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Magnitude of Hepatitis B and Hepatitis C virus and Associated Factors among Hemodialysis Patients in selected Public and Private Health Facilities in Addis Ababa, Ethiopia

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This is to certify that the thesis prepared by Messay Assefa, entitled: *Magnitude of Hepatitis B and Hepatitis C virus infections and Associated Factors among Hemodialysis Patients in selected Public and Private Health Facilities in Addis Ababa, Ethiopia*and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Diagnostic and Public Health Microbiology) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Table of Contents

List of Table

List of Figures

List of Annexes

Abbreviation

CKD	Chronic kidney disease
ELFA	Enzyme Linked Fluorescent Assay
ESKD	End stage kidney disease
ESRD	End stage renal disease
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HD	Hemodialysis
IgG	Immunoglobulin G
IgM	Immunoglobulin M
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
SPHMMCS	St. Paul's Hospital Millennium Medical College
SPR	Solid phase receptacle

Abstract

Background: Hepatitis B and Hepatitis C viruses are major health problems worldwide which spread mainly through contaminated blood and blood products, sexual contact and contaminated needles. Patients receiving maintenance hemodialysis are at higher risk for acquiring Hepatitis B and Hepatitis C Virus infections than the general population because the process of hemodialysis requires vascular access for prolonged periods.

Objective: To assess the magnitude of Hepatitis B and Hepatitis C virus infections and associated factors among hemodialysis patients in selected public and private hemodialysis centers of Addis Ababa, Ethiopia.

Methods: Hospital based cross-sectional study was conducted at St. Paul Millennium Medical College, Zewditu Memorial Hospital, Addis Hiwot Hospital, Bethel Teaching General Hospital and Sante Medical Centerover a period of 8 months (September 2018-April 2019) among patients on hemodialysis. By using questionnaire brief history and risk factors was taken from each volunteering patient. Serum sampleswas collected and screened for the presence of HBsAg and anti-HCV by rapid test strip and positive sample were confirmed using ELFA. SPSS version 16 was used to analyze the data and P value <0.05 was considered as statistically significant.

Results: A total of 301 patients on maintenance hemodialysis participated in this study of which 192 (63.8%) of them were males. The mean age of the patients was 40.86 years ± 14.9 SD with age range from 16-80 years. The overall magnitude of HBV and HCV was 4% and 0.7%, respectively. History of blood transfusion and using multiple HD centers were significantly associated with hepatitis B virus.

Conclusion: Moderate and low HBV and HCV burden was observed among hemodialysis patients. This suggests routine surveillance of patients to track early detection of the virus, plan early intervention and effective follow up. Moreover, there is a need toimproveinfection prevention control and increase patient's awareness about HBV and HCV infection in general.

Keywords: *HBV, HCV, Hemodialysis*

1.Introduction

1.1 Background

Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E. Hepatitis B is caused by the hepatitis B virus (HBV), an envelope virus containing double strand circular DNA genome and classified within the family of Hepadnavirus (1).Hepatitis C virus (HCV) is a small, enveloped RNA virus belonging to the Flaviviridae family within the Hepacivirusgenus,that causes acute and chronic liver disease in humans, including chronic hepatitis, cirrhosis, and hepatocellular carcinoma (2).

Hepatitis B and hepatitis C viruses are common health problems worldwide. HBV and HCV are hepatotropic virus whose primary replication occurs in the liver. Globally, WHO estimates that 2 billion people have evidence of past or present infection with HBV, and 248 million are chronic carriers of HBV. Geographic variation shows highest prevalence of HBsAgsero-prevalence has been recorded, (>5%) in sub- Saharan Africa, east Asia and South America and below 2% prevalence rate is seen in regions such as Central America, North America and Western Europe (3). WHO estimated 110 million persons have a history of HCV infection and 80 million have chronic viremia infection. Highest prevalence is seen in the general population (>3.5%) are Central and east Asia, North Africa and Middle East, moderate prevalence (1.5–3.5%) include South and South-East Asia, Sub-Saharan Africa, Latin America, Australasia, and eastern and western Europe and low-prevalence are seen (<1.5%) in Asia-Pacific, Latin America, and North America (3).

In 2012, worldwide 2.1 million patients were estimated to require hemodialysis and this number is expected to increase by 7% annually. Hemodialysis is routinely used as renal replacement therapy for end stage renal disease (ESRD) patients. This treatment modality carries high risk of transmitting blood born infection, such as hepatitis B virus, hepatitis C virus and human immunodeficiency virus to patients with chronic kidney disease (4).

Chronic hemodialysis patients are at high risk for infection since the process of hemodialysis requires vascular access for prolonged periods. In a situation where multiple patients receive dialysis concurrently, there is an increased chance for person-to-person transmission of

infectious agents, directly or indirectly via contaminated equipment, supplies and environmental surfaces. Furthermore, hemodialysis patients are immunosuppressed which makes them much more vulnerable to acquire such viruses and have lower response rate to hepatitis B vaccine. They also require frequent hospitalizations and surgery, which increases their exposure to nosocomial infections (5).

In hemodialysis, blood is removed from the patient with needles and plastic tubing and pumped past the dialysis membrane. Poisons and toxins cross the dialysis membrane into the dialysate, which is then discarded, and the blood is returned to the patient. Viral hepatitis and human immunodeficiency virus infection are lead causes of mortality and morbidity in patients with hemodialysis (HD). Hepatitis B virus (HBV) and hepatitis C virus (HCV) are the two most important viruses responsible for almost all the patient's morbidity in patients on HD (6).

Patients on hemodialysis are expected to have highest rates of hepatitis B and hepatitis C virus infections, this has been confirmed by a number of epidemiological studies. The presence of hepatitis B virus and hepatitis C virus in patients on hemodialysis increase the morbidity and mortality of the patients, increase the rate of kidney transplant rejection, response rate to antiviral treatment is decreased and the side effects of antiviral drugs are higher in chronic kidney disease patients on hemodialysis than patients without these infections. In addition, there are many risk factors which are associated with increased rates of blood born infections among hemodialysis patients. So, identifications of these risk factors and introduction of measures to address these factors is a priority in hemodialysis units (7).

1.2 Statement of the problem

Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in hemodialysis patients have wide range in prevalence rates in different parts of the world. Prevalence of HBV range between 0.6 - 6% in Western Europe, United States of America and Japan. By contrast in Asia Pacific it ranged from 1.3 to 14.6% (10).The prevalence of HCV in HD varies greatly ranging from a low 1% to as high as 70% being generally below 5% in high income countries (81).

In Arab countries, the prevalence of chronic HBsAg positivity among HD patients ranged from 2% in Morocco, to 11.8% in Bahrain. Also in Arab countries, the prevalence of HCV antibodies among HD patients has been reported to range from 27% in Lebanon to 75% in Syria (8). Variations in the prevalence rates among different dialysis centers in a single country have also been reported. For instance, in the previous studies from Iran, the prevalence rate of HCV antibody has been reported 4.9%, in patients of the central province, 5.5% in Shiraz, 9.55% in Rasht, 23.9% in Qazvin and 13.2 % in Tehran 19 (9).

In Africa, some published studies indicated that there was high prevalence of HBV which is estimated at 8% in west Africa and 5-7% in south Africa. The prevalence of HCV is even higher in some areas reaching up to 10% (11).

In Ethiopia, there was paucity of published data on the prevalence of HBV and HCV and their risk factor among HD patients. So, this study highlights the magnitude of HBV and HCV along with their risk factors in HD patients receiving service from selected public and privatehealth facilities in Addis Ababa.

1.3 Significance of the study

There is high prevalence of viral hepatitis among HD patient all over the world. Knowing the magnitude of HBV and HCV along with their risk factors in HD patients in Ethiopia would allow strengthening proper safety precaution in HD centers. Moreover, knowing the effect of this viruses among hemodialysis patient is essential for prevention and appropriate clinical management. This study will be more beneficial to the dialysis centers and to the patients. This study shall give additional information to clinicians so that they can choose the correct clinical care for their clients and for policy makers and other concern bodies to strengthen the relevant intervention measures and screening packages. It also adds information to the global data to be utilized by researchers.

2. Literature review

2.1 Chronic kidney disease

The primary purpose of the renal system is to maintain the body's state of homeostasis by carefully regulating fluid and electrolytes, removing wastes, and providing other functions. Dysfunction of the kidneys is common and may occur at any age and with varying degrees of severity. Chronic kidney disease (CKD) is a term that describes kidney damage or a decrease in the glomerular filtration rate lasting for three or more months (12).

Untreated CKD can result in end-stage kidney disease (ESKD), which is the final stage of renal failure. ESKD results in retention of waste products and the need for renal replacement therapies, dialysis, or kidney transplantation. The cause of renal failure may be a primary kidney disorder or secondary to a systemic disease or other urologic defects. Hemodialysis is used for patients who are acutely ill and require short-term dialysis ranging from days to weeks until kidney resumes its function as well for patients with advanced CKD and ESKD who require long-term or permanent renal replacement therapy (13).

Viral hepatitis, mainly HBV and HCV, and human immunodeficiency virus infection are lead causes of mortality and morbidity in patients with hemodialysis (HD). Both are further promoted by the characteristic immunological dysfunction that develops in renal failure and interferes with the patient's ability to eliminate these viruses (14).

2.2 Viral hepatitis

Hepatitis means inflammation of the liver and also refers to a group of viral infections that affect the liver but the term viral hepatitis generally implies the five hepatotoxic viruses: Hepatitis A, B, C, D and E viruses. Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections are among the most frequent viral infections in humans, and represent a major global public health problem and are among the principal causes of severe liver disease, including hepatocellular carcinoma and cirrhosis-related end-stage liver disease (15).

WHO estimates that in 2015, 257 million persons, or 3.5% of the population, were living with chronic HBV infection and 71million persons were living with HCV infection in the world (16). Liver diseases are common in Africa and account for high morbidity and mortality. Hospital based analysis indicate that acute viral hepatitis, chronic hepatitis,

cirrhosis and hepatocellular carcinoma are responsible for at least 12% of medical admissions and over 20% of hospital mortality in many parts of Africa (17).

2.2.1 Hepatitis B Virus

HBV is an enveloped, hepatotropic, non-cytopathic virus that can cause acute and chronic hepatitis. HBV is differentiated into many genotypes, according to genome sequence. To date, eight well-known genotypes (A-H) of the HBV genome have been defined. Moreover, two new genotypes, I and J, have also been identified (18). The viral genome of HBV is a double stranded circular DNA. The virus consists of a nucleocapsid and an outer envelope composed mainly of three hepatitis B surface antigens (HBsAgs) that play a central role in the diagnosis of HBV infection. The nucleocapsid contains hepatitis B core antigen (HBcAg), a DNA polymerase reverse transcriptase, the viral genome as well as cellular proteins (19). The sequelae of HBV infection include acute and chronic infection, cirrhosis of the liver and primary liver cancer. The likelihood of progression to chronic infection is inversely related to age at the time of infection. (20).

Transmission

HBV is spread predominantly by percutaneous or mucosal exposure to infected blood and various body fluids, including saliva and menstrual, vaginal and seminal fluids. Perinatal transmission is the major route of HBV transmission in many parts of the world. Transmission of the virus may also result from accidental inoculation of minute amounts of blood or fluid during medical, surgical and dental procedures, or from razors and similar objects contaminated with infected blood (3).

Global Epidemiology

More than two billion individuals alive today, about 1/3 of the world's population have been infected at some time in their lives with the HBV, of whom approximately 400 million are chronically infected carriers. Annual death rate exceeds a million among infected individuals (21). The geographical distribution of HBV infection is not uniform throughout the world. Depending on the prevalence, different areas are classified as high, intermediate or low endemicity. HBV infection is highly prevalent (>8%) in Southeast Asia, China, the Philippines, Africa, the Amazon basin and the Middle East. In Eastern Europe, Central Asia, Japan, Israel and Russia the prevalence is intermediate (2-8%), while in North America,

Western Europe, Australia and South America the prevalence is low (<2%). In Latin America, it ranges from 2 to 7%. In developed countries, the prevalence of HBV in patients treated with hemodialysis is 1%, while in developing countries the prevalence ranges from 2% to 20% (22).

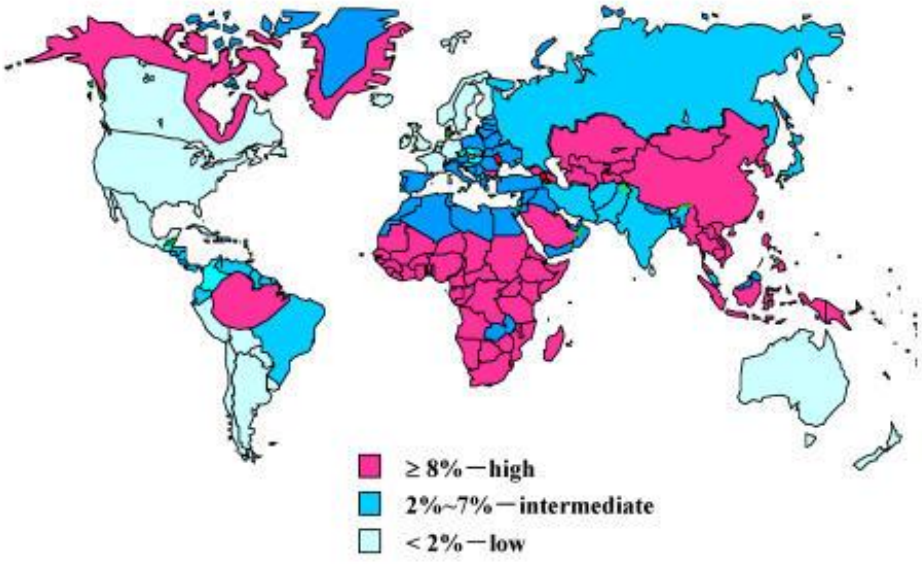

Figure 1: Estimated global prevalence of hepatitis B virus infection (78)

Prevention of hepatitis B

Prevention of chronic HBV infection has become a high priority in the global community. Immunization with HBV vaccine is the most effective means of preventing HBV infection (23). These rely on the use of one of the viral envelope proteins (hepatitis B surface antigen). The vaccine was originally prepared from plasma obtained from patients who had long-standing hepatitis B virus infection. However, currently, it is made using a synthetic recombinant DNA technology that does not contain blood products. One cannot be infected with hepatitis B from this vaccine (24). The risk of vertical transmission to the newborn can be drastically reduced,for instance Schillieet alfound HBV vaccine to be 75% effective, and HBIG to be 71% effective, and with combined efficacy of 94%(25).

Treatment of hepatitis B

Currently there is no treatment available for acute hepatitis B infection; most adults clear the infection spontaneously. On the other hand, treatment of chronic infection may be necessary to reduce the risk of cirrhosis and liver cancer. Chronically infected individuals with

persistently elevated serum alanine aminotransferase, a marker of liver damage, and HBV DNA levels are candidates for therapy (26). Early infant vaccination always remains the most important option for hepatitis B infection prevention.

2.2.2 Hepatitis C Virus

Hepatitis C virus is a spherical, enveloped RNA virus of the Flaviviridae family, classified within the Hepacivirus genus with multiple genotypes and subgenotypes, and their distribution varies substantially in different parts of the world. Hepatitis C virus causes both acute and chronic infection. Acute HCV infection is defined as the presence of certain markers of HCV infection within six months of exposure and is characterized by the appearance of HCV RNA, HCV core antigen (p22 Ag), and subsequently HCV antibodies, which may or may not be associated with viral clearance. Antibodies to HCV develop as part of acute infection and persist throughout life. Acute infection is usually clinically silent, and is only very rarely associated with life-threatening disease(3).

Spontaneous clearance of acute HCV infection generally occurs within six months of infection in 15–45% of infected individuals in the absence of treatment, but this varies by region and population. Antibodies to HCV develop as part of acute infection and persist throughout life. Almost all the remaining 55–85% of persons who do not clear HCV within six months are defined as having chronic HCV infection. Left untreated, chronic HCV infection can cause liver cirrhosis and liver failure (27).

Transmission

There are multiple routes of transmission of HCV. Since it is a blood-borne infection which is transmitted sexually and vertically and by iatrogenic, occupational, cultural and recreational activities. Unsafe transfusions and therapeutic injections and acupuncture are examples of iatrogenic transmission. Intravenous drug use, tattooing and ear-piercing are examples of recreational and cultural activities that may spread HCV. It may also be transmitted by needle-stick injuries (28).

Epidemiology

Hepatitis C virus infection is a major global public health problem in both developed and developing countries. More than 170 million people are chronically infected with HCV worldwide, and the infection results in the development of chronic liver diseases, including

liver cirrhosis and hepatocellular carcinoma (29). Epidemiological studies of HCV are challenging since most cases of HCV infection are asymptomatic and indistinguishable clinically from other causes of hepatitis. A laboratory diagnosis is therefore essential, but not always available, particularly in resource- limited settings (30).

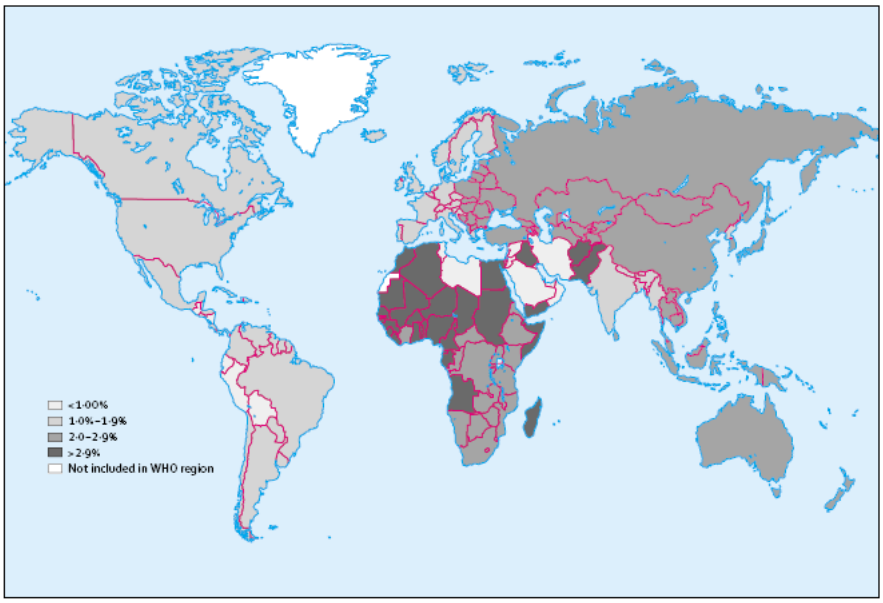

Figure 2: Estimated global prevalence of hepatitis C virus infection (79)

Prevention

Currently there is no vaccination against hepatitis C. Research is in progress but the high mutability of the HCV genome complicates vaccine development (31). Neither passive immunization with conventional or HCV hyper immune globulin preparations nor active immunization with an HCV vaccine are currently recommended or available (32). In absence of a vaccine, all precautions to prevent infection of HCV should target reduction of transmission of the virus. The only means of protection are the implementation of universal precautions and safe injection practices. Screening and treatment of blood products is the only way to prevent transfusion associated cases (33).

Treatment of Hepatitis C

Treatment of acute hepatitis is mainly supportive, consisting of bed rest and balanced diet with small frequent nitrous meals and hospitalization reserved only for cases of sever disease. The goal of treatment is to achieve a sustained viral response (SVR), as defined by the

absence of viremia 6 month after stopping the medications; SVR is associated with improved histology and decreased risk of morbidities (34). The rationales for treatment of chronic hepatitis are to reduce inflammation, to prevent progression to fibrosis and cirrhosis through the eradication of the virus in chronically infected patients, and to decrease infectivity and control the spread of the disease (35).

2.3 Magnitude of HBV and HCV infection on hemodialysis patients

Hemodialysis is the main renal replacement therapy in patients with end-stage kidney disease. This treatment modality carries high risk of transmitting blood born infections, such as hepatitis B virus, hepatitis C and human immunodeficiency virus to patients with chronic kidney disease (36). Hepatitis B and Hepatitis C viruses historically have been a critical infection issue within hemodialysis facilities (37).

Considerable transmission of HBV and HCV can occur between hemodialysis patients and staff. Hemodialysis patients are at increased risk for HBV and HCV infection because of the opportunity for exposure associated with the dialysis procedure. After infection with HBV and HCV, hemodialysis patients are at greater risk of becoming chronic carriers than the general population (38). The literature review points to the fact that viral hepatitis is a serious threat for hemodialysis patients as 1.9% of all deaths among this population were related to the consequence of viral hepatitis (23).

Study conducted in Argentina shows from a total of 172 hemodialysis patients 8.7% (15/172) of the patients were positive for HBsAg and 9.9% (17/172) were positive for anti-HCV. Stating that history of having received blood transfusions as a major risk factor for both HBV and HCV infection in hemodialysis (22). Another study conducted in Tehran on the prevalence of Hepatitis B and Hepatitis C infection from 360 patients found 1.39% HBsAg positive and 3.06% positive for HCV Ab. The study recommended educating people about HBV and HCV transmission and national vaccination for HBV to decrease the prevalence rate among HD patients (39). Similar study conducted in Kerman Province, South-East Iran shows patients on maintenance hemodialysis 7% of cases were Positive for HBsAg and 7% of the cases also found to be positive for HCV Ab, both viruses were detected in 1.7% cases. The study also found statistically significant relation of hepatitis C infection with blood transfusion (40).

Another study conducted in India on 186 hemodialysis patients showed, 6.99%(13/189) were

positive for anti HCV Ab. Six patients (3.23%) were positive for HBsAg. Statistically significant correlation was found between blood transfusion and anti HCV Ab and HBsAg positivity (41).

A cross sectional descriptive study conducted in Sudan at the Omdurman military teaching hospital (OMTH) renal unit shows from a total of 100 patients the prevalence of hepatitis B virus was 5% and the prevalence of hepatitis C virus was 6% (42). In Nigeria among the 1388 study subjects 83 (6.0%) patients were HBsAg positive, 16 (1.2%) were anti HCV positive while 1 (0.1%) patient tested positive for both HBsAg and HCV (43). Another study conducted in Sana, a City in Yamen shows higher prevalence of HCV infection among hemodialysis patient, 45(22.5%). Indicating significant statistical relation of Hepatitis C infection with duration of hemodialysis (44). A cross sectional study conducted in Ethiopia in five HD centers shows from a total of 253 1.2% (n=3/253) of the patients were positive for HBsAg and anti- HCV antibodies were detected in 2.8% (n=7/253) and 0.4% (n=1) were positive for both HBV and HCV infection (45).

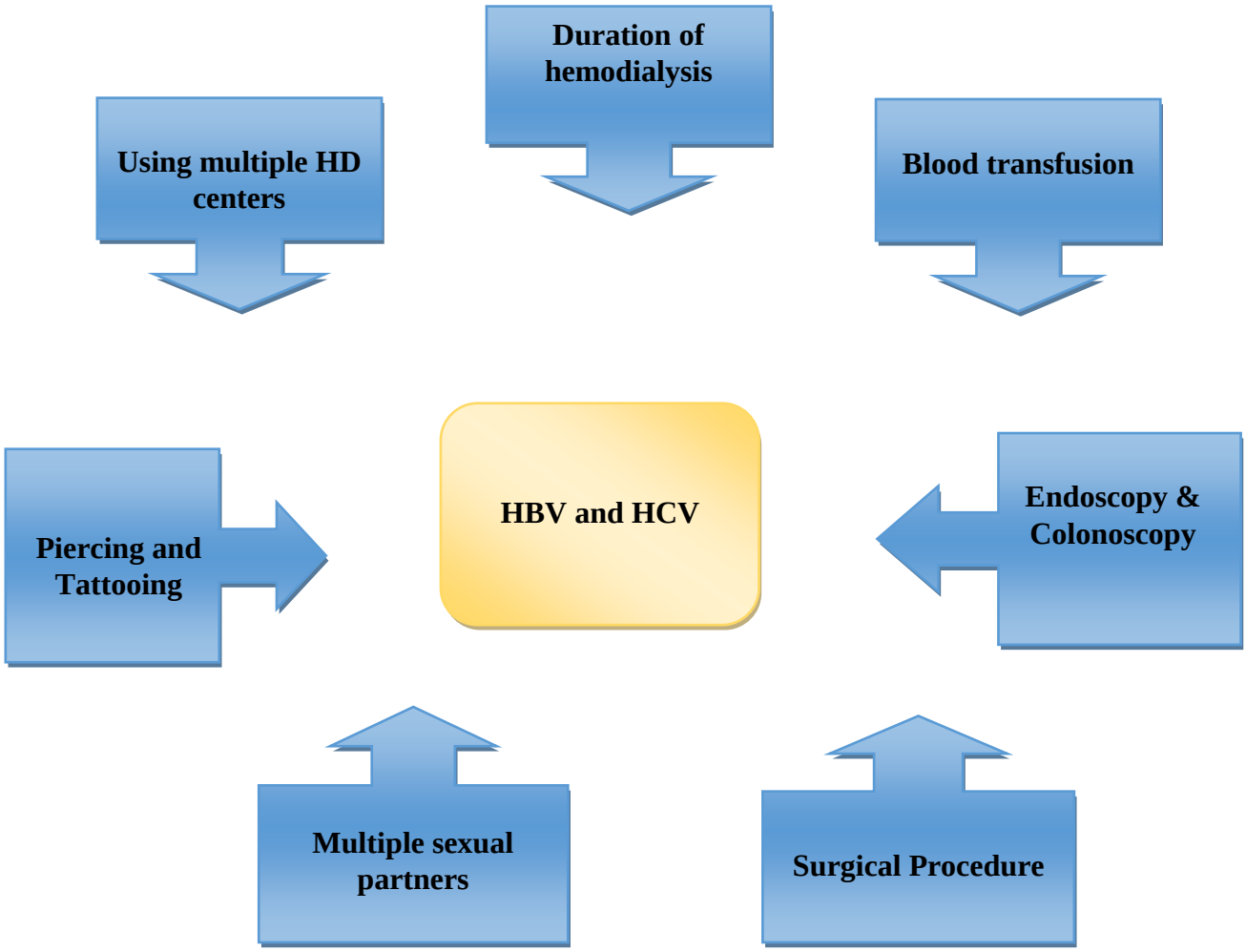

Figure 3
Conceptual frame work of HBV and HCV in relation with hemodialysisin Addis Ababa, Ethiopia.

3. Objective of the study

3.1 General objectives

To assess magnitude of HBV, HCV and its associated factor among hemodialysis patients in Addis Ababa, Ethiopia.

3.2 Specific Objective

- To determine the magnitude of HBV among hemodialysis patients.
- To determine the magnitude of HCV among hemodialysis patients.
- To identify the associated risk factors of HBV and HCV among hemodialysis patients

4 Material and Method

4.1 Study area

The study was conducted in Addis Ababa the capital city of Ethiopia, established in 1887. Addis Ababa has a total population of 3,384,569 (2007 census), located in the geographic center of the country which lies at an altitude of 7,546 feet (2,300 meters) with a grassland biome. There is a total of 42 Hospitals (public and private) in Addis Ababa city, four are under the Federal Ministry of Health (one of which is a teaching Hospital), one is a university Hospital under the Addis Ababa University, others are general hospitals and under the Addis Ababa regional health bureau the other two are Army and Police Hospitals (46).

The hospitals are also referral hospitals serving people coming from all over Ethiopia. Based on the number of patients they have and to cover both Federal and Addis Ababa HD centers. St. Paul Millennium Medical College, Zewditu Memorial Hospital, Addis Hiwot Hospital, Bethel Teaching General Hospital, Sante Medical Center were selected for the study.

1. St Paul's hospital Millennium Medical College, as it is known today, was established through a decree of the Council of Ministers in 2010, although the medical school opened in 2007 and the hospital was established in 1968 by the late Emperor Haile Selassie. It is governed by a board under the Federal Ministry of Health. The hospital has more than 20 dialysis machines.

2. Zewditu Hospital is a hospital in central Addis Ababa, Ethiopia. It was built, owned and operated by the Seventh-day Adventist Church, but was nationalized during the Derg regime in about 1976. The hospital is named after Empress Zewditu, the cousin and predecessor on the throne of Emperor Haile Selassie. Today Zewditu Hospital is operated by the Addis Ababa Health Bureau. The hospital has 7 dialysis machine.

3. Addis Hiwot Hospitallocated in the heart of Addis Ababa has good reputation in wide range of services the hospital provides dialysis service both for acute and chronic kidney failure. The center has 10 dialysis machines.

4. Bethel Teaching General Hospital owned and operated by an Ethiopian obstetrician and gynecologist Dr. YigeremuAsfaw; the hospital is located in Addis Ababa. In 2000 Bethel Teaching General Hospital opened and 2005 the second hospital was opened.

Between the two hospital more than 300 patents seen daily. The dialysis center has more than10 dialysis machine.

5. Santé Medical Center is located in the heart of Addis Ababa has good reputation in wide range of services particularly in renal medicine. Dialysis is one of the major service in the center; it has 6 dialysis machine.

4.2 Study Design and period

A cross-sectional study was conducted from September 2018 to April 2019 in Addis Ababa, Ethiopia

4.3 Source population

All patient receiving hemodialysis at HD center in Addis Ababa, Ethiopia.

4.3.1 Study Population

Patients receiving hemodialysis at selected health facilities during the study period and fulfilling the eligibility criteria were our study population.

4.4 Eligibility criteria

4.4.1 Inclusion criteria

- All voluntary patient receiving hemodialysis in specified health institution during the study period.

4.4.2 Exclusion criteria

- All patients who are in coma

4.5 Dependent and Independent Variable

4.5.1 Dependent variables

- Magnitude of HBV
- Magnitude of HCV

4.5.2 Independent variables

<u>Sociodemographic factors</u>

- Age.
- Sex.

- Marital status

Risk factors

- Occupational status
- Number of blood transfusion.
- Duration of hemodialysis.
- Frequency of hemodialysis.
- Multiple sexual partners.
- Surgical procedure.
- Piercing and Tattooing.

4.6 Sample size determination

The required sample size for this study was calculated based on the study in Sudan at Omdurman Military Teaching Hospital (OMTH) with HBV prevalence of 5% and HCV prevalence 6% (24).

Sample Size is determined by the following formula: $n = Z2\alpha/2\ P\ (1- P)/\ d2$

Where:

n: Sample population

P -is the estimated proportion.

Z- reflects the confidence interval; we will use 95 % confidence interval so the value of $z\alpha/2$ will be 1.96

d-is the margin of error, here it is 0.05

- For HBV: $n= \frac{(1.96)^2 * 0.05\ (1-0.05)}{0.05*0.05} = 73$
- For HCV: $n= \frac{(1.96)^2 * 0.06\ (1-0.06)}{0.05*0.05} = 87$

Thus, the minimum calculated sample size was 73 for HBV and 87 for HCV. But this study recruited a total of 301 patients on HD.

4.7 Sampling method

Convenient sampling technique was used in which selection of the sample was based on the easy accessibility of the patient during the study period

4.8 Data collection procedure

4.8.1 Demographic and risk factors data

Socio-demographic and risk factors data were collected with a standardized questionnaire from the study participants by the principal investigator and trained data collector (Annex III).

4.8.2 Laboratory analysis

Sample collection

Rapid HBsAg test and Rapid HCV Ab test uses plasma, whole blood and serum specimen. Serum was separated from whole blood testing was performed at the spot immediately after the specimen is collected and some samples transported to a testing area using ice box. For long term storage specimen was kept below -20°C. Frozen specimens were completely thawed and mixed well prior to testing.

4.8.3 RapidHBsAg Test

Rapid HBsAg test is a double antibody sandwich immunoassay from (Xiamen Boson Biotech, China). Colloidal gold conjugated anti-HBsAg antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip re-hydrating the gold conjugate complexes. If present, HBsAg will react with the gold conjugate complexes forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti- HBsAg antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until they are captured in the Control Zone(C) by immobilized goat anti- mouse IgG anybody aggregating a red line, which indicate the validity of the test (47).

HBV Test Result Interpretation

Positive Result

Two color bands appear within 20 minutes. One color band appears in the Control Zone (C) and another color band appears in the Test Zone (T). The test result is positive and valid no matter how faint the color band appears in the Test Zone (T), the test result should be considered as positive result.

Negative Result

One color band appears in the Control Zone (C) within 20 minutes. No color band appears in the Test Zone (T). The test result is negative and valid**.**

Invalid Result

No color band appears in the Control Zone (C) within 20 minutes. The test result is invalid.

4.8.4 Rapid HCV Ab Test

The HCV Ab rapid test strip serum/plasma from (Zhejiang Orient Gene Biotech, China) is a lateral flow chromatographic immunoassay based on the principle of the double antigen-sandwich technique. The test strip consists of a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG gold conjugates a nitrocellulose membrane strips containing a test band (T band) and control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and C band pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample pad of the strip, the specimen migrates by capillary action across the strip. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugate. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggested a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/ rabbit IgG- gold conjugate regardless the presence of any antibodies to HCV. Otherwise the test result is invalid and the specimen must be retested with another test strip (48).

HCV Test Result Interpretation

Positive Result

Two lines appear one on the Control Zone(C) and another on the Test Zone (T) within 15 minutes.

Negative Result

One color band appear in the Control Zone (C). No line appears on the Test Zone (T) within 15 minutes.

Invalid Result

Control line fail to appear. Insufficient specimen volume or incorrect procedure techniques are the most likely reasons for control line failure.

4.9 HBV and HCV ELFA

Positive HBsAg and HCV Ab test were confirmed using ELFA and the final result was analyzed and interpreted by SPSS statistical software.

4.9.1 HBsAg ELFA Assay Principle

The VIDAS HBs Ag test is an enzyme linked fluorescent immunoassay (ELFA, Biomerieux VIDAS, USA) that is performed in the automated VIDAS system. The solid phase receptacle (SPR) serves as the solid phase as well as the pipetting device for the assay. Regent for the assay are ready to use and pre- dispensed in the sealed reagent strips. All of the assay steps are preformed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. After the preliminary washing step, the antigen present in the sample will bind simultaneously to the monoclonal antibody coating the interior of the SPR and to the antibody conjugated with biotin. Unbounded sample components are washed away. The antigen bounded to the solid phase and to the biotinylated antibody is in contact streptavidine conjugated with alkaline phosphate, which will bind with biotin. Another wash step follows and removes unbound components.

During the final detection step, the substrate (4-Methylumbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product the (4- Methylumbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample. At the end of the assay, results are analyzed automatically by the instrument and are expressed as an index calculating using a standard. Once the assay is completed the result analyzed automatically by the computer. If the test value is < 0.13 it is interpreted as negative and if the test value is ≥ 0.13 it considered as positive (49).

4.9.2 Anti-HCV ELFA Assay Principle

The assay principle combines a two steps enzyme immunoassay sandwich method with a final fluorescent detection (ELFA, Biomerieux VIDAS, USA). The solid phase receptacle (SPR) serve as the solid phase as well as the pipetting device. Reagent for the assay are ready to use and are pre-dispensed in the sealed reagent strips. All of the assay steps are preformed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

During the first step, the sample is diluted and then cycled in and out of the SPR several times. The anti-HCV antibodies present in the sample will bind to the antigens representing

the HCV core, NS3 and NS4 proteins coated on the interior of the SPR. Unbound sample components are washed away. During the second step, mouse monoclonal anti-human IgG antibodies in Fab form, conjugated to recombinant alkaline phosphatase (yeast) are cycled in and out of the SPR several times and will bind to the human Ig bound to the molecules on the solid phase. Further wash steps remove unbound components. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescence product (4-Metthyl- umbelliferone) the florescence of which is measured at 450 nm. The intensity of the florescence is proportional to the concentration of antibody present in the sample. At the end of the assay, the result is automatically calculated by the instrument in relation to standard stored in memory. Once the assay is completed the result analyzed automatically by the computer. If the test value is < 1.00 it is interpreted as negative and if the test value is > 1.00 it considered as positive (49).

4.10 Quality Assurance

4.10.1 Pre-analytical phase

- Well organized data collection format was used.
- Training was given for data collectors by principal investigator
- The research aim was explained by principal investigator or data collector
- Questionnaire was used to obtain socio demographic and possible risk factors
- Consent was obtained from each patient
- 5 ml of blood was collected using standard procedure
- Sample was thoroughly separated from all cellular material by avoiding hemolysis

4.10.2 Analytical phase

- Aseptic techniques and safe handling of infectious material was applied.
- The collected sample was analyzed at the spot
- Standard operational procedure was strictly followed

4.10.3 Post-analytical phase

- Recording, verifying and reporting the results on the result log sheet
- Collected data checked and entered into SPSS by two individuals.
- The leftover negative blood sample was discarded using standard protocol

4.11 Data Analysis and Interpretation

Data entry and analysis was done using SPSS V.16 statistical software. Binary Logistic regression analysis was used to see the relationship between dependent and independent variables and assess their significant level. Multiple logistic regression analysis was subsequently conducted to determine the correlates of HBV and HCV infections by including those variables with p value<0.20 in the model. Odds ratio and 95% confidence interval were used to see the strength and direction of the association. P-value less than 0.05 was considered as statistically significant. Finally, the results presented on words, percentages, graphs and tables.

4.12 Ethical Considerations

Ethical clearance was obtained from departmental research and ethics committee of Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences. Official permission letter to collect data was obtained from Addis Ababa Health Bureau and management committee of selected hospitals. The study participants were informed about the purpose of the study and written informed consent was obtained from each participant and no names was used in the data collection process, only unique identity numbers were used. Sample taken from each patient was coded and results obtained were kept confidential. Individuals found to be positive for HBV and HCV were linked to physicians for monitoring and further treatment.

4.13 Dissemination of results

This study could serve as a reference material to researchers, experts or policy makers for intervention. To reach these bodies the finalized paper will be submitted to department of medical laboratory technology, Addis Ababa University so, it can serve as a reference in the library. In addition, a copy of this material will be given to Saint Paul's Hospital Millennium Medical College, Zewditu Memorial Hospital, Addis Hiwot Hospital, Bethel Teaching General Hospital, Santé Medical Center and Addis Ababa Health Bureau. The result will also be disseminated through publication in peer reviewed local and international journals and through presenting it in relevant conferences.

5. Results

5.1 Socio demographic characteristics

A total number of 301 patients were included in the study from 5 different HD centers in Addis Ababa, Ethiopia. Of them, 24.3% (n= 73) were recruited from St. Paul Hospital Millennium Medical college, 9.6% (n=29) were from Zewditu Memorial Hospital, 13.6% (n=41) were from Addis Hiwot Hospital, 25.2% (n=76) were from Sante Medical Center and the remaining 27.2% (n=82) were from Bethel Teaching General Hospital. Most of the patients were male 63.8% and 36.2 % were females. The mean age was 40.86 years ± 14.9 SD, with range from 16 to 80 years. In relation to marital status majority of the study participant were married 54.8%. Most were urban residents, attained above grade 12 and self-employed. Detailed socio-demographic characteristics are shown in Table 1.

Table 1. Socio-demographic characteristics of patients on Dialysis in selected public and private health facilities in Addis Ababa from September 2018 to April 2019 (n=301).

Socio-demographic characteristics		Number	Percent
Sex	Male	192	63.8
	Female	109	36.2
Age	16-25	44	14.6
	26-36	86	28.6
	37-47	65	21.6
	48-58	52	17.3
	>58	54	17.9
Marital status	Single	116	38.5
	Married	165	54.8
	Divorced	7	2.3
	Widowed	13	4.3
Residence	Urban	236	78.4
	Rural	65	21.6
Educational status	Illiterate	20	6.6
	Read and write	25	8.3
	Grade 1-8	42	14.0
	Grade9-12	75	24.9
	Above Grade 12	139	46.2
Occupation	Self-employed	129	42.9
	Government	62	20.6
	Student	26	8.6
	House wife	47	15.6
	Others	37	12.3

5.2 Magnitude of HBV and HCV in relation with socio-demographic factors and medical history

The overall magnitude of HBV and HCV was 12 (4%) and 2 (0.7%), respectively (Figure 4).

As shown in Table 2, there was no remarkable difference between male and females (4.2% versus 3.7%). None of the illiterates were seropositive for both viruses while 12% of those who were able to read and write were positive for HBV. Most of HBV seropositive patients belonged to the age group 26-47 years (9 out of 12), and were rural residents (1.7% versus 12.3%).

Hypertension and diabetes mellitus were highly prevalent in dialysis patients. At initiating of dialysis most patients have hypertension, diabetes mellitus or both. The primary etiology of end stage renal disease in this study is Hypertension 198 (65.8%), diabetes mellitus 69 (22.9%) and unknown cause 34 (11.3%). This study shows out of the twelve HBV positive patients seven of them had history of hypertension (58.3%) and three of the HBV positive patients had history of diabetics (25.0%). Regarding HCV infection this study shows out of the two HCV positive patients one had history of diabetics.

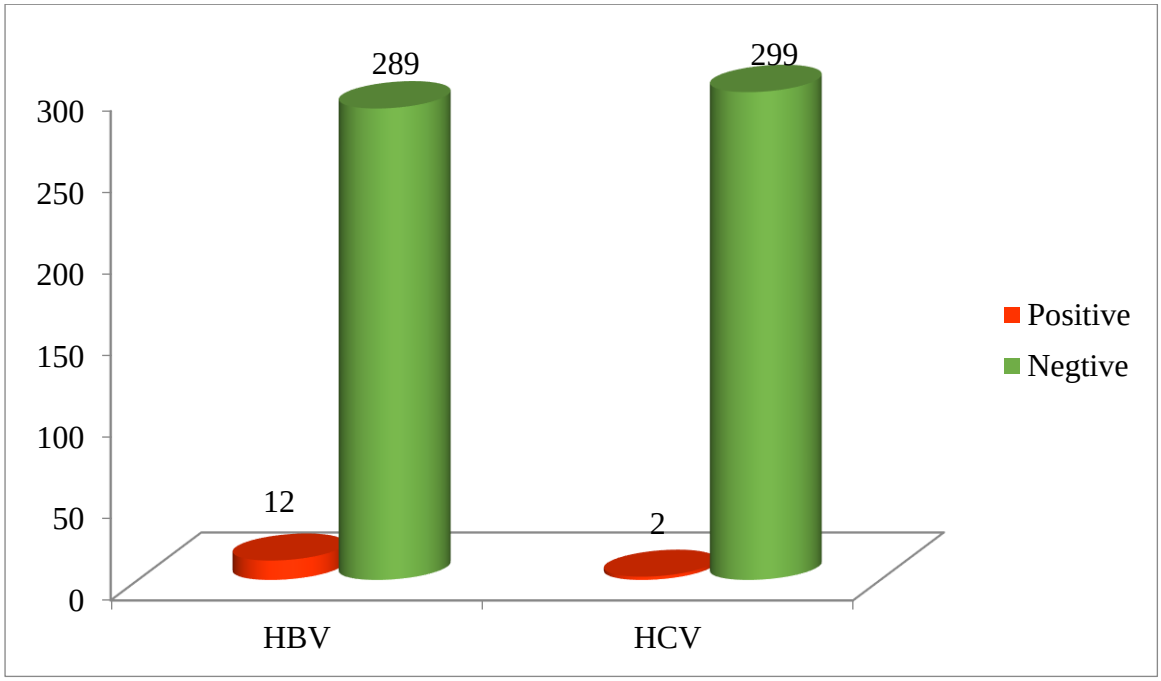

Figure 4. Magnitude of HBV and HCV among patients on Dialysis in selected public and private health facilities in Addis Ababa from September 2018 to April 2019 (n=301).

Table 2. Magnitude of HBV and HCV in relation with socio-demographic characteristics of patients on Dialysis in selected public and private health facilities in Addis Ababa from September 2018 to April 2019 (n=301).

Socio demographic characteristics		Sero-status for HBV		Sero-status for HCV	
		Positive No. (%)	Negative No. (%)	Positive No. (%)	Negative No. (%)
Sex	Male	8(4.2)	184(95.8)	1(0.5)	191(99.5)
	Female	4(3.7)	105(96.3)	1(0.9)	108(99.1)
Age	16- 25	1(2.3)	43(97.7)	---	44(100)
	26-36	5(5.8)	81(94.2)	1(1.2)	85(98.8)
	37-47	4(6.2)	61(93.8)	1(1.5)	64(98.5)
	48-58	1(1.9)	51(98.1)	---	52(100)
	≥58	1(1.9)	53(98.1)	---	54(100)
Marital status	Single	5(4.3)	111(95.7)	1(9)	115(99.1)
	Married	6(3.6)	159(96.4)	1(6)	164(99.4)
	Divorced	---	7(100)	---	7(100)
	Widowed	1(7.7)	12(92.3)	---	13(100)
Residence	Urban	4(1.7)	232(98.3)	2(0.8)	234(99.2)
	Rural	8(12.3)	57(87.7)	---	65(100)
Educational status	Illiterate	---	20(100)	---	20(100)
	Read and write	3(12)	22(88)	---	25(100)
	Grade 1-8	3(7.1)	39(92.9)	---	42(100)
	Grade9-12	3(4)	72(96)	-- -	75(100)
	Above Grade 12	3(2.2)	136(97.8)	2(1.4)	137(98.6)
Occupation	Self-employed	7(5.4)	122(94.6)	2(1.6)	127(98.4)
	Government	2(3.2)	60(96.8)	---	62(100)
	Student	---	26(100)	---	26(100)
	House wife	2(4.3)	45(95.7)	---	47(100)
	Others	1(2.7)	36(97.3)	---	37(100)

5.3. Risk factors of HBV and HCV infection

Among 301 HD patients 151 (50.2%) reported that they had a history of receiving HD service in more than one HD centers. Of them, 6.6% (10/151) were found to be positive for HBsAg and 1.3 % (2/151) were found to be positive for HCV Ab. Related to number of years on HD service, most of them, 170 (56.5%), have undergone 1-3years dialysis. Those patients who underwent HD service < 1year were 70 (23.3%), 4-6 years 53 (17.6%) while 8 patients (2.6%) had been on dialysis for more than 6 years. Higher positivity of hepatitis B infection was found in study participants who have been taking HD service for 4-6 years 9.4%(5/53) followed by 1-3 years 4.1%(7/170) though the difference was not statistically significant (P>0.05). In the case of hepatitis C infection, both HCV positive patients were on dialysis for 1-3 years. Regarding blood transfusion from a total of HD patients 51.2%(154/301) had transfused at least one unit of blood and shows a total of hepatitis B virus infection rate of 6.5% (10/154) and 1.3% (2/154) for hepatitis C virus infection, showing a majority of infection rate is from transfused individuals.

Two risk factors associated with hepatitis B infection. Dialysis outside the specified unit carries a high risk for hepatitis B infection, Ten out of twelve patients (83.3%) who had hepatitis B infection had a history of dialysis outside their units (P <0.05). Concerning blood transfusion same number (83.3%) of hepatitis B seropositive patients had a history of blood transfusion of at least one unit (P <0.05). On the other hand, none of hepatitis B infected patients were vaccinated for hepatitis B virus. Other risk factors like duration on hemodialysis, surgical procedure, smoking habits, examination by endoscopy/colonoscopy, injury by unknown sharp materials, multiple sexual partners, tattooing/body piercing and use of drug through injection by themselves were not associated with HBV infection (P >0.05). Relation of hepatitis B infection with risk factor are shown in Table 3.

Table 3. Bivariate logistic regression analysis of risk factor for hepatitis B infection of patients on dialysis in selected public and private health facilities in Addis Ababafrom September 2018 to April 2019 (n=301).

Variable	Frequency	No of HBsAg positive	P-value
Receiving hemodialysis service in more than one center	151	10	0.019*
Blood transfusion history	154	10	0.023*
Surgical procedure	84	5	0.278
Receive HBV Vaccine	27	0	0.267
Multiple sexual partner	12	1	0.432
Endoscopy/Colonoscopy procedure	42	1	0.566
Tattooing/Piercing	52	1	0.403
Cut with unknown sharp material	35	1	0.716
Use drug by injection	2	0	0.772
Hypertensive	198	7	0.579
Diabetics	69	3	0.861

*statically significant (P<0.05).

Regarding hepatitis C infection risk factors like, using multiple dialysis center, duration on dialysis, blood transfusion, surgical procedure, smoking, habits, examination by endoscopy/colonoscopy, injury by unknown sharp materials, multiple sexual partners, tattooing/body piercing and use of drug through injection by them self were not associated with hepatitis C infection ($P > 0.05$). Of note, only two individuals were positive for HCV and both were having history of blood transfusion and had service in more than one dialysis center. Relation of hepatitis C infection with risk factors are shown in Table 4.

Table 4. Bivariate logistic regression analysis of assessment of risk factor for hepatitis C infection of patients on dialysis in selected public and private health facilities in Addis Ababa from September 2018 to April 2019 (n=301).

Variable	Frequency	No of anti-HCV Ab positive	p-value
Receiving hemodialysis service in more than one center	151	2	0.157
Blood transfusion	154	2	0.166
Surgical procedure	84	1	0.485
Multiple sexual partner	12	0	0.772
Endoscopy/Colonoscopy procedure	42	0	0.568
Tattooing/Piercing	52	0	0.517
Cut with unknown sharp material	35	0	0.607
Use drug by injection	2	0	0.908
Hypertensive	189	0	0.490
Diabetics	69	1	0.361

6. Discussion

Hepatitis B and Hepatitis C virus infections are important community health problems in Ethiopia as different studies have examined Hepatitis B and Hepatitis C virus infections in different study population (50). The current study was set to examine the magnitude of Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections among hemodialysis patients.

The main cause of end stage renal disease in this study was hypertension in 65.8% (198/301), followed by diabetes 22.9% (69/301). The results from this study on 301 hemodialysis patients demonstrated that the occurrence of Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections among hemodialysis patients in five HD centers was 4% and 0.7%, respectively, which is lower compared with the general population of Ethiopia which is 7.4% for hepatitis B virus infection and 3.1% for hepatitis C virus infection (51).

The finding in the current study was also much lower compared to reports from different studies. For instance, study from Cameroon showed prevalence of hepatitis B and hepatitis C virus infections to be 10.6% and 19.2%, respectively (10) and in Sudan prevalence of hepatitis B and hepatitis C virus infections was 5% and 6% (42). Other study from Libya has reported higher prevalence of hepatitis C virus infection 31.1% in maintenance hemodialysis patients (52). Moreover, other studies from different parts of the world also report higher prevalence of hepatitis B and hepatitis C virus infection in HD patients. An Indian study has reported the occurrence of hepatitis B virus in patients under hemodialysis to vary from 3.4% to 42% (80), Saudi Arabia (10%) and Bahrain (11.8%) (14). Higher prevalence of hepatitis B virus infection also reported 7.8% in Cameron (53) and 7% in Iran (54) on hemodialysis patients. which is much higher than that seen in this study. However, our study showed high prevalence compared to other neighboring countries like one study from Libya which shows lower hepatitis B virus infection (2.6%) (52) and in HD patients of other regions including Japan (2.2%) and the USA (2.4%) (55).

Occurrence of hepatitis C virus infection, on the other hand, was much less than hepatitis B virus infection in our study this is probably due to few HD centers treats patient with HCV but in other part of the world it shows higher prevalence of hepatitis C virus infection such as in Iran HCV prevalence among hemodialysis patient is 5.2% (56). Another study in Iran also

show 13.2% prevalence of HCV among hemodialysis patients (57) and in Yamen it shows 22.5% (58). But other study from Brazil showed a significant decline of hepatitis C infection among end-stage renal disease, highlighting the importance of public health strategies such as screening for anti-HCV in blood banks and infection control measures for control and prevention of hepatitis C in the hemodialysis environment (59).

In relation to both hepatitis B and hepatitis C virus infections, the reasons for the relatively lower rate of sero prevalence in this study compared with other studies cannot be completely discerned. But, the difference in demographic characteristics of the study population, the difference in hepatitis epidemiology in these countries, awareness of the routes of hepatitis B and hepatitis C virus transmission, efforts made to implement universal precautions by health professionals, isolation of hepatitis positive patients, avoiding any sharing in hemodialysis centers and preliminary benefits due to the initiation of national programs of immunization of health professionals in Ethiopia might explain these discrepancies.

The sex specific frequency of hepatitis B infection is more among male than female but sex specific frequency of hepatitis C infection is similar in this study, this was not statistically significant ($P > 0.05$), This is also consistent with studies made in Iran (60) but it contradicts with study conducted in Argentina (74), whereas another study from Iran shows that male on hemodialysis had higher hepatitis C virus infection than female (40).

Results from this study showed that there was no statistically significant correlation between age of patients and infection with hepatitis B and hepatitis C virus, this is in line with what was found in Syria (61) and Egypt (62). On the other hand, our results differ from what was found in Iraq (63) and Sudan (64) where they found that HCV sero positivity was associated with age. Whereas another study from Palestine also reported a statistically significant relationship between HBV infection and age of the patients in a way that patients aged less than 40 years were found to be more susceptible to HBV than older patients (65).

This study found no statistical significant relationship between hepatitis B and hepatitis C virus infection with factors like age, sex, residence, occupation, marital status, educational status, duration of dialysis, surgical procedures, multiple sexual partner, smoking, endoscopy/colonoscopy, tattooing or previous cut with unknown sharp material and use drug by injection. This was in agreement with study conducted in Iran that showed no statistically significant relationship between age, sex, and time duration on hemodialysis with hepatitis B

and hepatitis C virus infection (66). The study was also in agreement with others conducted in Brazil which showed no statistical significant correlation between sex, residence and marital status with hepatitis B and hepatitis C virus infection (67). Another study from Sudan also agreed with the above statement, in which the study found no statistically significant correlation between tattooing and piercing with hepatitis C infection (68).

In our study, statistically significant relationship was found between hepatitis B infection and patients taking hemodialysis service in more than one hemodialysis centers ($P < 0.05$) and hepatitis B virus infection also increased significantly with blood transfusion ($P< 0.05$). This was in agreement with a previous study conducted in Palestine which showed strong statistically significant correlation between hepatitis B infection with blood transfusion and taking hemodialysis service in multiple hemodialysis centers (6),while another study from Jordan showed no relationship (69). With regards to HCV, in this study, no statistical significant relation was found between hepatitis C infection and blood transfusion ($P > 0.05$), this was in agreement with study conducted in Argentina (22) but it contradicts with study conducted in Vietnam (70) and in Iran (71) which shows strong relation between blood transfusion and hepatitis C infection. The study also revealed no statistically significant relationship between history of dialysis in multiple hemodialysis centers with hepatitis C infection, this was in agreement with study contradict in Gaza (65). But the study contradicts with study conducted in Sudan which showed strong statistical significant correlation between history of dialysis in multiple centers with hepatitis C infection ($P < 0.05$) (68).

Regarding to the duration of dialysis, this study showed no statistical significant relation with HBV and HCV positivity; this is in line with study conducted in China (72) but it contradicts with study conducted in Sudan (68) and Jordan (73) which showed statistical correlation between HBV and HCV with duration of hemodialysis.

No statistically significant relationship was found between hepatitis B infection and surgical operation in the current study. This result is in agreement with study conducted in Gaza (74) but it contradicts from a previous study conducted in Brazil that showed surgery as risk factor for acquiring hepatitis infection (75). This contradiction may be due to differences in the type of surgery or other factors related to the countries where surgeries are performed. Regarding hepatitis C infection, the study showed no statistical relation with history of surgery in contradiction with study conducted in Pakistan which found strong statistical correlation between hepatitis C virus and surgical procedure (76).

The introduction of hepatitis B vaccinations for hemodialysis patients has led to a decline the incidence of hepatitis B infection (39). In this study, all vaccinated patients tested negative for HBsAg which shows that the importance of vaccination for prevention of hepatitis B infection, this is in agreement with a previous study conducted in India which state the importance of vaccination for lower rate of hepatitis B infection (77).

In summary, this study has revealed low prevalence of hepatitis C infection and intermediate prevalence of hepatitis B infection on hemodialysis patients. However, neither associated risk factors nor associated socio-demographic characteristics have been significantly associated with acquisition of infection except patients who had history blood transfusion and those taking hemodialysis service in multiple hemodialysis centers with respect to hepatitis B infection.

7. Strength and Limitation of the study

The study adds information to the limited data on the subject available in Ethiopia and will help in increasing awareness regarding association of HBV and HCV with hemodialysis, thereby will help in reducing morbidity and mortality, create awareness among health professionals and reduce cost associated with these viruses. The study even more important on improving infection prevention protocols in hemodialysis centers. This study was, however, limited by our inability to assess patients with occult HBV infection and other markers of HBV and HCV were not included in the study.

8. Conclusion and Recommendation

Conclusion

This study shows magnitude of HBV and HCV 4% and 0.7% respectively. There was no statistical significance difference in acquisition of HBV and HCV infection with respect to socio- demographic characteristics but statically significant difference was found in HD patients who had history of blood transfusion and receiving HD service in more than one HD center for hepatitis B infection. Therefore, we conclude that HCV infection is low and HBV infection is intermediate among hemodialysis patients and history of blood transfusion have higher risk of acquisition of HBV infection than those who do not have history of blood transfusion and those who use more than one HD center have also higher risk of acquisition of HBV infection than their counter parts.

Recommendation

Since hepatitis B and hepatitis C infection are one of the major health problems in hemodialysis patients, the following recommendations must be carried out for its prevention.

- All patients receiving hemodialysis should be tested for HBV and HCV sero status regularly.
- Awareness creation on modes of transmission of the hepatitis B and hepatitis C infection is important to prevent viral infection.
- Multi-center studies in Ethiopia is needed as it will give a better picture of the burden of this blood borne viral infections in hemodialysis centers and other viral markers should be used.
- Patients who required maintenance hemodialysis should be vaccinated for HBV before the start of the treatment.
- Isolated dialysis machines/areas/rooms for hepatitis positive patients without sharing the same staff is important to avoid cross contamination.
- Adherence to comprehensive infection control protocols including infection control practices, effective follow up procedure, routine serological testing, training and education is important to control hepatitis infection in HD centers.

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10 Annexes

Annex I: English version of Participation information sheet Participant information sheet

Principal Investigator: Messay Assefa, Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences, Addis Ababa, Ethiopia.

Title of the research project: Magnitude of HBV and HCV and its Associated Factor Among Hemodialysis Patient in Addis Ababa, Ethiopia

First of all, I would like to thank you in advance for your cooperation for the permission that the study to be conducted in your health facility. Please read the general information about the study. If you have any question regarding the study please ask freely.

Background information

Background: Patients receiving maintenance hemodialysis (HD) are at higher risk for acquiring Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) infections than the general population because the process of hemodialysis requires vascular access for prolonged periods. It continuous to be exasperating problem in many HD centers, therefore knowledge of the prevalence of these infections will be helpful in the control and prevention of nosocomial transmission.

Purpose

The purpose of this study is to assess the Magnitude of HBV, HCV and its Associated Risk Factor Among Hemodialysis Patient in Addis Ababa, Ethiopia

Benefits from the study

The study participant will not have any financial incentive or other inducements from participating in this study. However, based on the diagnosis result you will be treated accordingly. Most importantly the result of the study will be beneficial to design effective prevention and control measure for hepatitis infection in HD center. Hence you are indirectly benefiting other patients and the society in this respect. If there is any positive finding in

laboratory investigation the result will be communicated with your physician and prescription of treatment and advice will be effected.

Risks and discomfort associated with the study

No harm is imposed to you. Taking 5ml of blood doesn't have any harm to your health except minor needle prick injury pain and every step of precaution will be taken to prevent any harm to the participant. However, if you have any discomfort you will be refer to physician for treatment.

Confidentiality

Any information that we collect about you during this research will be kept confidential. The information about your identity will be put away after recording your file and kept in secure place. Only the principal investigator will be able to link your identity with the code number. Information will be only disclosed for the study area and publication purpose.

Right to refuse

Since participation in this study is entirely voluntary. You can refuse to participate in this research at any time. Your refusal to participate in this study will not affect any of the benefits you are supposed to get from the center.

Assurance of Principal investigator

I put my signature below to confirm you that I take over the responsibility for the scientific ethical and technical conduct of the research project and for provision progress reports for all stockholders of the research project.

Messay Assefa (PI)

Signature: _____ Date: _____

Note: If you have any question about this study you should feel free to ask now or anytime throughout the study by contacting:

PI Address: Messay Assefa Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

Email: mes6say@gmail.com Tell- 0911659844

Annex II. Consent Form

I have been informed about the objective of the study entitled "Magnitude of HBV and HCV and its Associated Factor Among Hemodialysis Patient in Addis Ababa, Ethiopia" I am also informed that 5ml of blood will be drawn and all information contained within the questionnaire will be kept confidential. Moreover, I have also been assured that I can withdraw my consent at any time without penalty or loss of benefits. The proposal has been explained to me in the language I understand.

I_____ hereby give my consent for giving of the requested information and specimen for this study.
For children aged 16-17 years old: I agree provided my child provides his or her assent.

Name of the patient: ----------

Patient's signature: ----------

Name of Principal Investigator: ----------

Principal Investigator signature: ----------

Date: ----------

Witness: ----------

Respondent's ID: **……**

Respondent card Number**: …….**

Annex III: English Version Questionnaires for study participant

Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Science. Questionnaire for data collection to determine the magnitude and associated risk factor of HCV and HBV infection among hemodialysis patient.

Respondent's ID: _____HD Facility Name: _____

Part- 1: Socio-Demographic Characteristics of respondents

101	Sex	Male= 1 Female= 2	
102	Age	_____ years	
103	Residence	Urban= 1 Rural= 2	
104	Current occupational status	Self-employed= 1 Government employee= 2 Student= 3 House wife= 4 Driver= 5 Other specify_____	
105	Marital status	Single= 1 Married= 2 Divorced= 3 Widowed= 4	
106	Education status	Illiterate= 1 Read & Write= 2 Grade1- Grade 8= 3 Grade9- Grade 12= 4 Above Grade 12= 5	

<u>Part-2</u>: Potential Risk Factor for HBV and HCV infection among hemodialysis patient

201	Have you ever received HD service in another center before?	No= 1 Yes= 2	
202	How many times did you get the service/frequency	_____per week____ hr _____, years	
203	Have you ever been transfused blood?	No= 1 Yes- 2	
204	If yes for Q# 203, how many times have you being transfused blood?	_____ times (# of bag if possible)	
205	Have you ever been in any surgical procedure?	No= 1 Yes= 2	
206	Have you ever received vaccine for HBV?	No= 1 Yes= 2	
207	Do you have more than one sexual partner (Remember your previous practice)	No= 1 Yes= 2	
208	Have you ever preformed endoscopy/colonoscopy?	No= 1 Yes= 2	
209	Do you have any tattooing and body piercing?	No= 1 Yes= 2	
210	Have you ever been injured with unknown sharps in HD center or other area?	No= 1 Yes= 2	
211	Have you ever used drug by injection?	No= 1 Yes= 2	
212	Do you have hypertension, diabetic or any other chronic disease?	No= 1 Yes= 2	

Comment if you have any…….....

Thank you for your cooperation.

Annex IV ፡ለጥናቱመረጃናተሳታፊነትመግለጫናየስምምነትማረጋገጫቅጽ

ለጥናቱመረጃናተሳታፊነትመግለጫቅጽ

የጥናቱዓላማ

ሄፖታይተስ“ቢ”እናሄፖታይተስ“ሲ”ቫይረሶችዲያሊሲስበሚወስዱህሙማንላይለማጥናትየታቀደነው::

በጥናቱስለመሳተፍ

በዚህጥናትመሳተፍበሙሉፈቃደኝነትላይየተመሰረተነዉ:ስለሆነምበጥናቱእንዲሳተፉፈቃደኛነትዎንእንጠይቃለን:

ለመሳተፍከፈቀዱ 5 ሚሊሊትርየደምናሙናከክንድዎ

ተወስዶየላብራቶሪምርመራይደረግሎታል:: የላብራቶሪምርመራውምሄፖታይተስ “ቢ” እና “ሲ”ቫይረስንበደምውስጥመኖርናአለመኖርማረጋገጥይሆናል::ደምከመወሰዱበፊትእናከውጤበሁዋላየባለሙያየምክርአገ ልግሎትያገኛሉ:የደምናሙናዉምየሚወሰደዉንጽህናዉበተጠበቀአዲስእናበታሸገመርፌናስሪንጅነዉ፡፡

በጥናቱሊከሰቱየሚችሉተያያዥችግሮች

5

ሚሊሊትርየደምናሙናዉንለመዉሰድመርፌሲገባከሚፈጠረውየቅጽበትየህመምስሜትበስተቀርየጎላችግርአያመጣምነገርግ ንምኞትካልተሰማዎትህኪምእንዲያይዎትያደርጋል::

በጥናቱበመሳተፍየሚገኝጥቅም

የደምናሙናየላብራቶሪውጤትምንምአይነትችግርካሳየየመድሃኒትትእዛዝናየባለሙያምክርይሰጥዎታል::

የጥናቱመረጃዎችሚስጥራዊነት

በጥናቱውስጥየተሰበሰቡማናቸዉምግላዊመረጃዎችሚስጥራዊነታቸዉየተጠበቀይሆናል፡፡

ከማንነትዎጋርበቀጥታተያያዥነትያላቸዉመረጃዎችበሙሉበዋናተመራማሪዉሚስጥራዊበሆነየመረጃጥንቅርዘዴከተቀየሩበ ታላብቻለምርምርሂደቱየሚዉሉይሆናሉ፡፡

የጥናቱንውጤትስለማሳወቅ

የዚህጥናትውጤትበተለያዩየህትመትዉጤቶችየሚቀርብሲሆንይህከማንነትዎጋርየተያያዘምንምዓይነትመረጃንአያካትትም::

ስለዚህምየጥናቱንውጤትበሪፖርትእናቀርበዉዘንድፈቃዶንእንጠይቃለን::

ከጥናቱስለመውጣትናማቋረጥ

ይህጥናትበፈቃደኝነትላይየተመሰረተእንደመሆኑመጠንበማንኛውምወቅትበፈቃድዎ

ከጥናቱመወጣትይችላሉ::

ከጥናቱቢወጡምእንኳንየተለመደውንየህክምናእርዳታበጤናተቋሙውስጥበማንኛውምጊዜየማገኘውመብትአልዎት::

ስለስምምነቱማረጋገጫፊርማ

እኔስሜከታችየተገለፀዉየጥናቱተሳታፊለመሆንስወስንየጥናቱንአላማዎችአሰራሮችና ቅድመሁኔታዎችበግልጽበመረዳትናከጥናቱተሳታፍነትፈቃደኝነቴንበማንኛውምደረጃየማንሳቴንመብቴንበማረጋገጥነው::

እኔ

_____በጥናቱተሳታፊመሆኔንበፊርማዬእያረጋገጥሁይህንንስወስን5ሚሊሊትርየደምናሙናከከንድዎተወስዶየላብራቶሪምርመራይደረግሎታልበጥናቱሳቢያሊከሰቱየሚችሉ አደጋዎችበሚገባየተረዳሁናከጥናቱበማንኛውምደረጃእራሴንለመሰረዝብወስንተገቢየሆኑህክምናዎችናእገዛዎችሁሉእንደማይነፍጉኝበማመንነው:: እኒህመረጃዎችሁሉበሚገባበምረዳውቋንቋየተገለጸልኝመሆኑንበፊርማዬአረጋግጣለሁ::

ከ12-17 ዓመትለሆኑልጇከተስማማ/ማችበዚህጥናትእንድትሳተፍ/እንዲሳተፍፈቃደኝነቴንገልጫለሁ::

የበሽተኛውሙሉስም _____ፊርማ_____

የተመራማሪውሙሉስም፤ዶ/ር&አቶ&ወ/ሮ&ወ/ት _____

ፊርማ _____

የምስክርሙሉስም _____ፊርማ _____

የመላሹ/ የተጠያቂዉ/ መለያኮድ _____

በአማርኛቋንቋለጥናትተሳታፊዎችየተዘጋጀመጠየቅ

በአዲስአበባዩኒቨርስቲየህክምናፋክልቲ, የላብራቶሪትምህርትክፍልመረጃለመሰብሰብየተዘጋጀመጠይቅ“Magnitude of HBV and HCV and its Associated Factor Among Hemodialysis Patient in Addis Ababa, Ethiopia”እባክዎመልስዎንኮድበሚለውሳጥንውስጥመልሰዎየሚገኝበትቁጥርይሙሉ

የመላሹ/ የተጠያቂዉ/ መለያ _____.

ክፍል-1:የተጠያቂዉአጠቃላይጥያቄ

			ኮድ
101	ፆታ	ወንድ 1 ሴት 2	
102	እድሜ	_____.አመት	
103	መኖሪያአካባቢ	ገጠር 1 ከተማ 2	
104	የስራሁኔታ	የግል 1 የመንግስት 2 ተማሪ 3 የቤትእመቤት 4 ሹፌር 5 ሌላ (ይገለጽ).....	
105	የጋብቻሁኔታ	ያላገባ/ች 1 ያገባ/ች 2 የፈታ/ች 3 የሞተበት/ባት 4	
106	የትምህርትደረጃ	ያልተማረ 1 መፃፍናማንበብየሚችል 2 ክፍል 1 - ክፍል 8 3 ክፍል 9 - ክፍል 12 4 ከ 12 በላይ 5	

<u>ክፍል- 2</u>፡ለሄፖታይተስ “ቢ” እናለሄፖታይተስ “ሲ” ቫይረሶችሊያጋልጡየሚችሉድርጊቶች

			ኮድ
201	ኪዚህበፊትሌላቦታየደምማጣራትአገልግሎት በሌላቦታተደርጎሎትያውቃል?	አይደለም 1 አዎ 2	
202	ለምንያህልጊዜ	_____በሳምንት _____በሰአት _____በዓመት	
203	ደምተሳጥትያውቃልወይ	አይደለም 1 አዎ 2	
204	አዎከሆነለጥያቄ 203 ስንትጊዜደምወስደዋል	_____ጊዜ _____የቀረጢትብዛት	
205	ማንኛውምአይነትቀዶጥገናተደርጎሎትያዉቃል?	አይደለም 1 አዎ 2ከሆነበምንምክንያት?_____	
206	የሄፖታይተስቢቫይረስክትባትተከትበውያውቃሉ?	አይደለም 1 አዎ 2	
207	ከአንድበላይየትዳርጉደኛኖሮትያውቃል?	አይደለም 1 አዎ 2	
208	በኢንዶስኮፒ/ ኮሎኖስኮፒተመርምረውያወቃሉ?	አይደለም 1 አዎ 2	
209	በሰውነቶላይንቅሳት፣ጆሮወይምአፍንጫመበሳትአለ?	አይደለም 1 አዎ 2	
210	በህክምናቦታወይምሌላቦታስለትያለውነገርበድንገትቆርጦት/ ወግቶትያውቃል?	አይደለም 1 አዎ 2	
211	በመርፌየሚወጋመድሃኒትተጠቅመውያውቃሉ	አይደለም 1 አዎ 2	
212	ደምግፊትስ፣ርበሽታወይንምተዛማችበሽታዎችአለቦት?	አይደለም 1 አዎ 2	

አስተያየትካሎት: _____

ስለትብብርዎእናመሰግናለን

Annex V: Data Collection Format

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Hospital Name: _____

No	Respondent ID	Medical History	Result				ELFA Result	
			HBV		HCV		HBV	HCV
			Positive	Negative	Positive	Negative		
1								
2								
3								
4								
5								
6								
7								
8								

Annex VI: Sample Transportation Protocol

Materials and Equipment Required:

1. Transportation Box
2. Ice Box
3. Nunc Tube
4. Disposable gloves
5. Cotton /Tissue Rolls
6. Zip lock bags

Procedure:

- Each container labeled with a code, and date of collection.
- Specimens was collected with universal precautions and put in a leak-proof unbreakable Nunc tube. Made of plastic with capped.
- The container, after proper labeling kept in a non-leak able zip lock bag. This bag then placed in another bag containing adequate packing material (like tissue paper, cotton, etc.) to absorb liquid if leakage occurs accidentally.
- This package then placed in a cold box having ice packs to maintain proper cold chain system during transit. The box sealed securely.
- The box clearly labeled as" BIOHAZARD MATERIAL".
- Specimens sent to the laboratory as soon as possible.

11 Declaration

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

M.Sc. candidate: Messay Assefa (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: Aster Tsegaye (MSc, PhD) **Advisor: Kassu Desta (MSc, PhD candidate)**

Signature: _____ Signature: _____

Date: _____ Date: _____

Place: Addis Ababa, Ethiopia. Place: Addis Ababa, Ethiopia.