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Magnitude of HBV and HIV among woman at comprehensive abortion care units and their knowledge, attitude and practice at selected sub-cities health institution in Addis Ababa, Ethiopia.

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“This is to certify that the thesis prepared by THOMAS BOGALE, entitled:

Magnitude of HBV and HIV among woman at comprehensive abortion care units and their knowledge, attitude and practice at selected sub-cities health institution in Addis Ababa, Ethiopia” and submitted in partial fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Diagnostic and Public Health Microbiology) complies with the regulation of the university and meets the accepted standards with respect to originality and quality.

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Contents

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List tables

List of figures

Abbreviations

Anti-HBcA	Anti-Hepatitis B Core Antigen
Anti-HBeA	Anti-Hepatitis B envelope Antigen
Anti-HBsA	Anti-Hepatitis B Surface Antigen
AOR	Adjusted Odds Ratio
CAC	Comprehensive Abortion and Care
CDC	Center for Disease Control and Prevention
CHB	Chronic Hepatitis B virus
CIs	Confidence Intervals
CS	Cross Sectional Study Design
DAAs	Direct Acting Antiviral Drugs
DNA	Deoxy Ribonucleic Acid HAV-Hepatitis A Virus
HAART	Highly active anti-retroviral therapy
HBeAg	Hepatitis envelope Antigen
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCC	Hepatocellular Carcinoma
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
INF	Interferon
IRB	Institutional Review Board
IU	International Unit
Kb	Kilo Base
MCH	Mother and Child Health
Ml	Milliliter
Nm	nanometer
NS	Non-Structural Protein
OR	Odds Ratio
RNA	Ribonucleic Acid
SES	Socio-economic Status
SPSS	Statistical Package for the Social Sciences

Ss	Single stranded
UNAIDS	The joint United Nations program on HIV/AIDS
WHO	World Health Organization

Abstract

Background: HIV and HBV are major public health problem worldwide with highly prevalent in developing countries like Asia and Sub-Saharan Africa. Both of these infections share similar mode of transmission which is horizontal and parental transmission. Community primarily based studies regarding the prevalence of every viral infection among women on comprehensive abortion and care unit at selected sub cities in Addis Ababa Ethiopia has not been conducted.

Objective: To determine the Magnitude of HBV and HIV among woman at comprehensive abortion care units and their knowledge, attitude and practice at selected public health institute in Addis Ababa, Ethiopia from December 2019 to May 2020.

Methods: Across sectional study was conducted among 423womenattending on comprehensive abortion and care at private and government health care units, at Addis Ababa, Ethiopia from December 2019 to May 2020. A structured questionnaire was used to collect data on, socio-demographic characteristics, associated risk factors, knowledge, attitude and practice via face to face interview. The presence of antibodies to HIV was tested based on the national testing algorithm. Hepatitis B surface antigen was tested using rapid test in adherence with the manufacturer instruction and positive results was confirmed by Bio-Rad ELISA kits. Data entry and analysis was done using SPSS.

Results: The overall prevalence of HBV and HIV among participants was7.6% (n=32/423) and 4.7% (n=20/423) respectively. The prevalence of HIV is higher in the age group of 20-24 years old with 7.8 %(n=8/103). Similarly, HBV was higher in the age group of 30-34 years old with 13.6% (n= 9/66). From the total participants, 78.6% did not know how the disease is transmitted, 77.8% (n=329/423) believed that HBV can be transmitted through contaminated water, 81.6(n=343(/423) had no information about the availability of HBV vaccine and 96% (n=406/423) were not vaccinated.

Conclusion: The magnitude of HBV and HIV among participants of the study was intermediate it might be due to low knowledge, attitude and practice towards the transmission and prevention of the disease. Therefore, necessary to creating awareness for woman about the transmission and prevention mechanisms of HBV and HIV infection**.** Large scale study is recommended at national level.

Key words: HIV and HBV, Sero-prevalence, KAP, knowledge, attitudes and practice.

1. Introduction

1.1 Background

Women in sexual relationships and victims of sexual assault are at larger danger of getting Human Immune deficiency Virus (HIV) and Hepatitis B virus (HBV) because of unprotected sexual practices [1, 2]. Presences of other sexually transmitted infections expand the probability of HIV and HBV acquisition [1, 2,3].HIV and HBV are a group of infectious or communicable disease in which their important mode of transmission is through sexual contact, exposure to infected body fluids in developing countries. Of these, sexual contact is the predominant mode of transmission [4].

Worldwide, the most commonly reported reason women cite for having an abortion is to postpone or stop childbearing. The second most common reason—socioeconomic concerns—includes disruption of education or employment; lack of support from the father; desire to provide schooling for existing children; and poverty, unemployment or inability to afford additional children. In addition, relationship problems with a husband or partner and a woman's perception that she is too young constitute other important categories of reasons. Women's characteristics are associated with their reasons for having an abortion: With few exceptions, older women and married women are the most likely to identify limiting childbearing as their main reason for abortion. [5]. High abortion rate and low contraceptive prevalence rates are common in Ethiopia [6]. In Ethiopia, condom use as a form of birth control is poor. Few adolescents take advantage of HIV testing and counseling services [1]. Studies have shown that the proportion of women who participate in sexual practices prior to marriage has increased and the age at first sexual intercourse decreased [1,6].These un protected sexual practice increase STIs among young women [1].HIV and HBV infections are the two most important infectious diseases in developing countries [7]. HBV are transmitted during the prenatal period from mother to fetus or infant through sexual contact, exposure to contaminated body fluids and. Of these, un protected sexual contact is the predominant mode of transmission for HIV and HBV [7, 8]. Transmission of HBV in sub-Saharan Africa commonly occurs during childhood. Sexual and parenteral routes are also important particularly in areas where unprotected sex is a common practice [9].Hepatitis B virus (HBV)-associated infection is one of the leading causes of liver

diseases causing serious public health problem worldwide. Since the majority of infected individuals remain as asymptomatic carriers, most infected individuals die due to the virus without notice and hence called as a "silent killer"[10].One - third of the world's populations have serologic evidence of HBV infection [11, 12]. Sub-Saharan Africa is considered a highly endemic area for HBV by WHO [9]. Among young women, the prevalence of HBV infection is 6–20 % and varies among different regions [11-13]. In Ethiopia, a 1.8–6.6 % and 3–7.3 % prevalence of HIV and HBV infections, respectively reported in other risk populations [14–17].

In Ethiopia, Young women aged 15-24 are the most vulnerable group for HIV and HBV because of the extremely low levels of contraception usage and hepatitis B vaccine coverage. [14-17].Viral hepatitis is a leading cause of maternal complication and vertical transmission that cause fetal and neonatal hepatitis which can have serious effects on the neonate, leading to impaired mental and physical health later in life [18]. HBV as leading cause of maternal mortality is also said to be the most familiar cause of jaundice in pregnancy [19]. Perinatal HBV transmission also occurs when the mother is acutely infected during late pregnancy, in the first postpartum phase, or when the mother is a chronic carrier. [20].Hepatitis B virus (HBV) infections are having a major effect on health worldwide, and in developing countries the issue is greater very particularly, in Africa. The two most important viruses share similar means of transmission in humans, which is responsible for the high incidence of co-infections with HIV-HBV. [21].

Women are members of key populations at higher risk of acquiring or transmitting HIV via sexual routes. Sub-Saharan Africa is a region with the highest numbers of HIV positive adolescents. In 2012, the world HIV prevalence in youth aged 15–24 was 0.8 and 4.7 % in sub-Saharan Africa. In sub-Saharan Africa, women face a higher risk of early HIV acquisition due to biological factors and gender disparities that lead to unequal relationships of influence, access to education and economic opportunities [22].

1.1.1 Hepatitis B infection

Natural history of HBV infection

Hepatitis B virus is an enveloped DNA virus, measuring 42–47 nm in diameter and a member of the family Hepadina viridian hepatotoxic DNA viruses. Hepatitis B viral hepatitis virus causes both acute and chronic infection that may range from symptomless infection or mild illness to severe or sudden hepatitis. Acute hepatitis B is typically a self-limiting illness marked by acute inflammation and hepatocellular necrosis, with a case death rate of 0.5–1%. Chronic hepatitis B (CHB) encompasses a spectrum of illness, and is defined as persistent HBV infection (the presence of detectable within the blood or serum for extended than six months), with or without associated active viral replication and evidence of hepatocellular injury and inflammation [23].

HBV Mode of Transmission

Transmission of HBV results from exposure to infectious blood or body fluids, unprotected sexual contact, blood transfusion, reuse of contaminated needles and syringes, and vertical transmission from mother to child. Other high-risk adult populations include persons with multiple heterosexual partners, and healthcare workers without education. The risk of prenatal HBV transmission is greatest for infants born to women who are HBeAg positive [24].

1.1.2 HIV infection

Natural history of HIV infection

Human immunodeficiency virus (HIV) is a lent virus that causes acquired immunodeficiency syndrome (AIDS). This is an RNA virus that belongs to a family of viruses known as retroviruses. The name comes from the fact that these viruses convert their RNA into a DNA copy using an enzyme known as reverse transcriptase. HIV is a highly variable virus which mutates very readily. This means there are many different strains of HIV, even with in the body of a single infected person [25]. HIV infects vital cells in the human immune system such as helper T cells (specifically CD4+Tcell) and it's infection leads to low levels of CD4+Tcells through three main mechanisms: First, direct viral killing of infected cells; second, through increasing the rates of apoptosis in infected cells; and third, killing of infected CD4+T cells by CD8 cytotoxic lymphocytes that recognize infected cells. When CD4+ T cell numbers decline below a critical level, cell-mediated immunity is lost and the body becomes progressively more susceptible to opportunistic infection [26]. There are two types of HIV:HIV-1 and HIV-2.Both types are transmitted by sexual contact, through blood and from mother to child as well these

types appear to cause clinically indistinguishable AIDS. However, it seems that HIV-2 is less easily transmitted and the period between initial infection and illness is longer in the case of HIV-2 .the geographical distribution of type- 1 is predominant through the world where as type -2 is relatively un common and is concentrated in west Africa.[27]

HIV mode of transmission

Transmission of HIV results from exposure to infectious blood or body fluids, unprotected sexual contact, blood transfusion, reuse of contaminated needles and syringes, and vertical transmission from mother to child. Other high-risk adult populations include persons with multiple heterosexual partners [27]

1.2 Statement of the problem

HIV and HBV are a major public health problem through the world, especially in developing countries. They are highly prevalent among pregnant women in Africa and cause significant maternal and prenatal morbidity [1]. In addition they have been associated with a number of adverse pregnancy out comes including abortion and stillbirth. Therefore; diagnosing and treating of these devastating disease agents at an early stage may result in preventing the spread of such infections not only pregnant woman but also for their new born in infants [28].

According to UNAIDS epidemiological report, 33 million people infected with HIV worldwide, of these 18 million were woman that indicates new infection is rising all over the world each year where the greater percentage of this population is found in developing countries of Africa and Asia. [29].

Hepatitis B virus(HBV) is Viral hepatitis which affecting millions of individuals every year, causing disability and death around 500 million individuals are chronically infected with hepatitis B virus (HBV) within the world and approximately 1.4 million individuals die each year (~2.7% of all deaths) from causes associated with viral hepatitis, most commonly liver disease, including liver cancer [30]. Estimated 57% of cases of liver cirrhosis and 78% of cases of primary liver cancer result from HBV infection [31]. Viral hepatitis places a heavy burden on the health care system due to the costs of treatment, of liver failure and chronic liver disease. In many countries, viral hepatitis is the leading cause of liver transplants. Such end-stage treatments are expensive, simply reaching up to many thousands of dollars per person [32]. Chronic viral hepatitis also leads to loss of productivity [33]. Recent information indicates that from 1990 to 2005 the prevalence of HBV infection was reduced on the average below 2% in Central and

Tropical Latin American regions. But it remained 2-4% in Caribbean, Indian, and South American regions [34].All countries within the African Region consider viral hepatitis an urgent public health issue. The burden of viral hepatitis, although not accurately known, is believed to be one of the highest within the world. Hepatitis A, B and C are the types mostly found within the Addis Ababa. The prevalence of HBV is estimated at 8% in West Africa and 5-7% in Central, eastern and Southern Africa. [33].

Studies from the Horn of Africa, particularly Ethiopia, report a carriage rate between 5.4% and 15% [25]. Several researchers have investigated prevalence rates of HBV and HIV infections in various groups (health care workers, blood donors, medical waste handlers, and others). However, there was no previous study conducted on HIV and HBV infections among women seeking abortion for unwanted pregnancies on comprehensive abortion and care unit at selected sub cities of Addis Ababa in Yeka, Kirkos and Bole. Therefore, determining the magnitude of HIV and HBV in these populations helps to quantify the magnitude of STI risk and inform prevention effort. Moreover, reducing new HIV and HBV infections among women of reproductive age is important to keep women healthy, eliminate mother to child transmission and reduce the burden of HIV and HBV in the community. This study will conducting to determine the magnitude of HBV and HIV infections with associated factors, knowledge, attitude and practice of HBV and HIV among woman on comprehensive abortion and care unit at selected sub cities of Addis Ababa in Yeka, Kirkos and Bole sub cities.

1.3 Significance of the study

This study provides the following information to the responsible bodies:

- To generate information on the prevalence, knowledge and attitude of hepatitis B virus and human immune virus among woman on comprehensive abortion and care at Selected sub cities that helps health policy makers for designing appropriate intervention strategies.
- Designing preventive mechanisms for HIV, HBV spread of disease among woman as well as in the general population.
- Draw the attention of stake holders to focus on such life threatening but preventable infection.
- Finally, the information obtained from knowledge; attitude and practice of participants about the disease can give clue to the responsible bodies for planning health education program based on the level of understanding of targeted group.

2. Literature Review

Sero-prevalence of HIV, HBV infections is well recognized worldwide but has been reported to be more common in developing countries especially in Africa and Asia. Perhaps it's wide spread all over the world; different epidemiological studies suggest that the prevalence of such common sexually transmitted in factions has been shown to vary from one country to other among different groups. In addition to this the focus has now shifted to the management of concurrent illnesses as chronic HBV infections, which have the potential to increase long-term morbidity and mortality [34].

Globally, 35.3 million people were living with HIV in all adult aged 15-45. Out of this globally estimated infection of HIV, there were around 1.6 million [1.5 million-1.9 million] deaths related to the acquired immune deficiency syndrome (AIDS) and 2.3 million new infections (6,300 new HIV infections per day). Women represent about half (52%) of all people living with HIV worldwide and the infection is leading cause of death among women of reproductive age. The burden of epidemic considerably varied between countries and regions. Sub-Saharan Africa remains most severely affected, with 25.0 million people living with HIV and 1.6 million newly affected individuals. Latin America and the Caribbean are second to Sub-Saharan Africa with 1.6 million living with HIV and 98,000 newly infected people [35, 36]. HIV prevalence among the adult population in Sub-Saharan Africa and Caribbean sub region was estimated to be 4.7% and 1% respectively, while the global adult prevalence was estimated at 0.8 %. In other part of the world ,adult prevalence rate ranges from less than 0.1% (East Asia) to 0.5 % (North America).where as in the Eastern Europe/central Asia the prevalence rate were 0.7%(UNAIDS,2012) [36]

In study from India by Krunal D et al 2013, a total of 1038 samples from antenatal patients were screened for hepatitis B virus and HIV infection. The overall prevalence was 2.9% for and 0.38% for HIV. There was no co-infection found between hepatitis B and HIV [37].

In Iran 850 pregnant women were studied by Leila K *et al* 2012, the prevalence of positive test results was 0.59% in the study population. Positive was significantly correlated with abortion. However, there was no significant association between results and other variables. They concluded that, although the prevalence of positive was relatively low among pregnant women in Dehloran city, HBV screening during pregnancy is highly recommended [38].

In study from Nigeria by Christy N *et al*2004, from 1120 pregnant women 8.6% were seropositive for HIV, 9.3% for and 0.7% for both HIV and co-infection. Infection rates for HIV, HBV and HIV/HBV co-infection were significantly associated with age groups, marital status and occupation of the subjects. The prevalence rates of the infections were inversely associated with increase in educational status. They conclude that both HIV and HBV were endemic in Nigeria (39).

In a study conducted in Cameroon by Lem*et al*, 2015, 301 Pregnant Women were participated. Majority of them (72.1%) were in the age group of 20-30 years and 89.4% were urban residents. A total of 224 (74.4%) study subjects were married. The highest number of women 157(52.2%) attended tertiary school and 193 (64.1%) women were pregnant for more than once. They reported that the overall prevalence of HIV infection among pregnant women was 6.6% while HBV was 6.0%. The prevalence of HIV and HBV co-infection was 1.7% [40].

A report from Kenya, 2016, established that the prevalence of HBV infections among pregnant women attending antenatal clinic at Mbagathi District Hospital was 3.8% with highest infection rate among the 20-24 years age group. Seventy six (60.8 %) of the participants reported sexual encounters in less than a month before the interview of which 5 (7.6%) reported encounters involving other partners apart from their spouses. HBV awareness among the study participants was 12.2%. Before the interview, those with at least tertiary education were more informed about HBV infection as compared to those with primary and secondary education. In regards to assessment of the risk factors; type of family, parity, History of abortions, early, at first sexual encounter were significantly associated with HBV positivity. They concluded that the prevalence of HBV infection among pregnant women attending Antenatal clinic (ANC) at Mbagathi District hospital, Nairobi was lower (3.8%) than the prevalence among pregnant women nationally (9.4%), [35].

A study from Cameron, 2015, by jean J *et al* to know the Prevalence and infectivity of HBV infection among pregnant women, reported that 33 women (10.2%) were -positive, of whom 4 (12.1%) were positive to HBeAg. The prevalence of HIV infection was 2.5% (8/325). Overall, 5 (1.5%) women were co-infected with HIV and HBV. Most participants (97.2%) were married, housewives (96.4%), and less than secondary school education level (80%). Only 4 women (1.2%) had been vaccinated against HBV. They concluded that the prevalence of HBV infection among pregnant women in that rural area was high. History of blood transfusion and HIV

infection were highly associated with HBV infection. The relatively low rate of women positive to both and HBeAg suggested that perinatal transmission of HBV might not be the prevailing mode of HBV transmission in that study area [42].

In a study conducted by Wondemagegn M et al 2016, Ethiopia, 360 young women aged 15–24 years were studied. Totally, 4.4 % were positive for either HBV or HIV infections. The prevalence of HIV and HBV infections were 2.5 % and 1.94 % respectively. The mean age of first sexual intercourse was 17.6 and 19.3 in HIV and HBV infected women, respectively. The prevalence of HIV infection was significantly associated with lower educational status, divorced marital status and ever had symptom of other sexually transmitted infections. The proportion of HBV was higher in women aged 15–17 years [22].

In a report by Regea D, 2018, Ethiopia, a total of 421 pregnant mothers involved in the study among them the majority were urban resident 254 (60.3%), Oromo ethnic 380(90.3%), Protestant religion follower (59.14%), housewife or unemployed 352(83.6%), 16-24 years old 285(67.7%), married 406(96.4%), secondary and above education level 314(74.6%), first pregnant 224(53.2%), and attending the ANC services for first time 210(49.9%). The prevalence of HBV was different in each of their study area. It was 5.2% in Sire Health Center, 3.8% in ArjoGudetu Health Center and 2.0% in Nekemte Health center [43].

According to the report of Anteneh A *et al,* in Yirgalem, 2018, among Pregnant Women the sero prevalence of was 34 (7.2%), of whom 13 (38.8%) were positive for HBeAg. The prevalence of HIV infection was 10.1% (48/475). Ten out of 34 HBV positive cases (29.4%) were co-infected with HIV. The overall HBV/HIV co-infection rate was 2.1% (10/475). Women with history of multiple sexual partners and being HIV positive were significantly associated with positivity. Among the study participants, 35.4% were aware of motet to child transmission of HBV and only 12 (2.5%) have taken HBV vaccine. They concluded tha*t the* high prevalence of and HBeAg as well as low awareness and practices of HBV prevention methods suggested perinatal transmission of HBV might be the prevailing mode of HBV transmission in their study area [44].

In a cross-sectional study conducted in Adjibar Rural Health Center, 2018, by Yeshi M *et al*, a total of 385 pregnant women were enrolled in their study within the age range of 18 - 42 years and their mean age was 26.6 years. The overall prevalence of HBV was 3.4%. The HBV infection was significantly higher among patients who had history of multiple sexual practices [45].

In other cross-sectional study conducted in southern Ethiopia, 2016, the overall sero prevalence of among 269 pregnant women was 7.8%. The prevalence of HIV infection was 5.2%, of whom two participants (14.2%) were also positive for. Study participants with no formal education were more likely to be infected with HBV than those who had completed at least secondary school. Although was detected more often in pregnant women who had multiple exposure factors than in pregnant women who had not experienced possible risk factors this difference was not statistically significant. They concluded that there was high prevalence of HBV infection detected in the study population. Neither the type of risk factors nor exposure to multiple risk factors was significantly associated with HBV infection. They recommended that screening pregnant women regardless of risk factors and improving awareness of the transmission routes of HBV within that group may reduce the risk of HBV infections [46].

In a study conducted by Zelalem D and his colleagues, Addis Ababa, Ethiopia, 2016 to know the prevalence of Hepatitis B and human immunodeficiency virus co‐infection among pregnant women in resource‐limited high endemic setting, the prevalence of hepatitis B virus infection was 6 %. Among the total, 4.2 % of the positive cases were detected among primary school completed. A total of 4.2 % women were found to be HIV seropositive, of whom 22.2 % were co-infected with HBV (47).

3. Objectives

3.1 General objective

To determine the magnitude of HBV and HIV among woman that get service at comprehensive abortion and care units and their knowledge, attitude and practice at selected sub-cities health care units in Addis Ababa, Ethiopia

3.2. Specific objectives

- To determine the prevalence of HIV among woman at comprehensive abortion care units at selected sub-cities health care unit in Addis Ababa, Ethiopia
- To determine the prevalence of HBV among woman at comprehensive abortion and care units at selected sub-cities health care unit in Addis Ababa, Ethiopia
- To assess knowledge, attitude and practice about HBV and HIV infection woman at comprehensive abortion and care units at selected sub-cities health care unit in Addis Ababa, Ethiopia

4. Hypothesis

Null hypothesis (HO)

- The Prevalence of HBV and HIV among woman on comprehensive abortion and care unit at selected sub cities is not different than the other society.

5. Materials and methods

5.1. Study area:

The study was conducted at selected governmental and nongovernmental health institutions found in selected sub cities in Yeka, Kirkos and Bole which is selected by lottery method in Addis Ababa. Addis Ababa is the capital city of Ethiopia. It is geographically located at the center of the country. The altitude of the city ranges between 2000 and 3000 meters above sea level. Based on the 2005 (EFY) Health and Health Related indicators publication by FMOH Addis Ababa has 33 Hospitals, 28 Health Centers (HC) and 35 Health Posts. Based on the 2000 figure from the central Statistics agency (CSA) of Ethiopia, Addis Ababa has an estimated total population of 3,147,000 consisting of 1,511,000 men and 1,636,000 women. Health facilities within the selected sub city are found in different woreda. These Health facilities are found in yeka (woreda 5, 9, 13), Kirkos (woreda5, 8, 11) and Bole (woreda 6, 8, 13)

5.2. Study design and period:

A cross sectional study was conducted from December 2019 to May 2020 on women who attended comprehensive abortion and care unit in selected sub cities at governmental and none governmental health care unit at Yeka, Kirkos and Bole sub cities of health institutions in Addis Ababa, Ethiopia

5.3. Population:

5.3.1. Source population:

The source population was all CAC attending women at selected governmental & nongovernmental health institution in selected sub cities during the study period.

5.3.2. Study subjects

The study subjects was all customers attended at selected governmental & nongovernmental health institution in selected sub cities for abortion of unwanted pregnancies that full fill inclusion criteria.

5.4. Inclusion and exclusion criteria:

5.4.1. Inclusion criteria: All women those attended the institution for safe abortion of unwanted pregnancies and who were volunteer to participate in the study during the study period.

5.4.2. Exclusion criteria:

Those who are unable to communicate for different reasons

Those who knew their status of HBV and HIV

5.5. Study variables

5.5.1. Dependent variables:

- Prevalence of HBV and HIV among women on comprehensive abortion and care unit.
- Knowledge, attitude and practice of HBV and HIV among women on comprehensive abortion and care unit.

5.5.2. Independent variables

- Socio demographic (Age, , marital status, educational status, …)
- Risk factors for HBV and HIV (multiple sexual partners, blood transfusion history, history of surgical procedure, ear/nose piercing, contact with jaundiced patients, dental extraction, tattooing, shaving by barbers, previous abortion).

5.6. Sample size calculation and Sampling method

5.6.1. Sample size calculation

The sample size was calculated using a formula for single population proportion considering the following assumptions

Assumptions: With the assumptions of Confidence interval = 95%, Critical value

Zα/2 = 1.96, Degree of precision d = 0.05. The proportion (p) = 50% since there was no research done in the same.

Using $n = \frac{(Z\ \alpha/2)^2\ p\ (1-p)}{d^2}$

Where, n= the required sample size

Z α/2= the standardized normal distribution curve value for the 95% confidence interval (1.96)

P= the level of KAP of federal police crime prevention staffs were unknown so we take as 50%

d= degree of precision (the margin of error between the sample and population, 5%) = 0.05

$n = \frac{(1.96)^2(0.5)\ (1-0.5)}{}$

$(0.05)^2$n= 384

By taking additional 10% contingency for non-response rate, the sample size were = 423

Therefore, a minimum of 423 participants was included for our study.

5.6.2. Sampling Method

A multi stage sampling technique was used in this study since, there are 10 sub cities in Addis Ababa we couldn't cover all sub cities with in short period of time and limited budget and we used lottery method to select three sub cities Yeka, Bole and Kirkos from all sub cities .we also used again lottery method to select private and government health care unit since we couldn't cover all. Finally, we used convenient sampling method to select study participants who attended in selected health care institution of comprehensive abortion and care unit within the specified time of the study.

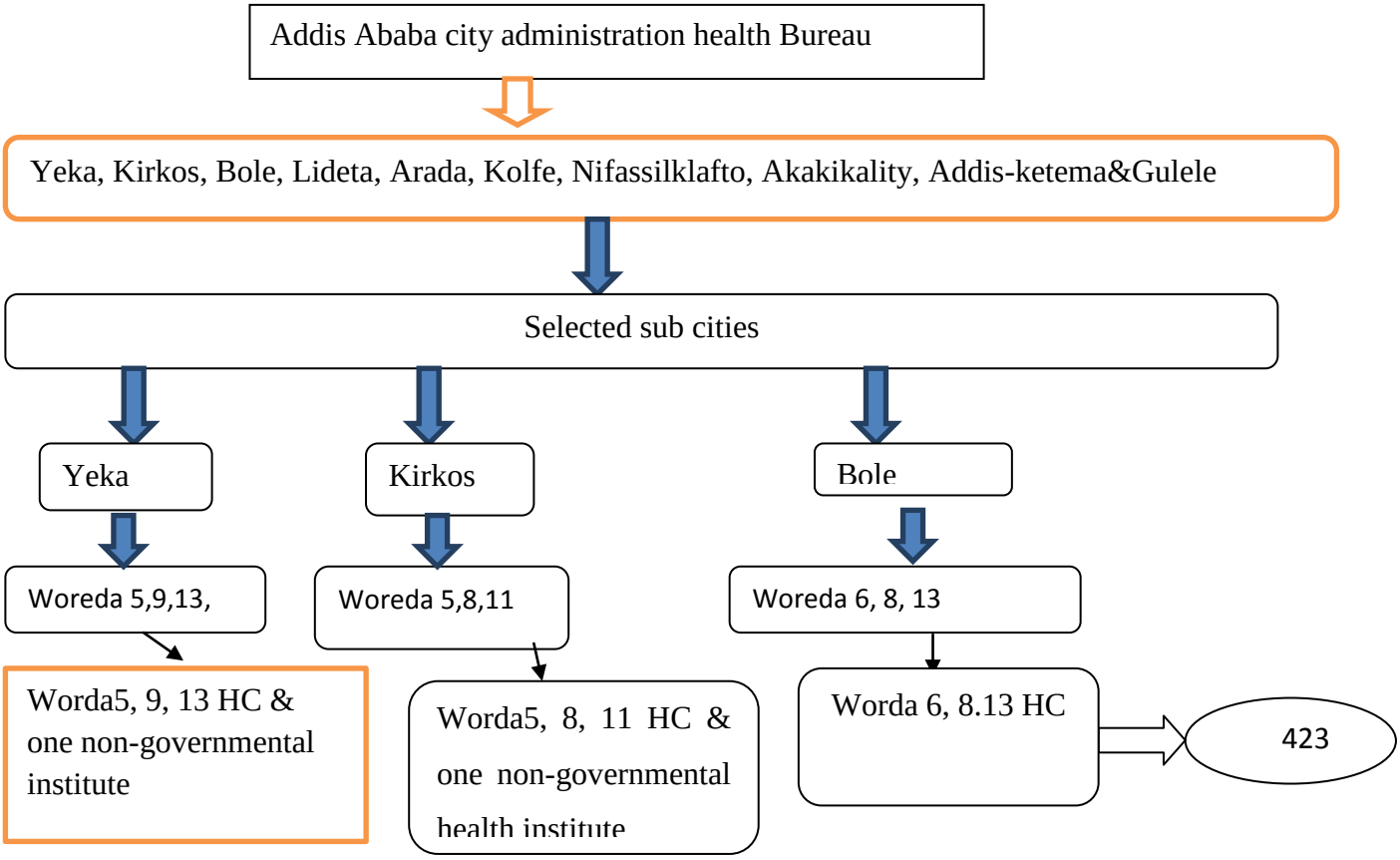

Figure 1 Sampling method

5.7. Measurement and Data collection

5.7.1. Data collection procedure:

Demographic data collection

A structured questionnaire was used to collect socio demographic data of the study participants by face to face interview. The data was collected by principal investigator.

Specimen collection and processing

Five milliliter of venous blood was collected by trained personnel in the CAC and transported to the health facility laboratory by using triple package system. The blood was allowed to clot and serum was separated by centrifugation at room temperature at 3000 rpm for four minutes and stored in the freezer at -20 $^{\circ}$C until being tested.

5.7.2. Laboratory analysis

5.7.2.2. **Hepatitis B (surface antigen) Test Strip** (Serum/Plasma)

The WONDFO one step test strip (serum/plasma) is a rapid visual immune chromatographic assay for the qualitative determination of hepatitis B surface antigen (kit insert) in human serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of infection.

Principle

The SMI One Step Test Device (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of in serum or plasma. The membrane is pre-coated with anti- antibodies on the test line region of the test. During testing, the serum or plasma specimen reacts with the particle coated with anti- antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti- antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Interpretation of Results

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.(Test kit insert sheet)

5.7.2.3 ELISA test principle

This is a Sandwich Enzyme linked Immune-sorbent assay method in which polystyrene micro well strips are pre-coated with monoclonal antibodies specific to. Participant's serum or plasma sample is added to the micro-wells together with a secondary antibody conjugated with horseradish peroxidase (HRP) and directed against a different epitope of. During incubation, the specific immune-complex formed in the case of presence of in the sample, is captured on the solid phase. After washing to remove sample serum protein and unbound HRP conjugate, chromogen solution containing Tetra-methyl Benzedrine (TMB) and urea peroxidase are added to the walls. In the presence of the antibody-antigen-antibody (HRP) sandwich immune complex, the colorless chromogens are hydrolyzed by the bound HPR conjugate a blue colored product. The blue color turns to yellow after stopping the reaction with sulfuric acid. The amount of color can be measured and is proportional to the amount of antigen in the sample (Test kit insert sheet).

5.7.2.3 HIV test

Base on the national testing algorithm of HIV, whole blood or Sera will first test for the qualitative detection of HIV-1/2 anti-bodies by using:

1. HIV ½ stat-pack rapid testing (Test 1)
2. Abon HIV 1.2.0 HIV rapid testing (Test 2)
3. SD Bioline ½ HIV rapid testing (Test 3)

According to the national testing algorithm of HIV, when the first test (HIV ½ stat-pack) is non-reactive, then the final test result is Negative .When first test (HIV ½ stat-pack) is reactive,

the result was tested by the second test (Abon HIV 1.2.0 HIV rapid testing); and if it is reactive, the result was tested by the third test (SD Bioline ½ HIV rapid testing) and if it is reactive the final result was positive. When T1 is reactive, and T2 is non-reactive, then repeat both T1 and T2.If the result is the same, report the final result as HIV negative. After repeating if T1 is non-reactive and T2 is non-reactive report HIV negative .After repeating the test if both T1 and T2 are reactive, proceed to the third test (T3).If T3 is reactive report HIV positive. If T3 is non-reactive report HIV inconclusive and repeat in 14 days.

Principle

- The sample is applied to the SAMPLE (S) well followed by the addition of running buffer.
- The buffer facilitates the lateral flow of the released products and promotes the binding of antibodies to the antigens.
- If present, the antibodies bind to the gold conjugated antibody binding protein.
- In a **reactive sample,** the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a pink/purple line.
- In the absence of HIV antibodies, there is no pink/purple line in the TEST (T) area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area containing IgG antigens.
- This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: Discard the used sample loop, test device and any other test material into a biohazard waste container. Do not re-use loop.

5.8. Data Quality Assurance

All specimens were collected according to the standard operating procedure of specimen collection. The quality of test results was maintained using the internal quality control of the test kits and by using a known negative and positive sample with external quality control.

During the entry of data, it was cross checked to assure the right data was entered correctly.

5.9. Data analysis and interpretation

Data entry and analysis was done using SPSS version 23.0 computer software. Data was summarized and presented in descriptive measures such as a table, figures, mean and percentage. Chi-square test was used to establish association between serological results, knowledge, attitude and different risk factors considered in the study. It was used to compare categorical data, and to evaluate the difference in prevalence between groups in the bivariate logistic analysis as well as the statistical significance between relevant variables. The result at p-value < 0.05 was considered as statistically significant. To determine the correlation between the data obtained from the questionnaire and the laboratory results, odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) was calculated using logistic regression analysis. This is to determine whether a variable will associated with the infections.

5.10. Operational definitions:

Reactive: In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region, that indicate the presence of in the serum.

Non-Reactive: only one colored band appears on the control (C) region. No apparent band on the test (T) region that indicates the absence of in the serum.

Invalid:-No visible band at all or there is a visible band only in the test region but not in the control region

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

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

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

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

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

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

Safe abortion care: - is an evidence-based intervention that prevents maternal mortality and morbidity.

Knowledge: - information stored in memory assessed in terms of what the participants know about HBV/HIV.

Attitude: - complex interaction of beliefs, feelings, and values to respond in a manner towards HBV/HIV.

Practice: - what the respondents actually practice for prevention and control of HBV/HIV.

5.11Interpretation of KAP questioner answer

For the interpretation of KAP questioner which were administered for the study participants the following criteria was employed. For Knowledge questioner study participants who answered questions $\geq$ 70% correctly considered as good/high level of knowledge. For Knowledge questioner study participants who answered questions $\leq$ 70% questions correctly considered as low level/limited knowledge. For attitude questioner study participants who answered $\geq$ 3 questions correctly considered as positive attitude. For attitude questioner study participants who answered $\leq$ 2 questions correctly considered as negative attitude. For practice questioner study participants who answered $\geq$ 2 questions correctly considered as good practice. For practice questioner study participants who answered $\leq$ 2 questions correctly considered as poor practice.

5.12. Ethical considerations

The study was carried out after it was approved by Addis Ababa University, College of Health Sciences, Department of Medical laboratory Ethical Review Committee (DRERC) of Addis Ababa University, College of Health Science, Department of Medical Laboratory Science, and Addis Ababa Health Bureau. A letter was submitted to each Health institutes to get permission to

undergo the study. The purpose of the study was explained to each participant and sample was obtained only after each participant gives his/ her written consent. All information obtained held securely and stored on paper and computer files with a unique identification number. No one except the interviewers knew the participant took part in the study and the answers were given by the participant marked with an especial study number only, and not the name. All positive results were communicated with respective health professionals.

5.13. Dissemination of the result:

This study can serve as a reference material to researchers, experts or policy makers for intervention. To reach these bodies the finalized paper will be submitted to College of Health Sciences, Department of Medical Laboratory Silences, and Addis Ababa University. So it can serve as a reference in the library. The result will also be disseminated through publication in reviewed local and international journals and through presenting it in relevant workshops and seminars.

5.14 Work flow:

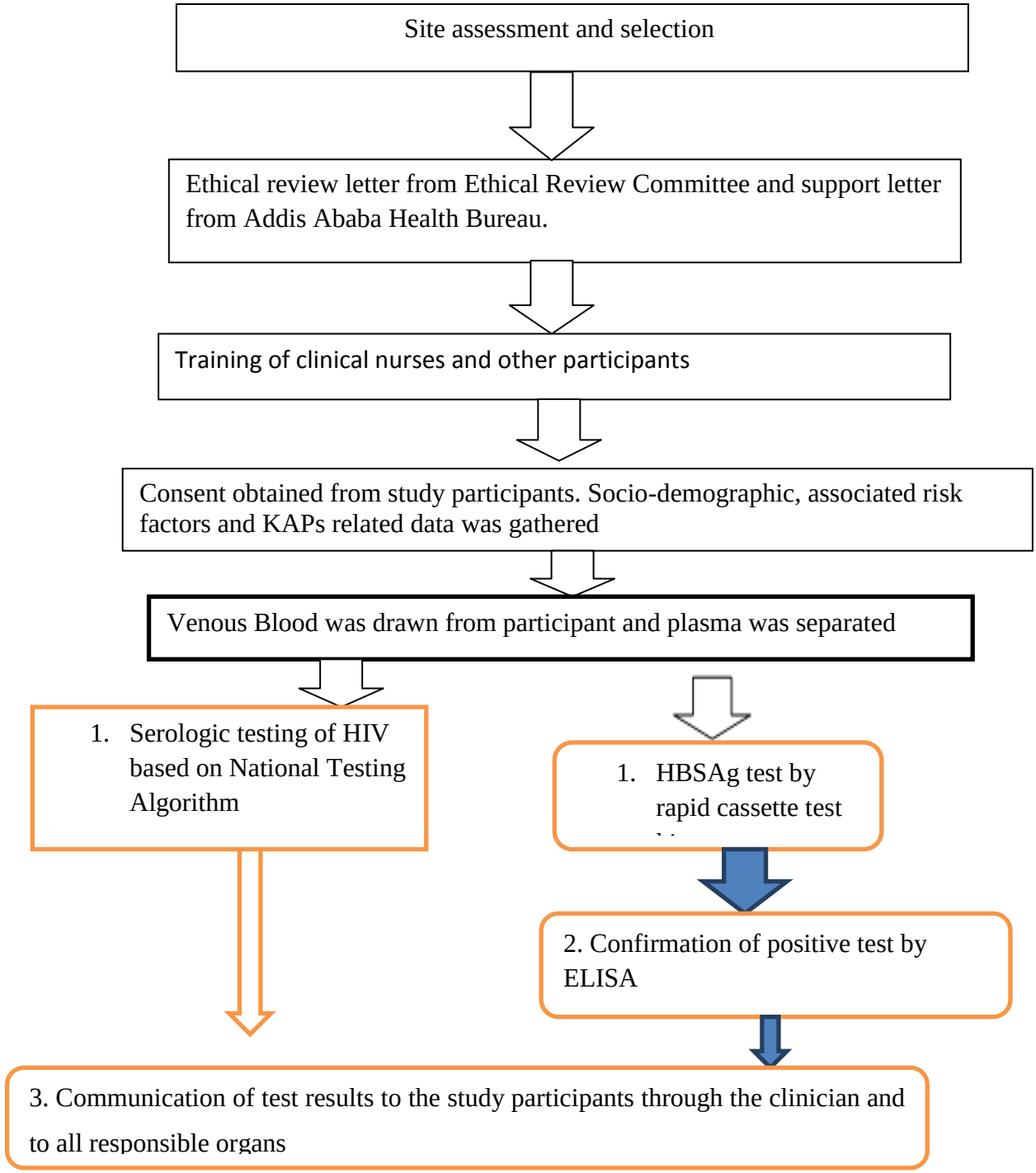

Figure 2 workflow

6. Results

6.1: Socio Demographic Characteristics

During the study 439 volunteer clients have given their consent to be participating in the study and the questionnaire was filled, but 9 participants were excluded due to improper blood collection and 7 participants were rejected with incomplete of the questionnaire with the total rejection of 3.6% (n=16/439). The age range of the participants' were17-39 years old and the mean age was 26.5±9.3SD**.** Majority of age group was 25-29, 34.8% (n=147/423). Related to marital status, 67.1% (n=284/423) of them were unmarried and 27.9% (n=118/423) of them married. Related to educational status, 33.6% (142/423) & 43.3% (183/423) participants were elementary& high school level respectively as showed in (Table 6.1).

Table 6.1:Socio-DemographicCharacteristicsamongwomen attending at selected public health institutes of CAC service Addis Ababa, Ethiopia, January to May 2020(n=423), 2020.

Variables		Frequency	**Percentage (%)**
Age(Years)(n=423)	≤20	68	16.1
	21-24	103	24.3
	25-29	147	34.8
	30-34	66	15.6
	35-39	39	9.2
Marital status	Single	284	67.1
	Married	118	27.9
	Divorced	16	3.8
	Widowed	5	1.2
Education(N=423)	No formal education	19	4.5
	Primary education	142	33.6
	High school	183	43.3
	College level & above	79	18.7
Occupation(N=423)	Self –employed	76	18.0
	Gov.t employed	35	8.3
	Private employed	184	43.5
	Not employed	128	30.3

n=total sample size

6.2. Magnitude of HBV and HIV

All participants were screened with and HIV rapid tests. From those 7.6% (n=32/423) were positive for HBV and 4.7% (n=20/423) were positive for HIV. From those confirmed positive results for HIV & HBV about 5.7% (n=3/52) were co infected with both. ELISA confirmed prevalence of HBV among positive result with screening test was 7.6% (n= 32/423).The prevalence of HIV is higher in the age group of 20-24 years old with 7.8 %(n=8/103). Similarly, HBV was higher in the age group of 30-34 years old with 13.6% (n= 9/66). Participants who were positive for HBV8.5% (n=10/118) and 3.4% (n=4/118) positive for HIV were married. In the case of educational status 11.3% (n=16/142) for HBV positive and 8.5% (n=12/142) for HIV positive were educated at elementary level (Table 6.2.1& 6.2.2).

Table 6.2.1: magnitude of HIV in relation to socio demographic characteristics among women attending at selected public health institutes of CAC service Addis Ababa, Ethiopia, January to May 2020(n=423).

Variables			HIV		P value
		N (%)	Pos (%)	Neg (%)	
Age category	≤ 20	68 (16.1)	4 (5.9)	64 (94.1)	0.002
	20-24	103 (24.3)	8 (7.8)	95 (92.2)	
	25-29	147 (34.8)	5 (3.4)	142(96.6)	
	30-34	66 (15.6)	2 (3)	64(97)	
	35-39	39 (9.2)	1(2.6)	38(97.4)	
Marital status	Single	284(67.1%)	13(4.6)	271(95.4)	0.052
	Married	118(27.9)	4(3.4)	114(96.6)	
	Divorced	16(3.8)	3(18.8)	13(81.3)	
	Widowed	5(1.2%)	0(0)	5(100)	
Education	No formal education	19(4.5)	3(15.8)	16(84.2)	0.002
	Primary education	142(33.6)	12(8.5)	130(91.5)	
	High school	183(43.3)	5(2.7)	178(97.3)	
	College level & above	79(18.6)	0(0)	79(100)	
Occupation	Self – employed	76(18)	4(5.3)	72(94.7)	0.911
	Gov.t employed	35(8.3)	1(2.9)	34(97.1)	
	Private employed	184(43.5)	8(4.3)	176(95.7)	
	Not employed	128(30.2)	7(5.5)	121(94.5)	

Table 6.2.2: magnitude of HBV in relation to socio demographic characteristics among women attending at selected public health institutes of CAC service Addis Ababa, Ethiopia, January to May 2020(n=423).

Variables			HBV		P value
		N (%)	Pos (%)	Neg(%)	
Age category	<20	68 (16.1)	3(4.4)	65(93.6)	0.126
	20-24	103 (24.3)	5(4.9)	98(95.1)	
	25-29	147 (34.8)	10(6.8)	137(97.2)	
	30-34	66 (15.6)	9(13.6)	57(86.4)	
	35-39	39 (9.2)	5(12.8)	34(87.2)	
Marital status	Single	284(67.1%)	18(6.3)	266(93.7)	0.032
	Married	118(27.9%)	10(8.5)	108(91.5)	
	Divorced	16(3.8)	2(12.5)	14(87.5)	
	Widowed	5(1.2)	2(40)	3(60)	
Education	No formal education	19(4.5)	1(5.3)	18(94.7)	0.187
	Primary education	142(33.6)	16(11.3)	126(88.7)	
	High school	183((43.3)	12(6.6)	171(93.7)	
	College level & above	79(18.6)	3(3.8)	76(96.2)	
Occupation	Self – employed	76(18%)	3(3.9)	73(96.1)	0.557
	Gov.t employed	35((8.3%)	3(8.6)	32(91.4)	
	Private employed	184(43.5%)	14(7.6)	170(92.4)	
	Not employed	128(30.2)	12(9.4)	116(90.6)	

HBV: Hepatitis B Virus

ELISA: Enzyme Linked Immunoassay

Table 6.2.3 magnitude of HBV& HIV co infection among women attending at selected public health institutes of CAC service Addis Ababa, Ethiopia, January to May 2020(n=423).

	HIV		HBV		Co infected with HIV& HBV
	Positive	Negative	Positive	Negative	
N= 423	20	403	32	391	3

6.3. Knowledge, Attitude and Practices (KAP) assessment on HIV and HBV

6.3.1. Knowledge of participants

From the participants 72.1% (n=305/423) were never heard about HBV& HIVand79.4% (n=336/423) and 82.7% (350/423) were never know the transmission of HBV and HIV with Blood and blood products and Needles and sharps injury respectively. Similarly 74.7% (316/423) were never know the transmission of the virus through sexual contact. In case of vaccine 81.1% (n=343/4233) do not have idea about availability of HBV vaccine and 65.2% (n=276/423) also consider to have effective treatment of HBV and HIV at all (Table4).

6.3.2. Attitude of participants

In this study 77.8% (n=37329/423) participants believed that HBV can transmit through contaminated water and 74.7 (n=316/423) participants were believed that HBV can transmit through faeco-oral. About 78.5% (n=332/423) participants were believe that HBV and HIV is not serious public health problems and78.7% (n=333/423) participants were believed that vaccine of HBV is not safe (Table.4)

6.3.3 Practice of participants

With regard to vaccination, 96% (n=406/423) were not vaccinated to HBV. Screening of HBV and HIV, 80.8% (n=342/423) were not screened, 86.1% (n=364/423) of participants did not have history of blood transfusion (Table 4).

Table 6.3.Knowledge, Attitude and Practice assessment on HIV and HBV among women attending at selected public health institutes of CAC service Addis Ababa, Ethiopia, January to May 2020(n=423), 2020.

Knowledge items	**Yes** N (%)	**No** **N (%)**	
have you heard of HIV and HBV	118 (27.9)	305(72.1)	
Blood and blood products	87(20.6)	336(79.4)	
Needles and sharps injury	73(17.3)	350(82.7)	
Sexual intercourse	107(25.3)	316(74.7)	
Vertically from mother to child	75(17.7)	348(82.3)	
Faeco-oral	316(74.7)	107(25.3)	
Contaminated water	329(77.8)	94(22.2)	
Does HBV have vaccine?	80(18.9)	343(81.1)	
Is there effective treatment for HBV and HIV?	276(65.2)	147(34.8)	
Attitude	**Positive**	**Negative**	
	N	**%**	**N**	**%**	
	143	**34**	**280**	**66%**	
Practice	**Good**	**Poor**	
	N	**%**	**N**	**%**	
	49	11.6	374	88.4%	

7. Discussion

The present study demonstrated the first in its kind for the magnitude of HIV and HBV among woman at comprehensive abortion and care unit and there KAP in Ethiopia. Therefore, this study participant deemed good representatives of HIV and HBV magnitude and KAP acquired through unprotected sex and other mechanism of transmission in the region. There are no data on the magnitude of HIV and HBV among woman at comprehensive abortion and care unit and there KAP in Ethiopia. Therefore we could not compare our results directly with similar study participants.

In the present study, 423volunteers were enrolled. All of the participants were females. Majority of age group was in the age group of 25-29, 34.8% (n=147/423).

According to this study, the prevalence of HBV is 7.6%(n=32/423) which is higher than a study done by Krunal D *et al* in which the prevalence was 2.9% and studied by Leila K *et al* in Iran in which the prevalence was 0.59%[37,38]. This finding is lower than a study from Nigeria by Christy N *et al with* prevalence of 9.3%, and a study from Cameron in 2015, by Jean J *et al*in which the prevalence was 10.2% [39,42]. This study is in agreement with study done in in Ethiopia by Anteneh A *et al,* in Yirgalem, 2018 which found the prevalence of HBV to be 7.2% [44]. This shows studies done in Ethiopia indicate the prevalence of HBV is lower than study done in other African countries but higher than studies done in non-African countries. This difference may be due to sample size, study group and study area.

In our study the prevalence of HIV among the participants is 4.7%(n=20/423) which is higher than a study done by Krunal D et al in which the prevalence was 0.38 % and a study from Cameron in 2015, by Jean J *et al*in which the prevalence was 2.5% [36,41] .The finding of this study is lower than a finding In study from Nigeria by Christy N *et al*2004 with prevalence of HIV to be 8.6% and study done by Anteneh A *et al,* in Yirgalem, 2018 with prevalence of 10.1%.The finding of this study is closer to a study which is done in south region of Ethiopia in 2016,the prevalence was 5.2 %[39,44,46]. This difference may be due to sample size, study group and study area.

In this study a co-infection of HIV and HBV among the participants was 5.7% (n=3/52) which is higher than a study done by Krunal D et al in which the co-infection was 2.9%,A study from Cameron, 2015, by jean J *et al which is 1.5%* and a study from Nigeria by Christy

N *et al*2004 with 0.7% co-infection of HIV and HBV [37,39,42].

The prevalence of HIV is higher in the age group of 20-24 years old with 7.8 %(n=8/103). Similarly, HBV was higher in the age group of 30-34 years old with 13.6% (n= 9/66).This finding is similar with study done by Zenebe *et al* in Bahir Dar in which they found the prevalence of HIV is higher in this age group [48]. In this study also assessed the knowledge, attitudes and practices of participants towards HIV and HBV infection. The cutoff value was taken from relative study in Gondar [49].From participants forinstance72.1% (n=305/423) were responded that they have never heard about HBV infection in other ways they had low knowledge of hepatitis infection. The study in Gonder, (73.4%) the study participants replied that they do not have knowledge in terms of hepatitis viral disease. In another study conducted in eastern Ghana in 2016 showed that 40.2% of pregnant women had good knowledge [49, 50]. Interms of mode of transmission 336 (79.4), 336(79.4),316(74.7)and 348(82.3) were never know how the HBV and HIV infection transmitted through Blood and blood products, Needles and sharps injury, Sexual intercourse and Vertically from mother to child respectively. This low level of knowledge of ways of HBV and HIV transmission calls for targeted health education in order to prevent and control the spread of the virus. These results highly contradicted with a study by Chan and colleagues, (2012) from China, who demonstrated quite high level of knowledge (82%) about the routes of transmission through blood and blood product. Moreover, 59% and 58% of their participants knew that HBV is transmitted through unsafe sex and from mother to child, respectively [51]. In case of vaccine 343 (81.1) participants did not have information about availability of HBV vaccine, in Gondar (68.9%) participants answered that there is a vaccination available for these diseases [49] The above data showed that almost all the majority of participants have limited knowledge about HBV and HIV infection, transmission and protection. Therefore, the magnitude of HBV and HIV will be increased in the woman who had poor knowledge unless we have creating awareness with formulating health education program in the society.

With regard to participants attitude, of the total participants, 143 (34%) were having positive attitude (who answered attitude questions correctly) and 280(66%) were having negative attitude for HIV and HBV (who answered attitude questions incorrectly). In another study conducted in at the University of Gondar Comprehensive Specialized Hospital, Northwest Ethiopia of the total participants, 191 (54%) were having positive attitude and 163(46%) were

having negative attitude. These results highly contradicted with a study in Hawassa referral hospital, south Ethiopia about 97.4% of the participants were positive attitude for HIV. Most of the participants 332(78.5) think that hepatitis infection & HIV is not serious public health problem [48, 52].

In relation to participants practice, screening and vaccination of HBV and HIV was assessed using questioner. Out of the 423 participants, 374 (88.4%) were within the poor practice range while 49 (11.6%) showed good practice. Majority of the respondents (342, 80.8%) had never screened for HBV and HIV, and 406 (96 %) are not immunized against HBV.

8. Strength and Limitation of the study

8.1. Strength of the study

- The findings of the study particularly the KAP of participants about HBV& HIV can be used as base line information for other researchers; it will initiate more studies on this subject
- The research was performed among high risk groups

8.2 Limitation of the Study

- The study was conducted in selected sub cities and therefore results of the research may not be representative of the entire participants of Addis Ababa.
- The risk factors of study participants were not included in the study.
- Tests are not performed to screen out either vaccinated or previously exposed participants.
- We did ELISA only for those sera which were positive by rapid tests
- There is no any KAP document recorded among woman in comprehensive abortion and care unit to compare our results; however it was possible to compare with KAP of pregnant women from other studies

9. Conclusion and Recommendation

9.1. Conclusion

- The prevalence of HBV and HIV was 7.6% and 4.7% respectively
- The high prevalence was seen among those 20-24yearsold7.8 %(n=8/103) & 30-34 years old 13.6 (n= 9/66) were positive for HIV & HBV respectively and in elementary level educated participants 11.3% (n=11/142) for HBV positive and 8.5% (n=12/142) for HIV positive. Also high prevalence was seen in self-employed (5.3% for HIV& 3.9% for HBV).
- The overall knowledge of the participants was found to be poor and their attitude and practice were also limited. In this study, most participants had poor knowledge about the etiology, symptom, transmission and prevention of hepatitis B and HBV. Moreover, most were not vaccinated due to lack of knowledge about the presence of HBV vaccine.
- Inadequate knowledge is probably an important factor in HBV and HIV infection. According to these findings there is a lack of understanding of the basics of infection control and the prevention of transmission of HBV and HIV.

Recommendation

Based on the findings of this study, the following recommendations are forwarded for future plan and implementation aiming at the community programmers and policy makers of health-related issues.

- Increase awareness on screening, vaccination must be introduced through health education by the concerned bodies
- Further study should be done to identify the risk factors related to the HBV and HIV
- Extensive health education campaign should be provided to general population and especially to pregnant to increase their awareness towards HBV and HIV infection

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10. Annex

Annexes I Information letter to participants of the study

1. Information Sheet

Hello, how are you? My name is _____. This is an interview to be done with you for a study that is being conducted at Addis Ababa University, college of health Science, department of medical laboratory sciences.

Title of the study

The title of the study is the determination of prevalence, associated risk factors, knowledge, attitude and practice for Human immune deficiency virus (HIV) and viral hepatitis (HBV) infections among women at selected public health institutes on comprehensive abortion and care unit, Addis Ababa, Ethiopia.

Purpose of the study

The purpose of the study is to determine the prevalence, associated risk factors, knowledge, attitude and practice of HIV and HBV among women at selected public health institute on comprehensive abortion and care unit.

What it will mean if you decide to take part in the study?

If you agree to participate in this study, you will participate in this interview in a private place. The interview will last for about10-20minutes and will be facilitated by me and my colleague. During the interview, you will be asked to respond questions related to Human immune deficiency virus, hepatitis infections and their predisposing or risk factors. During the interview, my colleague will write down what you say. The recorded data will not contain your names or other identifying information. They will just be labeled with a study number.

The results will assist policy makers, planners and health service providers for making considerations regarding the risk factors, transmission and prevalence of viral infections among federal police. It will also help to contribute in the subsequent efforts to improve prevention, diagnosis, treatment and support of viral hepatitis in relation to their family, children and fetus, at large in the community.

Risks and discomforts

There is no possible risk associated with participating in this study. But there is a little pain during drawing venous blood which will be collected by professional phlebotomists. You are

free to decline answering any question that you do not wish to answer and you may leave our interview at any time you want to.

Confidentiality

All information obtained will be held securely and stored on paper, and computer files. No one except the interviewers will know that you took part in the study the answers that you give will be marked with a special study number only, and not your name. The data will protect information about you in this research to be the best of our ability.

Voluntary participation

Your participation is voluntary. You may withdraw from the interview at any time without giving a reason and without any penalty. If you have questions regarding this study or would like to be informed of the results after its completion, please do not hesitate to contact:

Investigator: Thomas Bogale, Cell phone: +251913708804

Email: **bogalethomas@gmail.com**

Advisors: WontatirNigatu (PhD),+251910851900

Regassa Diriba: regedire@gmail.com,),+251913934968

For additional information, please contact Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences at: Telephone +251112755170

Annexes II Consent Form

I have read the information sheet concerning this study (or have understood the verbal explanation) and I understand what will be required of me and what will happen to me if I take part in it. I also understand that any time I may withdraw from this study without giving a reason and without me or my families' are being affected for my refusal.

May I continue the interview?

1. Yes _____Continue the interview
2. No _____Stop the interview and thank the respondent

Witness's signature certifying that the informed consent has been given

Witness's signature _____ Date _____

Introduction to the interview

Thank you for deciding to participate in the interview and for coming to this session, previously (on the statement of consent form), we have discussed briefly on the purpose of the research,

how you were identified, and your part in the research study. Now I am going to have discussion with you on the relevant topic items. Before going to the discussion, would you tell me important backgrounds such as age, educational background etc.? There is no right or wrong answers. All answers /responses/ ideas you provide are equally important and you are requested to respond honestly from your experiences and beliefs. I may interrupt and probe your ideas. Once again I would like to tell you that what we are going to discuss is very confidential and it will be used only for the research.

Annex III information letter Amharic version: ስለጥናቱ ማስተዋወቂያና በጥናቱ ለመሳተፍ ፈቃደኝነት መጠየቂያ የአማርኛ ቅጽ

በአዲስአበባከተማአስተዳደርስርበሚገኙበተመረጡየተቀናጀየፅንስማቋረጥአገልግሎትበሚሰጡጤናተቋማትላይየኤችአይቪእና የጉበትበሽታንየሚያመጡረቂቅተህዋሥያንስርጭት(መጠን፣ግንዛቤናአጋላጭምክንያቶችላይየሚደረግጥናት፡፡

ስለጥናቱማስተዋወቂያቅፅጥናቱየሚካሄደውበአዲስአበባከተማአስተዳደርስርበሚገኙበተመረጡየተቀናጀየፅንስማቋረጥአገልግሎትበሚሰጡጤናተቋማትላይየኤችአይቪእናየጉበትበሽታንየሚያመጡረቂቅተህዋሥያንስርጭት፣መጠን፣ግንዛቤናአጋላጭምክንያቶችየሚልነው፤የጥናቱአላማበረቂቅተህዋስያንየሚመጣየኤችአይቪእናየጉበትንበሽታንመጠን፤ስርጭት፣ግንዛቤናአጋላጭምክንያቶችንማጥናትነው፡፡እርሰዎንየኤችአይቪኤድስእናየጉበትበሽታንየሚያመጡረቂቅተህዋሥያንስርጭት (መጠን),ግንዛቤናአጋላጭምክንያቶችተያያዥነትያላቸውንጥያቄዎችእነጠይቀዎታለን፡፡ጥናቱለእርሰዎቀጥተኛየሆነጥቅምባይኖረውምለፖሊሲአውጭዎችናአስፈጻሚዎችእንዲሁምለማህበረሰቡስለአጋላጭሁኔታዎችናስለመከላከያመንገዶችለማወቅይረዳል፡፡ በሌላበኩልምስለበሽታውግንዛቤናጥንቃቄለማገኘትይረዳል፡፡የደምዎናሙናበላብራቶሪሲመረመርምንምአይነትችግርካሳየባለሙያምክርይሰጥዎታል፡፡እርሰዎንምበዚህጥናትእንዲሳተፉበትህትናእንጠይቀዎታለን፡፡በዚህጥናትበመሳተፈዎየምናገኘውመረጃለጥናታችንውጤታማነትእነዲሁምበጥናቱውጤትላይከፍተኛአስተዋፅዎይኖረዋል፡፡ስለዚህምበዚህቃለመጠይቅበመሳተፈዎምስጋናዬየላቀነው፡፡

በጥናቱበመሳተፈዎምክንያትየሚመጣበዎትምንምአይነትችግርአይኖርም፡፡ነገርግን5ሚሊሊትርየደምናሙናለመዉሰድመርፌሲገባከሚፈጥረዉየቅጽበትየህመምስሜትበስተቀርየጎላችግርአያመጣም፤ምኞትካልተሰማዎትባለሙያእንዲያይዎትይደረጋል፡፡በጥናቱውስጥስምዎበማንኛውምሁኔታአይገለጽም፤ስለሆነምየሚሠጡትመረጃሙሉበሙሉሚስጢራዊነቱየተጠበቀነው፡፡ስለዚህበጥናቱለመሳተፍየእርሥዎሙሉፈቃድአስፈላጊነው፡፡በተጨማሪምለመመለስየማይፈልጉዋቸውጥያቄዎችካሉጥያቄዎችንለመመለስአይገደዱም፡፡አንዲሁምበጥናቱላለመሳተፍከፈለጉየሚያመጠውምንምአይነትጉዳትየለውም፡፡ቃለመጠየቁንበተመለከተወይንምአጠቃላይስለጥናቱማንኛውንምአይነትጥያቄናአስተያየተቢኖረዎትበሚከተሉትአድራሻዎችመጠቀምይችላሉ፡፡ቶማስቦጋለ፡ስልክ፡ሞባይል፤0913708804ኢሜይል፤bogalethomas@gmail.comለተጨማሪመረጃ፡አዲስአበባዩኒቨርሲቲ፤የሕክምናላብራቶሪሳይንስት/ክፍልይጠይቁ፡፡ስልክ+251112755170

Annexes IV consent form Amharic version **ስምምነት ማረጋገጫ ቅፅ**

ከላይበመግቢያውላይየተጠቀሰውንመረጃአንብቢያለሁወይምበቃልየተሰጠኝንማብራሪያተረድቻለሁ፡፡ በዚህመሰረትከእኔየሚጠበቅብኝንድርሻበሚገባአውቄያለሁእናምበዚህጥናትላይበመሳተፌሊከሰቱየሚችሉትንሁኔታዎችተገንዝቢያለሁ፡፡ከዚህጥናትበማንኛውምሠዓትያለምንምቅድመሁኔታናምክንያትእራሴንከተሳታፊነትየማግለልሙሉመብትእንዳለኝተረድቻለሁ፡፡ይህንውሳኔዬንተከትሎበእኔምሆነበቤተሰቦቼላይበምንፈልገውየጤናአገልግሎትላይምንምአይነትአሉታዊተጽዕኖእንደማይደርስብኝተረድቻለሁ፡፡ በመሆኑምስለጥናቱማብራሪያየተሰጠመሆኑንበተለመደውፊርማዬአረጋግጣለሁ፡፡

የተሳታፊውስም/ቁጥር/----------ፊርማ ----------ቀን----------

Annexes V questionnaire

Addis Ababa University

College of health sciences

Department of Medical laboratory Sciences

1. Socio-demographic information			
S.NO	Questions	Answer	Remark
1	Age	……years	
2	Occupation	1. Self-employed 2. Gov.t employed 3.private employed 4.not employed	
3	Educational status	1. No formal education 2. 1-8 3. 9-12 4. College and above	
4	Marital status	1. Married 2. Single 3. Divorced 4. Widowed	
5	Religion	1. Muslim 2. Orthodox 3. Protestant 4.Catholic 5. Other, specify _____	
6	Residence (your background residence)	1. Rural 2. Urban	
7	Ethnicity	1. Oromo 3. Tigray 4. Gurage 2. Amhara 5. Wolayta 6. Others specify ……...	

2. Knowledge about Human immune deficiency virus &Hepatitis B virus infection questions			
1	Do you know or have you heard of Human immune deficiency virus and Hepatitis B&?	1. Yes 2. No	

2	If you hear, from where did you hear?	1. Books and journal articles 2. Lectures and seminars 3. Media 4. Family and friends 5. Special workshops 6. Other specify……	
3	Which part of our organ does Hepatitis B affects?	1. Liver 2. Heart 3. Kidneys 4. Brain 5. Not sure	
4	Route of transmission of Hepatitis B & HIV infection (answer each of the following choices)	1. Blood and blood products A. yes B. No 2. Needles and sharps injury A. yes B. No 3. Sexual intercourse A. yes B. No 4. Vertically from mother to child. A. yes B. No 5. Faeco-oral A. yes B. No 6. Contaminated water A. yes B. No	
5	Does HBV have vaccine?	1. Yes 2. No	
6	Is there effective treatment for HBV and HIV?	1. Yes 2. No	
3. Attitude Regarding Hepatitis Band HIV viral infection			
1	Do you think your job puts you at a high risk of acquiring Hepatitis B and HIV virus?	1. Yes 2. No 3. I don't have idea	
2	Do you think hepatitis B vaccine costs too much?	1. Yes 2. No	
3	Do you think taking HBV vaccine is safe?	1. Yes 2. No	
4	Do you believe HIV and HBV infection is serious public health problem?	1. Yes 2. No	
4. Associated risk factors of hepatitis B and HIV viruses infection			
1	Do you have history of Jaundice or Diagnosed for liver disease?	1. Yes 2. No	
2	Have you ever taken care of hepatitis patient?	1. Yes 2. No	
3	History of operation/ surgery for yourself?	1. Yes 2. No	
4	Do you have history of multi sexual partner in life?	1. Yes 2. No	
5	Do you have sharing of sharp materials with others?	1. Yes 2. No	
6	Do you have history of tattooing?	1. Yes 2. No	

7	Do you have history of tooth extraction?	1. Yes	2. No	
8	Do you have History of ear piercing?	1. Yes	2. No	
5. Participants practice towards HBV and HIV infection				
1	Have you received HBV vaccination?	1. Yes	2. No	
2	Do you have history of blood transfusion	1. Yes	2. No	
3	Have you screened for HBV and HIV?	1. Yes	2. No	
6. Final Laboratory result				
	POSETIVE	NEGATIVE	REMARK	
HIV1/2				
HBV				

VI. Questioner Amharic version መጠይቅ

አዲስአበባዩኒቨርስቲ

የህክምናፋኩልቲ

የላቦራቶትሪትምህርትክፍል

ለመረጃስብሳቢዎች፤ጥያቄዉንከጠየቃቸሁበኋላመልሱንከተሰጡትአማራጮችያክብቡ፡፡

1. መለያቁጥር_____መረጃውየተሰበሰበበትቀን_____

1. የማህበራዊናስነ-ህዝብሁኔታየሚዳስሱጥያቄዎች			
ተ.ቁ	ጥያቄ	መልስ	ምርመራ
1	ጾታ	1. ወንድ 2. ሴት	
2	እድሜ	----------ዓመት	
3	የትምህርትሁኔታ	1.መሰረታዊት/ትያልተማረ 2.1-8 3.9-12 4. ኮሌጅናከዛበላይ	
4	የጋብቻሁኔታ	1. ያገባ /ች 3. የፈታ/ች 2. ያላገባች/ች 4, የሞተበት/ባት	
5	ኃይማኖት	1.ሙሲሊም 2.አርቶዶክስ 3. ፕሮተስታንት 4. ካቶልክ 5. ለላ----------	
6	የትዉልድአከባቢ	1. ገጠር2 .ከተማ	
7	ብሔርዎምንድነው?	1. ኦሮሞ4. ጉራጌ 2. አማራ5. ወላይታ 3. ትግሬ6. ሌላ (ይገለጽ) ----------	
2.የግንዛቤመጠንመለኪያጥያቄ			
1	የጉበትበሽታተህዋስያንቢእናየኤችአይቪበሽታንሰምተውትያዉቃሉ?	1. አወ2. አላውቀውም	
2	ሰምተውትከሆነከየትነውየሰሙት?	1. ከመፅሀፍናከጋዜጦች 2. ከአስተማሪዎችእናከተለያዩስብስባዎች 3. ከሚዲያ 4.ከቤተሰብናከጓደኞች5.ከተለያዩቦታዎች	
3	የጉበትበሽታአምጭተህዋስያንቢየትኛውንየሰውነትክፍልያጠቃሉ?	1. ጉበት2. ልብ 3. ኩላሊት 4.ጭንቅላት 5.አላውቀውም	
4	የጉበትበሽታተህዋስያንቢናሲመተላለፊያመንገድ	1. ደምናየደምውጤቶችህ. አወለ.የለም2. መርፌናስለታማነገሮችህ.	

		አወለ.የለም 3. በግብረስጋግንኙነትሀ. አወለ.የለም 4. ቀጥታከእናትወደልጅሀ. አወለ.የለም 5. ከተበከለእጅወደአፍሀ. አወለ.የለም 6. ከተበከለውሀሀ. አወለ.የለም	
5	ለጉበትበሽታተህዋስያንቢከትባት አለብለውያስባሉ?	ሀ. አወለ.የለም	
6	ለጉበትበሽታተህዋስያንቢናየኤችአይቪበሽታንመድሀኒቶችአሉብለውያስባሉ?	ሀ. አወለ.የለም	
	3. የአኩዋሓን (Attitude) መጠንመለኪያጥያቄ		
1	የስራሁኔታየጉበትበሽታተህዋስቢያጋሊጣልብለውያስባሉ□	ሀ. አወ ለ. የለም	
2	የጉበትበሽታተህዋስያንቢ.ክትባቱዉድብለውያስባሉ□	ሀ. አወ ለ.የለም	
3	የጉበትበሽታተህዋስያንቢ.ክትባቱመዉሰድበሽታንይከላከላልብለው ያስባሉ□	ሀ. አወ ለ.የለም	
4	ጉበትበሽታለሕብረተሰቡፈተናብለውያስባሉ□	ሀ. አወ ለ.የለም	
	4.የጉበት በሽታቢናየኤችአይቪበሽታአደጋኢጋላጭሁኔታመለኪያጥያቅዎች		
1	በጉበትበሽታእናበኤችአይቪበሽታንተይዘውያውቃሉ?	ሀ. አወ ለ.የለም	
2	ከቤተሰበዎበጉበትበሽታተይዞእሚያውቅአለ?	ሀ. አወ ለ.የለም	
3	ሆስፒታልውስጥታመዉተኝተዎያቃሉ?	ሀ. አወ ለ.የለም	
4	ከአንድሰውበላይየጸታግንኙነትአድርገውያውቃሉ?	ሀ. አወ ለ.የለም	
5	ስለታማነገርቆርጦዎትያውቃል?	ሀ. አወ ለ.የለም	
6	ሰውነተዎላይንቅሳትአለ?	ሀ. አወ ለ.የለም	
7	ጥርሰዎንአስነቅሎያውቃሉ?	ሀ. አወ ለ.የለም	
8	ጀሮዎንተበስተውያውቃሉ?	ሀ. አወ ለ.የለም	
	5.የጉበት በሽታቢልምምድ (practice) ሁነታመለኪያጥያቅዎች		
1	የጉበትበሽታክትባትተከትበውያውቃሉ?	ሀ. አወለ.የለም	
2	ከሌላሰውደምተቀብለዎያውቃሉ?	ሀ. አወለ.የለም	
3	የጉበትበሽታምርመራአድርገውያውቃሉ?	ሀ. አወለ.የለም	

Annexes VII Laboratory test procedure

HIV test

Base on the national testing algorithm of HIV, whole blood or Sera will first test for the qualitative detection of HIV-1/2 anti-bodies by using:

HIV ½ stat-pack rapid testing (Test 1)

Abon HIV 1.2.0 HIV rapid testing (Test 2)

SD Bioline ½ HIV rapid testing (Test 3)

According to the national testing algorithm of HIV, when the first test (HIV ½ stat-pack) is non-reactive, then the final test result is Negative .When first test (HIV ½ stat-pack) is reactive, the result was tested by the second test (Abon HIV 1.2.0 HIV rapid testing); and if it is reactive, the result was tested by the third test (SD Bioline ½ HIV rapid testing) and if it is reactive the final result was positive. When T1 is reactive, and T2 is non-reactive, then repeat both T1 and T2.If the result is the same, report the final result as HIV negative. After repeating if T1 is non-reactive and T2 is non-reactive report HIV negative .After repeating the test if both T1 and T2 are reactive, proceed to the third test (T3).If T3 is reactive report HIV positive. If T3 is non-reactive report HIV inconclusive and repeat in 14 days.

HIV ½ stat-pack rapid testing

Specimen Collection & Preparation

• This one-step HIV test can be performed using serum, plasma or whole blood.

• Separate the serum or plasma as soon as possible to avoid hemolysis. Only clear, non hemolyzed specimens can be used.

• Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below - 20°C.

• Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

• If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

Principle

- The sample is applied to the SAMPLE (S) well followed by the addition of running buffer.
- The buffer facilitates the lateral flow of the released products and promotes the binding of antibodies to the antigens.
- If present, the antibodies bind to the gold conjugated antibody binding protein.
- In a **reactive sample,** the dye conjugated-immune complex migrates on the nitrocellulose membrane and is captured by the antigens immobilized in the TEST (T) area producing a pink/purple line.
- In the absence of HIV antibodies, there is no pink/purple line in the TEST (T) area. The sample continues to migrate along the membrane and produces a pink/purple line in the CONTROL (C) area containing IgG antigens.
- This procedural control serves to demonstrate that specimen and reagents have been properly applied and have migrated through the device.

Directions for Use:

- Remove the test device and sample pipette from the foil pouch and place it on a flat, dry surface
- Label the test device with patient name or identification number Touch the 5 µL sample loop provided to the specimen, allowing the opening of the loop to fill with the liquid.
- Holding the sample loop vertically, touch it to the sample pad in the centre of the SAMPLE (S) well of the device to dispense ~5 µL of sample (serum, plasma or whole blood) onto the sample pad.
- Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well.
- Add 3 drops (~ 105 µL) of buffer slowly, drop-wise, into the SAMPLE (S) well
    - Observe for development of colored bands on the result window
- Read the test result 15 minutes after the addition of the Running Buffer
- Do not read results after 20 minutes.

Interpretation of Results:

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: Discard the used sample loop, test device and any other test material into a biohazard waste container. Do not re-use loop.

ABON™ HIV ½

Test Procedure

- Allow the test device, buffer and specimen to reach room temperature (15-30 °C) prior to testing.
- Remove the test device from the foil pouch and use it as soon as possible (within one hour).
- Place the test device on a clean and level surface. Label with specimen ID.
- For serum or plasma specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma(approximately 25 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 uL) and start the timer.
- For vein puncture whole blood specimens: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer.
- For finger stick whole blood specimens: Take whole blood specimen with a 50 µL capillary tube until mark line. And add drawn specimen (about 50 µL) on the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer.
- Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not read results after 20 minutes.

Test result interpretation

- REACTIVE: Two or three distinct coloured lines appear. One line should always appear in the control line region (C), and another one or two apparent coloured line(s) should appear in the test line region(s) (T1 and/or T2).
- NOTE 1:The intensity of the colour in the test line region (T1 and/or T2) will vary but any shade of colour in the test line region (T1 and/or T2) should be considered reactive.
- NOTE 2: Dual infection of HIV-1 and HIV-2 is quite rare.
- Dual reactivity observed in Abon HIV 1/2 /O Tri-line HIV Rapid Test Device, i.e. HIV-1 line and HIV-2 line both reactive, is more likely to be caused by antibody cross-reactivity.
- Any specimen with dual reactivity should be referred for specific HIV-2 confirmatory testing, if a discretionary result is required.
- NON-REACTIVE: One colored line appears in the control region (C). No apparent colored lines appear in the test line regions (T1 and/or T2).
- INVALID: No line appears in the control line region (C). If this occurs, read the test procedure again and repeat the test with a new test device. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

SD-Bioline HIV1/2

Test procedure

- Remove the test device and sample pipette from the foil pouch and place it on a clean, flat and dry surface.
- Using a capillary pipette add 20µl of drawn blood specimen with a 20µl capillary pipette into the sample well(s) or using a micropipette add 10µl of plasma or serum specimen (20µl of blood specimen) into the sample well(s).
- Add 4 drops of assay diluents vertically into sample well(s).
- Time to result is 10 to 20 minutes. After adding the diluent, read the result after 10 minutes but not more than 20 minutes
- Observe for development of colored bands on the result window and
- Interpret test result at 10-20 minutes. Do not interpret the test results after 20 minutes.

Interpretation

- The presence of two lines as control line (C) and test line 1 (1) within the result window indicates a positive result for HIV-1.
- The presence of two lines as control line (C) and test line 2 (2) within the result window indicates a positive result for HIV-2.

  The presence of three lines as control line (C), test line 1 (1) and test line 2 (2) within the result window indicates a positive result for HIV-1 and/or HIV-2.
- If the colour intensity of the test line 1 is darker than one of test line 2 in the result window, you can interpret the result as HIV-1 positive.
- If the colour intensity of the test line 2 is darker than one of test line 1 in the result window, you can interpret the result as HIV-2 positive.
- No presence of control line (C) within the result window indicates an invalid result.

Hepatitis B surface antigen
Specimen Collection & Preparation

• This One Step Test Device (Serum/Plasma) can be performed using either serum or plasma.

• Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.

• Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below - 20°C.

• Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

• If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

Principle

The SMI One Step Test Device (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of in serum or plasma. The membrane is pre-coated with anti- antibodies on the test line region of the test. During testing, the serum or plasma specimen reacts with the particle coated with anti- antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti- antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence

indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Directions for Use:

Allow test device, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results were obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface. Add 60µl of serum or plasma to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.

3. Wait for the red line(s) to appear. The result should be read at 15 minutes. Note: A low concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

Interpretation of Results: (Please refer to the illustration)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

ELISA test principle

This is a Sandwich Enzyme linked Immune-sorbent assay method in which polystyrene micro well strips are pre-coated with monoclonal antibodies specific to . Participant's serum or plasma sample is added to the micro-wells together with a secondary antibody conjugated with

horseradish peroxidase (HRP) and directed against a different epitope of . During incubation, the specific immune-complex formed in the case of presence of in the sample, is captured on the solid phase. After washing to remove sample serum protein and unbound HRP conjugate, chromogen solution containing Tetra-methyl Benzedrine (TMB) and urea peroxidase are added to the walls. In the presence of the antibody-antigen-antibody (HRP) sandwich immune complex, the colorless chromogens are hydrolyzed by the bound HPR conjugate a blue colored product. The blue color turns to yellow after stopping the reaction with sulfuric acid. The amount of color can be measured and is proportional to the amount of antigen in the sample (Test kit insert sheet).

Declaration

The under signed declares that this thesis complies with the regulation of the university and meets the accepted standards with respect to originally and quality. PI also agrees to accept responsibility for the scientific and technical conduct of the research project and for provision of required progress reports.

M.Sc. candidate: Thomas Bogale (B.Sc.)

Signature _____

Date of submission_____

This thesis has been submitted with our approval as advisors.

Advisors

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Date _____

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