hepatitis B vaccine to help the immune system develop protection from hepatitis B viral diseases.

Perception: Perception is defined by numerous disciplines in many ways and its interdisciplinary concept is complex. Wikipedia (2008) defines perception as the process of attaining awareness or understanding of sensory information. The Collins Essential English Dictionary (2006) describes perception as: “1. insight or intuition 2. Way of viewing.” Merriam-Webster (n.d.b) also defines perception as an individual’s view making it a powerful driving force for action”.

In this study, the concept ‘perception’ is defined as the study participants’ recognition, perception, and interpretation of the information about HBV prevention measures among pregnant women in Ethiopia, and the information that influences their practice in the HBV prevention measures among pregnant women.

Views: Merriam-Webster defines views as “(1. extent or range of vision, 2 the act of seeing or examining, opinion or judgment colored by the feeling or bias of its holder”.

The operational definition of ‘views’ in this current study is the opinion and belief of the study participants on the factors that influence the prevention of HBV infection among pregnant women in Ethiopia.

Healthcare workers: WHO (2006:4) defines health care workers as “all people engaged in actions whose primary intent is to enhance health”. Health workers are also defined as “all people engaged in the promotion, protection or improvement of the health of the population” (Poz, Kinfu, Dräger & Kunjumen 2007:4). In this study midwives and obstetricians engaged in antenatal care (ANC) and maternal and child health care as well as maternal delivery services were considered as healthcare workers and were included in this study.

1.8 Theoretical Foundations of the Study

This study has been constructed based on the philosophical concept of research paradigm and theoretical framework. Thus, constructivist paradigm has been used to organize the concept of this qualitative research as well as the socio-ecological model (SEM) (Bronfenbrenner 1986:513-531) was adapted and used to drive the study.

1.8.1 Research Paradigm

Research paradigms are philosophical ideas or a set of beliefs that a researcher brings to a study (Creswell 2014:35). Because research paradigms influence the practice of the research, researchers need to identify their paradigms during the planning phase of a research study (Creswell 2014:35). Creswell (2014:35) indicates four main types of research paradigms including post-positivism, transformative, pragmatism and constructivism.

Post-positivism: In this research paradigm, researchers generate knowledge or build to a theory based on cause-and-effect relationships of variables (independent and dependent variables). They believe that there is a truth that should be discovered through scientific methods of a study. Positivists measured independent and dependent variables objectively, and therefore they are used in quantitative methods such as experimental studies (Creswell 2014:36; Hennink 2011:14).

Transformative: This is another research paradigm which focuses on individuals or societies who are marginalized and holds an agenda needs to reform the lives of the participants, the institutions where the participants live or works and the researchers' life (Creswell 2014:38).

Pragmatism: This is another paradigm based on the principle that reality is constantly debated, interpreted, and therefore the best method to use is the one that solves the problem. In this paradigm, researchers focus on the research problem, instead of the methods, and use all approaches to completely understand and explore the problem. Therefore, researchers collect both quantitative and qualitative data to provide the best knowledge about the problem under study (Creswell 2014:38-40).

Researchers use one of the research paradigms to use as a guideline for developing a research methodology that is most valid and appropriate to answer the problem under study.

Constructivism: The constructivism paradigm defined by Brawn and Clarke (2013:29) as knowledge is perspectival, meaning that a singular absolute truth is impossible, guided this study. Because constructivists rely on the participants' views of the problem being studied, they are more likely to use qualitative methods to get those multiple realities, and researchers in this paradigm use open-ended questions to understand the participant's experience (Creswell 2014:37-38). Therefore, this study used qualitative studies to explore the views and perceptions of the participants regarding the prevention measures of HBV infection among pregnant women in Ethiopia. Qualitative methods are appropriate to explore best practices on HBV prevention measures as few empirical studies have been conducted in Ethiopia to date. To address the objectives of this study, a qualitative study was used to explore, describe and contextualise perceptions and views of healthcare workers and pregnant women regarding HBV infection prevention among pregnant women in Ethiopia.

1.8.2 Theoretical framework

Different scholars have given various definitions of theories. Creswell (2014:86) defines theory, as "an interrelated set of constructs or variables formed into propositions, or hypothesis that specify the relationship among variables". In qualitative research, theories are used in studies in several ways such as in a broad explanation for behavior and attitudes (Creswell 2014:98).

The socio-ecological model

The socio-ecological model (SEM) (Bronfenbrenner 1986:513-531) was employed in this study to understand factors influencing the prevention of HBV infection among pregnant women in Tigray regional state, Ethiopia. The SEM emphasizes interdependence and interaction of five factors across all levels of the environment as well as individual to influence a health problem (Bronfenbrenner 1986:513-519). These factors are as follows:

- 1) Individual-level factors, which include knowledge, attitude, and beliefs
- 2) Interpersonal (such as those close proximity to the individual such as immediate family)
- 3) Organisational (environment, ethos)
- 4) Community (such as local health facilities, transport, church) and
- 5) Public policy (the wider population such as policy and strategy surrounding system-level influences).

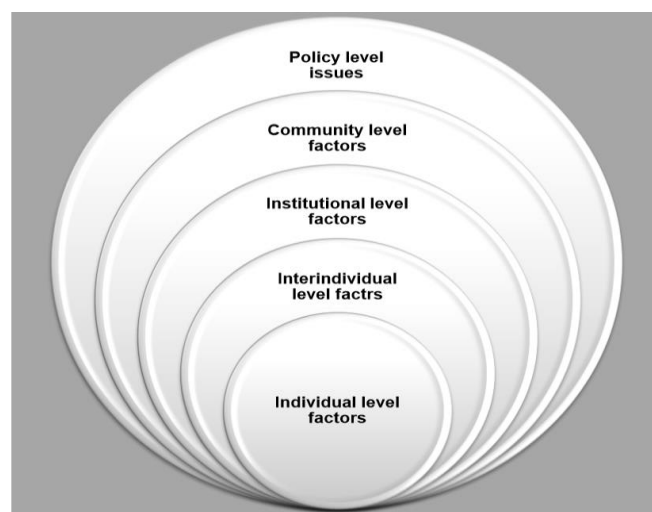


Figure 1. Five level socioecological model (Adapted from Baral et al 2013; McLeroy et al 1988).

As depicted in Figure 1 above, the SEM, unlike many individual behaviour-based models, identifies a multitude of individual and environmental factors and their interactions to influence health behaviours (McLeroy, Bibeau, Steckler & Glanz 1988:351-377) and health outcomes (Sallis, Owen & Fisher 2008:465-486). Although no single theory is sufficient to fit the findings of existing theory in a study, the SEM, which categorises factors influencing health behaviours into those related to the individual, inter-individual, institutional, community, and policy, is used to fit the finding of this study into the existing literature as other studies that have investigated factors affecting the perception of prevention of hepatitis B virus to fall into the same categories (Yang, Ding, Cui, Wu, Yu, Chen, Xu, Deng, Li, Liu & Yin 2017). Other researchers

have also used the SEM to investigate factors that influence the prevention of human immunodeficiency virus (HIV) infection (Baral, Logie, Grosso, Wirtz & Beyrer 2013:2-8). The SEM has been used to examine and understand various health conditions such as cervical cancer prevention (Daly & Carnwell 2001: 57-63). Chimphamba et al (2012), also employed the SEM to identify barriers to sexual and reproductive health utilisation, which has similar characteristics to HBV service utilization.

The SEM provides a broader view and understanding of broad social, environmental, and contextual factors that influence the effectiveness of prevention of HBV infection among women in Ethiopia. Literature has revealed that gaps in the prevention of hepatitis B virus transmission can be categorised into five categories including those related to individual pregnant woman, interpersonal relations, organisation, community, and public policy (McLeroy et al 1988:351-377).

Individual-level factors: Studies have identified gaps in the prevention of HBV infection among pregnant women related to individual pregnant women and health care providers. Such factors have included their socio-demographics, medical history and past health behaviour of pregnant women, and knowledge, attitude, practice, health beliefs, perceptions, barriers and support, communication with health care providers of pregnant women (Yaseen, Aziz, & Aftab 2014; Rosmawati, Wen, Zainol & Wong 2012; McLeroy et al 1988).

Inter-personal level factors: These factors resemble formal and informal networks such as families, friends, neighbours, and colleagues (Frew, Alhanti, Vo-Green, Zhang, Liu, Nguyen, Schamel, Saint-Victor & Nguyen 2014). This level can affect the level of knowledge, attitude, and practice on the prevention of HBV infection among pregnant women.

Institutional level factors: Factors such as antenatal, delivery, and postnatal care, quality, and availability of diagnostic laboratory infrastructure, hepatitis-related administrative structure, and communication mechanisms can influence the health-seeking behaviour of pregnant women. The health staff knowledge, skill, and attitude also are included under this level (Frew et al 2014; Katamba, Mukunya, Kwesiga, & Nankabirwa 2019).

Community-level factors: These includes social networks, such as schools, churches, neighbours, friends, Social norms and support, Cultural factors and beliefs (Frew et al 2014; Yaseen et al 2014). This can influence pregnant mothers' knowledge, attitude and practice through raising or reducing their knowledge or attitude in seeking behaviour of the HBV infection.

Social policy level factors:

These factors include the national, regional, district, and local policies and their implementations and interpretations concerning the prevention of HBV infection among pregnant women (Katamba et al 2019; Bhate, Saraf, Parikh, Ingle, Phadk & Sawant 2015). This level can affect both the knowledge, attitude, and practice of pregnant women and health care providers.

1.9 Research Methodology

Research approach

A research design is a conceptual structure within which research is conducted. It constitutes the blueprint for the collection,

measurement, and analysis of data (Creswell 2014:273). The approach and design employed in this study were applied in three phases, namely: Phase 1: Integrative literature review; Phase 2: Qualitative exploratory descriptive contextual design; Phase 3: Development and validation of strategies. The phases are described and applied as follows:

Phase 1: Integrative literature review: Exploration of best practices in the prevention of HBV infection among pregnant women

An integrative literature review was conducted to explore the best practices in the prevention of HBV infections among pregnant women. According to Soares, Komura, Peduzzi, Sangaleti, Yonekura and Silva (2014:329-339), an integrative literature review summarises past empirical or theoretical literature to provide a more comprehensive understanding of a specific phenomenon (Soares et al 2014:329-339). An integrative literature review also evaluates the strength of the existing scientific evidence (Russell 2005:8-13). Well-done integrative reviews present the state of the science, contribute to theory development, and have direct applicability to practice and policy (Soares et al 2014:329-339; Whittemore & Knafl 2005:548-551).

This current study employed an integrative literature review because integrative review allows for a combination of various research methodologies and different forms of synthesis to generate new knowledge (Whittemore & Knafl, 2005:548-551). The following five steps of an integrative review proposed by Whittemore and Knafl (2005:548-551) were applied in conducting this integrative review of the current study. The five steps are: 1) problem identification, 2) literature search, 3) evaluation of data, 4) data analysis, and 5) interpretation and presentation of the results (Whittemore & Knafl 2005:548-551). These five steps are further explained in Chapter three.

Phase 2: Qualitative exploratory descriptive contextual design

In the second phase of this study, a qualitative exploratory descriptive contextual design was employed. This design is described as follows:

A qualitative research approach will be employed to explore a more in-depth understanding of the views and perceptions of pregnant women and healthcare workers on HBV prevention measures among pregnant women. A qualitative study focuses on human experiences, meaning, and understanding from the research participants' point of view in the context in which the action takes place (Creswell 2009:175; Creswell 2014:234; Grove, Gray & Burns 2015:67). Pregnant women and health care workers were interviewed to better understand their views and perceptions regarding factors influencing the prevention of HBV infection among pregnant women in Ethiopia.

Exploratory design aims at increasing the knowledge of the study (Ponelis 2015:535-550). The researcher probed to gather in-depth data from pregnant women and health care workers regarding their views and perceptions on factors influencing the prevention of HBV infection among pregnant women in Tigray regional state, Ethiopia.

Descriptive design is where more information is required in a certain field through the provision of a picture of the phenomenon as it naturally occurs (Grove et al 2015:502). In this research, more data was obtained from pregnant women and healthcare

workers regarding their perceptions on factors influencing the prevention of HBV infection among pregnant women in Tigray regional state, Ethiopia.

Contextual: Qualitative researches should be conducted in the natural setting of the study participants without disturbing the natural context of the phenomena under investigation Creswell (2014:235-240). Participants in this type of research usually provide information honestly and freely because it is conducted in their natural site under no form of manipulation (Creswell 2013; Creswell 2014:236). This current research was contextual, in nature, because the data was collected in the four healthcare facilities in Tigray regional state, Ethiopia. This phase is further explained in Chapter 3.

Phase 3 Development and validation of strategies

The third phase of this study addresses objective 4, which is to develop and validate strategies to promote the prevention of hepatitis B virus infection among pregnant women in Ethiopia. Strategy development is the process of researching and identifying strategic options, selecting the most promising, and deciding how resources will be allocated across the organisation to achieve objectives (Hill, Charles, Jones & Gareth 2012:21). The current researcher formulated the draft of the strategies. The formulation of the strategies was developed:

- based on the findings of the integrative review of evidence base best practices in preventing HBV infection among pregnant women, phase one of the current study
- based on the findings from the interviews with pregnant women and healthcare workers to seek their views and perceptions on prevention of HBV infection among pregnant women, phase of the current study. The findings were described and presented to indicate significance. Categories of views and perceptions of the study participants on factors influencing HBV infection prevention measures have been indicated.
- by the researcher supported by the supervisors, with input from pregnant women and health professional groups
- using a transparent process and methods
- subject to a consultation with stakeholders

As already discussed, this study was conducted in three phases. Phase 1 involved an integrative literature review to identify best practices for preventing HBV infection among pregnant women. Phase 2 involved interviews with pregnant women and healthcare workers to learn their views and perceptions of HBV prevention services. Phase 3 involved developing and validating strategies to promote the prevention of HBV infection among pregnant women.

The results of phases 1 and 2 informed the development of strategies for preventing HBV infection among pregnant women. The research approach for developing strategies involved the use of the SWOT analysis framework. The draft strategies were validated using consultative meeting with stakeholders including pregnant women, healthcare workers (midwives and obstetricians), and other stakeholders such as policymakers, program managers, and members of the medical and midwifery regulatory councils. The process of strategies development and validation including the SWOT analysis and consultative meetings with stakeholders as used in this study are described in detail in Chapter 3.

1.9.1 Ethical considerations

According to Akaranga and Ongong'a (2013:8), ethics refers to a way of life and social norms for conduct that differentiates between acceptable and unacceptable behaviour. Creswell (2014:290) has also defined a code of ethics as the ethical rules and principles that scholar researches follow in their area of discipline. The investigators complied the ethical principles throughout the study, following the principle of beneficence, respect for human dignity and justice (Brink et al 2018:28; Geoffrey, David & David 2005:23). The investigators followed the following ethical principles in the study: Autonomy, beneficence and non-maleficence and justice.

The Tigray Regional Health Bureau and the directors of the four selected healthcare facilities issued permission on request to interview participants before the commencement of data collection for cooperation, and successful data collection purposes.

1.10 Scope and Limitation of the Study

The study explored and described the best practices of HBV infection prevention among pregnant women. This study also explored the views and perceptions of healthcare workers working in ANC clinics and pregnant women attending ANC services in the selected healthcare facilities on factors influencing HBV infection prevention. Based on these findings, strategies to promote the prevention of HBV infection among pregnant women were developed. Those strategies will contribute to the World Health Organization's target of HBV elimination by 2030.

Regarding the limitation of this study, some of the collected data were based on pregnant women and healthcare workers' views and perspectives on the factors influencing HBV infection prevention measures, which is subject to social desirability bias, whereby the study participants might report the most desirable answers about the factors influencing HBV infection prevention measures.

1.11 Thesis Structure

The sections and sub-sections of this thesis are organized in six chapters. The flow and illustrated descriptions of each of these chapters are given below.

Chapter-1: Study orientation: This chapter provides introduction to the study and research problem, the purpose, objectives and research questions of the study and overall provides background information. The chapter also highlights the main concepts and operational definitions, methodology, theory, ethical considerations as well as scope and limitation of the study.

Chapter-2: Literature review: This chapter provides the literature review. It briefly describes the importance of literature review, literature search strategy, appraisal of identifying literature and themes that emerged from the literature reviewed. The chapter presents the magnitude of HBV infection among the general population and pregnant women globally, regionally and in Ethiopia. Literatures on mode of transmission and infection prevention measures are also highlighted in the study. The views and perceptions of pregnant women on factors influencing HBV infection prevention measures have been also highlighted in this chapter. Similarly, the views and perceptions of health care workers on HBV infection prevention have been documented in this chapter. The last section, limitation of the existing literature

while highlighting the gaps in the existing literature is documented properly.

Chapter-3: Research methodology: This study was conducted in three phases and this chapter provides detailed information regarding the methodology for each phase. In phase one and two, detailed information regarding research approach, study design, and methodology of the study are provided accordingly. Moreover, this chapter presents a description of the study site, sample and sampling method; data collection method, data management and statistical analysis for each phase. Measures taken to ensure rigour and trustworthiness as well as ethical issues are also described in this chapter. Simultaneously, a detailed description of the process followed for strategies development in phase three is presented in detail.

Chapter 4: Analysis, interpretation, presentation, and discussion of research findings

The analysis, interpretation, presentation, and discussion of the research findings have been described in detailed in this chapter. The chapter also presented the steps taken to conduct qualitative data analysis and to develop strategies to promote HBV prevention. The discussion of the research finding, which focused on the factors influencing HBV infection prevention and on the best practices to prevent HBV infection are included in this chapter.

Chapter-5: Development and validation of strategies to promote HBV prevention. This chapter will present the strategies

developed based on the findings of this study. In this chapter, development of strategies, model assumptions, strategies validation process and validation findings were discussed and synthesized properly.

Chapter-6: Conclusions, limitations, and recommendations. In this chapter, the conclusions of the main research findings are summarized and presented in relation to the research objectives. Brief contribution and limitations of the study have been documented precisely. Key recommendations for policy makers, program managers and researchers drawn from the study are also included in this chapter.

1.12 Conclusion

Overall, this chapter provides the background of the study, the problem statement, the concepts definition, the purpose of the study, objectives and research questions. The theoretical and conceptual foundation of the study, an overview of the research methodology, ethical issues and scope of the study are also discussed and documented briefly in this chapter. The literature review on the factors influencing the prevention of HBV infection among pregnant women and also on the views and perceptions of pregnant women and healthcare workers on factors influencing HBV infection prevention among pregnant women is described in chapter two of this study.

CHAPTER TWO

2. Literature Review

2.1 Conclusion

A literature review is defined as a critical analysis of a segment of a published body of knowledge through classification, comparison, and summary of prior research studies and theoretical articles (Levy & Ellis 2006: 181-212; Ramdhani, Ramdhani & Amin 2014:47-56). The goal of a literature review is to bring the reader up to date with current literature on a specific topic and form the basis for future research justification in the area. A good literature review gathers information for specific subject areas from different sources. It should contain a clear search and selection strategy to form a good structure and enhanced flow and readability of the review (Carnwell & Daly 2001:57-63; Colling 2003:297-299; Cronin, Ryan & Coughlan 2008:38-43). In this study, a literature review has been conducted on prior studies focussing on prevalence, prevention, knowledge, attitude, practice on HBV among pregnant mothers. A further integrative literature review will also be conducted to explore best practices in hepatitis B virus management among pregnant women.

2.2 Prevalence of Hepatitis B Virus Infection

In 2015, the global prevalence of HBV infection in the general population was 3.5% (WHO 2015). The WHO (2015) estimated that between 5% and 10% of the adult population in SSA and East Asia were chronically infected with HBV (WHO 2015). A modelling study for data from 120 countries conducted in 2016 estimated the global prevalence of HBsAg at 3.9% (Razavi, Gamkrelidze, Nguyen, Chen, Van, Abbas, Abdulla, Abou, Adda,

Aho & Akarca 2018:383-403). Studies have shown that about 60% of Africans are exposed to HBV infection across their lifetime and 8% have an active infection at any point in time (Howell, Lemoine & Thursz 2014:381-396). It is estimated that in SSA, HBV infections account for 87890 deaths annually (WHO 2017). In Ethiopia, HBV infection is endemic with 7.4% of prevalence among the general population (Belyhun et al 2016:761).

Different studies indicated that the risk of vertical transmission is much higher than the horizontal transmission where the rate of chronicity is 30– 50% when infected before 6 years of age and <5% when infected in adulthood (Gambarin-Gelwan 2007:945-963; Lai, Ratziu, Yuen & Poynard 2003: 2089–2094; Gentile & Borgia 2014: 605). Even though there is improved childhood vaccination against HBV worldwide, MTCT still accounts for about 50% and one-third of new infections in high endemic countries and low endemic countries respectively (Giles, Grace, Tai, Michalak & Walker 2013:231-235; Xu, Liu, Wang, Hao, Li & Song 2013; Thio, Guo, Xie, Nelson & Ehrhardt 2015:981-985; Vodkin & Patton 2014:205-214). Therefore, preventing HBV infection among pregnant women is a crucial element for decreasing the prevalence and improve the elimination of HBV.

2.3 The Transmission, Prevention, and Control of Hepatitis B Virus Infection

Mother to child transmission is a major mode of transmission of HBV infection, worldwide (WHO 2015). The WHO (2015) has stated that around 90% of infants infected with HBV progress to chronic disease. In high and intermediate endemic areas, perinatal and early childhood transmissions are the main routes of HBV

(WHO 2009: 405-419). More than one-third of chronic cases of HBV infections subside due to early transmission of HBV via MTCT (Keane, Funk & Shimakawa 2016:1005-1017). Without any prophylaxis, women who are infected with HBV are likely to transmit the virus to their offspring at the time of delivery (Chang 2007:160–167). A study conducted in Ethiopia in 2012 showed that about 75% of newborns to HBV -infected women were positive with hepatitis B surface antigen (HBsAg) (Tegegne et al 2014:239).

2.4 Knowledge, Attitude, and Practice of Hepatitis B Virus Infection

Knowledge, attitude, and practice are among the various factors that influence the prevention of HBV infection (Frew et al. 2014). A study in Bangladesh outpatient clinics revealed that only 20% of pregnant women knew about HBV mode of transmission (Rahman & Mannan 2010:29-31). However, 50% of women had various misconceptions regarding the HBV mode of transmission (Rahman & Mannan 2010:29-31). Another study conducted in India found that about 42% of the participants were aware of HBV (Swetha & Srinivas 2019:3183-3188). However, only 33.3% were aware that HBV is transmitted by unprotected sex and 8.2% were knowledgeable of MTCT routes. Most of the pregnant women feared stigma associated with HBV than its health consequences (Swetha & Srinivas 2019:3183-3188). The study also found that of the 350 participants, 70% would vaccinate their children to prevent HBV. Women with greater knowledge about HBV had a better attitude and practice towards the prevention of the infection (Swetha & Srinivas 2019:3183-3188).

A study conducted in Saudi Arabia in 2017 among 890 healthy population found that 76.9% of them knew that hepatitis B affects the liver, but only 34% of them believed that it can cause liver cancer (Wedhaya, Abyadh, Alhabbi, Alrehaily, Kurban, Alzahrani, Alshamrani, Alqahtani, Mansi & Mofareh 2017). The same study indicated that 52.8% of participants had good knowledge about symptoms of HBV and 63% of them were aware that HBV is transmitted through unsafe sex.

An intervention trial in the United States of America (USA), which involved Vietnamese, Hmong, Korean- and Cambodian-Americans found that awareness of HBV infection transmission varied considerably, from 45% to 79% (Maxwell et al 2012:1687-1692). Additionally, the majority of them correctly identified sharing needles and childbirth as transmission channels for HBV infection (Maxwell et al 2012:1687-1692). However, the same study found that a significant number of participants incorrectly thought that HBV could be transmitted by coughing, sneezing, or sharing food, drink, or eating utensils (Maxwell et al 2012:1687-1692).

In Guangdong China, 53.3% of pregnant women did not know that HBV can be transmitted through unprotected sexual intercourse and nearly 20% were unaware of MTCT (Han et al 2017:4). In this study, 83% of women were willing to be screened for HBV and 85% were willing to allow vaccination of their babies. However, only 16.5% of participants were willing to take HBV drugs that are known not to harm the fetus (Han et al 2017:4).

In India, Swetha and Srinivas (2019:3183-3188) found about 84% hesitated to have casual contact with HBV infected persons. Regarding practice, a study from Bangladesh in 2010 evidenced that 4% of women, 30% of children up to 5 years, and 15% of

children above 5 years were fully immunized with hepatitis B vaccine (Rahman & Mannan 2010:29-31). Similarly, 30% of pregnant women insisted on healthcare providers using safe equipment and blood products which reduced the risk of transmission. Women with greater knowledge about HBV had better practice towards its prevention (Swetha & Srinivas 2019:3183-3188). A study conducted in Nigeria among 108 health care workers found that 17.6% of them felt at risk of contracting HBV at their workplace (Fufore, Cook & Kirfi 2015).

2.5 Views and Perceptions of Pregnant Women on Factors Influencing Hbv Infection Prevention

Several studies conducted in SSA countries indicated that HBV prevention efforts among pregnant women are hampered by several barriers mainly: a) low awareness and knowledge of the public including pregnant women about HBV and its prevention (Abdulai, Baiden, Adjei & Owusu-Agyei 2016:157–162, Ngaira, Kimotho, Mirigi & Osman 2016:315). b) Health systems are not well prepared to provide antenatal screening, treatment and prevention services of HBV since HBV services are accessible only in a few urban healthcare settings and are not affordable. Moreover, lack of community and peer support, structural and financial barriers significantly make uptake of HBV prevention measures challenging (Ma, Fang, Shive, Toubbeh, Tan & Siu. 2007:213; Bond & Nolan 2011:943). c) Insufficient information about pregnant women's beliefs, perceptions and behavioural intentions in relation to HBV risk and prevention. Brandon and Proctor (2010:590-597 indicates that if inaccurate HBV diseases perceptions are not rectified, it negatively affects behavioural response geared towards HBV prevention in the population.

Different studies carried out in different countries in SSA on HBV awareness among pregnant women showed 70-80% of the participants had poor knowledge and not aware of the infection (Chan et al 2012:1–8, Frambo et al 2014:394, Bassey 2009). A cross-sectional study in Uganda among pregnant women in 2016-2017 also showed about half of all participants perceived their lifetime risk of acquiring HBV and liver cancer and more than 75% of the participants reported low perceived risk of acquiring liver cancer, given HBV infection (Nankya-Mutyoba et al 2019:760). Another cross-sectional study on HBV awareness conducted in Nairobi, Kenya among pregnant women attending ANC on HBV awareness showed only 12.2% of the study participants knew about hepatitis B virus. The same study showed women with limited information were 37.6%, while 50.2% had not heard about HBV infection before interview. Participants that had attained primary and secondary levels of education reported significantly limited awareness on HBV infection (Ngaira 2016:315).

Mkandawire, Richmond, Dixon, Luginaah and Tobias (2013:89–96) reported extremely low levels of knowledge and misconceptions of HBV among pregnant women in the Upper West Region of Ghana. A similar study conducted in Ghana showed there was a low level of knowledge and awareness of HBV among pregnant women attending ANC and the study participants indicated that this could potentially hamper effective HBV prevention and control in Ghana and other similar settings (Abdulai et al 2016:157–162).

A study in south-western Uganda revealed a varied level of awareness of HBV infection among pregnant women. Most of them acquired knowledge on HBV infection through radio.

However, in the same study, a significant number of the participants did not know about HBV infection (Mugisha et al. 2019). Likewise, a significant number of participants reported that they did not know how HBV is transmitted (Mugisha et al 2019).

2.6 Views, Perceptions and Knowledge of Healthcare Workers on Factors Influencing Hbv Infection Prevention

Several studies conducted in Sub-Saharan Africa showed suboptimal overall knowledge of healthcare workers on HBV prevention, care and related work practices (Abdela et al 2016:410, Tatsilong et al 2016:706 and Adjei 2016:537). Healthcare workers in different qualitative studies conducted in low and middle-income countries have reported that factors including cost, lack of availability of rapid diagnostic test in rural healthcare facilities, lack of trained human resources, low educational level of community are the major challenges in the prevention of HBV infection prevention among pregnant women (Chabrol 2019; Giles-Vernick 2016:1368–1375). A study in southwestern Uganda (Mugisha et al. 2019:304) indicated that a lack of diagnostic facilities and limited access to healthcare professionals and medications contribute to the challenges facing HBV prevention, diagnosis, and therapy in the community.

According to a study conducted among healthcare workers in Senegal (Djaogol et al 2019:627), cost of HBV testing for pregnant women, lack of availability of rapid diagnostic tests in primary healthcare posts and difficulties to communicate information about the disease to patients with a low educational level were the three dominant challenges mentioned by the study participants. In the same study physicians indicated that limited human, technical, and financial resources of the community as well as low educational level pose significant challenges to health care workers in HBV prevention and control efforts (Djaogol et al 2019:627). The study participants in the same study also indicated that cold chain problems including power failures diminish vaccine efficacy and also immunization services. In the same study, it was also found majority of the study participants believed that screening pregnant women for HBV is critical to prevent HBV infection among pregnant women and also to prevent mother to child transmission (Djaogol et al 2019:627).

In resource-limited countries, including Ethiopia, some healthcare workers who work in antenatal care clinics declared that they did not actually propose HBV screening for pregnant women, which could negatively influence the progress of the HBV elimination measures. Qualitative interviews of healthcare workers in Senegal, Ghana, Uganda, and Ethiopia showed low level of health care worker's knowledge on HBV and recommended the need of capacity building interventions, including refresher trainings for healthcare workers working at ANC to improve the quality of HBV screening, treatment, and care among pregnant women (Fassil 2016:769; Abdela et al 2016:410; Djaogol et al 2019:627; Mugisha et al 2019:305. According to Djaogol et al (2019:627) healthcare workers who participated in the study indicated that pregnant women with low level of education could not understand the risks and consequences of HBV infection, which makes poor HBV services uptake. The study participants in the same study also indicated that cold chain problems including power failures diminish vaccine efficacy and also immunization services (Djaogol et al 2019:627).

Another study in the south western Uganda (Mugisha et al 2019:305) showed five out of eight healthcare workers reported that HBV is sexually transmitted and can also be transmitted through other exposures to infected body fluids. According to the study participants in the same study, people who consumed alcohol or those who engage in risky sexual behaviors were considered to be at risk of contracting HBV infection (Mugisha et al 2019:305). In the same study, it was also found majority of the study participants believed that screening pregnant women for HBV is critical to prevent HBV infection among pregnant women and also to prevent mother to child transmission (Djaogol et al 2019:627). However, the study indicated only 68% of those who work in antenatal care clinic declared that they had actually proposed HBV screening for pregnant women during the previous month of the study, which could negatively influence the progress of the HBV infection prevention measures. The same study using qualitative interviews showed low level of health care worker's knowledge on HBV. More specifically, the causes of HBV were confused with other risk factors of liver disease such as alcohol or peanut consumption (Djaogol et al 2019:627). The study participants also indicated that pregnant women with low level of education could not understand the risks and consequences of HBV infection, which makes poor HBV services uptake. The study participants also indicated that cold chain problems including power failures diminish vaccine efficacy and also immunization services (Djaogol et al 2019:627).

According to Djaogol et al (2019:627), the same study conducted in Senegal, only 45% of the study participants believed that effective treatment for HBV infection exist and 55% of the study participants perceived that antiviral treatment is effective strategy to reduce vertical transmission of HBV infection. The study participants also acknowledged their limited knowledge and skills in screening, management and care of HBV infected individuals. The study participants also highlighted frequent use of traditional medicine as a first line treatment which delayed linkage to care. They indicated that HBV positive patients only go for hospital consultation after their condition reached at a critical stage and where improvement is almost impossible. According to the study participants, HBV antiviral treatments are not accessible because of high cost and unavailability in most healthcare facilities. They also indicated that HBV treatment services are provided for free to only HIV-HBV co-infected patients and thus people with mono-HBV infection did not have any easy access (Djaogol et al (2019:627).

Nankya-Mutyoba et al. (2019:760) examined factors that influence the community level, providers-related and social networks, as well as individual-level factors influencing HBV infection prevention measures. The study examined factors that influence on HBV screening and vaccination across a range of factors including socio-demographic, psychosocial, provider, access to care, and community issues. The study found that access to care factors including lack of insurance coverage and unavailability of funds to pay for medical treatment, transport to medical services, and price elasticity of HBV screening and vaccination are among the major factors challenging the HBV prevention measures. A study in Burkina Faso highlighted that one of the major barriers to HBV linkage to care is poor knowledge of HBV among healthcare workers (Giles-Vernick, Hejoaka, Sanou, Shimakawa, Bamba & Traore, 2016:1368-1375).

2.7 Conclusion

In summary, most of the studies reviewed knowledge and practice of pregnant women regarding transmission and prevention of HBV. Literatures on views and perceptions of healthcare workers on challenges of HBV infection prevention have been reviewed. Overall, limited knowledge of pregnant women on HBV infection, lack of human and financial resources for HBV screening, treatment, and care as well as structural challenges of the healthcare system are among the factors hindering the HBV

infection prevention measures in low income countries. Even though few qualitative studies conducted in SSA have highlighted the challenges faced by healthcare workers on HBV prevention activities, there are limited recent studies documenting the challenges and factors influencing the HBV prevention measures among pregnant women in Ethiopia. The availability of the information on best practice to prevent HBV among pregnant women in resource limited countries including Ethiopia is also suboptimal.

CHAPTER THREE

3. Research Design and Methods

3.1 Introduction

This chapter describes the research design and the methods used to collect data to answer the research questions related to the objectives of this study. This study employed exploratory, descriptive, contextual, qualitative research design (Grove et al 2014:287). This study was conducted in three phases, namely phase 1, 2, and 3. In phase one, an integrative literature review is conducted to explore the best practices of Hepatitis B virus (HBV) prevention among pregnant women. In phase two, a qualitative research approach was employed to explore a more in-depth understanding of the views and perceptions of pregnant women and healthcare workers on HBV prevention measures among pregnant women. Phase 3 was the development and validation of strategies to promote the prevention of HBV among pregnant women. This chapter also presents the study population, sample size, and sampling techniques as well as data collection methods and procedures and data analysis techniques for the three phases. The research materials (tools) for the data collection are also highlighted in this chapter. The ethical issues that have been considered in conducting this study are also described at the end of this chapter.

3.2 Study Design and Approach

A research design is a conceptual structure within which research is conducted. It constitutes the blueprint for the collection, measurement, and analysis of data (Creswell 2014:273). A research study design includes an outline of what the researcher will do from writing the hypothesis and its operational implications to the final analysis of data (Kothari 2005:31). A research design is a structured approach followed by a researcher to conduct a study in answering a particular research question (Polit and Beck 2010: 254). Researchers decide the methods of their studies based on mainly whether the research goal is attained either by qualitative or quantitative methods or perhaps by using the two together i.e. mixed methods (Ágoston 2016:22). The asset is to weigh between the feasibility to conduct different designs, the available resources and cost to cover implementation, the adequacy and accessibility of respondents in terms of sample size and representativeness and ethical implications (Creswell 2014:49-53; Sudan National Ministry of Health, 2010:7).

Creswell (2014:31) also highlights the following three criteria that researchers should consider in selecting their research design for their studies: The first criterion is the nature of the problem to be

investigated, the second criterion is the personal experience of the researcher and the third one is the audience of the study. This study employed a qualitative explorative descriptive contextual study design.

Qualitative research is one of the research methods used to “explore and understand the meaning that individuals or groups ascribe to a social or human problem” (Creswell (2014:294). Creswell (2014:295) and Creswell (2013:45) also highlight the characteristics of qualitative research such as collecting data at the site (natural setting) where the participants experience the problem, the emergent nature of the research process, gathering multiple sources of data rather than relying on a single source to make sense of it and develop themes, the inductive and deductive nature of data analysis techniques. That is to establish comprehensive patterns and themes from the bottom up (inductive analysis) and look back the data from the themes to check whether the evidence collected can support each theme or if there is a need to collect more data (deductive analysis) and finally making interpretation and conclusion on the meaning of the data (Creswell 2014:287-295).

The design and the approach in this study were applied in three phases, namely: Phase 1: Integrative literature review; Phase 2: Qualitative exploratory descriptive contextual design; Phase 3: Development and validation of strategies. The phases are described and applied as follows:

3.3 Phase 1: Integrative literature review to explore best practices on HBV prevention among pregnant women

3.3.1 Study Design

In phase one of this study, an integrative literature review was conducted to explore the best practices in the prevention of HBV infections among pregnant women. According to Soares, Komura, Peduzzi, Sangaleti, Yonekura and Silva (2014:329-339), an integrative literature review summarises past empirical or theoretical literature to provide a more comprehensive understanding of a specific phenomenon (Soares et al 2014:329-339). An integrative literature review also evaluates the strength of the existing scientific evidence (Russell 2005:8-13). Well-done integrative reviews present the state of the science, contribute to theory development, and have direct applicability to practice and policy (Soares et al 2014:329-339; Whittemore & Knafl 2005:548-551).

This current study employed an integrative literature review because integrative review allows for a combination of various

research methodologies and different forms of synthesis to generate new knowledge (Whittemore & Knafl, 2005:548-551).

3.3.2 Study Setting

The setting for the integrative literature review were studies conducted in low and middle-income countries, focusing on Sub-Saharan African countries. Studies conducted in middle-income countries in the Middle East and Asia regions were also considered for the review.

3.3.3 Study Population

According to Russell (2005:8-18), the study population for an integrative literature review study is “all relevant studies that pertain to the topic”. For this integrative literature review section of this current study, all published primary studies, published or grey policy documents and clinical practice guidelines on the prevention of HBV among pregnant women were the potential study population. All of the studies and policy documents were screened and reviewed based on the eligibility criteria.

3.3.3.1 Eligibility criteria

Inclusion criteria

- Available articles on hepatitis B virus infection prevention or halting transmission among pregnant women in full for free access and be an original peer-reviewed article published in English. There are no potentially published articles in the local language of Amharic and Tigrigna.
- Studies conducted using observational cross-sectional, cohort, case-control study, experimental study designs, systematic and meta-analysis on HBV prevention, and transmission among pregnant women.
- Studies available in PubMed, Web of Science, ERIC, Scopus, EbscoHost databases, Academic Search Ultimate, Africa-Wide Information, CINAHL, Health Source - Consumer Edition, Health Source: Nursing/Academic Edition and MEDLINE.
- Relevant policy documents, grey literature, and guidelines either web-based or not focused on the prevention, halting transmission on HBV among pregnant women were included in the integrated review.

Exclusion criteria

- Studies before 2005 and after 2020 publication date.
- If the data collection period of the study is not reported.
- Articles without full text.
- Studies on best practices/strategies /guidelines on non-pregnant individuals
- Research studies not written in English.

3.3.4 Sample Size Calculation

Russell (2005:8-13) indicates that the sample size in an integrative literature review is determined by the number of primary studies to be reviewed unlike the sample size for primary research where the sample size is determined by the researcher's time and resources. Therefore, the sampling size for this phase of the current study (integrative literature review) was determined based on the existing

primary studies on the research topic. The sample was limited by the exclusion and inclusion criteria after the literature search and screening of the literature (Russell 2005).

3.3.5 Sampling Technique

The sampling strategy was comprehensive computer-assisted search using the keyword of HBV prevention in the searching databases of PubMed, Web of Science, ERIC, Scopus, EbscoHost databases, Academic Search Ultimate, Africa-Wide Information, CINAHL, Health Source - Consumer Edition, Health Source: Nursing/Academic Edition and MEDLINE.

3.3.6 Data Collection, Analysis, And Interpretation

The integrative literature review was conducted to identify best practices in the prevention of HBV among pregnant women. The following five steps of an integrative review proposed by Whittemore and Knafl (2005:548-551) were employed in conducting the integrative review of the current study. The five steps are: 1) problem identification, 2) literature search, 3) evaluation of data, 4) data analysis, and 5) interpretation and presentation of the results (Whittemore & Knafl 2005:548-551). These five steps will be applied in this study as follows:

3.3.6.1 Step 1: Problem identification

Every literature review starts with the identification of the problem (Whittemore & Knafl 2005:548). According to Whittemore and Knafl (2005:548), defining the guiding question is important in determining the studies which will be included and reviewed. The problem identification process also includes the development of conceptual and operational definitions to be examined (Russell 2005:8-13). For this study, the criteria for a clear problem statement including variables, concepts, and the target population were applied (Whittemore & Knafl 2005:548). The primary problem motivating this review was the lack of strategies to prevent HBV infection among pregnant women in Ethiopia. The review question that guided the search is: What are the best practices in the prevention of HBV infection among pregnant women? The purpose of the review in this regard was to explore best practices in the prevention of HBV infection among pregnant women. The review question and conceptualization were reviewed by the study supervisors.

3.3.6.2 Step 2: Literature search

A “well-defined literature search strategy” should be used to enhance the quality of any type of review including an integrative review (Whittemore & Knafl 2005:548). This is because a poorly designed literature search strategy can lead to incomplete and biased search results, which then would finally produce inaccurate study results (Whittemore & Knafl 2005:550). During this stage, the researcher used different search engines to obtain relevant results, including electronic searches, and hand searches. Published articles or guidelines were searched with well-defined literature search strategies for a rigour review. To identify the maximum amount of relevant literature, the researcher collaborated with the librarian for assistance.

The search terms and inclusion and exclusion criteria directed the search in databases used (Whittemore & Knafl, 2005:548-549). The PICOT search string was used for the selection of concepts for literature search, and to guide the inclusion and exclusion criteria (Welty, Hofstettler & Schulte 2012:476). (P) stands for

participants; (I) is for intervention; (C) is comparison; (O) stands outcome, and T is the time interval. In this study, components of PICOT were (P) pregnant women; (I) HBV prevention measures and practice, HBV infection prevention strategies (C) no comparisons were made, (O) improved clinical judgment, clinical outcomes, and (T) 2005-2020. The researcher applied the seven criteria during electronic and documentation search as stipulated by Russell (2005:11) and Whitemore and Knafl (2005:549). These criteria are: 1) Databases searched; 2) Name of host 3) Date searched 4) Years covered by search 5) Complete search strategy 6) One or two sentence summaries of the search strategy and 7) Language restrictions.

For this study, the researcher used the following inclusion criteria: a) studies conducted on best practice, strategies or guidelines for HBV prevention among pregnant women; b) peer-reviewed research articles c) the studies must be published in the English language from 2005-2020, d) qualitative, quantitative, and mixed methods designs, meta-synthesis are acceptable, e) relevant policy documents and grey literature will also be included. No age limit will be imposed on the target population. Exclusion criteria were: 1) studies on best practices, strategies or guidelines on non-pregnant individuals; 2) research studies not written in English c). Published before 2005 or after 2020. The year 2005 has been chosen because this is when a highly potent HBV drug treatment with a low resistance rate became available and since then the development of HBV best practice treatment and care guidelines have started (Abara, Qaseem, Schillie, McMahon & Harris 2017). Studies that did not report the period of data collection were also excluded from the review.

The researcher sought help from the librarian to identify relevant search engines and databases. These included among others: PubMed, Web of Science, ERIC, Scopus, EbscoHost databases, Academic Search Ultimate, Africa-Wide Information, CINAHL, Health Source - Consumer Edition, Health Source: Nursing/Academic Edition, African Index Medicus, African Journals Online (AJOL), WHO Afro Library Database EBSCOhost; CINAHL with full text, ERIC, Healthsource-Consumer Edition, Health Source: Nursing/Academic Edition, Medical Literature Analysis, and Retrieval System on-line with full text (MEDLINE), the World Health Organization Reproductive Health Library (RHL), web pages of Ministries of Health. Search terms including Hepatitis-B Virus, Hepatitis-B virus prevention, Hepatitis B virus infection, prevention, transmission, pregnant women, best practices, evidence-based practices, low-income countries, resource-limited countries, Sub Saharan Africa, were used to search for relevant literature.

Furthermore, a manual scan and review of relevant unpublished documents (grey literature) from Ethiopia Ministry of Health, and Tigray regional health bureau libraries were conducted to identify and document best practices in the prevention of HBV among pregnant women. All eligible studies and documents were retrieved to form a complete dataset to be reviewed through the current study.

The data literature search process including selection of studies, data extraction, and screening has been displayed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al 2009) flow diagram below.

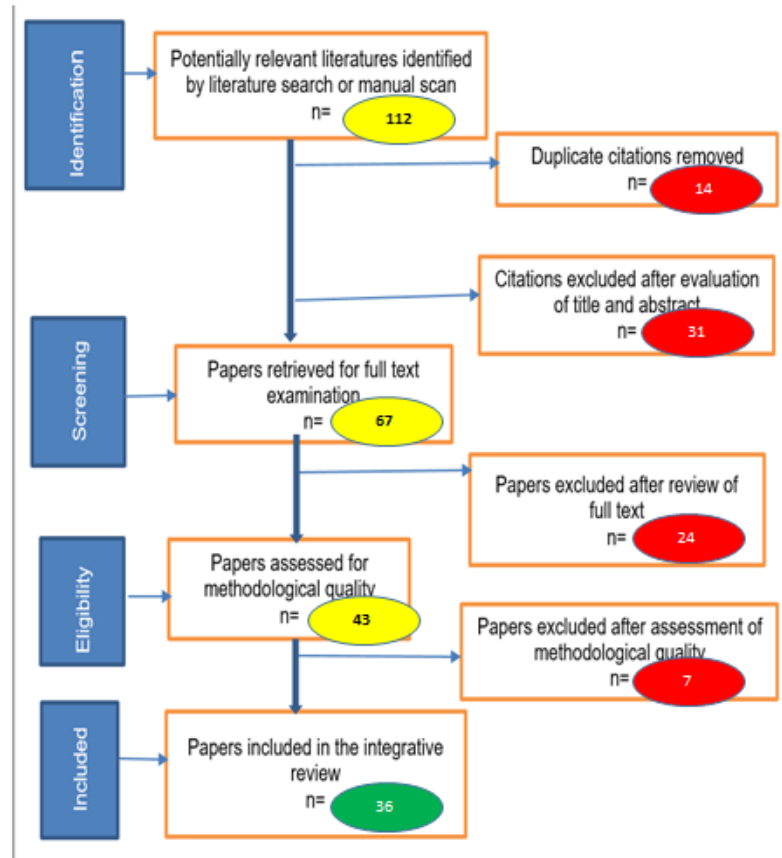


Figure 2. PRISMA diagram for the integrative search process (Moher et al 2009)

3.3.6.3 Step 3: Evaluation of data

During this step, the reviewer should critically evaluate the quality of the article to decide if its data or result should be included in the study data set to be reviewed or not (Cooper 1998, Russell 2005:8-13). Individual studies should be critically examined for the strength of the relationships, the methodological quality, the reliability of the results, and might be discarded or weighed accordingly (Russell 2005:8-13). Whittemore and Knafl (2005:549) state that different research instruments can be used for studies conducted using different research methodologies. Scores could be used as criteria for inclusion and exclusion criteria in the data analysis stage (Jadad et al 1998, Conn & Rantz 2003). However, an integrative literature review includes various types of studies and makes quality score complex (Russell 2005:8-13). To simplify this complexity in an integrative review with diverse empirical and theoretical sources, different quality criteria instruments could be developed for each type of source (Russell 2005:8-13).

However, an integrative literature review includes various types of studies and makes quality score complex (Russell 2005:8-13). To simplify this complexity in an integrative review with diverse empirical and theoretical sources, different quality criteria instruments could be developed for each type of source. According to Whittemore and Knafl (2005:549), different research instruments can be used for studies conducted using different research methodologies. Cooper (1998) also suggested that reviewers should evaluate individual studies objectively to minimise reviewer's bias, which means evaluating studies negatively or positively based on the reviewer's own belief.

Since the integrative review in this current study involved multiple types of studies including quantitative and qualitative studies as well as relevant guidelines, the researcher used different quality assessment tools for each type of source. In this study, the researchers used the Critical Appraisal Skills Programme (CASP) instruments (Burls 2014) to critically analyse the literature to be included in the review. The standard quality assessment checklist (Annexure L) of the CASP developed by Kmet, Lee, and Cook (2004:4-5) was used to objectively and critically evaluate the quality of quantitative and qualitative primary studies to be included in the review. The standard quality assessment checklist contains 14 questions (Annexure L1) to evaluate relevant quantitative studies, and 10 questions (Annexure L2) to evaluate qualitative studies. The quality assessment tools were used to facilitate the systematic appraisal of studies with regards to the clarity of aims, objectives, methods, and appropriate analysis of data as well as credibility and relevance of the study. Two reviewers, who are experienced in integrative or systematic review used the standard quality assessment checklist to independently evaluate and score studies identified through the electronic and manual search. Primary studies scored $\geq 60\%$ average of the CASP standard quality assessment criteria were included and reviewed.

Similarly, the Appraisal of Guidelines for Research & Evaluation (AGREE) II was used to assess the best HBV practice guidelines. The AGREE II is one of the best tools to evaluate the quality of guidelines (Brouwers et al 2010:839-842). The AGREE II has been modified to five domains of quality and a Likert scale quality score tool (Annexure M) was used to evaluate the guidelines for each of the five AGREE II domains. The five domain scores are

independent and should not be aggregated into a single quality score. A total of 23 questions (Annexure M) have been adapted from the AGREE II guidelines (Brouwers et al 2010:839-842) to assess the quality of the potential guidelines for this review. Four appraisers who have experience in guideline development and evaluations used the tool to evaluate the potential best HBV practice guidelines. The decisions to use the guideline in the review were made by the appraisers under the guidance of the AGREE II tool. The CASP standard quality assessment checklist and the AGREE II tool instruments have been obtained online (Brouwers et al 2010: 839-842; Kmet et al 2004). The researcher, supervisor, and co-supervisor have been working together in this regard.

The selection of the studies started through the analysis of the title, followed by the abstracts reading for the identification of those that would be evaluated in their entirety, independently, by the reviewers. All of the papers were screened and those with duplicate records were removed from the integrated literature review.

3.3.6.4 Step 4: Data analysis

In any integrative review, the data analysis step is not developed according to a specific standard. However, the general aim of the analysis step is to critically analyze and examine the literature including summarizing the main ideas of the issue (Whittemore & Knafl 2005:551). At this stage, data from primary sources are ordered, coded, categorized, and summarized into a unified and integrated conclusion about the research problem (Whittemore et al 2005: 546-547). The identified best practices were ordered, categorized and sommarized into an integrated conclusion about the best practices for HBV prevention among pregnant women. The four steps of data analysis proposed by Whittemore and Knafl (2005:551) were applied in this study. The steps are: 1) data reduction, 2) data display, 3) data comparison, and 4) drawing conclusions and verification (Whittemore & Knafl 2005:551).

- Data reduction: Data were organised into two primary categories, namely the theoretical and empirical studies. Each article was abstracted into a manageable unit of study with similar features hosted in a table on the Excel sheets for future coding.
- Data display: The second step is to display the extracted data in the form of graphs, charts or networks. When it is prepared this way, it is conducive for the iterative comparison across studies (Whittemore & Knafl 2005:551). The researcher created a table to embed all the abstracted information for subsequent iterative comparison and statistical analysis.
- Data comparison: The goal of data comparison is in order to recognise patterns, themes, or relationships among the data displays (Whittemore & Knafl 2005). An iterative comparison was conducted across the selected articles. This process allows the researcher to convert the abstracted information into meaningful clusters, where patterns, themes, differences, and relationships emerge.
- Conclusion drawing and verification: In this step, all identified themes are used to classify the extant research into a method of synthesis or summary (Whittemore & Knafl 2005:552). To verify the synthesis or summary, each of the articles in the data were reviewed repeatedly to ensure that there was no misinterpretation and that each article was congruent with the initially selected sources.

3.3.6.5 Step 5: Interpretation and presentation of the results

This stage is equivalent to conclusion drawing whereby explicit evidence is used to support patterns and relationships from each primary source (Whittemore & Knafl, 2005:551). In this study, the final conclusion regarding the best practices for HBV prevention among pregnant women were clearly highlighted and outlined.

3.3.7 Rigour for Phase 1: Integrative Literature Review:

Researchers should maintain the rigour of any type of literature reviews including integrative reviews. This is because the accuracy and consistency in a research design determines the validity of the results. The validity of the results in turn influences the interpretation and conclusions about the study under investigation (Gray et al 2017).

The threats to validity in an integrative review include inadequate sampling, incomplete literature search, incorrect data extraction and interpretation. Another threat to validity in an integrative review is the discrepancy between collected studies and the target population (Cooper 1998; Russell 2005:8-13). The threat to external validity, which is a threat to the generalisability of the results to other population also exists in integrative reviews. Rigour can also be compromised when diverse methodologies are combined during synthesis (Whittemore & Knafl, 2005:547).

Whittemore and Knafl (2005:546-551) proposed strategies which help researchers to ensure the methodological rigour of an integrative review. Using a systematic and clear methodological approach and designs reduces the possibility of error. In this study, the researcher followed systematic and comprehensive methods to enhance rigour. A more detailed discussion involving all five steps of the current integrative review have been provided in the data collection section (3.3.6) of this study. To ensure the rigour of this integrative review, the researcher applied the quality criteria proposed by Whittemore (2005:61). The quality criteria are listed in the box below.

Quality criteria in the integrative research review

- 1. Well-defined problem and review purpose
- 2. Explicit identification of review method
- 3. Investigators with expertise in content and methodology
- 4. Clear specification of review process and protocol
- 5. Comprehensive and explicit literature search
- 6. Explicit, unbiased and reproducible data extraction for content and quality
- 7. Primary study quality considered in the analysis
- 8. Data analysis is systematic, and variability of findings addressed
- 9. Evidence included from primary studies

Adapted from Whittemore (2005:61)

3.4 Phase 2: Qualitative Exploratory Descriptive Contextual Design

3.4.1 Study Design

In the second phase of this study, a qualitative exploratory descriptive contextual design was employed. This design is described as follows:

A qualitative research approach was employed to explore a more in-depth understanding of the views and perceptions of pregnant women and healthcare workers on HBV prevention measures among pregnant women. A qualitative study focuses on human experiences, meaning, and understanding from the research participants’ point of view in the context in which the action takes place (Creswell 2009:175; Creswell 2014:234; Grove, Gray & Burns 2015:67). Pregnant women and healthcare workers were interviewed to better understand their views and perceptions regarding factors influencing the prevention of HBV infection among pregnant women in Ethiopia.

3.4.1.1 Exploratory design aims at increasing the knowledge of the study (Ponelis 2015:535-550). The researcher probed to gather in-depth data from pregnant women and healthcare workers regarding their views and perceptions on factors influencing the prevention of HBV infection among pregnant women in Tigray regional state, Ethiopia.

3.4.1.2 Descriptive design is where more information is required in a certain field through the provision of a picture of the phenomenon as it naturally occurs (Grove et al 2015:502). In this research, more data will be obtained from pregnant women and healthcare workers regarding their perceptions on factors influencing the prevention of HBV infection among pregnant women in Tigray regional state, Ethiopia.

3.4.1.3 Contextual: Qualitative researches should be conducted in the natural setting of the study participants without disturbing the natural context of the phenomena under investigation Creswell (2014:235-240). Participants in this type of research usually provide information honestly and freely because it is conducted in their natural site under no form of manipulation (Creswell 2013; Creswell 2014:236). This current research was contextual, in nature, because the data was collected in the four healthcare facilities in Tigray regional state, Ethiopia.

3.4.2 Study Setting

The research setting can be seen as the physical, cultural, and social site in which the researcher conducts the study (Bhattacharya 2008:788). Qualitative researchers conduct the study and collect the information in a natural setting where the phenomenon occurs (Creswell 2013:45; Creswell 2014:235). Studying phenomena in their natural settings enhances the understanding of the participants’ perceptions and views regarding the problem under investigation.

Ethiopia, officially The Federal Democratic Republic of Ethiopia, is one of the East African countries and a landlocked country situated in the horn of Africa. It covers an area of 1.1 km² divided into 9 regions and 2 administrative cities, namely Tigray, Afar, Amhara, Oromia, Somali, Benishangul-Gumuz, Southern Nations Nationalities and People Regions (SNNPR), Gambella, Harari, Addis Ababa City administration and Dire-

Dawa City administration (Kebede, Abateneh and Belay 2018:322). Ethiopia is bordered by Kenya, South Sudan, Sudan, Djibouti, Eritrea, and Somalia, Ethiopia had an estimated population of 110.14 million in 2019, which ranked 14th in the world. The country is home to various ethnicities, predominantly the Oromo at 34.4% of the country's population and the Amhara, who account for 27% of the population. Other major ethnic groups include the Somali (6.2%), Tigray (6.1%), Sidama (4%), Gurage (2.5%), Welayta (2.3%), Afar (1.7%), Hadiya (1.7%), and Gamo (1.5%). The largest city and capital of Ethiopia is Addis Ababa, which has an estimated population of 3.6 million. Other major cities include Adama (324,000), Gondar (324,000), Mekelle (324,000), and Hawassa (302,000) (world population review 2019). The current study was conducted in Tigray regional state.

Tigray regional state is the northernmost of the nine regions of Ethiopia (as indicated in the map below). Tigray is bordered by Eritrea to the North, Sudan to the West, the Afar Region to the East, and the Amhara Region to the South and southwest. Mekelle is the capital city of Tigray regional state which is located 783Kms north of Addis Ababa. The region is subdivided into 7 administrative zones, including the special administrative zone of

Mekelle City and 52 districts of which 12 are urban districts. Tigray region has an estimated population of 5.3 Million and has an estimated area of 54,573 square kilometres. The climate is generally subtropical. The overall health service coverage of the region has reached 90% having two comprehensive specialized referral hospital, 15 general hospitals, 22 Primary hospitals, 202 health centres and 712 health posts. Besides, there are 1600 HEWs working at the community level to support for health promotion and disease prevention activities (Tigray regional health bureau 2015; UNICEF 2016).

Tigray regional state has been selected for this study mainly because it has a relatively higher estimated prevalence (5.5%) of HBV infection among pregnant women (Araya et al 2018:507) as compared with the national estimated prevalence (4.7%) of the infection (Kebede et al 2018:761). In addition to this, the researcher's home is based in this region, making accessibility to study sites easier and practical. Furthermore, the researcher is familiar with the environment and has a supportive network for data collection from people in the region, including the selected healthcare facilities (Table 3.1 below).

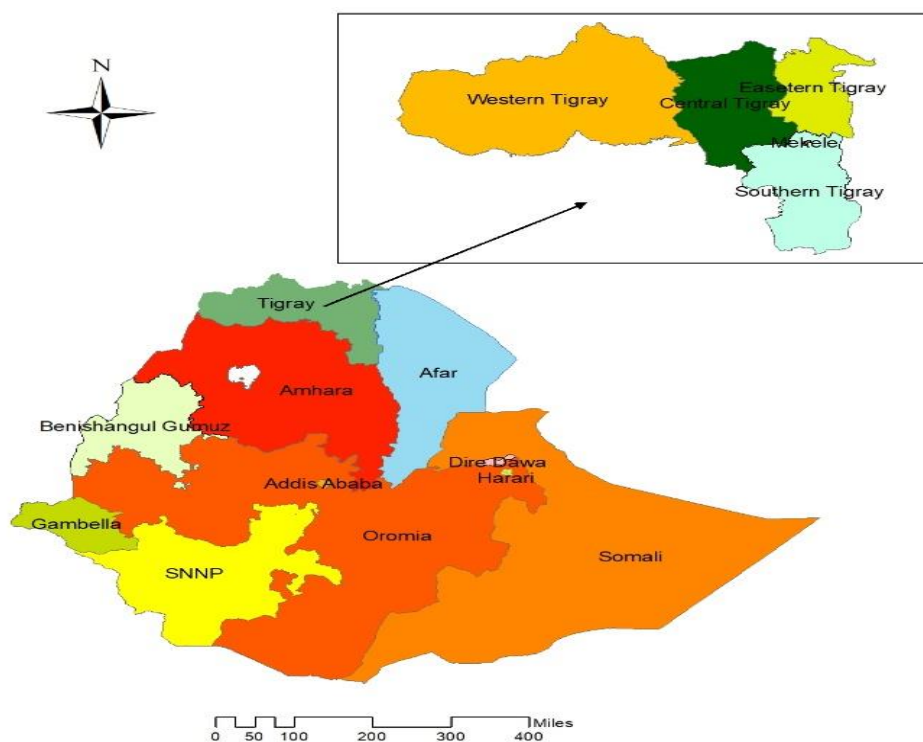


Figure 3 Map of the study area by regional state, Ethiopia

The Ethiopian health system structure, including the Tigray region, is based on a three-tier level, namely tertiary, secondary, and primary. The structure and role of each level are briefly described below:

- The tertiary level comprises national and regional specialised hospitals. This level provides consultative health care service, usually for inpatients and on referral from the secondary or primary level of the healthcare system, in a facility that has personnel and facilities for advanced medical investigation

and treatment, such as a tertiary referral hospital (Ethiopia Ministry of Health 2015). Comprised

- The secondary level comprises regional general hospitals. In the second tier of the health system, patients from primary health care are referred to specialists in general hospitals to seek treatment and better support (Ethiopia Ministry of Health 2015).
- The primary level is established at the district level and comprises primary hospitals, health centres, and health posts.

The primary health care approach provides five types of care: promotive; preventive; curative; rehabilitative; and supportive/palliative services (Ethiopia Ministry of Health 2015). In delivering each type of care, under the primary health care approach, the focus is on preventing illness and promoting health (Ethiopia Ministry of Health 2015).

The second phase of the study was conducted in four purposively selected healthcare facilities (Table 3.1 below), one tertiary, one secondary, and two primary level facilities in Tigray regional state, Ethiopia. The study sites are briefly described as follows:

- Ayder Referral Hospital is in Mekelle City, the capital city of Tigray regional state located 761 km north of Addis Ababa.
- Suhul Hospital is in Shire Endasslassie, north-western Zone of Tigray regional state which is located 1023 km north of Addis Ababa.
- Adigudom Hospital is in Adigudom town southern Zone of Tigray regional state which is located 690 km north of Addis Ababa.
- Adigrat health centre is in Adigrat town eastern Zone of Tigray regional state which is situated 954 km north of Addis Ababa.

Ayder Referral Hospital, one of the biggest hospitals in Ethiopia, and the only tertiary-level hospital in Tigray regional state commenced rendering its referral and non-referral services in 2008 to around nine million population in its catchment areas of the Tigray regional state, and some other neighboring regions, mainly Afar and Amhara regional states. It provides a broad range of medical services to both in and outpatients of all age groups. The hospital has above 80 specialists, in various areas of medical specializations and fairly adequate numbers of all the other health professionals constituting the healthcare team. It has over 2165 staff among them 80 provides directly with maternal care services including HBV infection prevention and care services. The hospital has the highest patient flow in the region. According to unpublished reports of the Tigray Regional Health Bureau report (2018), the total outpatient visits to Ayder specialized hospital were about 562220 people in the year.

The second health facility selected for this study, which is Suhul Hospital, is one of the secondary level healthcare facilities in the regional state. The hospital provides routine care and referral centre for medical, obstetrical, and other services for approximately half a million population of its catchment area in the north-western Zone of Tigray regional state. The hospital has over 300 staff including 20 maternal care service providers. There were 120541 outpatient visits in the hospital in 2018 (Tigray Regional Health 2018).

Likewise, Adigudom primary hospital and Adigrat health centre are among the primary level health care system of the region. The two healthcare facilities serve for a total of around 350000 population of their catchment areas. Adigudom hospital has 75 staffs of which 10 directly provides maternal health services. The fourth health care facility, Adigrat health centre, consists of 10 maternal health care providers. These two health facilities provide medical service mainly to the rural communities in Tigray regional state.

All of these selected healthcare facilities have been providing comprehensive maternal and child health services including, antenatal care (ANC), and maternal delivery services. Hepatitis B virus screening, treatment, care, and infection prevention is one of the maternal health care services offered for all pregnant women attending ANC services. In each study site, ANC services, including HBV infection prevention, care, and management services, are provided regularly on follow-up visits in all of the maternal and child health clinics of the selected healthcare facilities. These four health facilities have been selected purposively to provide a picture of the different levels of the healthcare system as well as the urban and rural context of HBV infection prevention-related services of the healthcare system in Ethiopia. The study healthcare facilities also provide easy access and feasibility for data collection.

Table 1. Selected health care facilities by level in Tigray region, Ethiopia

Name of health facility	Level
Ayder Referral hospital	Tertiary
Suhul General hospital	Secondary
Adigudom Primary hospital	Primary
Adigrat health centre	Primary

3.4.3 Study Population

The second phase of the current study was conducted among two population groups, pregnant women and healthcare workers. These two population groups are described below.

3.4.3.1 Pregnant women

Pregnant women attending ANC services in the four selected healthcare facilities in Tigray regional state of Ethiopia were among the study population for this phase of the study. A total of 2400 pregnant women is expected to access antenatal care services in all of the four selected healthcare facilities during the study period from July 2020 through December 2020. The expected number of pregnant women during the study period has been calculated based on the number of pregnant women who attended antenatal care services in the four selected health care facilities during the same period in 2018 (Tigray Regional Health Bureau 2018).

3.4.3.1.1 Eligibility criteria for pregnant women

Inclusion criteria

- Pregnant mothers above 18 years of age
- Pregnant mothers permanently resided in Tigray regional state
- Pregnant mothers voluntary and available to participate in the study

Exclusion criteria

- Disabled pregnant women who cannot properly communicate with the interviewers

- Pregnant women who are seriously ill at the time of the visit to ANC

3.4.3.2 Health care workers

The second study population group for the second phase of this study were health care workers; specifically, obstetricians and midwives, and who have worked for more than six months at maternal care activities. These groups of health care workers are presumed to have better knowledge and experience in maternal care specifically pregnant mothers confirmed with HBV. Health care workers who have worked for at least 6 months will be considered as eligible participants for the interviews since after 6 months of working they are presumed to have gained enough insight in the subject being investigated. Based on the Tigray regional health bureau report (2018) there were around 848 midwives and 17 obstetricians in Tigray regional state.

3.4.3.2.1 Eligibility criteria for healthcare workers

Inclusion criteria

- Healthcare workers who have worked for at least 6 months at ANC and delivery clinic
- Health care workers who will volunteer and are available to participate in the study
- Currently working in clinical practice of ANC and maternal health care services

Exclusion criteria

- Health care workers in annual or sick leave were excluded from the study
- Health workers out of midwives and obstetrician were not considered

3.4.4 Sample Size Calculation

The sample size in qualitative research is determined based on the principle of category saturation (Creswell 2014:237). Category saturation is based on the principle that when new information no

longer emerges during the data collection process (Creswell 2014: 237-238; Grove et al 2015: 274). In qualitative research, the depth, quality of data, and evidence collected to investigate the problem under study is more important than the number of study participants (Hennik 2011:110; Liamputtong 2013; Hennink, Hutter & Bailey 2011:110–112). However, it is argued that the sample size should be as large as possible with a minimum number of participants ranging from 12-30 individuals (Creswell 2013). Therefore, considering the above assumptions and scholarly arguments, the sample size for pregnant women and health care workers in this study was determined by category saturation.

However, a minimum of 12 pregnant women: four from Ayder Referral Hospital, three from Suhul hospital, three from Adigudom Primary Hospital, two from Adigrat health centre were recruited in the study. Similarly, there were four focus group discussion sessions containing six to eight participants each among the health care workers in the selected health care facilities. The sampling was continuing until a redundancy of information occurs in each theme to get deeper information regarding the views and perceptions of pregnant women and healthcare workers on the factors influencing the prevention of HBV infection among pregnant women.

3.4.5 Sampling Technique

In a qualitative study, researchers use a non-probability purposive sampling technique to select study participants with rich and diverse relevant information to the problem under investigation (Brazeley 2013). Purposive sampling is a non-probability sampling technique that is used to select information-rich cases based on the objective of the study. Pregnant women and health care workers were selected using a non-probable purposive sampling technique. Pregnant women attending ANC services and who are above eighteen years of age were selected for this study. Similarly, healthcare workers specifically midwives and obstetricians who have worked for more than six months in ANC and delivery clinics were selected to provide information regarding HBV infection prevention measures among pregnant women in Ethiopia.

Table 2. The study phases, objectives, methods, study population and sample sizes

Phase	Objectives	Methods	Participants and sample size
Phase 1	Explore best practices in the prevention of HBV infection among pregnant women	Integrative reviews	Existing articles or guidelines on HBV prevention among pregnant women
Phase 2	Explore views and perceptions of pregnant women regarding factors influencing the prevention of HBV infection among pregnant women	Qualitative semi-structured interviews	Semi-structured interview with at least 12 pregnant women
	Explore the views and perceptions of healthcare workers on factors influencing HBV infection among pregnant women	Focus group discussions	Focus group discussions with 24 healthcare workers
Phase 3	Development and validation of strategies to promote HBV prevention among pregnant women	Analysis of the study results of research questions related to objectives 1, 2, 3 (phase 1 and 2), SWOT analysis and stakeholder's consultation	Informed by the study results of research questions related to objectives 1,2, and 3

3.4.6 Data Collection Methods and Procedures

Upon the permission of the study from the Tigray Health Research Institute and permission of Tigray Regional Health Bureau and managers of each health care facilities, the researchers visited the health care facilities to introduce the study objectives and recruit pregnant women and healthcare workers. Meetings were conducted at different hospitals to request participation. During the meetings, the researcher presented the study aims, objectives, and voluntary participation. After receiving permission from the health facility administration, the investigators visited the ANC site to meet the health care workers and pregnant women to conduct interviews upon their voluntariness. Participants who agreed to participate in the study were requested to sign a consent form to participate in the interview process.

Due to travel restrictions and physical distancing policy in place as a result of the COVID-19 pandemic, the researcher contacted the directors of the selected healthcare facilities via emails and telephone call to introduce the study objectives. The researcher also requested the directors for their permission to recruit pregnant women attending the ANC services at their respective hospitals as well as healthcare workers providing care for the study. Moreover, the researcher requested ANC clinic heads of the selected healthcare facilities to select the study participants and to collect contact details of the selected study participants.

The researcher contacted the study participants through emails and telephone calls to explain the nature of the study and to request them to participate in the study. The informed consent form was sent to the study participants via emails and WhatsApp messages which were the most feasible way of reaching them. The researcher set up an appointment with the participants to discuss on the nature of the study, its objectives, voluntary participation, the anticipated risk and benefit of participation (information sheets) and also to discuss about consent process (consent form) via telephone. The study participants were also requested to have one person to witness their consent to take part in the study from their end. The researcher had also one person to witness the consent process from his end.

Audio or WhatsApp video were recorded during the consent form signing process. The image of the signed informed consent was shared among the researcher, the participant and the witness via cell phone WhatsApp message, or email scanned copy. The participants and the researcher agreed that there will be in-person signing after COVID-19 (delayed re-signing). The researcher requested those who accept to take part in the study to schedule for a telephone interview. The data collection process was conducted as follows:

3.4.6.1 Data collection methods and procedures for pregnant women

In this study, an individual face to face semi-structured interview was conducted to obtain data from pregnant women. In the event of COVID-19 pandemic, one-to-one interviews through telephone calls was conducted as opposed to face-to-face interview. Using semi-structured interviews, open-ended questions were asked, and their responses was recorded for transcription, analysis, and interpretation (Braun & Clarke 2013; Creswell 2014:239). All verbal and non-verbal responses (in case of face-to-face interviews) were captured throughout the whole interview sessions.

A semi-structured interview guide with open-ended questions (Annexure I) was developed for this study to guide the interview. The interview guide covers pregnant women related, sociocultural, and health service factors influencing the HBV infection prevention measures among pregnant women in Ethiopia. The socio-ecological model (SEM) was used to generate the questions or different themes in developing the data collection tools of this study.

The semi-structured interview guide of this study was pilot tested to check if the questions are comprehensive and not ambiguous. The time required to complete an interview session was also estimated during the pilot test of the interview guide. The permission to invite pregnant women was sought from managers at selected healthcare facilities. Participants were recruited during their ANC visit by the aid of the midwives working in the health care facilities. Participants were provided with a detailed information sheet (Annexure A). When telephone interview was considered, the researcher read the information sheet and consent form to the study participants before the start of the interviews. For those who agreed to participate in the study, they were requested to sign a consent form (Annexure B) and were invited to participate in a face-to-face or telephone interview using the semi-structured interview guide. When telephone interview was considered, the researcher and the participant have had a person present to co-sign and witness the signing process. Since more than 51% of women in Ethiopia are unable to read and write (United Nations Educational, Scientific, and Cultural Organization (UNESCO 2015) and also due to limited internet access in most districts of Tigray regional state, telephone interviews will be a practical method of data collection during this COVID-19 pandemic as compared with emails and video interviews.

The interviews process including the information sheet and consent form were facilitated in the local language, Tigrigna whereby both the researcher, the research assistant, and the participants are conversant. The researcher, and the researcher assistant who are Ethiopians in nationality, facilitated the interview in the local language. The researcher was responsible to facilitate the face-to-face or telephone interview with the help of a research assistant. When face-to-face interview was possible, the interview was conducted in a quiet and private room within the healthcare facility. In case of telephone interview, the participants were requested to attend the telephone interview in a quiet and private place from their end. The researcher recorded the interview, upon permission from the participants, and transcribed and translated the interviews back to English.

3.4.6.2 Data collection methods and procedure for healthcare workers

This study employed focus group discussions to collect data from healthcare workers working in the selected healthcare facilities. In case of COVID-19 pandemic, a Zoom or Skype video conferences was considered instead of in-person focus group discussions to avoid risk of infection. This focus group discussions or video conferences helped the researcher to obtain a detailed understanding of the study participants' perspectives about factors influencing the prevention of HBV infection among pregnant women in Ethiopia. Focus group discussions via in-person or video conferences help researchers to explore concepts and ideas and to obtain in-depth information. Researchers also get a window into

the internal thinking of the study participants. Moreover, study participants' reactions to each other is another strength in focus group discussions as they complement ideas and learn from each other (Christensen, Johnson, & Turner 2011:59). The researcher was reinforcing them to tell their experiences and knowledge during the discussion session.

An interview guide (Annexure J) was used to guide the process of focus group discussions. The interview guide was pretested before the data collection exercise. In the case of online platform focus group discussions, the quality of the voices and backup recordings were checked before the actual virtual focus group discussions. Participants were provided with a detailed information sheet (Annexure C). For those who agreed to participate, a consent form (Annexure D) with a cover letter was sent via email inviting them for the focus group discussions or for the video conferences (in case of COVID-19 pandemic). The participants had one person each present with them to witness the signing process from their end. The focus group discussions were conducted in a quiet and private room within the healthcare facility. All verbal and non-verbal reactions were written in field notes and audio was recorded during the focus group discussions. When video conferences were considered, the participants were requested to attend the Video Conference from a quiet and private place from their end and were requested for their consent to record the video conference discussions for later transcription and report writing.

3.4.7 Data Analysis

Data analysis refers to the technique used to reduce, organize and providing meaning to the data (Grove et al 2015:502). The data analysis strategies for each phase of this study are described as follows:

3.4.7.1 Data analysis method for pregnant women and healthcare workers

Transcribing of collected data will be verbatim. Tesch's 8-step of data analysis has been followed to analyze data (Creswell 2014:245). A qualified co-coder was sought to independently code data using the provided protocol by the researcher. Both the researcher and the co-coder arrived at an agreement for the good and purpose of enhancing trustworthiness. The steps are described as follows:

Step 1) Get a sense of the whole: The researcher read all transcripts and wrote down the ideas coming out. This will help the researcher to get a background of all transcripts.

Step 2) Pick one transcript : The researchers started by picking one transcript at a time, read it through to get the topics that are revealed in the transcript. These topics were written down on the margin of the document.

Step 3) After reading all transcripts, with a whole list of topics compiled, the researcher documented all the topics in one document. All topics were compared, and then similar ones were grouped together. Headings were used to distinguish the different topics. Main topics were highlighted.

Step 4): These topics were abbreviated with codes. These codes were then be indicated in the data in the appropriate sections.

Step 5: The topics were then be given descriptive words and grouped together in categories. Categories which were similar or

relate to each other were then be grouped together to avoid having many categories.

Step 6): The researcher should decide on the labelling of each category and codes to avoid duplication.

Step 7): Data belonging to each category were put together. The content of each category was analyzed to check whether they are relevant to the research question. Those that are not relevant were discarded.

Step 8): In order to get the whole meaning and general of sense of data, the researcher recoded the data. General ideas were also be written down.

3.4.8 Rigour for Phase 2: Qualitative Exploratory, descriptive contextual study

In a qualitative study, credibility, dependability, conformability, transferability, and authenticity are often used to present the trustworthiness and rigour of qualitative content analysis (Elo et al 2014). These elements are discussed below.

3.4.8. Credibility

Credibility refers to having confidence in the truth of data and its interpretation. Credibility has two components: trustworthiness and expertise, which both have objective and subjective components (Pilot & Beck 2017:539). Similarly, expertise can be subjectively perceived, but also includes relatively objective characteristics of the source message. To ensure credibility, this study used various participants, settings to get a diverse understanding of the hepatitis B virus infection prevention measures. Also, this study involved different qualitative methodologies (interviews), and adequate engagement in data collection to ensure the richness of information. Moreover, the final outcome (the strategies) will be validated through systematic methods.

3.4.8.2 Dependability

The stability (reliability) of data over time and over conditions is called dependability (Polit & Beck 2017:539). Dependability is the consistency of the relationship between the methods, data, and results (Liamputtong 2013). In general, it shows us how justifiable the method is concerning the data and results. Detailed documentation of the methods employed, data collection, analysis, and results has been done to ensure the dependability of this study. The same screening tool for all reviewed articles and guidelines and the same interview guides were applied to all selected pregnant women and health care workers. The researchers wrote down all field notes to ensure that all the non-verbal reactions are fully recorded. All the field notes and audio recorded sounds are stored in a safe storage place.

3.4.8.3 Conformability

Conformability demonstrates the extent of links between the data and the results, to ensure the qualitative findings are not personal thoughts of the researcher (Liamputtong 2013:26). In this current study, the researchers applied conformability by following the ethics, Tigray Health Research Institute and obtaining approval to conduct the study from Tigray Regional Health Bureau and selected health care facility managers. Direct quotes were used to demonstrate the relationship between the themes and the data. Independent reviewers to assess the eligibility of the literature for phase one and independent co-coders were used for phase two of

the study. The researcher also compared the information written in field notes and recoded audios. In addition, the investigator has requested the co-coder to compare the recorded voice and the transcripts. For the third phase, to enhance conformability and dependability, a copy of the study results including strategies developed from this study has been provided to eight pregnant women, eight healthcare providers (four midwives and four obstetricians) and 12 stakeholders to obtain their feedback on the strategies conformability. They were also offered the option of providing comments on the strategies. A transparent description (Lincoln & Guba 1985) of the research steps taken from the start of the research project to the development and reporting of findings and development of strategies were provided to further establish conformability that, indeed the strategies will arise from the study findings rather from the researcher's opinion.

3.4.8.4 Transferability

Transferability, which also refers to a rich description for the data, is a measure of how applicable the findings are to other settings or groups with similar participants (Grove et al 2015:513). Transferability was achieved by providing adequate data so that the readers can evaluate the applicability of the research findings to other situations. In addition, the researchers provided a detailed research report to allow the readers to decide if the findings of the particular study will be applied to other similar settings. Also, a detailed description of the study settings was done to enhance the transferability of the findings to a similar context. Interaction of the investigator and participants was taken place until the level of data saturation to maintain the study transferability.

3.4.8.5 Authenticity:

Authenticity involves shifting away from concerns about the reliability and validity of research to concerns about research that is worthwhile and thinking about its impact on members of the culture or community being researched (Grove et al 2015:519). The HBV infection prevention among pregnant women was directed to relevant bodies through several stakeholder involvement events in the interview to direct this work and to focus the key themes that this research addresses to take action based on the findings.

3.5 Phase 3: Development and Validation Of Strategies

The third phase of this study addressed objective 4 which is to develop and validate strategies to promote the prevention of hepatitis B virus infection among pregnant women in Ethiopia. Strategy development is the process of researching and identifying strategic options, selecting the most promising and deciding how resources will be allocated across the organization to achieve objectives (Hill, Charles, Jones & Gareth 2012:21). The researcher has formulated the draft of the strategies. The formulation of the strategies was developed:

- Based on the findings of the integrative review of evidence based best practices in preventing HBV infection among pregnant women, phase one of the current study
- Based on the findings from the interviews with pregnant women and healthcare workers to seek their views and perceptions on the prevention of HBV infection among pregnant women, phase of the current study. The findings

were described and presented to indicate significance. Categories of views and perceptions of the study participants on factors influencing HBV infection prevention measures were indicated.

- By the researcher supported by the supervisors, with input from pregnant women and health professional groups
- Using a transparent process and methods
- Subject to a consultation with stakeholders

As already discussed, this study was conducted in three phases. Phase 1 involved an integrative literature review to identify best practices for preventing HBV infection among pregnant women. Phase 2 involved interviews with pregnant women and healthcare workers to seek their views and perception of HBV prevention services for pregnant women. Phase 3 was the development and validation of strategies that would promote the prevention of HBV infection among pregnant women.

The results of phases 1 and 2 informed the development of strategies for preventing HBV infection among pregnant women. The research approach for developing strategies involved the use of the SWOT analysis framework. The draft strategies were validated using consultative meetings with stakeholders including pregnant women, healthcare workers (midwives and obstetricians), and other stakeholders such as policymakers, program managers, and members of the medical and midwifery regulatory councils. The process of strategies development and validation including the SWOT analysis and consultative meetings with stakeholders as used in this study are described in detail below.

3.5.1 Strategies Development Process and Data Analysis Strategies

As discussed above, the results of phases 1 and 2 informed the development of strategies for preventing HBV infection among pregnant women. The research approach for developing strategies involved the use of the SWOT analysis framework. The draft strategies were validated using consultative meeting with stakeholders including pregnant women, healthcare workers (midwives and obstetricians), and other stakeholders such as policymakers, program managers, and members of the medical and midwifery regulatory councils. The process of the SWOT analysis and consultative meetings with stakeholders, as used in this study are described below.

3.5.1.1 SWOT analysis

The SWOT analysis framework formed the foundation for developing strategies aimed at preventing HBV infection among pregnant women. SWOT Analysis, which stands for: Strengths, Weaknesses, Opportunities, and Threats is known worldwide and widely applied in many companies in formulating strategies (Hande 2014:336 – 339). SWOT analysis is a structured process that aims to identify and analyse strengths, weaknesses, opportunities, and threats of different strategies and plans that aim to achieve set objectives (Hande 2014:336–339). SWOT analysis as a conceptual framework that aims at identifying and appraising strengths, weaknesses, opportunities, and threats of phenomena of interest have been used by different scholars, academicians, policymakers, and public health practitioners to develop strategies

(Van Durme, Macq, Anthierens, Symons, Schmitz, Paulus, Vanden Heede, Remmen 2014:1- 17).

Definition of Strength, Weaknesses, Opportunities, and Threats

- Strengths: Internal attributes and resources that support a successful outcome.
- Weaknesses: Internal attributes and resources that work against a successful outcome.
- Opportunities: External factors that the entity can capitalize on or use to its advantage.
- Threats: External factors that could jeopardize the entity's success.

The SWOT analysis framework lends organizational planners with a tool to conduct external and internal analysis. The SWOT framework was used to identify and classify the findings from phase 2 of the current study into strengths, weaknesses, opportunities, and threats to preventing hepatitis B infection among pregnant women. Phase 1 results, best practices in preventing HBV infection among pregnant women, were used as a benchmark to determine and categorize findings of phase 2 into strength, weaknesses, opportunities, or threats. By comparing the results of phase 2 with phase 1 (best practices) as already explained above, the researcher identified the critical threats and opportunities to prevent HBV infection among pregnant women in the environment.

It is also useful in examining and understanding how threats in this environment are likely to evolve and what implications that evolution has for the threats and opportunities to the prevention of HBV among pregnant women. While external analysis focused on the environmental threats and opportunities facing the provision of HBV infection prevention services for pregnant women that are external to the healthcare facility, the internal analysis identified the healthcare facility's strengths and weaknesses. This analysis also identified resources and capabilities within the healthcare facilities that are likely sources of competitive advantage for preventing HBV infection among pregnant women and those that are less likely to be sources of such advantages.

Through the application of the SWOT analysis conceptual framework and comparing of the findings of phase 2 with phase 1 results, internal- and external-factors that would be helpful or harmful in the facilitation of the prevention of HBV infection among pregnant women were identified to be overcome or manipulated. Examples of internal factors include human resources, competence, financial costs and services, and external factors include political, economic, sociocultural, technological, legal, and environmental. Based on SWOT Analysis, appropriate strategies for preventing HBV infection among pregnant women were developed. The researcher leveraged the findings and outcomes of the SWOT analysis to develop possible strategies that could enhance the prevention of HBV infection among pregnant women.

In addition, the drafted strategies were appraised based on the findings of phase 1, best practices, to estimate the resources needs for their implementation to ascertain feasibility. The activities and associated costs needed to facilitate the implementation of the proposed strategies were identified to determine whether or not

there are sufficient resources within the health system to implement the proposed strategies. The proposed strategies were appraised based on the expected outputs, the short- and long-term outcomes, as well as the perceived impacts. After this stage, only ideas or proposed strategies that would be deemed feasible would be promoted. The researcher would leverage on building strategies that overcome threats and weaknesses of the current systems while also exploring opportunities that will best support the achievement of prevention of HBV infection among pregnant women. Also, strategies would be built to minimize the chances of them failing to attain the desired goals.

3.5.2 Validation of Strategies

The Foundation WKK (2004:40-45) defines the validation of strategies as determining their feasibility, applicability, acceptability, and sustainability of these strategies to attain desired goals. Key stakeholders need to evaluate the developed strategies to ensure that they do not undermine or violate the values of different health system users (Acland 2012: 1-5; Griffin & Otter 2014).

The validation of strategies was conducted at three levels.

Level one involved holding a consultation meeting with eight pregnant women to assess their views on the acceptability and affordability of the drafted patient-related strategies. The pregnant women who were chosen for the validation meeting were not among those who participated in phase 2 of the current study to improve objectivity, as interviewees in phase 2 may not want to contradict their earlier views on a strategy they contributed to earlier.

Level two also involved holding a consultation meeting (via Zoom meeting in case of COVID-19) with eight healthcare workers, including four obstetricians and four midwives. The healthcare workers to take part in validating the draft strategies were selected according to their experience (5 years plus) and expertise in providing HBV infection prevention services to pregnant women. Also, they should not have participated in phase two of the current study to enhance their objectivity by avoiding any form of bias caused by fear of contradicting earlier perceptions and views of a phenomenon.

Lastly, level three involved holding a consultation meeting with 12 stakeholders (three policymakers, three academicians, three program managers, and three medical and members of the midwifery professional governing bodies). Zoom meetings was considered in case of COVID-19 pandemic travel restrictions and physical distancing policy in place. The process of these three levels is described below.

3.5.2.1 Level one: Consultation meeting with pregnant women

Also critical in the validation process is the need for key stakeholders particularly the intended users of the service to evaluate strategies under development to ensure conformity with the values of users of the health system. Therefore, strategies developed in this study were validated using a consultation meeting or telephone discussion with eight pregnant women. The eight pregnant women had not have participated in phase 2 of the current study. As mentioned earlier these women have not had taken part in phase 2 of the current study to avoid any form of bias. The women were requested to give their views on the acceptability,

practicability, effectiveness, and sustainability of the proposed strategies in preventing HBV infection among pregnant women in Ethiopia. Acceptability is one of the quality components in health care, apart from efficiency, optimality, legitimacy and equity. It is defined as conformity to the wishes, desires and expectations of patients and responsible members of their families.

3.5.2.2 Level two: Consultation meeting with healthcare workers

The researcher presented the draft strategies to eight healthcare workers (four midwives and four obstetricians) in a meeting organized at the health bureau board room at the Tigray region. During the meeting the healthcare workers were requested to review, comment, and provide suggestions to improve the effectiveness of the proposed strategies to prevent HBV infection among pregnant women. During COVID-19, the researcher sent the draft strategies to the healthcare workers via emails for the validation process. The healthcare workers then assessed the proposed strategies on effectiveness, clarity, simplicity, generality, value, accessibility and perceived utility in relation to practice and importance of the formulated strategies (Chinn & Kramer 2011:197). The researcher revised the draft strategies based on the comments, inputs, and suggestions of the healthcare workers.

3.5.2.3 Level three: Consultation meeting with stakeholders

As already mentioned, a consultative meeting to validate the draft strategies was held with 12 stakeholders (3 policymakers, 3 academicians, 3 program managers, and 3 medical and members of the midwifery professional governing bodies). The stakeholders were consulted (via emails in case of COVID-19) to obtain their opinions on feasibility, accessibility, and sustainability of the proposed strategies. They were requested to review and refine the strategies. Only individuals with extensive knowledge of hepatitis B virus infection prevention among pregnant women, as evidenced by their academic, scholarly background, and work experience were purposively selected for this purpose. Participants who have experience and knowledge of infectious diseases infection prevention, in health care strategies development, in strategies formulation, and strategies evaluation.

In consultation with pregnant women, healthcare workers, and other key stakeholders, the NICE (2014:4) tools and the Chinn and Kramer (2011:197) of critical reflection were used as guidelines during the consultative meetings to validate the draft strategies. Using the tools (Annexure M), key stakeholders' opinions on the five domains of the AGREE II (scope and purpose, stakeholders' involvement, rigour of development, clarity of presentation, and applicability of the proposed strategies) were sought. The experts were provided with the following guidance on how to conduct a critical reflection on the strategies for promoting HBV infection prevention measures among pregnant women (Chinn & Kramer, 2011:197):

Clarity: refers to how well the strategies' intended purpose can be understood and how consistently the ideas are conceptualized.

Simplicity: refers to the number of elements within the description of each category, how simple they are and whether the strategies give straightforward instructions

Generality: refers to whether the guidelines can be used in a wider context, i.e., primary, secondary and tertiary level prevention of health care challenges.

Accessibility: refers to the ability of healthcare workers, midwives, obstetricians, and other health care professionals to use the formulated strategies.

Importance: refers to the extent to which the strategies lead to improved practice in HBV care, management and infection prevention measures.

Strategies will be reviewed and revised based on the stakeholder's feedback to develop the final accepted strategies for prevention of hepatitis B infection among pregnant women in Ethiopia and other similar settings.

Also, the researcher was the critical reflection method as proposed by Chinn and Kramer (2011:184) to finalize the draft strategies. Critical reflection is a method used to examine the usefulness of the strategies regarding the purpose for which they are developed (Chinn & Kramer 2011:184). The comments and suggestions from the experts were then finally used to modify the strategies. The final strategies will be submitted for approval and publications.

3.6 Ethical Considerations

According to Akaranga and Ongong'a (2013:8), ethics refers to a way of life and social norms for conduct that differentiates between acceptable and unacceptable behaviour. Creswell (2014:290) has also defined a code of ethics as the ethical rules and principles that scholar researches in their area of discipline. The investigators complied the ethical principles throughout the study, following the principle of beneficence, respect for human dignity and justice (Brink et al 2018:28; Geoffrey, David & David 2005:23). The investigators followed the following ethical principles in the study: Autonomy, beneficence and non-maleficence and justice.

Autonomy: is an agreement to respect another right to support of self-decision and self-determination (Brink et al 2018:29). The study participants will be supported to decide to participate in the study independently without fear and consequence. Participating in the study was purely voluntarily and under no form of obligation.

Beneficence: Requires that good should result, or at least no harm (no maleficence), and/or benefits of participating in a study should justify the expected risk or harm or protect from harm and discomfort from physically, psychologically, spiritually, socially and legally.

- **Respect for rights** includes the free choice of the individual (autonomy) to become a study subject or to withdraw at any point in the study. Protection for those individuals with diminished autonomy should be assured. Participants were informed that it is their right not to participate in this study, and no consequence will be imposed on them for not participating in this study.
- **Justice:** Which requires an equal distribution of burden and benefits and a fair selection of participants (Brink et al 2018:30). The researcher of this study is a public health expert and epidemiologist with a high passion for the quality of the data to be generated. Selection of participants is randomly and voluntary without any bias. All procedures of the study were

adhered to the principles of scientific validity and social value to maintain justice.

3.6.1 Scientific Integrity

The study was conducted based on the university's scientific writing guideline with clear and attainable objectives. A protocol with sound methodology, which is adequate to answer the research questions, was followed during the whole process of the research. The methods were sound enough to produce a meaningful and valid scientific conclusion. This study is envisioned to advance knowledge and contribute to the development of a strategy for a public health intervention.

3.6.2 Ethical clearance

Ethical clearance has been obtained from Tigray Regional Health Research Ethics Review Committee.

3.6.3 Permission to conduct the study

The Tigray regional health bureau and the directors of the four selected health care facilities have issued permission on request to interview participants before the commencement of data collection for cooperation, and successful data collection purposes. The issued documentation has been included as annexes E and F respectively.

3.6.4 Informed consent

Participants of this study were given the information sheets and consent forms. The pregnant women were given including the translated version of the consent form (Annexure B) and also the translated version of the information sheet (Annexure A). Similarly, the healthcare workers were given the informed consent form (Annex D) as well as the information sheet (Annex C). The information sheets have information about the nature of the research study, its purpose, and the possible risk of participation. Participants will be given time to read, understand, and ask questions whether they are clear or not. The researchers read the information sheet and the consent form for participants who were not able to read. After that, they were requested to sign the consent form to participate in the study.

3.6.5 Respect for persons

The researchers informed the study participants that participation in the study is entirely voluntary. Participants of the study were informed to have the right to decline or withdraw to answer any questions that make them uncomfortable at any stage of the interview. The researchers clearly explained that refusal to participate in the study would have no consequence on their service provision in the health facility or anywhere else. The confidentiality of the information given by the study participants was respected. The researchers also ensured the participants including pregnant women that any participant's name and any other information that could identify the person will not be presented and reported in any published outputs.

3.6.6 Privacy and Confidentiality

Participants of this study were informed that their participation is confidential, as their personal details will only be written on the

consent forms that will be safely locked for a period of five years. Unauthorized individuals will not have access to the participants' information.

Regarding healthcare workers, who participated in focus group discussions, the researchers took several measures to maintain confidentiality though it is difficult in focus group discussions. The researchers will not disclose or publish any personal identifiable information or any links in anywhere. Ground rules were set to emphasize shared responsibilities and obligations of participants regarding privacy and confidentiality. At the end of the interview, the participants were debriefed to ensure what they discussed is true and any information misinterpreted or transcribed wrongly were removed immediately.

For confidentiality purposes, the semi-structured interviews and focus group discussions were conducted in a private and quiet place. The research assistant who worked as a data collector along with the investigator signed a confidentiality agreement (Annexure G) to ensure that participants remain anonymous and that confidentiality is maintained.

However, it is difficult to absolutely maintain confidentiality in healthcare workers focus group discussions as group members can disclose the information discussed in the group to others outside of the group. As a result, researchers cannot guarantee the confidentiality of taking part of this group discussion assumes that the participants are willing to assume those risks.

Participants were informed about the use of audiotapes to capture data during interviews. For pregnant women in the semi-structured interviews, it was explained to them that only the researchers will listen to the recordings for purposes of capturing the interviews during data transcription and other data analysis and interpretation procedures. The participants were informed that the audio-recorded and written notes of the interview will be securely placed in locked cabinets of the researcher and in a password-protected computer only accessed by the researcher in case soft copies. The audio-recorded and written notes of the interview will be stored for a period of five years.

3.7 Conclusion

This chapter described the research methods for the three phases including integrative review, descriptive qualitative exploratory contextual design and development and validation of strategies. Each step of the integrative review process such as problem identification, literature review, data evaluation, data analysis, interpretation and conclusion have been explained in detail. Similarly, the methods and procedures of phase 2 such as study setting, population, sampling strategies, data collection and analysis techniques have also been presented for the three phases. Detail methods of data collection including the methods of data collection from pregnant women and healthcare workers to explore the factors influencing HBV prevention among pregnant women have been explained. The strategies development and validation procedures, phase 3, have also been clearly described. Finally, measures taken to ensure trustworthiness and the ethical issues considered for this study were presented. Chapter 4 presented findings and discussions of the study as below.

CHAPTER FOUR

4. Results and Discussions

4.1 Phase 1: Integrative Literature Review to Explore Best Practices on Hbv Prevention among Pregnant Women

4.1.1 Results of integrative literature review

Fifteen studies that fully satisfied the inclusion criteria were included in the analysis. The selected studies covered literature from Africa as a region and some countries such as South Africa, Uganda, Burkina Faso, and Nigeria. Retrieved studies reported several interventions that contributed to preventing HBV in pregnant women and averting mother-to-child transmission (MTCT) as well. We have retrieved different types of articles that address hepatitis B prevention in pregnant women, including original research articles, reviews, perspective, comment and series (Table 1). Furthermore, our literature search retrieved 11 articles reporting that HBV screening for pregnant women is necessary to avoid transmission of this virus. Also, nine studies have indicated that antiviral treatment for pregnant women infected with HBV is essential to prevent disease transmission. Moreover, three studies showed that following an immunization program through HBV vaccination contributed to reducing virus transmission. Other intervention such as using HIV screening programs to include HBV, increasing knowledge of health care workers (HCWs) and pregnant women are key interventions in combatting disease transmission.

Twelve studies have indicated that antenatal screening is essential during pregnancy to identify women who are infected with HBV and should be done during the first trimester of pregnancy. Studies have shown that identification of pregnant women infected with HBV not only prevents mother-to-child transmission (MTCT), but also can help in identifying infected partners. Literature indicated that in high endemic areas, the majority of HBV infection was due to MTCT in early childhood. Based on our literature search, routine screening of pregnant women during each prenatal visit is good strategy to break the cycle of HBV infection and decrease the impact of MTCT (1–12).

Our literature search found that HIV has a great burden for prevention of hepatitis B in pregnant women. Studies have shown that HIV-HBV co-infection occurred due to inadequate screening of mothers during pregnancy which contributed to transmitting these viruses to their children. Inadequate screening of mother lead to absence of prophylaxis for the HBV during pregnancy. HIV infection also increases the risk of HBV transmission before starting antiviral treatment. This study recommended to expanding

the existing HIV MTCT program to deliver care for pregnant women infected with HBV (13,14). Findings from a study conducted in South Africa found that screening pregnant women is a good strategy to prevent HBV MTCT and it was inexpensive, reliable and acceptable for study participants. Following an antenatal screening and treatment strategy was able to reduce perinatal HBV infection by 90% in South Africa and this intervention was cost-effective (7). Also, blood transfusion during pregnancy is critical and screening blood donation was recommended to reduce the risk of HVB transmission.

Our search revealed that nine studies have reported that maternal antiviral prophylaxis and therapy for pregnant women infected with HBV was good strategy to prevent disease transmission. Screening and antiviral treatment considered as a cost-effective intervention to prevent HBV MTCT. These studies showed that elimination of HBV MTCT could be achieved through antiviral prophylaxis. Finding from these studies explain the importance of administering antiviral therapy such as lamivudine, telbivudine, or tenofovir during the third trimester of pregnancy in reducing the vertical transmission of HBV (1,2,4,5,7,9–11,14).

In addition, in our literature review we found that three studies reported that active vaccination can interrupt the transmission of HBV in pregnant women. These studies insisted on implementing mass vaccine coverage for HBV for the general population and particularly pregnant women. Increasing the immunization of pregnant women through vaccination is considered as a cornerstone in preventing HBV MTCT. So, pregnant women infected with HBV should be identified at an earlier phase of pregnancy in order to implement necessary action before delivery. All pregnant women who did not immunize against HBV should receive vaccine doses (4,5,15).

Based on our literature search, intervention to prevent HBV transmission in pregnant women included increasing the knowledge of both pregnant women and health care workers in the key areas of HBV infection. One study suggested that for prevention of HBV MTCT transmission we have to improve the knowledge of health care workers (HCWs) in key areas of HBV infection. In addition, another study reported that pregnant women's knowledge of their HBV status is essential in the interruption of disease transmission(10,12) .

Our literature review provided evidence that HBV prevention in pregnant women includes screening for HBV during pregnancy, antiviral treatment for infected pregnant women, immunization through vaccination, and to increase the knowledge of HBV among HCWs and pregnant women as well.

Table 3: Summary of retrieved articles

No	Paper title	Author / year of publication	Type of paper	HBV screening	Antiviral therapy	vaccination	Other intervention	Country
1	Call to Action: Prevention of Mother Call to Action: Prevention of Mother-to-Child Transmission of Hepatitis B in Africa	Peyton Wilson, et al. 2018	Perspective		Treatment of pregnant women with high HBV viral loads		HIV PMTCT programs could be expanded to deliver care for HBV-infected pregnant women	
2	Prevention of mother to child transmission of hepatitis B virus infection in Nigeria: A call to action	Eke CB, et al, 2016	Article	timely prenatal screening	Antiviral therapy			Nigeria
3	Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021	WHO, 2021						
4	Elimination of Vertical Transmission of Hepatitis B in Africa: A Review of Available Tools and New Opportunities	Jodie Dionne-Odom, et al 2018	Review	Identification of HBV through screening	Treatment of pregnant women reduce the risk of vertical transmission			
5	Identifying gaps across the cascade of care for the prevention of HBV mother-to-child transmission in Burkina Faso: Findings from the real world	Alice N, et al 2020	Original article	HBV screening				Burkina Faso
6	Mother-to-child transmission of hepatitis B virus in sub-Saharan Africa : time to action	Monique IAndersson,et al 2015	Comment		Antiviral therapy	Active immunization for pregnant women		Africa
7	Hepatitis B in sub-Saharan Africa: strategies to achieve the 2030 elimination targets	C Wendy Spearman, 2017	Series	Mandatory HBV screening	Initiation of tenofovir 300 mg daily at 28–32 weeks of pregnancy if hepatitis B virus	Vaccination,		Africa

8	Prenatal hepatitis B screening and associated factors in a high prevalence district of Lira, northern Uganda: a community based cross sectional study	Paul Semakula Katamba, et al 2019	Article	HBV screening among pregnant women				Uganda
9	Modelling cost-effectiveness of tenofovir for prevention of mother to child transmission of hepatitis B virus (HBV) infection in South Africa	Jolynne Mokaya , et al 2019	Article	HBV screening	Antiviral treatment			South Africa
10	Point-of-care screening for hepatitis B virus infection in pregnant women at an antenatal clinic: A South African experience	Nafiisah Chotun, et al. 2017	Article	HBV screening				South Africa
11	Hepatitis B virus infection in HIV-exposed infants in the Western Cape, South Africa	NafiisahChotun, et al 2015	Article	HBV screening	HBV-targeted antiviral therapy			South Africa
12	Prevention and care of hepatitis B in the rural region of Fatick in Senegal: a healthcare workers' perspective using a mixed methods approach	Tchadine Djaogol1, et al 2019	Article	Providing low cost HBV RDT screening	Antiviral reatment		Increasing HCW knowledge in HBV infection	Senegal
13	Prevention of hepatitis B mother-to-child transmission in Namibia: A cost-effectiveness analysis	Cynthia Raissa Tamandjou Tchuem, at al 2020	Article	Screening	Prophylaxis therapy			Namibia
14	Prevention of Mother-to-Child Transmission of Hepatitis B in the Urban District Health Baskuy Burkina Faso	Alice Nanelin Guingané1,2*,et al 2016	Article	routine screening VHB			improved knowledge of mothers	Burkina Faso
15	The status of hepatitis B control in the African region	Lucy Breakwell1, et al 2017	Review			Increase vaccination coverage		Africa

4.1.2 Discussions and Conclusions: Integrative literature review

Recent data show that hepatitis B causes 1.5 million new infections and 820000 deaths per year. Only 10% of people who were infected with chronic hepatitis B were diagnosed and 22% of those who received treatment. The target of the sustainable development goals is to achieve a 90% reduction in new cases of hepatitis B and C infections by 2030. In African region, new infections of hepatitis B virus account for 990000 new infections and 80000 deaths (13).

Based on our systematic review, hepatitis B prevention in pregnant women includes hepatitis B screening, antiviral treatment, vaccination, HBV knowledge among health care workers and pregnant women (16). In United State of America, the advisory Committee on Immunization Practices (ACIP) and CDC regarding the prevention of HBV infection recommended testing all pregnant women for hepatitis B surface antigen, antiviral treatment for infected pregnant women, and administering vaccination of high-risk group, including pregnant women. This HBV prevention strategy has been implemented successfully in the United states to eliminate HBV transmission over three decades (17).

A study conducted in Italy to screen immigrant pregnant women for chronic HBV revealed a high infection rate and recommended and emphasized the need for universal screening for people from high burden countries (18). In 2019, the Chinese Society of Infectious Diseases and the Chinese Society of Hepatology update the guidelines for the prevention and treatment of chronic hepatitis B to achieve the World Health Organization's goal to eliminate viral hepatitis as a major public health threat by 2030. To eliminate HBV transmission, Chinese societies recommended screening pregnant women for hepatitis B surface antigen and treating those who reacted positive for HBV infection. Also, they recommended hepatitis B vaccination for those who were negative for HBV markers (16).

HBV vaccination is effective and one of the best tools to control hepatitis B infection. Following the HBV vaccination strategy has resulted in a substantial decrease in chronic hepatitis infection, and mortality and morbidity related to HBV infection. Three-dose HBV coverage reached 85% worldwide in 2019 (19). Administration of HBV vaccine has great impact on preventing mother-to-child transmission during pregnancy. A clinical study reported that HBV vaccination during pregnancy reduced newborn infection by 80% compared to the placebo group. In addition, hepatitis b Immunoglobulin is an effective alternative for positive pregnant women to prevent mother-to-infant transmission (20).

Intervention to eliminate HBV transmission is to treat infected pregnant women with antiviral drugs. Antiviral treatment during pregnancy can significantly reduce transmission rates, particularly among highly viremic mothers. This intervention through reducing the viral contributes in reducing MTCT (21). This intervention recommended a viral load testing for pregnant women infected with HBV in the third trimester of pregnancy. In addition, infected pregnant women can continue breast-feeding, putting in mind that their infants to receive immunoprophylaxis at birth. So, treatment with antiviral and hepatitis B high immunoglobulin substantially resulted in a rapid reduction of hepatitis B viral load in high risk pregnant women which can protect infants from HBV infection (22).

Health care workers, particularly nurses and midwives have an important role in caring for pregnant women infected with HBV. Evidence suggests that health care workers' behaviors are affected by knowledge, attitudes and practices (23). A study conducted in Sudan concluded that most of the nurses and midwives working in two hospitals were aware of HBV infection. However, substantial proportion of study participants lack the necessary knowledge about prevention measures and post exposure management (24). Moreover, pregnant women knowledges of HBV infection is essential and can help in dealing with their infection status. In a study to assess the knowledge, attitude and practice of pregnant women to management HBV infection in Ghana and Mozambique, the participants knowledge was very limited and mothers were uncertain that HBV could be transmitted to their newborn infants (25,26).

A systematic review reported that the prevalence of hepatitis B infection among pregnant women in Ethiopia 4.7% (ranged between 2.3% to 7.9%) (27). Furthermore, another study conducted in Ethiopia found that pregnant women with blood transfusion history had a greater risk to get HBV infection (28). Infection of pregnant women with HBV ranks the Ethiopia among countries with a high burden of HBV agross the globe This evidence is supported by a study conducted in Denmark where HBV infection among pregnant women was 0.2%. The low prevalence of HBV in developed countries might be attributed to universal screening and vaccination for HBV infection where vaccination coverage has increased up to 96% among pregnant women (29).

Therefore, there is an essential need to establish strategies to reduce HBV infection in pregnant women by implementing adequate interventions, strategies that can be implemented based on the general health policies of the country.

4.2 Phase 2: Qualitative exploratory study: Data analysis, Interpretation and presentation of findings

2.2.1 Introduction

The chapter summarizes the findings of the second phase of the current study. It started with describing and discussing the pilot phase, followed by findings of the qualitative data collection which are presented in more detail. A descriptive analysis of the demographical information was performed and is presented using statistics; it covers all study participants which are pregnant women attending ANC service and health care workers, who were recruited from all levels of the healthcare system. Semi-structured interviews among pregnant women and Focus Group Discussions (FGDs) among healthcare workers were conducted. The qualitative data analysis from semi-structured interviews among pregnant women attending ANC services and the focus group discussions among health care workers who works in maternal and child health units was done by merging transcripts from both data collection methods using the 8 Tesch 's steps of data analysis (briefly described below). The individual interviews were also analysed manually.

As indicated in the methodology section, chapter three, Tesch's 8-step of data analysis were followed to analyse the data, which involved the following steps: get a sense of the whole, pick one transcript, after reading all transcripts, with a whole list of topics compiled, the researcher documented all the topics in one

document. All topics were compared, and then similar ones were grouped together. Thematic areas were used to distinguish the different topics. Data belonging to each category were put together. The content of each category was analysed to check whether they are relevant to the research question. Those that are not relevant have been discarded.

4.2.1.1 Pilot phase

As indicated in the method section (chapter 3), prior to data collection, pretesting of the research survey tools was conducted over two days in Mekelle, Tigray region, in early December 2020. One FGD which has 10 healthcare workers, and one semi-structured interview with a pregnant women attendant of ANC service, were carried out. The consent and confidentiality forms and the demographic forms were used in each case, as shown in Annexes C to G. The researcher, moderator and one research assistant participated in the pilot phase of the study. The findings were as follows:

The interview-guide was amended in terms of the number and the flow of the questions. one question was also rephrased so that it was correct and made better sense. Two questions from the FGD interview guide and four questions from the semi-structured interview were removed as they solicited duplicate answers. The English version of the interview guides had to be used together with the Tigrigna and Amharic version, the first language is widely spoken and is the indigenous language in Tigray region and the second language is the Ethiopia official language and main language in Addis Ababa, the capital city of Ethiopia.

The researchers decided that the moderator would not read the introduction during the actual research, as in the pilot, as it appeared more natural to talk as a way of introduction than to read, and they gave more confidence to the respondents. In addition, it was decided that each respondent would do a 30 seconds introduction about themselves, to put them at ease and to make them feel significant.

During the actual data collection, it was decided that for the consent forms, both English and Tigrigna versions would be on offer and that the explanations about them could come from either or both versions and that the respondent would sign in the language they were comfortable with. The English demographic forms were adequate for collecting information - the Tigrigna and Amharic versions were not necessary. The duration of the focus-group interview was one hour and 10 minutes, while the in- depth interview took 45 minutes. Both times were deemed appropriate.

4.2.1.2 Data collection phase: Demographic data for pregnant women

The semi-structured interview was collected among pregnant women who attended ANC service in the four healthcare facilities selected for this study (table 4.1 below). Four demographic variables, age, religion, marital status and ethnicity were collected from the respondents. Distribution of respondents of these variables is summarized in section 4.1.1 below. The sample size calculated for this study, as indicated in the method section, was based on data saturation, thus data was saturated after interviewing 25 respondents.

Table 4. Distribution of study participants by healthcare facility, Tigray region, Ethiopia (N=25)

Name of facility	level	Focus group discussion	In-depth interviews
Ayder Referral Hospital	Tertiary	12	10
Suhul General Hospital	Secondary	8	7
Adigudom Primary Hospital	Primary	6	4
Adigrat Health Centre	Primary	6	4

Twenty-five semi-structured interviews distributed across all the levels of the healthcare facilities selected for this study were conducted. A total of four FGDs, one in each selected facility were conducted. A total of 32 health care workers participated in the FGDs. The total sample size of respondents both in FGDs and individual interviews came to 57 (25 for in-depth interviews and 32 FGDs).

4.2.1.3 Distribution of pregnant women by demographic variables

Distribution of respondents by age group

Of the total 25 pregnant women interviewed, 10 (40%) were aged 26-30 years, and seven (28%) were aged 31-35 years and the remaining were all above 36 years and below 25 years.

Distribution of respondents by marital status

Majority of the the pregnant women interviewed, 20 (80%) were married, 4(16%) were single and physically separated, there was no divorced or widowed among the respondents., as shown in Figure 4.2 below.

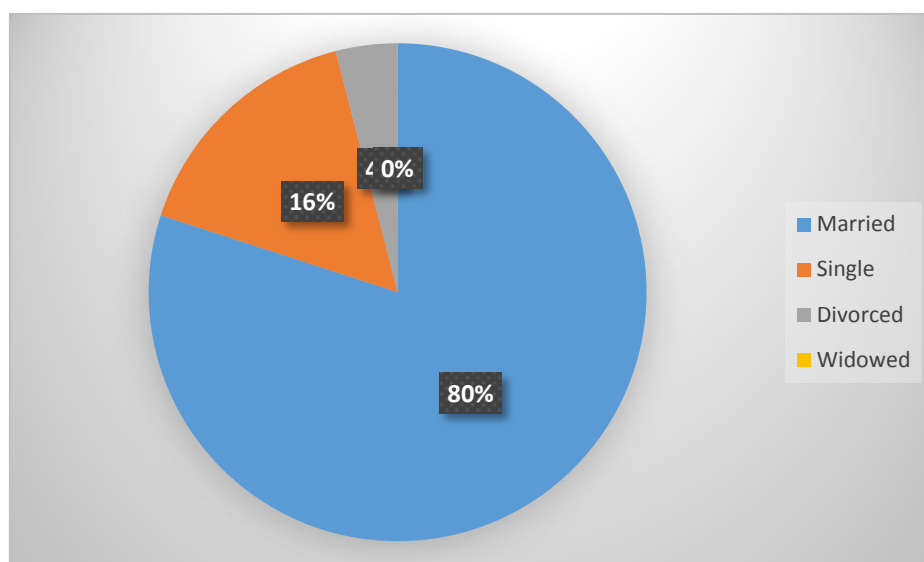


Figure 4. Distribution of respondents by marital status, Tigray, Ethiopia.

Distribution of respondents by ethnicity

Majority of the interviewed pregnant women 68% (N=17) were Tigrayans and the remaining 16 % (N=4) were Amara. (Figure 4.2 below).

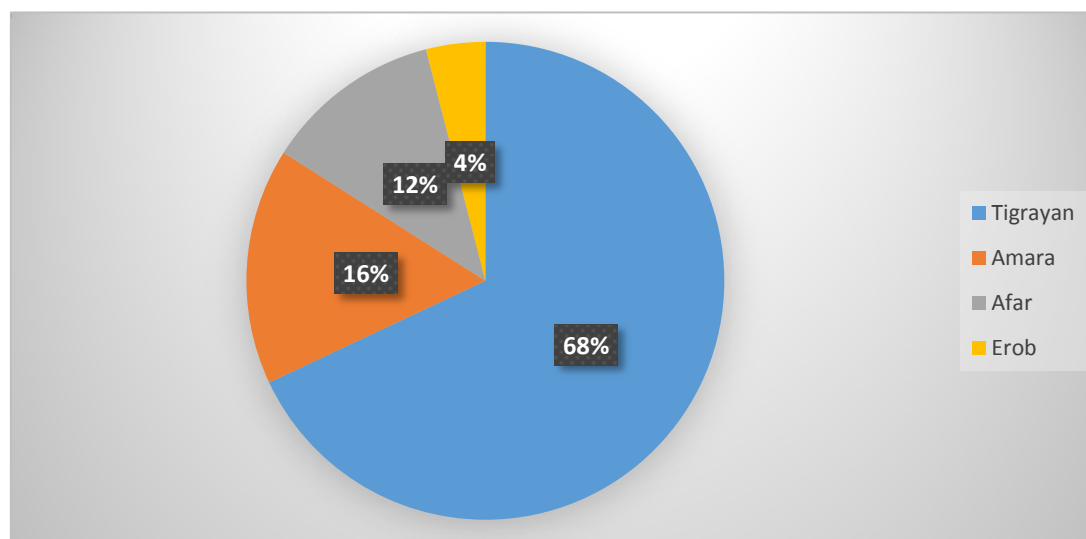


Figure 5. Distribution of respondents by ethnicity, September 2021, Tigray Region, Ethiopia

4.3 Results from Pregnant Women Interviews

4.3.1 Theme 1: HBV and knowledge

The following questions were asked under this theme: Can you discuss your understanding of HBV? Can you tell us the causes of HBV, how is it possible for people to get infected by HBV? (transmission route?), how can promote the spread of HBV? how can one minimize

Less than half of the pregnant women 11(45%) interviewed have heard about HBV through midwives during their ANC follow up, and some 9 (36%) from mostly teachers at school and other nurses at clinics or hospitals. However, five women interviewed did not heard about HBV. Even though the respondents also have heard talking about the virus from general people in the community, doctors, workmates, friends, parents, and relatives, their understanding on its cause, the complication of infections and mode of transmission is very low. Only 7 (28%) of the interviewed

pregnant women mentioned some of the correct mode of transmission i.e through unsafe sexual practice, blood transfusion, mother to child infection during delivery, contaminated objects and other body fluids contamination. Likewise, their level of understanding on methods to minimize spread of HBV infection is not satisfactory as most of them could not explain the correct ways to prevent infection. A significant number of pregnant women 13(52%) said they have not heard about HBV and they did not have answer to the questions mentioned above.

“I once went and got tested for HIV and HBV. The midwife was the one who gave me information about HBV. I was to receive blood donation So, before you receive blood, they first counsel you about HIV and AIDS” (PW 18, Adigrat Health Centre).

“I was told about HBV by my aunt or ‘Silas’, and my sister too. They advised me not to be in relationship with HBV or HIV/AIDS positive men, not to use sharp objects for example razors or needles that have been used by an HIV positive person. They also

told me not to touch anyone's blood because you never know their status" PW05, Ayder referral Hospital)

"I think it is caused by virus or bacteria, but am not sure, I only know it causes yellowish eye and can kill you if not treated. I also know it is bad for my child if I have HBV" (PW 07, Ayder referral hospital). Is not similar to HIV/AIDS, most of the time, the doctors ask me if I know my HIV/AIDS status, but I do not remember about HBV" (PW 12, Suhul Hospital). Respondents PW23, PW25, from Adigrat Health Centre, PW 04, PW 02, PW09 from Ayder referral Hospital, and also responder PW19, PW20 from Adigdom Health Center did not know how HBV can be prevented.

Epidemic drivers, from the women's perspective, comprise several elements. Having multiple sex partner and using contaminated sharp materials were highlighted by the respondents as the main culprit for transmission. Lack of vaccination, and treatment were also described as what promotes the spread of HIV. Thirdly, rape, blood transfusion, unprotected sex knowing one is HBV positive, lack of knowledge about one's HBV status, unsafe sex practice, that is not using condom, lack of discipline, lack of information by HBV positive mothers to seek treatment whilst pregnant, lack of disclosure when HBV positive were all described as promoters of the HBV epidemic.

The most common methods to prevent HBV infection that were mentioned were using condoms during sex with multiple partners, abstinence, faithfulness to sex partner and getting tested to know one's status. Most of the respondents indicated more than one method is available to prevent infection but could not tell the best and affordable method. Prompt treatment when infected and avoiding contaminated needles were also mentioned by some respondents. Most women knew at least one way to reduce the spread of HBV infection:

"Both wife and husband also have to be faithful each other and avoid sleep with someone else. If you are married, you have to stick to your spouse, God also likes this" Abstinence also minimises the chances of getting HBV" (Responder 08, Ayder referral hospital).

"I believe condom reduces the chances of infection by almost 100%. I think you must advocate for proper condom use especially for those young girls and boys, maybe to abstain until marriage if possible. I may be wrong but that is my opinion. I am 35 years old and if I was married seven years ago until then I was virgin and single. At 27 years of age, I was more informed and at a better position in making decisions on how to engage someone for sexual relationships and then God I am now happy and healthy. In my opinion, the youth needs education, information and all the consequence of unsafe and unplanned sexual (PW06 Ayder referral hospital).

4.3.2 Theme 2: Perceptions, Believes, and Practices of Pregnant Women on Hbv

Under this theme, the pregnant women were asked: if they have received vaccination for HBV and if no why, if they believe it is important pregnant women to know their HBV status, what makes HBV infection among pregnant women more serious than infection among the general population.

Most of the respondents, 17 (68%) indicated they do not know if they have received HBV vaccination, but they mentioned they have

taken various type of vaccines. "doctors do not tell me if I took vaccine against HBV, but I am sure I took different type of vaccines, one of them should be HBV, I guess, but what I know is doctors are only interested and focus on HIV testing and counseling (PW10, Ayder referral hospital). Many pregnant women are not literate and are not going for testing. They also don't disclose their status. One may know that they are HBV positive and then they still go on to have more than one sex partner. HBV information should also be UCNght to teenagers at elementary and secondary schools." (PW03, Ayder referral hospital).

Regarding the importance of pregnant women to know their HBV status, all of them believed it is important to know their status. "I believe it's important for me to know my HBV status so that if I am infected, I would want to know how to live with the virus. If it turns out that I don't have it, I would continue to protect myself. This is why it is important for me to know my status" (PW15, Suhul Hospital).

"It is also important to know your status if you are expecting, because you can go for the whole nine months and go on to give birth to an HIV positive baby. However, if you know your status, you can take preventative measures so that you do not pass the virus to your unborn baby" (PW 14, Suhul Hospital).

"If you think from health perspective, it is important to know your status because if you know you are positive, you will immediately start taking treatment. Even from the social relationship perspective, now a days the stigma associated with HIV and AIDS is less, and I believe it will even more less any stigma with HBV, so it is better to know your status and do whatever your doctor tells you to do" (PW 24, Adigrat Health Centre).

However, most of the pregnant women interviewed are not aware why HBV infection among pregnant women is more serious than among the general population. They gave different responses including pregnant women cannot eat well during pregnancy and the virus can easily kill her, because pregnant women may need blood transfusion during pregnancy and if she is HBV positive, she may not be given the blood, not sure if it is serious in pregnant women etc.

In terms of information adequacy, most effective channel was viewed as midwives and nurses working at ANC clinics, followed by Health Extension Workers (HEWs).

"I think some of the nurses are trying their best to tell us information about sexually transmitted diseases. But in televisions, most of the time there are dramas about AIDS and as a result people relate to what they see" (PW 02, Ayder referral Hospital).

4.3.3 Theme 3 Community and social related factors

In this theme, the pregnant women were asked questions such as what is the role, if there is any, religion or spiritual have in the prevention of HBV infection among pregnant women, how do they see the effect of close families or peer friends of pregnant women on prevention of HBV infection, what aspects of culture in Ethiopia promote the spread of HBV infection among pregnant women, what aspects of culture in Ethiopia help in reducing the spread of HBV infection among pregnant women, and they were

also asked to discuss the extent to which cultural aspects influences in the HBV management among pregnant women in Ethiopia.

All of the respondents believed that spirituality had a pivotal role in the prevention of HBV infection prevention. Similarly, all of the interviewed pregnant women believed that religion has a preventive role in HBV infection prevention. “in my opinion, yes, my religion for example orthodox Christian does not allow to have multiple partners, and polygamy is not allowed unlike Muslims, so if you follow the command of the priests, you will only have one partner and you will not get HBV infection if you are loyal to him (PW 04, Ayder referral hospital).

But some of the respondents, 8 (32%) felt people now a days are not respecting the norms and values of religions because of mainly poverty and increased socialization.

“When women are poor, they violate their religion norms in order to get money and look after their children. They start sleeping with many men just to get money. They may forget to take preventative measures to protect themselves, that is, using condoms and things like that (PW 05, Ayder referral hospital).

Respondents described how religion and spiritual influence the prevention of HBV infection among pregnant women. Examples of what was described include teaching women and men about HIV and AIDS, a disease came as demonstration of punishment from God for these who are not faithful to their spouse. The respondents also felt that if church leaders, elders, pastors and other leaders include HBV related issues in teaching it would greatly contribute to increase awareness on prevention of HBV infection prevention.

“Yes, religion does play a critical role, especially in changing behavior. everyone goes to church every Sunday morning and always try to get spiritual information” (PW 21, Adigudom Health center).

“I do not know about other churches but my church, the orthodox Church, advocates for respecting the words of God that is faith among spouses) PW 01, Ayder Hospital.

“At mosques, there are discussions about how people should be safe from sexually transmitted diseases. This topic usually comes up when issues of trustworthiness are discussed. These topics are also specifically directed at us the youth (PW 09, Ayder hospital).

Regarding the aspects of cultural influence to promote the spread of HBV among pregnant women, researchers asked the pregnant women on cculture aspects which promote the spread of HBV infection, cultural aspects which help in reducing the spread of HBV infection among pregnant women, and to discuss the extent to which cultural aspects influence in the HBV management among pregnant women in Ethiopia.

Cultural aspects which promote HBV infection among pregnant women: Some of the pregnant women gave similar responses regarding the Ethiopian culture that promote the spread of HBV, with kissing to show love and sharing food being the most common. However, majority of the respondents, 18 (72%) were not sure which cultural aspects could influence HBV prevention among pregnant women and also among the general population.

Cultural aspects that reduce the spread of HIV and AIDS are the encouragement of abstinence especially for girls, a norm and or expectation that females are to submit and not cheat on their

husband, male circumcision, sticking to one partner as a Christian, no sex before marriage, sticking to one partner, dressing decently.

“When the girl child was growing up, she was advised not to have relationships with men before marriage. She was encouraged not be involved in any sexual encounters. She was also encouraged to wait until she was old enough for marriage, at least at about 25 years. This in turn helped to minimise the spread of not only HBV but also HIV/AIDS. Unfortunately, these days, you will find sexually active 15-year-old girls and yet years back, women got married when they were 25 years or older” (PW 07, Ayder referral hospital).

4.3.4 Theme 5: Healthcare system, policy and related factors

In this theme, the pregnant women were asked questions related to the quality of service they receive during ANC attendance, access to vaccination, diagnostic services and treatment services, health care workers attitude. Questions related to the role of Government, policy makers, and the laws playing role in HBV prevention among pregnant women and they were also asked to provide recommendations to improve HBV infection prevention among pregnant women.

Most of the respondents indicated the quality of service is fairly good, especially during ANC services including the access to vaccination, diagnostic services and treatments. However, almost half of the pregnant women complained on the attitude of health care workers, not respecting their time, sometimes, they do not find healthcare workers on duty stations etc. Regarding the role of Government and policy makers, majority of them 19 (76%) could not describe what the government plays in the prevention of HBV among pregnant women,

“No unfortunately I am not aware of what the Government is contributing in the prevention of HBV infection among pregnant women, and also am not aware of any laws that have been put in place” (PW 20, Adigudom Health Centre).

4.4 Results of Focus Group Discussion among Healthcare Workers

Focus Group Discussions (FGDs) were conducted among healthcare workers (HCWs) working at ANC clinics in the four healthcare facilities selected for this study (table 4.1 above). Three demographic variables, age, number of years worked in an ANC clinic educational level were collected from the respondents. Distribution of respondents of these variables is summarized in section 4.3.1 below. The sample size calculated for this study, as indicated in the method section, was based on data saturation, thus data was saturated after conducting four focus group discussions comprised a total of 32 respondents.

The first FGDs (FGD1) was conducted in Ayder referral hospital among 12 HCWs, the second was in Suhul Hospital among eight HCWs, the third and fourth FGDs were conducted in Adigudom and Aigrat health centers among six HCWs each making a total of 32 HCWs attended in the FGDs as highlighted above.

4.4.1 Socio-demographic characteristics of the HCWs

The mean age of the respondents was 38 years and majority 22 (68.7%) of them were within the age group of 30-45 years. Majority of the HCWs 23 (71%) were diploma by qualification

and only 5 (15%) were medical doctors, the remaining were others such as first degree in nursing and clinical officers (CHOs).

4.4.2 Results from Focus group discussions among healthcare workers

4.4.2.1 Theme: Health service-related factors

The following questions were asked under this theme: What is your experience in providing hepatitis B prevention activities? What are your views on the quality of services for the prevention of hepatitis B virus infection amongst pregnant women at your healthcare facility? What are your views on the effectiveness of screening pregnant women for hepatitis B virus infection at antenatal care clinic to identifying high-risk groups in the elimination of hepatitis B? What are the different services that healthcare providers should provide to prevent hepatitis B virus transmission amongst women? What are the different services that you or your colleagues are currently providing to prevent hepatitis B transmission amongst women? What are the challenges that you or your colleagues experience in providing hepatitis B prevention services to pregnant women? (Annex UCN).

In FGD01, the respondents had various experience in prevention of HBV among pregnant women. They highlighted HBV is one of the conditions screened for any pregnant women coming for ANC services. They all agreed that HBV like other blood borne diseases is prioritized especially for HIV positive pregnant women. However, they all agreed that they have not received any training related to HBV case management and treatment. During FGD01, at Ayder Hospital, few of the HCWs, four of the twelve HCWs (33.3%) felt the service is good, especially in screening during

ANC first visits and linking to treatment. However, majority of them, 8(66.7%) felt that HBV is neglected as compared to other diseases such as HIV.

Most HCWs during the FGDs pointed out that lack of treatment guidelines, diagnostic materials, and prophylaxis are the major challenges in the prevention of HBV among pregnant women. The HCWs also indicated lack of information among pregnant women on HBV transmission and its complications during pregnancy, which makes it difficult for counselling and follow up of positive pregnant women. In FGD02, Shul hospital, all HCWs agreed there is limited awareness among HCWs about the need to screen for HBV among pregnant women, especially for high risk pregnant women. One of the HCWs during the FGDs said “everyone is talking about HIV, there is no even any protocol available for us to screen, diagnose and manage hepatitis cases”. The respondents however know the risk factors for HBV transmission such as unsafe sexual relationship, unsafe delivery, lack of immunization etc. In terms of socio-cultural effects, the HCWs all mentioned the same factors for HIV applies for HBV which includes early marriage, multiple sexual partner, stigma, poor knowledge on mode of transmission, etc.

Overall, the FGDs result showed there is limited attention and service for HBV prevention and control activities especially at lower level of the healthcare system in Ethiopia. Lack of diagnostic test kits, lack of treatment guidelines, training, supervision, and other capacity building factors are some of the factors hindering the HBV prevention related service.

CHAPTER FIVE

5.1 Development and Validation of Strategies

As discussed in Chapter 3, this study was conducted in three phases. Phase 1 involved an integrative literature review to identify best practices for preventing HBV infection among pregnant women. Phase 2 involved interviews with pregnant women and healthcare workers to seek their views and perception of HBV prevention services for pregnant women. Phase 3 involved the development and validation of strategies that would promote the prevention of HBV infection among pregnant women. Therefore, this chapter presented the strategies developed based on this study.

The current researcher formulated the draft of the strategies:

- based on the findings of the integrative review of evidence base best practices in preventing HBV infection among pregnant women, phase one of the current study
- based on the findings from the interviews with pregnant women and healthcare workers to seek their views and

perceptions on prevention of HBV infection among pregnant women, phase of the current study

- based on consultation with stakeholders

The results of phases 1 and 2, as indicated above, informed the development of strategies for preventing HBV infection among pregnant women. The research approach for developing strategies involved the use of the SWOT analysis framework. This is the concluding chapter of the study and two key recommendations and strategies are detailed. These are guided by the themes, sub-themes and categories outlined in the Results Chapter. The draft strategies were validated using consultative meeting with stakeholders including pregnant women, healthcare workers (midwives and obstetricians), and other stakeholders such as policymakers, program managers, and members of the medical and midwifery regulatory councils.

The process of strategies development and validation including the SWOT analysis and consultative meetings with stakeholders as used in this study are described in detail in Chapter 3 of this study.

Table 5.Strategies to promote HBV prevention among pregnant women in Ethiopia.

Theme	Strategies and recommendations
Knowledge on HBV prevention among pregnant women	- Promote the knowledge of pregnant women and women of childbearing age on HBV causes, its infection complications and methods of infection prevention - Give priority to the most accessible media channels to women, which are broadcast media (television and radio), and social media using mobile phone technology. - Radio is the most suitable mass media channel for HBV and other infectious diseases related communication as it is cheaper and viewed by organizations as having a wider coverage especially for rural areas - Explore the use of 'Radio diaries' whereby HBV infected mothers share their stories on radio, including as part of a series. - Organizations to formulate high-quality HIV awareness programmes and adverts for local and satellite television. - Advertise the programmes flighted on broadcast media (radio and television) to ensure that the public are knowledgeable about the days and the times they are flighted. - Healthcare workers should consider HBV among the diseases during health education to clients in their respective healthcare facilities. - Pregnant women should be well educated on the epidemic drivers of HBV pandemic, the mode of transmission and the risk factors for infection - Improve the understanding childbearing age, especially pregnant women on HBV through various health education and promotion techniques.
Knowledge of pregnant women on HBV prevention strategies	- Communicate the full spectrum of HBV prevention and the various risk factors for infection - Communicate all possible HBV transmission routes, to dispel misconceptions. Also communicate ways in which HBV cannot be transmitted.
Perception, believes and practices	- Increase dialogue on the role of pregnant women on HBV prevention and control activities, so that women understand it and be cooperative. - Increase knowledge of pregnant women on immunization, its advantage, the various antigen being provided and their specific advantages. - Promote vaccination among pregnant women during all ANC visits, minimize opportunities
Community and social related factors	- Identify communities in urban areas and their leaders and get their buy-in, then approach Government and NGOs for support including training and allowances - Encourage community members to volunteer for structured community involvement to promote cultures which influence positively on HBV prevention and discourage cultures who negatively affect the HBV prevention strategies. - Identify, recruit, train and retain community-based volunteers to address social and cultural norms. - Community health workers, community committees, community-based organizations and community leaders need to be brought together and their roles and responsibilities clearly defined, so that synergy is created, and duplication minimised. - Encourage community engagement in HBV communication and innovations for less structured community involvement, also through volunteering. - Encourage community conversations whereby the community brainstorms and strategizes with the help of an experienced facilitator. - The community, in the form of the family unit, to be encouraged, through HBV communication, to support and counsel family members who disclose their HBV status - Strengthen involvement of families, the smallest community unit, in HBV communication.
Healthcare system and policy related factors	- Government, including local government, and policy makers, needs to engage women of childbearing age in such a manner that the Government are visible and such that the women are aware of their involvement in HBV prevention and control activities. - Laws, policies and strategies that directly and indirectly relate to HBV need to be better publicised and explained in a simplified manner to women. This way, women are well informed, empowered, reassured and motivated to be do their part. Innovative methods to achieve this can be formulated - HBV vaccination, diagnostic and treatment services to be given attention, especially at the lower level of the healthcare system. - HBV diagnostic and treatment protocols to be revised, made accessible to healthcare workers, especially for those who work in ANC clinics.

Healthcare workers perceptions	1. Healthcare workers share be provided updated information including HBV statistics, including figures related to women, so that they have a correct perception and are aware of the current HBV infection levels, how the epidemic is evolving including the socio-cultural related drivers of infection
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5.2 Validations of the Strategies

As highlighted in the method section (chapter 3), the validation of strategies was conducted at three levels. Level one involved holding a consultation meeting with eight pregnant women to assess their views on the acceptability and affordability of the drafted patient-related strategies. Level two involved holding a consultation meeting with eight healthcare workers, including four obstetricians and four midwives. The healthcare workers to take part in the validation of the draft strategies were selected according to their experience (5 years plus) and expertise in the provision of HBV infection prevention services to pregnant women. Lastly, level three involved holding a consultation meeting with 12 stakeholders (3 policymakers, 3 academicians, 3 program managers, and 3 medical and members of the midwifery professional governing bodies). The validation process was guided by the SWOT (Strength, Weakness, Opportunities, Threats) framework.

Therefore, the above strategies were reviewed if internal attributes and resources can support those strategies for successful mitigation

of HBV infection among pregnant women. Similarly, possible internal attributes and resources that work against these strategies were also critically examined. External factors that the entity can capitalize on or use to its advantage and external factors that could jeopardize the proposed strategies were reviewed. The proposed strategies were also validated for Clarity, i.e. if the strategies ' intended purpose can be understood and how consistently the ideas are conceptualized. The Simplicity of the strategies which is the number of elements within the description of each category, how simple they are and whether the strategies give straightforward instructions were also found valid. The validation process also showed the strategies can be used in a wider context, i.e., primary, secondary and tertiary level prevention of health care challenges.

The healthcare workers, midwives, obstetricians, and other health care professionals also agreed that the formulated strategies can be used easily by the relevant stakeholders. The stakeholders during the validation process also agreed that the strategies will lead to improved practice in HBV care, management and infection prevention measures.

CHAPTER SIX

6.1 Conclusions and Contribution of the Study

To the researcher's knowledge, there are no existing HBV prevention and control strategies which address the various drivers of infection transmission. There has been limited data on knowledge and perceptions of pregnant women and healthcare workers on HBV infection transmission among pregnant women. This study has explored the views, perceptions of pregnant women as well as HCWs on HBV infection and its prevention strategies. This study also explored the best practices on HBV infection prevention among pregnant women. The strategies were validated through SWOT analysis framework and various stakeholders' consultative meetings.

Even though the contents of the strategies outlined above are not all entirely new, the researcher has consolidated information primarily from the first phase of this study, integrative literature review on best practices of HBV infection prevention among pregnant women and , as well as from the second phase, exploring the views and perceptions of pregnant women and HCWs on HBV infection prevention among pregnant women. They are therefore evidence-informed strategies. The strategies are for the Ethiopia Ministry of Health, Tigray regional Health Office, and their partners, including donors, implementing partners and NGOs. These strategies can also be used not only in Ethiopia, but also in other African countries in similar settings. Beyond HBV, it is also anticipated that the strategies can be adapted for other related public health areas in Ethiopia and beyond, for example, sexual and reproductive health programmes.

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Dedication

The study is dedicated to my beloved and strong mother, who always inspires me, gives me courage, and supports me in pushing my studies forward. This study is also dedicated to my son, Samuel Gebrekrstos Negash, and my daughter, Arsema Gebrekrstos Negash, who have been my hope and the source of all inspiration to complete my PhD study.

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8. ANNEXURES

8.1 Annex A. INFORMATION SHEET FOR PREGNANT WOMEN

Date: August 20, 2021

TITLE: Strategies to promote the prevention of hepatitis B virus among pregnant women in Ethiopia

Investigator: DGebrekrstos Negash Gebru

Dear Prospective Participant

My name is Gebrekrstos Negash Gebru, a student doing a Doctoral degree at the UCNAmerica University in the Department of Public Health. I am inviting you to participate in a research study entitled: Strategies to promote the prevention of Hepatitis B Virus among pregnant women in Ethiopia.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to explore the best practices in the prevention of hepatitis B virus infection and then develop strategies to promote the prevention the hepatitis B virus infections among pregnant women in Ethiopia.

WHAT IS THE NATURE OF MY PARTICIPATION IN THIS STUDY?

The researcher will inquire about your views and perceptions on hepatitis B virus infection among pregnant women through face to face interviews or phone interview in the event of COVID-19 pandemic that will last about 45-60 minutes.

Your participation is important to understand the different challenges in the prevention of the hepatitis B virus infection among pregnant women in Ethiopia. You will be asked to answer questions about your views and perceptions on hepatitis B virus infection prevention activities. With your permission, the interviews will be conducted in a separate room in a convenient place within this healthcare facility to capture the required information. If the interview is through phone, you will be requested to identify a quiet and private place from your end for the interview. I kindly request you to allow me to audio record the interview so that I will be able to retrieve all the information during the data transcription.

CAN I WITHDRAW FROM THIS STUDY EVEN AFTER HAVING AGREED TO PARTICIPATE?

Participating in this study is purely voluntary and you are under no obligation forced to consent to participation. If you decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You have a full right to withdraw at any time and without giving any reason to do so and no penalty will be imposed on you.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

There are potential benefits in undertaking this study. The benefits are that this study may bring in designing appropriate strategies for prevention of hepatitis B virus transmission among pregnant women.

ARE THERE ANY NEGATIVE CONSEQUENCES FOR ME IF I PARTICIPATE IN THE RESEARCH PROJECT?

Even though the research study, in general, is not inconvenienced to the participants including you, some of the questions regarding hepatitis B virus may be culturally or religiously upsetting to you. You may be burdened by the amount of time that we will be taking during the interview. In addition to this, you may also fear denial for maternal and other health-related services in the health facility if you don't agree to participate in the interview. As a result of this, you may experience psychological-emotional discomfort such as distress or embarrassment by participating in this study. However, there is no form of intimidation from healthcare providers or other persons as the real names of the participants will be withheld, the researcher will only use code names on all material used for the research study. If you experience any of the above adverse events at any stage of the interview, you can stop the interview and the researcher will take necessary measures to minimise the adverse effect of the events.

WILL THE INFORMATION THAT I CONVEY TO THE RESEARCHER AND MY IDENTITY BE KEPT CONFIDENTIAL

Confidentiality and anonymity will be ensured during the interview. Your name or identifiable information will not be used or appear on any public documents. Data will only be accessed by the researcher, supervisor and independent coder. The data collectors will sign an agreement to ensure that participants remain anonymous and that confidentiality is maintained.

Confidentiality agreement will be submitted to the Health Studies' Research Ethics Committee (HSREC) for consideration. Your answers may be reviewed by people responsible for making sure that the research is done properly, including the external coder. Records that identify you will only be available to people working on the study. Your anonymous data may be used for other purposes, such as research reports, journal articles and/or conference proceedings.

HOW WILL THE RESEARCHER(S) PROTECT THE SECURITY OF DATA?

Hard copies of your answers will be stored by the researcher in a lockable cupboard/ filing cabinet for a period of five years so as to use for future research or academic purposes; electronic information will be stored on a password-protected computer. Data will be stored and will be subjected to further Research Ethics Review and approval if applicable. Hard copies will be shredded, and electronic copies will be permanently deleted from the hard drive of the computer.

WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

Participants will not receive any form of rewards. Any costs incurred by the participant for transport, mobile data or other activities related to the research study will be appropriately reimbursed in adherence to the principle of fair procedures (justice).

HAS THE STUDY RECEIVED ETHICS APPROVAL?

This study has received approval from the HSREC of the College of Health Sciences, at UCN. A copy of the approval letter can be obtained from the researcher if you need it.

HOW WILL I BE INFORMED OF THE FINDINGS/RESULTS OF THE RESEARCH?

If you would like to be informed of the final research findings, please contact **Gebrekrstos Negash Gebru** on mobile phone: +23230378887/+251-921567379 or send an email at this negash_gebre1@yahoo.com The findings will be accessible in four weeks' time after the publication of the study. Should you require any further information or want to contact the researcher about any aspect of this study, please contact **Mr. Gebrekrstos Negash Gebru**, as above.

Thank you for taking time to read this information sheet and for participating in this study.

Gebrekrstos Negash Gebru

ልጋብ ሰጠ

ቅጥረ ስምምነት ሓበሬታ ተሳተፍቲ

ዕለት: ሰኔ 10, 2012

ርእሲ: ስትራቴጂያት አብ ምወሳኽ ምክልኻል ሄፓታይቲስ ቢ ቫይረስ አብ መንጎ ኣድዩታት አብ ኢትዮጵያ

ተመራማሪ: ገብረከርስቶስ ነጋሽ ገብሩ

ክቡራት ተሳተፍቲ

ስመይ ገብረከርስቶስ ነጋሽ ገብሩ ይባሃል፣ አብ ዩኒቨርሲቲ ደቡብ ኣፍሪካ ክፍሊ ትምህርቲ መፅናዕቲያት ጥዕና ተምሃራይ ሳልሳይ ድግሪ እዮ። ንመማልኢ ሳልሳይ ዲግሪይ ዝኸውን ምርምር ምስ ቶቕፃፀሪታይ ዶክተር ከሁኖ ኤስ ኤች እናሰራሕኹ እዮ።

ብኣርእስቲ ስትራቴጂያት አብ ምወሳኽ ምክልኻል ሄፓታይቲስ ቢ ቫይረስ አብ መንጎ ኣድዩታት አብ ኢትዮጵያ (Strategies to enhance prevention of Hepatitis B Virus among pregnant women in Ethiopia.) ንዝሰርሖ ፅንዓት ምርምር ንክሳተፋ ይዕድም።

ዕላማ እዚ ፅንዓት እንታይ እዩ?

ዕላማ እዚ መፅናዕቲ አብ ኢትዮጵያ አብ ምክልኻልን ምቁፅፃርን ሄፓታይቲስ ቢ ዘለው ክፍታት ብምንፃር ረኽሲ ሄፓታይቲስ ቢ አብ ጥኑሳት ምክልኻልን ምቁፅፃርን እዩ።

ንምንታይ እየ እነ ንክሳተፍ ተጋቢዘ?

ጥኑሳት ኣዴታት: እዚ ተመራማሪ ንክትሳተፉ ዝመረፀክን ኣብዚ ዝተመረፀ ትካል ክንክን ጥዕና ቅድመ ወሊድ ክትትል ብምግባርክን እዩ።

ኣብዚ ፅንዓት ናተይ ተፈጥራዊ ተሳትፎ እንታይ እዩ?

እቲ ተመራማሪ አብ ሀፓታይቲስ ቢ (hepatitis B virus) ረኽሲ ምክልኻልን ምቁፅፃርን ዘለክን ፍልጠት፣ ኣመለካከታን ተግባርን ብ ቃለ መጠየቂ ቅጥረ ኣቢሉ ግጽ ንግጽ ቀሪብ ወይ ድማ ብስልኪ ክሓተክን እዩ። እቲ ቃለ መተየቂ ካብ 30 ክሳብ 45 ደቂቃ ክወስድ ይከውን እዩ።

ኣካል እዚ መፅናዕቲ ምዃን ጠቓሚ እዩ፣ ንስኽን ኣብ ቀመራዊ መፅናዕቲ ክትሳተፉ እኺን። ኣብ ቀመራዊ መፅናዕቲ ተሳተፍቲ መሕትት ዝውሃብ እንትኾና ነዞም ሕቶታት ውን መልሲ ንክህባ ክሕተታ እየን። ናይቲ ቫይረስ ካብ ኣዶ ናብ ኣሰል ምምህልላፍ ናይ ምክልኻልን ምቁፅፃርን ቀንዲ ምህልካታት ንምርዳእ ናይክን ተሳትፎ ብታኣሚ ኣገዳሲ እዩ። ስለዚ እቲ ተመራማሪ አብ ሄፓታይቲስ ቢ ቫይረስ (hepatitis B virus) ረኽሲ ምክልኻልን ምቁፅፃርን ዘለክን ፍልጠት፣ ኣመለካከታን ተግባርን

ከሐተክን እየ። ብፍቻድ ተሳተፍቲ፤ ዝድለ ሓበሬታ ንምእካብ ተሳተፍቲ ኣብ ዝምቐዎን ዝተፈለየ ክፍሊ ቃለ መሕትት ክግበረለን እዩ። ኣብ ግዝዩ ኮቪድ-19 ድማ ተሳተፍቲ እዚ መጽናእቲ ዝምቐዎም ቦታ ንክምርጹ ኪክህትቱ እዮም።

ዋላ ንምስታፍ ድሕሪ ምስምዕምዐይ ክቋርፅ ይኽእል ድዩ?

ኣብዚ ፅንዓት እዚ ንምስታፍ ዝግበር ተፅዕኖ ዘየለን ብፍፁም ድሌትን እዩ። ንምስታፍ እንተወሲነን፤ ናይዚ ሓበሬታ ቅጥዒ ክህልወንን ስምምዕነት ቅጥዒ ክፍርማን እየን። ኣብ ዝኾነ ይኹን ግዜ ምኽንያት ከየቐረባ ኣብ ልዕሊኡን ምንም መጠንቀቓታ ከይተፅዓነን ክወፃ መሉእ መሰል ኣለወን።

ኣካል እዚ መፅናዕቲ ምዃን ክህልዎ ዝኽእል ጥቕሚ እንታይ እዩ?

እዚ መፅናዕቲ ምክያድ ክህቦ ዝኽእል ጥቕሚ ኣሎ እዩ። እዚ መፅናዕቲ እዚ ምክያድ ንምቁፅፃርን ምክልኻልን ሄፓታይትስ ቢ ምቕው ዝኾኑ ሽቶታት ንምቕራፅን ካብ ኣዶ ናብ ዕሽል ንምግታእ ከምኡ ውን ኣብ ሓፋሽ ዘሎ ምምሕልላፍ ንምግታእን እዩ።

ኣብዚ ፅንዓት እዚ እንድሕር ዝሳተፍ ኮይነ ኣሉታዊ ሳዕቤን የጋጥመኒ ዶ?

ዋላካ እቲ ዝካየድ ምርምር ብሓፈሻ ንተሳተፍቲ ምቕት ዘስእን ተዘይኮነ፤ ኣብ ሄፓታይትስ ቢ ዘለወን ተመኩሮ ብምክፋለን፤ ሓደ ሓደ ስለ ሄፓታይትስ ቢ ቫይረስ ሕቶታት ብ ባህላውን ሃይማኖታውን ተቐባልነት ዘይብሎም ክኮኑ ይክእሉ እዮም። ኣብ ኣዋን ቃለ መሕተቲ ዝውዳእ ግዝዩ እውን ክትሸላቕ ትኮና እክን፤ ብተውስኪ ኣብዚ ጽንዓት እዚ ይኸከል ዘይተሳተፍክን ንዚተፈላለዩ ግልጋሎት ሂክምና ንክይትክልኦ ክትፍርሓ ቲኮና። ናይዙይ ኩሉ ሳዒብየን ድማ ንዝተፈላለዩ ስነ ኣእምራዊን ስነልባዊን ቀውሲ ከም ኣብነት ጭንቅትን ሕፍረትን ክስምዐክን ይክእል እዩ። ኮይኑ ግን ምንም ኣይነት ምቕትኩም ዘስእን ወይም ጉድኣት የብሉን። ብዛእባ እፍሽዋ ልምድኹም ብምክፋልኩም ሽምቡም ብካለሊእ ዘይፍለጥን ምንም ጉድኣት ካብ መገልገልቲ ጥዕና ወይ ካዓ ካብ ካልኣት ሰባት ምንም ዓይነት ናይ መፈራርሒ መንገዲ የለን፤ ተመራማሪውን ንምርምር ፅንዓት ዝውዕሉ ኩሎም ናውትታት ናይ መለለይ ቁፅሪ ጥራሕ እዩ ዝጥቀም።

ናተይ ማንነትን መረዳእታ ዝሕቦ ንተመራመርቲ ሚስጥረይ ይዕቀብ ዶ?

ብክፋል ዝተወቀረ መሕትት ሚጥራዊነቱ ዝተሓለወ እዩ። ናትኩም ሽም ይኩን ብኣኩም ዝፍለ ሓበሬታ ኣብ ዝኾነ ይኹን ናይ ሕዝቢ ሰነድ ኣይረኣይን ፡፡እቲ መረዳእታ ዝረኽብዎ ብተመራማሪ፤ ብተቆፃፃሪን ገለልተኛ ወሃቢ ኮድን እዩ። መረዳእታ ምርካብ ዝኽእሉ ካልኣት ናይ ምርምር ስነምግባር ኮሚቴ ኣባላት ሚስጥራዊ ስምምእነት ሰነድ ዝፈረሙ እዮም።ናይ ሚስጥር ስምምእነት ኣብ ግምት ንምእታው ናብ ምርምር ስነምግባር ኮሚቴ ክላእኽ እዩ። እቲ ፅንዓት ብትክክል ምፍፃሙ ንምርግጋፅ ዝሃብኩምዎ መልሲ ሓላፍነት ብተውሃቦም ክግምገም ይኽእል እዩ። እንስኩም እትብልዎ ኣብቲ ፅንዓት ንዝሰርሑ ጥራሕ እዩ። ናትኩም ሽም ኣልባ መረዳእታ ኣብ ውፅኢት ፅንዓት ሪፖርት ፣ ኣብ ሕትመት ኮንፈረንስ ከይዲ ዝኣመሰሉ ዕላማ ከገልግል ይኽእል እዩ።

እዚ መፅናዕቲ መረዳእታቱ ከመይ ይከላኸል?

ናይዚ ፅንዓት መልሲ ዝኾነ ናይ ወረቐት ፅሑፋት ኣብ ክቐለፍ ዝኽእል ካቢኔት ኣብ ቤት ፅሕፈት ኮሌጅ ፅንዓታት ጥዕና ንቐፃዒ ምርምራትን ትምህርታዊ ዓላማታትን ክጠቅም ምእእንታን ንሓሙሽተ ዓመታት ዝእከል ተኸዚኑ ክቐመጥ እዩ፤ ኤሌክትሮኒካዊ ሓበሬታ ከዓ ብይለፍ ቃል ኣቢሉ ኣብ ኮምፑዩተር ክቐመጥ እዩ። መረዳእታ ተቐሚጡ ኣድላዩ እንተኾይኑ ናይ መፅናዕቲ ስነ ምግባርን ኮሚቴ ክግምገምን ከፅድቕን ይኽእል እዩ። ናይ ወረቐት ፅሑፋት ክውግዱ፤ ኤሌክትሮኒክ ፅሑፋት ከዓ ካብ ኮምፕዩተር መለኦም ብዘለቑነት ክድምሰሱ እዮም።

ኣብዚ ፅንዓት እዚ ምስታፊይ ዝረኽቦ ክፍሊት ወይ ጥቕማ ጥቕሚ ኣሎ ድዩ?

ተሳተፍቲ ዝኾነ ይኹን ውህብቶ ኣይረኽባን እየን። ብተሳተፍቲ ንመጓዓዝያን ንኻልኣት ምስ እዚ ፅንዓት ዝተተሓሓዘ ምንቅስቃሳት ንዘውፅእኦ ወፃኢ ብፍትሓዊነት ክምለሰለን እዩ።

እዚ መፅናዕቲ ናይ ስነ ምግባር መረጋገፂ ረኽቡ ድዩ?

እዚ መፅናዕቲ እዚ ካብ ምጋጋሚ ስነምግባር መፅናዕቲ ኮሚቴ ኮሌጅ ጥዕና ሳይንስ ዩንቨርስቲ ደቡብ ኣፍሪካ ናይ ፅሑፍ መረጋገፂ ዝረኽቦ እዩ። ቅዳሕ ናይዚ መረጋገፂ ደብዳቤ እንተደለኹም ካብቲ ተመራማሪ ምርካብ ይካእል እዩ።

ርካባት እዚ መፅናዕቲ ብከመይ ይነግሮም/ ውፅኢታት እዚ መፅናዕቲ?

ናይዚ መፅናዕቲ እዚ መወዳእታ ውፅኢት ክፈልጡ እንተደልዮም፤ በይዘኣን ንኣይተ ገብረክርስቶስ ነጋሽ ገብሩ ብ ቁፅሪ ስልኪ፡ +23230378887 ወይ ናብ ኤሌክትሮኒክ መልእኽቲ ኣድራሻ ይልኣኻ ወይ ዌብሳይት ይወከሳ። ውፅኢት እዚ መፅናዕቲ ድሕሪ ምሕታሙ ን4 ሰሙን ዝኸውን ግዜ ቅሩብ ክኸውን እዩ።

ናይዚ መፅናዕቲ ዝምልከት ተወሳኺ ሓበሬታ እንተደልየን ንተመራማሪ ኣይተ ገብረክርስቶስ ነጋሽ ገብሩ ምውካስ ይኽእሉ እየን። ኣብ ዝካየድ ዘሎ መፅናዕቲን ምርምርን ስግኣት እንተሃልይወን፤ በይዘኣን ንተቐፃፀሪታይ ዶ/ር ኤስ ኤች ክሁኖ ኣብ ኤሌክትሮኒክ ወይ ናብ ቁፅሪ ስልኪ (012) 429 6290 ክውከሳ ይኽእሉ እየን። ብተወሳኺ ንዝኾነ ይኹን ናይ ስነ ምግባር ስግኣታት እንተሃልይወን ናይቲ ፅንዓታት ስነ ምግባር ኮሚቴ ሰብሳቢት **Prof JM Mathibe-Neke** ብኤሌክትሮኒክ መልእኽቲ ክውከሳ ይኽእሉ እየን።

ነዚ ሓበሬታ ግዜ ሂብክን ብምንባብን ኣብዚ መፅናዕቲ ብምስታፍክንን የመስግነክን።

ገብረክርስቶስ ነጋሽ ገብሩ

8.2 Annex B. Consent form for INFORMED CONSENT FOR PREGNANT WOMEN IN ETHIOPIA

Gebrekrstos Negash Gebru*

Mekelle, Tigray, Ethiopia

Telephone: +232-30378887/+251-921567379

Email: negash_gebre1@yahoo.com

28 July 2020

In case of COVID-19 pandemic, this informed consent form will be sent to the study participants and to one-person witness each via WhatsApp cell phone messages before the start of the telephone interview. The researcher will set up an appointment with the study participant to discuss this informed consent. During the signing process, the participants will be requested to record the signing process. The researcher, in the presence of the witness will read the following information on the phone as follows:

I, **Gebrekrstos Negash Gebru**, am conducting a research study as required for PhD degree at **University of Central Nicaragua (UCN)**. I wish to invite you to participate in this research study entitled **“Strategies to promote the prevention of hepatitis B virus among pregnant women in Ethiopia”**.

The main objective of this study is to develop strategies to prevent HBV infections among pregnant women in Ethiopia. As a participant, you will be required to participate in an interview that will last between 45 and 60 minutes approximately. Some of the questions regarding hepatitis B virus may be culturally or religiously upsetting to you. You may be burdened by the amount of time that we will be taking during the interview. In addition to this, you may also fear denial for maternal and other health-related services in the health facility if you don't agree to participate in the interview. As a result of this, you may experience psychological-emotional discomfort such as distress or embarrassment by participating in this study. However, there is no form of intimidation from health care providers or other persons as the real names of the participants will be withheld, the researcher will only use code names on all material used for the research study. If you experience any of the above adverse events at any stage of the interview, you can stop the interview and the researcher will take necessary measures to minimise the adverse effect of the events.

Confidentiality and anonymity will be ensured during the interview. Your name or identifiable information will not be used or appear on any public documents. Data will only be accessed by the researcher, supervisors and independent coder. All data will be kept in a secure place and will not be shared with any other person without your permission. Your participation in this study is voluntary and you have the right to withdraw at any time of the research study without penalty. The findings of the study will be used to develop strategies to prevent HBV infections among pregnant women in Ethiopia. The results of the study will be made available to you upon request.

If you have any questions please contact the researcher at +232-30378887/+251-921567379 (cell) or email: negash_gebre1@yahoo.com

After COVID-19 there will be delayed re-signing of this informed consent form. After you and us sign this informed consent, the copy will be shared to you via WhatsApp cell phone message.

The participant will be asked if he/she have had sufficient opportunity to read or listen the consent form and ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant's Name _____ Signature.....Date.....

The participant has fully understood about the study and agreed to participate in the study.

Participant's witness name _____ Signature.....Date.....

I herewith confirm that the participant has been fully informed about the nature and conduct of the study.

Researcher's Signature..... Date.....

Researcher's contact details:

Researcher's witness name _____ Signature.....Date.....

ልጋብ ለ፡ ስምምዕነት ሓበሬታ ንጥነታዊ አደጋታት ኣብ ኢትዮጵያ

ገበረከርስቶስ ነጋሽ ገበየ

አድራሻ

አብ ኮቪድ (COVID-19) ግዝይ እንድህር ኮይኑ፤ እዚ ዶክመንት ብ WhatsApp መልክቲ መመሃላለፊ ንተሳተፍቲ ከስደደሎም እዩ። አቲ ተመራመሪ ናይ ቃል መሀተቲ ጊዝዩ ኪሃትት እዩ። ኹማው እውን፤ ሃደ ስብ ምስክር ንክረክቡ ክንገርም እዩ። እዚ ዝስዕብ ሃብረታ ን ተሳተፍቲ ክንበብሎም እዩ። ብፍቃድ ተሳተፍቲ እቲ ፡፡ይ ፈርማ ሂደት ክቅረጽ እዩ።

እነ፡ **ኣይተ ገብረከርስቶስ ነጋሽ ገብሩ ዝተብሃልኩ** ኣብ ዩኒቨርሲቲ ደቡብ ኣፍሪካ ክፍሊ ትምህርቲ ጥዕና ንዶክትሬት ድግሪ ዝኾውን ፅንዓት ኣብ ትሕቲ ስፖርቪዥን ዶ/ር ሲሲንያና ሃና ካኑ እናሰራሕኹ ይርከብ። ተምሃራይ ዝኾኑ ኣይተ ገብረከርስቶስ ነጋሽ ገብሩ ዘካይድዎ መፅናዕቲ ኣባል መፅናዕታዊ ጉጅለ እዮ። ኣነ ስትራተጂታት ኣብ ምውሳኽ ምክልኻል ሄፓታይትስ ቢ ቫይረስ ካብ ኣዶ ናብ ዕሽል ኣብ ኢትዮጵያ (Strategies to enhance prevention of mother to child transmission of Hepatitis B virus in Ethiopia) መረዳእታ ኣብምትእኻብ ይርከብ ። ኣነ ኣብ ዘፅንዖ “መወሰኺ ስትራተጂታት ምክልኻልን ምቁፅፃርን ሄፓታይትስ ቢ ኣብ መንጎ ጥኑሳት ኣዴታት ኣብ ኢትዮጵያ” ኣብ ዝብል ርእሲ ንክትሳተፉ ክዕድም ይፈቱ። ናይዚ መፅናዕቲ ቀንዲ ዕላማ ኣብ ምክልኻልን ምቁፅፃርን ሄፓታይትስ ቢ ዘለዉ ክፍተታት ብምፍላይ ኣብ ምክልኻልን ምቁፅፃርን ረኽሲ ሄፓታይትስ ቢ ኣብ ጥኑሳት ኣነስቲ ኣመልኪቱ ስትራተጂ ንምምዕባል እዩ። እዚ መፅናዕቲ እዚ ብኮሚታት መፅናዕቲን ስነ ምግባርን ዩኒቨርሲቲ ደቡብ ኣፍሪካን ሃገረ ኢትዮጵያን ተገምጊሙ ዝፀደቐ እዩ። ከም ተሳታፊይ መጠን ካባኺ/ኹም ዝድለ ኣብዚ ብፍርቃዊ ምዕራፅ ዘለዎ መሕትት ንኣስታት 45 ክሳብ 60 ደቂቓ ዝውድእ ቃለ መሕትት ምክያድ እዩ።

ዋላካ አቲ ዝካየድ ምርምር ብሓፈሻ ንተሳተፍቲ ምቕቓት ዘስእን ተዘይኮነ፤ ኣብ ሄፓታይትስ ቢ ዘለዎን ተመኩር ብምክፋሉን፤ ሓደ ሓደ ስለ ሄፓታይትስ ቢ ቫይረስ ሕቶታት ብ ባህላውን ሃይማኖታውን ተቅባልነት ዘይበሉም ክኮኑ ይክእሉ እዮም። ኣብ አዋን ቃለ መሕተቲ ዝውዳእ ግዝዬ እውን ክትሸላቸዎ ትኮና እክን፤ ብተውስኪ ኣብዚ ጽንዓት እዙይ እንድሕር ዘይተሳተፍኩን ንዚተፈላለዩ ግልጋሎት ሂክምና ንክይትክልኣ ክትፍርሓ ቲኮና። ናይዙይ ኩሉ ሳዒብዮን ድማ ንዝተፈላለዩ ስነ ኣእምራዊን ስነልባዊን ቀወሲ ከም ኣብነት ጭንቅትን ሕፍረትን ክስምወክን ይክእል እዩ። ኮይኑ ግን ምንም ኣይነት ምቕቓትኩም ዘስእን ወይም ጉድኣት ዮብሉን። ብዛእባ እፍሽዎ ልምድኹም ብምክፋልኩም ሽምኩም ብካለሊኦ ዘይፍለጥን ምንም ጉድኣት ካብ መገልገልቲ ጥዕና ወይ ካዓ ካብ ካልኣት ሰባት ምንም ዓይነት ናይ መፈራርሒ መንገዲ የለን፤ ተመራማሪውን ንምርምር ፅንዓት ዝውዕሉ ኩሎም ናውታታት ናይ መለለይ ቁፅሪ ጥራሕ እዩ ዝጥቀም።

ኣብዚ ቃለ መሕትት እትህብዎ ሓበሬታ ብዝምልከት ምሽጥራዊነቱ ዝተሓለወ እንትኾውን ሽምኩም ምስ ውልቀ መረዳእታኹም ተዛማዲ ኣብ ዝኾነ ይኹን ናይ ህዝቢ ሰነዳት ኣይፅራሕን እዩ። ነዚ መረዳእታ ክሪኦ ዝፍቀዶም ተመራማሪ፤ ሱፐርቫይዘር ወይ ካዓ ተቐማገሪን ተቐማገሪ ዘይብሉ ኮድ ወሃቢን ጥራሕ እዮም። ኩሎም መረዳእታታት ኣብ ውሕስ ዝኾነ ቦታ ዝቐመጡ ኣንትኹን ብዘይ ፍቓድ ንዝኾነ ይኹን ሰብ ኣይዋሃብን። ኣብዚ መፅናዕቲ ምስታፍ ብድሌትኩም ኣንትኹን ኣብ ዝኾነ ይኹን ግዜ እዚ መፅናዕቲ ብዘይ ዝኾነ ይኹን ቅፅዓት ንክተቃርፁ መሰል ኣለኩም እዩ። ርካባት እዚ መፅናዕቲ ኣብ ኢትዮጵያ ንዘለዎ ጥኑሳት ኣዴታት ንምክልኻልን ምቁፅፃርን ሄፓታይትስ ቢ ኣብ ምምዕባል ሽቶታት ክጠቅም እዩ። ውፅኢት እዚ መፅናዕቲ ኣብ ዝደለኻ/ኻ ሽቶ ክትረኽቡ/ብዮ ክግበር እዩ።

በይዛኹም/ኺ ሕቶታት እንተሃልዩኩም ቦቲ ናይ ዋና ተመራማሪ ቁፅሪ ስልክ +232-30378887/+251-921567379 (ጦባይል) ወይ ካዓ

እዚ ስምምዕነት ቅፅዒ ንምንባብን ሕቶታት ንምሕታትን እኹል ዕድል ስለ ዝረኽቡኩ ባዕለይ ኣብዚ ፅንዓት ከም ዝሳተፍ የፍልጥ።

ተሳታፊ ፌርማ..... ዕለት.....

ተሳታፊይ ምስ ምክያድ እዚ መፅናዕቲ እኹል ሓበሬታ ምርካብ የረጋግፅ።

ናይ ተሳተፊ ምስክር ስም.....ፌርማዕለት.....

ፌርማ ተመራማሪ..... ዕለት.....

ተመራማሪ ኣድራሻ:

ናይ ተመራመሪ ምስክር ስም.....ፌርማ.....

8.3 Annex C. INFORMED CONSENT FOR HEALTH CARE WORKERS IN ETHIOPIA

Mekelle, Tigray

Ethiopia

Telephone: +232-30378887/+251-921567379

Email: negash_gebre1@yahoo.com

28 June 2020

In case of COVID-19 pandemic, this informed consent form will be sent to the study participants and to one person witness each via WhatsApp cell phone messages before the start of the telephone interview. The researcher will set up an appointment with the study participant to discuss this informed consent. During the signing process, the participants will be requested to record the signing process. The researcher, in the presence of the witness will read the following information on the phone as follows:

I, **Gebrekrstos Negash Gebru**, am conducting a research study as required for PhD degree in Health Studies at UCNAmerica University.

I wish to invite you to participate (in a group of 6 to 8 healthcare workers) in this research study entitled “**Strategies to promote the prevention of hepatitis B virus among pregnant women in Ethiopia**”. The main objective of this study is to identify the gaps in hepatitis B virus (HBV) prevention activities, and then develop strategies to prevent HBV infections among pregnant women in Ethiopia. As a participant, you will be required to participate in a group of 6 to 8 healthcare workers’ discussions that will last between 60 to 90 minutes approximately. There may be questions that may cause discomfort to you as they involve reminding of experiences that were unpleasant to you. If you find questions that make you feel uncomfortable, you are free not to answer such questions and this will not have any negative consequences on you. Your participation in this study is voluntary and you have the right to withdraw at any time of the research study or not to discuss some questions without penalty.

The researchers will not disclose your name or identifiable information in any public documents or publications. Data will only be accessed by the researcher, supervisors and independent coder. All data will be kept in a locked cabinet and will not be shared with any other person without your permission. The moderator in the group discussion will also set ground rules which entails obligations and responsibilities of participants to respect privacy and confidentiality of other group members in the discussions.

However, absolute guarantee of confidentiality and privacy is difficult as focus group members can disclose what has been discussed in this study to any person outside of this group, and researchers will not have the ability to avoid such risks. Therefore, participating in this group discussions has some risks on you and giving consent assumes taking those anticipated risks. The findings of the study will be used to develop strategies to prevent HBV infections among pregnant women in Ethiopia. The results of the study will be made available to you upon request. I kindly request permission for me to record this interview to enable me to capture all that you have said. Only the researchers will listen to this recording, therefore, no one will be able to identify you by your voice.

I, _____ (Print name), agree to participate in this research titled: “Strategies to promote the prevention of hepatitis B virus among pregnant women in Ethiopia” that is being conducted by Gebrekrstos Negash Gebru. I have had sufficient opportunity to read the consent form, and I have understood the risks and benefits of participating in this research and ask questions and (of my own free will) declare myself prepared to participate in the study.

After COVID-19 there will be delayed re-signing of this informed consent form. After you and us sign this informed consent, the copy will be shared to you via WhatsApp cell phone message.

The participant will be asked if he/she have had sufficient opportunity to read or listen the consent form and ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant’s Name _____ Signature.....Date.....

The participant has fully understood about the study, and agreed to participate in the study.

Participant’s witness name _____ Signature.....Date.....

I herewith confirm that the participant has been fully informed about the nature and conduct of the study.

Researcher’s Signature..... Date.....

Researcher’s contact details:

Researcher’s witness name _____ Signature.....Date.....

8.5 Annex G. Confidentiality agreement for data collectors

Developing strategies to promote the prevention of hepatitis B virus amongst pregnant women in Ethiopia

Name of researcher: Gebrekrstos Negash Gebru

28 June 2020

I, Mr/Dr _____ have been selected as data collector for the study, led by the researcher Gebrekrstos Negash Gebru, titled as “**Strategies to promote the prevention of hepatitis B virus amongst pregnant women in Ethiopia**”. I have received adequate training on the nature of the study, objectives, methods and techniques of data collection. I have received training on the research ethics principles. I have agreed to ensure the following measures in the whole process of the data collection activity.

- 1) I will ensure the confidentiality of any data collected from pregnant women and health care workers interview.
- 2) I will keep overall confidentiality, respect social norms and culture of the public health system.

- 3) I will keep all the data collected confidential by using coding system whereby no one will have access to individual identifiable information and no name will be recorded in the data collection tools (semi-structured interview guide for pregnant women, interview guide for focus group discussion among healthcare workers)
- 4) The interview with pregnant women and with health workers will be conducted in a free separate room, where no one except the data collectors will be allowed to enter the room during the interview process. In COVID-19 situation where there are travel restrictions and physical distance policy in place, the data collection will be through telephone interviews and Zoom meetings. In this case the interviews and Zoom meetings will be conducted privately using secure network connection and the video will be immediately transferred to password protected electronic device.
- 5) I will secure the privacy and will not share the interview guides used to interview with any unauthorised persons and I will keep the confidentiality of the information collected in this research project.
- 6) In addition, I will fully explain the aim of this research to study participants and I will give sufficient information to study participants about risks and benefits of this study, and will seek informed decision, and delayed written signed consent if data will be collected during COVID-19 pandemic.

Name of data collector: _____

Date: _____ signature: _____

Name of researcher _____

Date _____ Signature _____

8.6 Annex I. Semi-structured interview guide for pregnant women

Topic: **Strategies to promote the prevention of Hepatitis B Virus among pregnant women in Ethiopia**

After giving the study participant the information sheet and obtaining informed consent

Introduction and Orientation

Good morning, my name is Gebrekrstos Negash Gebru. I am a PhD student at the UCN. I will interview you to find out about hepatitis B virus infection among pregnant women in Ethiopia. The aim of this interview is to obtain views on the factors which influence the prevention of HBV infection transmission among pregnant women in Ethiopia.

Remember to record now – say location and date

Date of interview: DD/MM/UCN

Name of participant _____

Name of interviewer _____ **Signature** _____

Name of research assistant _____ **Signature** _____

THEME 1: Demographic information for participant

1. Can you tell us your age?
2. What is your religion?
3. What is your ethnicity?

THEME 2: HBV and KNOWLEDGE

1. Can you discuss your understanding of HBV?
2. Can you tell us the causes of HBV?
3. How is it possible for people to get infected by HBV?
 - a. Probe for the different transmission routes
4. What can promote the spread of HBV? (Epidemic drivers).
5. How can one minimise chances of getting HBV?

THEME 3: PERCEPTIONS, BELIEFS AND PRACTICES

1. Have you received vaccination for hepatitis B virus? If no, why?
2. Do pregnant women believe it is important that they know their HBV status? Explain your answers.
3. What makes HBV infection among pregnant woman more serious than infection among the general people?
4. How do you see the adequacy of information available to you about HBV?

THEME 4: Community and social-related factors

2. Discuss what role, if any, religion or spirituality have in the prevention of HBV among pregnant women matters?
3. How do you see the effect of close families or peer friends of pregnant women on prevention of HBV infection?
4. What aspects of culture in Ethiopia promote the spread of HBV among pregnant women?
5. What aspects of culture in Ethiopia help in reducing the spread of HBV infection among pregnant women?
6. Discuss the extent to which cultural aspects influence in the HBV management among pregnant women in Ethiopia?

THEME 5: Health care system and policy related factors

1. How do you see the quality of services that you receive when you attend ANC regarding HBV care, treatment and prevention in the nearest health facility?
 - a. Probe for access to vaccination, diagnostic service, treatment service, healthcare workers attitude etc.
2. What role have you seen government, policymakers and the law playing in HBV prevention measures for the Ethiopian pregnant woman?
3. Do you have any recommendation to improve HBV infection prevention among pregnant women?

Thank you for your participation.

ልጋብ ሐ. ብሙሉአነት ዘይተወቐረ መራሒ መሕትት ንነበሰ ፀ-ር ኣዴታት

ርእሲ፡ ምምሕዳሽ ሽቶታት ንምትብባዕ ምክልኻል ዕፍሽዋ (ሄፓታይትስ ቢ) ኣብ መንጎ ጥነባት ኣዴታት ኣብ ኢትዮጵያ

ድሕሪ ምሃብ ሓበሬታ ቅጥዒን ሰነድ፡ ስምምዕነትን ተሳተፍቲ እዚ መፅናዕቲ

መእተዊን ምእዘናን

ከመይ ሓዲርኩን፡ ስመይ ገብረከርስቶስ ነጋሽ ገብሩ ይብሃል፡፡ ኣብ ዩኒቨርስቲ ደቡብ ኣፍሪካ ናይ 3ይ ድግሪ ተምሃራይ እየ፡፡ ኣብ ኢትዮጵያ ኣብ መንጎ ነበሰ ፀ-ር ኣዴታት ንዘሎ ረኽሲ ዕፍሽዋ (ሄፓታይትስ ቢ) መሰረት ገይረ ቃለ መሕተት ከገብረልኩን እየ፡፡ ዕላማ እዚ ቃለ መሕተት ኣብ ኢትዮጵያ ኣብ ነበሰ ፀ-ር ኣዴታት ንዘሎ ምክልኻል ረኽሲን ምምሕልላፍን ዕፍሽዋ (ሄፓታይትስ ቢ) ዘሎ ረዳሒ ፅዕንቶ ምልከታ ንምርካብ እየ፡፡

ሕጂ ንምምዝጋብ ኣስታውሱ- ቦታን ዕለትን በል

ኣርእስቲ 1፡ ስነ ህዝባዊ መረዳእታ ተሳታፊ

1. ዕድመኣን ከነግራና ይኽእላ ዶ?
2. ሃይማኖተን እንታይ እየ?
3. ብሄረን እንታይ እየ?
4. ዝኾነ ይኹን ስሩዕ ትምህርቲ ተኸታቲለን ይፈልግ ዶ? እወ እንድሕር ኮይኑ፡ ዝለዓለ ብርኪ ትምህርተን ከንደይ እየ? ----
5. ኣብዚ ሕጂ እዋን ተመርዒኺ ወይ ምስ ሰብኣይ ሓቢርኪ ትንበሪ ዲኺ እንድሕር ዳኣ ተመርዒኺ
6. ካብ መንበሪ ቦታኹን ናብቲ ዝቐረበ ጥዕና ትካል ዘሎ ርሕቐት ብ ኪሜ ብግምት ከንደይ ይኸውን?

ኣርእስቲ 2፡ ዕፍሽዋ ሄፓታይትስ ቢ ቫይረስን ፍልጠትን

1. ኣብ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስን ዘለወን ርድኢት ይግለፃ
2. ምኽንያት ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ከነግራኒ ይኽእላ ዶ?
3. ሰባት ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ከሓልፈን ዝኽእል ብከመይ እየ?
 - a. ሀ. ብዝተፈለለዩ መመሓላለፍቲ መንገድታት ሕተት
4. ንምስፍሕፋሕ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ከተባብዕ ዝኽእል እንታይ እየ? (መምፃእቲ ለባዳ)
5. ዝኾነ ሰብ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ናይ ምትሓዝ ዕድሉ ብኸመይ ይቐንስ?

ኣርእስቲ 3፡ ዝገባለታት፤ እምነታትን ተግባራትን

1. ከታበት ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ረኽበን ዶ? እንድሕር ኣይፋል፤ ንምንታይ?
2. ኣብ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ዘለወን እዋነዊ ኩነታት እንታይ እየ? (ግላዊ ፀብፃብ)
3. ኣብ ኤች ኣይ ቪ ዘለወን እዋነዊ ኩነታት እንታይ እየ? (ግላዊ ፀብፃብ)
4. ኣብ ሄፓታይትስ ቢ ዘለወን እዋነዊ ኩነታት እንታይ እየ? (ግላዊ ፀብፃብ)
5. ነበሰ ፀ-ር ኣዴታት ኩነታት ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ምፍላጠን ጠቓሚ እዩ ኢሉን ይኣምና ዶ? መልሱን ይግለፃ፡፡
6. ረኽሲ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነበሰ ፀ-ር ኣዴታት ካብ ሓፈሻ ህዝቢ ብዝለዓለ ዕቱብ ዝገብር እንታይ እየ?
7. ብዛዕባ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ እኹል ሓበሬታ ይረከብ እየ ኢሉን ዶ ይኣምና?
8. ተንከባኸቢ ጥዕና ወሃቢ ንምርካብ ናይ መጓፃዝያ ግልጋሎት ትረኽባሉ ግዘ ከመይ እየ፤ ክልኒክ ወይ ሆስፒታል?

ኣርእስቲ 4. ማሕበረሰብን ማሕበራዊን ዝመስሉ ረጅሒታት

1. ግደ ዝኾኑ ሃይማኖታዊ ወይ መንፈሳዊ እምነት ኣብ ምክልኻል ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነበሰ ፀ-ር ኣዴታት ክህልዎም ዝኽእል ግደ እንታይ ከም ዝኾነ ይግለፃ?
2. ምስ ናይ ቀረባ ስድራቤታት ወይ መስታ ኣዕርኽቲ ዘሎ ቅርርብ ኣብ ምክልኻል ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነበሰ ፀ-ር ኣዴታት ዘሎዎ ፋይዳ ከመይ ይርከብ?
3. ኣብ ኢትዮጵያ ንምስፍሕፋሕ ረኽሲ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነበሰ ፀ-ር ኣዴታት ዘተባብዑ ባህላዊ ዛዕባታት እንታይ እየም?
4. ኣብ ኢትዮጵያ ንምቐናጃጃ ምስፍሕፋሕ ረኽሲ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነበሰ ፀ-ር ኣዴታት ዝሕግዙ ባህላዊ መዳያት እንታይ እየም?

5. ኣብ ኢትዮጵያ ንምሕደራ ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነብስ ፀር ኣደጋታት ዝህልዉ ዕዕንቶ ባህላዊ መደያት ይግለፃ?

6. ንምክልኻል ዕፍሽዋ (ሄፓታይትስ ቢ) ቫይረስ ኣብ ነብስ ፀር ኢትዮጵያውያን ኣደጋታት ግደ መንግስቲ ፡ መምርሒ መውፃኣቲን ሕጊ ኣብ ስጉምቲታትን እንታይ ሪክን?

ንተሓትፎኡን የመስግን፡፡

8.7 Annex J. Focus Group Discussions interview guide for healthcare workers

Topic: **Strategies to promote the prevention of Hepatitis B Virus among pregnant women in Ethiopia**

After giving the study participant the information sheet and obtaining informed consent

Introduction and Orientation

Good morning, my name is Gebrekrstos Negash Gebru. I am a PhD student at the UCN. We will discuss with you to find out about hepatitis B virus infection among pregnant women in Ethiopia. This interview aims to obtain views on the factors that influence the prevention of hepatitis B virus infection among pregnant women. I have a moderator (give names) and assistant researcher (Give name) who have more than ten years of experience in this type of study. The moderator will facilitate the discussion and I and the assistant moderator will take notes as we also assist in the facilitation of the discussion.

Focus group number:

Number of participants in this group:

Date:

Start time: _____ End time: _____

Name of moderator:

Phone number of moderator:

Name of research assistant:

Phone number of research assistant:

REMEMBER TO START RECORDING/ AUDIO RECORDING

SECTION 1: DEMOGRAPHIC DATA

Can you please clarify the following?

- What is your age?
- For how many years have you worked in this clinic?
- Highest educational qualification?

SECTION 2: HEALTH SERVICE RELATED FACTORS

4. What is your experience in providing hepatitis B prevention activities?
5. What are your views on the quality of services for the prevention of hepatitis B virus infection among pregnant women at your healthcare facility?
6. What are your views on the effectiveness of screening pregnant women for hepatitis B virus infection at antenatal care clinics in identifying high-risk groups in the elimination of hepatitis B?
7. What are the different services that healthcare providers should provide to prevent hepatitis B virus transmission among pregnant women?
8. What are the different services that you or your colleagues are currently providing to prevent hepatitis B transmission among women?
9. What are the challenges that you or your colleagues experience in providing hepatitis B prevention services to pregnant women?
 - a. Probe for challenges they face during screening, diagnosis, treatment, and care of pregnant women with hepatitis B infection and their newborns including their competencies

SECTION 3: SOCIOCULTURAL RELATED FACTORS

1. What aspects of culture in Ethiopia promote the spread of HBV among women pregnant women?
2. What aspects of culture in Ethiopia help in spreading the spread of HBV among pregnant women?
 - a. probe for pregnant women and community perceptions and beliefs, stigma, and discrimination
3. What are gaps that exist in the prevention of hepatitis B virus infection among pregnant women?
4. What factors make it easier for you or your colleagues to provide hepatitis B prevention services to pregnant women?
5. Please tell me about what you know about the recommended practices for screening pregnant women for hepatitis B infection.
6. What do you think are the risk factors for the increasing hepatitis B virus infection among pregnant women?
7. Kindly give me suggestions to improve the prevention of hepatitis B virus infection among pregnant women.

CONCLUSION.

Thank you very much for taking your time to come to the interviews and for answering my questions

