



Addis Ababa University College of Health Sciences Department of Medical Laboratory science

Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors in Arbaminch Blood Bank SNNPR, Ethiopia

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## **Abbreviations**

|       |  |
|-------|--|
| CDC   | Communicable disease control             |
| CO    | Cut-off                                  |
| ELISA | Enzyme linked immunosorbent assay        |
| HBsAg | Hepatitis B surface Antigen              |
| HBV   | Hepatitis B virus                        |
| HBc   | Hepatitis B core antigen                 |
| HCV   | Hepatitis C virus                        |
| HIV   | Human immunodeficiency virus             |
| HRP   | Horseradish peroxidase                   |
| IgG   | Immunoglobulin G                         |
| NC    | Negative control                         |
| OD    | Optical density                          |
| RNA   | Ribonucleic acid                         |
| SNNPR | South nation nationalities people region |
| TMB   | Tetramethylbenzidine                     |
| WHO   | World health organization                |

## **Abstract**

**Background:** Hepatitis B virus (HBV) and Hepatitis C virus (HCV) is major public health problems that affect million people worldwide and people who are infected assumed to develop liver cirrhosis or hepatocelular carcinoma. Infected peoples are at latent stage before clinical sign and symptom, screening of blood donors is very important for healthy and safe blood donation.

**Objective:** To assess prevalence and associated risk factor of HBV and HCV among volunteer blood donors in Arbaminch blood bank.

**Method:** A cross sectional study design was conducted among blood donors in Arbaminch blood bank from Feb 2015-Aug 2015. A total of 359 volunteer blood donors who came to Arbaminch blood Bank were interviewed face to face, then data was collected by using structured and pre-tested questionnaire, and finally blood sample drown and tested for HBV and HCV by using ELISA (enzyme linked immunosorbent assay) technique. Descriptive statistics was calculated for most variables in the study. OR and 95% CI was used to assess the association.

**Result:** Prevalence of HBV and HCV among study participant was 4.7% and 0% respectively. From 17 participants tested positive for HBV, 8 (47%) were males. The test positivity among male was 8/197 (4.1%) while among females was 9/162 (5.6%) and more than three forth participants tested positive were age less than 25. After multivariate analysis, when positivity was compared among study participants grouped based on average monthly income, participants earning 581-1,300 were 32.2% less likely to have infection than participants earning below 580 birr per month. (AOR= 0.322, 95%CI =0.108-0.961). Volunteer donors who exposed to unsafe therapeutic drug injection was 8(2.2%) and from those 3(37.5%) was positive for HBV. When compare to volunteers who did not exposed 14(4%), exposed donors 11 times increased risk of HBV infection. This was statistically significant (AOR=11.090, p=2.258-54.475).

**Conclusion:** Prevalence HBV of among volunteer blood donors in Arbaminch Blood Bank was 4.7%. Low monthly income and using unsafe therapeutic injection were related to HBV infection.

**Recommendation:** Improve community awareness, infection control and post counseling will be done to control infection.

**Key words:** hepatitis B virus, hepatitis C virus, volunteer blood donor.

# Chapter one

## 1. Introduction

### 1.1. Global Epidemiology of HBV and HCV

Worldwide, two billion people have been infected with HBV, 360 million have chronic infection, and 600,000 die each year from HBV-related liver disease or hepato cellular carcinoma (1). On the other hand HCV affects 130-210 million people worldwide and one of the major risk factors for hepatocellular carcinoma. Globally, at least one third of hepatocellular carcinoma cases are attributed to HCV infection and 350,000 people died from HCV related diseases per year (2).

Europe In 2012, 17,329 cases of hepatitis B were reported in 29 counties (no data from Belgium and Liechtenstein), resulting in an overall crude rate of 3.5 per 100,000 population (3). HCV in Western Europe, peak prevalence increases from 2.5% in 1990 to 3.9% in 2005. Eastern Europe is estimated to have the highest peak prevalence at 5.2%, followed by Central Europe with prevalence of 4.7 % (4).

In the United States, 2,890 cases of acute hepatitis B were reported to CDC (communicable disease control) in 2011(5). From 1990 to 2005, the prevalence of hepatitis B infection fell on average to below 2% in the central and tropical Latin American regions, while it remained between 2% and 4% in the Caribbean, Andean and southern Latin American regions (6). HCV In 2005, Andean Latin America had the highest peak prevalence (P: 4.9%) followed by the Caribbean (P: 4.6%) Central Latin America (P: 3.9%) Southern Latin America (P: 3.3%) and Tropical Latin America (P: 3.0) (4).

In South-East Asia Region there is an estimated 100 million people living with chronic HBV infection out of those 65% HBV cirrhosis or liver cancer many years later (7). Western Pacific Region contains only 28% of the global population, almost half the estimated 350 million people with chronic HBV infections (8). Total prevalence of HCV in East Asia increases from 2.2% in 1990 to 3.7% in 2005, whereas changes in other regions were not significant (4).

The prevalence of HBV is estimated at 8% in West Africa and 5-7% in Central, Eastern and Southern Africa (9). HCV prevalence pattern across age is similar in East, Central, and Southern sub-Saharan Africa, with the latter two having considerably lower prevalence compared to other

sub-Saharan African regions. Differences in prevalence across age and total prevalence between 1990 and 2005 for sub-Saharan Africa are not significant, except in the West region, where total prevalence decreased from 4.0% in 1990 to 2.8% in 2005(4).

In sub-Saharan Africa and other resource-limited settings, transfusion-transmitted HBV and HCV infections remain a public health burden. From 2000 to 2011, the number of countries in sub-Saharan Africa screening at least 95% of donated blood units for HBV and HCV increased from 76% to 94% and 34% to 86%, respectively. During the same period, the median percentage of HBV marker-reactive units decreased from 7.1% to 4.4%, and the median percentage of HCV marker-reactive units decreased from 1.4% to 0.9%. In Ethiopian blood donors Marker-reactive rates in 2000/2004 from 24,000 donors was 4% Hepatitis B and 2% for hepatitis C and 2010/2011 from 92,218 donors was 3.42% Hepatitis B and 0.47% hepatitis C and 2000/2004 to 2010/2011 ratio was 0.86% Hepatitis B and 0.23% for hepatitis C (10).

## **1.2. Associated Risk factors of HBV and HCV**

HBV is transmitted through exposure to infectious blood, semen, and other body fluids. HBV can be transmitted from infected mothers to infants at the time of birth, or from family members to infants in early childhood. Transmission may also occur through unsafe sexual intercourse, transfusions of HBV-infected blood and blood products, contaminated injections during medical procedures, and sharing of needles and syringes among injecting drug users. HBV also poses a risk to healthcare workers who sustain accidental needle-stick injuries while caring for HBV-infected people. HCV is mostly transmitted through exposure to infectious blood. This may happen through transfusions of HCV-infected blood and blood products, contaminated injections during medical procedures, and sharing of needles and syringes among injecting drug users. Sexual or interfamilial transmission is also possible, but is much less common (9). Immigration, cheap air travel, and globalization are all factors contributing to a worldwide spread of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection (11).

### 1.3. Genome HBV and HCV

HBV is a well-known hepadnavirus with a double-stranded circular DNA (deoxyribonucleic acid) genome (12). Because the HBV reverse transcriptase lacks a proofreading function, many HBV genotypes, sub genotypes, mutants, and recombinants exist. At least 10 HBV genotypes (HBV-A through J) with distinct geographic distributions have been identified; by definition, their complete genomic sequences diverge by more than 8%. HBV genotype is increasingly becoming recognized as an important factor in the progression and clinical outcome of HBV induced disease (13).

HCV was first described in 1989 as the putative viral agent of non-A non-B hepatitis. It is a member of the Flaviviridae family (14). HCV is a small (~55 to 65 nm), spherical, enveloped, hepatotropic RNA (ribonucleic acid) virus (15). HCV is a positive RNA virus with a genome containing approximately 9,500 nucleotides. It has an open reading frame that encodes a large polyprotein of about 3,000 amino acids (14). It has been reported that HCV-coding proteins interact with host-cell factors that are involved in cell cycle regulation, transcriptional regulation, cell proliferation and apoptosis. (16). It is characterized by extensive genetic diversity. It has been classified into at least 6 major genotypes with many subtypes and circulates within an infected individual as a number of closely related but distinct variants known as quasi species (14).

#### 1.4. Statement of Problem

Viral hepatitis is a global public health problem affecting millions of people every year, causing disability and death. Around 500,000,000 people are chronically infected with HBV or HCV (9). Approximately 1 000,000 people die each year (~2.7% of all deaths) from causes related to viral hepatitis most commonly liver disease including liver cancer (17). An estimated 57% of cases of liver cirrhosis and 78% of cases of primary liver cancer result from HBV or HCV infection (18). Overall, initial hepatitis B infections will progress to chronic in approximately 5-10% of unimmunized older children and adults. For hepatitis C virus there is an overall 75-85% chance of an acute infection resulting in a chronic infection (19).

The World Health Organization (WHO) estimated that transfusion of unsafe blood accounted for 8-16 million hepatitis B virus infections and 2.3-4.7 million hepatitis C infections each year (20). It is estimated that in sub-Saharan Africa, more than 45,000 hepatitis B viruses or hepatitis C virus infections are transmitted through contaminated transfusions annually (10). In Ethiopia different study indicated that prevalence of HBV and HCV on blood donors varies from 2.1%-25%, 0.2%-13.3% respectively (21-24). And concerning study area there is no previous studied data on blood donors.

Millions of people are living with viral hepatitis and millions more are at risk. This is because of most people who were infected long ago with HBV or HCV are unaware of their chronic infection. They are at high risk of developing severe chronic liver disease and can unknowingly transmit the infection to other people (9) though exposure to infected blood via blood transfusion or unsafe injection practices, and transmission from mother to child during pregnancy and delivery (25). Due to those risks evaluation and monitoring the prevalence of transfusion-transmissible viral infections in blood donors is a valuable index of donor selection and blood safety (26).

There were different studies in Ethiopia on HBV and HCV on blood donors (2.1%-25%, 0.2%-13.3%) (21-24). But those studies did not cover SNNPR especially Arbaminich and also those researches based on three donors category (volunteer, replacement and commercial) So the purpose of this study was to assess the prevalence and associated risk factors of Hepatitis B and C virus among volunteer blood donors. Replacement and commercial donors not included.

### **1.5. Significance of the study**

There were different studies in the different parts of the country on the blood donors but there is no study specifically in the study area. As the result; this study was identify prevalence and associated risk factor of HBV and HCV among volunteer blood donors. The information is important in the debate about HBV and HCV on volunteer's blood donor and the study result was generate important information about HBV and HCV and associated risk factor and also help further developing national intervention program. This study was also allow collection of baseline data that can be used to track the magnitude and prevalence of HBV and HCV and that will help blood safe and safe blood donation.

## Chapter Two

### 2. Literature Review

#### 2.1. Prevalence of Hepatitis B and C Virus

In recent decades, viral hepatitis has not received the attention it deserves from the global community, although the burden of disease is very high (9). This problem also addressed by different research from different parts of world.

Study conducted by shrestha et al. on transfusion-transmissible infections among blood donors in Central Blood Transfusion Service (CBTS) in Nepal found the prevalence of HBV and HCV was 0.47% (95% CI = 0.39-0.57), 0.64% (95% CI = 0.54-0.75) respectively (27).

Another study by Al-juboury et al. on Seroprevalence of Hepatitis B& C among Blood Donors in Babylon Governorate-Iraq found that from 23336 donors Only 287 donors (1.2%) were infected with the hepatitis (B or C). The number of HBsAg seropositive blood donors was 171 with prevalence of (0.7 %) while the number of Anti – HCV seropositive blood donors was 116 (113 males and 3 females) with prevalence of (0.5 %) (28). Similarly study from Jordan by Al-Gani et show that from 24173 blood donors, 370 were found to be positive for HBsAg, giving an overall prevalence of HBsAg of 1.4% and Infection with HCV was detected in 73 (0.9%) of 8190 donors. (29).

A cross-sectional study was conducted by Viet et al. on the Prevalence of hepatitis B & hepatitis C virus infections in potential blood donors in two rural communities in Quang Tri, Vietnam and the analyses showed that 11.4% of study samples (137/1200, 95% CI 9.6 - 13.2) were positive for HBsAg, 51.7% (620/1200, 95% CI 48.8 - 54.5) were anti-HBc-positive, while 9.5% (114/1200, 95% CI 7.9 - 11.3) were positive for both HBsAg and anti-HBc. Further, 1.9% (23/1200, 95% CI 1.2 -2.8) of the serum samples were positive for HBsAg and negative for anti-HBc; and 42.2% (506/1200, 95% CI 39.4 - 45.0) negative for HBsAg and positive for anti-HBc. There were only two positive anti-HCV samples (0.17%) (30).

On the other hand study conducted by Huang et al. on the prevalence and risk factors of hepatitis C among former blood donors in rural China and found that out of 520 villagers, HCV infection was detected in 148 (28.5%) from those 70 were males and 78 were females. Of the villagers who had sold blood or plasma, 101 were infected, only 47 of those who had never sold blood or

plasma were seropositive. HCV seroprevalence in donors was 2.6 times higher than in the villagers who had not sold blood or plasma (31). In addition study conducted by Al-waleedi et al. on the Prevalence of hepatitis B and C infections and associated factors found that from 469 blood donors, 24 (5.1%) were positive for HBsAg and 6 (1.3%) were positive for anti-HCV. The prevalence of hepatitis B and hepatitis C was significantly lower among those with history of blood donations ( $P = 0.01$ ) and higher among those with a history of blood transfusion ( $P = 0.01$ ) (32).

Study by Khan et al. on the Prevalence of HCV among the young male blood donors in Quetta region of Baluchistan, Pakistan indicated that an overall HCV prevalence was 20.8%. Among the HCV positive cases, the age group with 25 years was more frequently infected with a prevalence of 26.3% (33). In addition studies by Dhruva et al. on Transfusion Transmitted Diseases/Infections among blood donors in a Tertiary Care Hospital in Gujarat, India indicate seroprevalence of HBV and HCV was, 0.68%, 0.074% respectively. The prevalence of HIV (0.08%), HBV (0.68%) and HCV (0.08%) was found to be higher in males as compared to females (34).

Beside different study from parts of the world different studies were done in Africa. Study conducted by Nwankwo et al. on Seroprevalence of major blood-borne infections among blood donors and the result of the study show that seroprevalences HBsAg and HCV among the 280 blood donors was 11.1%, 1.8% respectively. The prevalence of transfusion associated viral infections in the 3 blood donor categories. The prevalence of HBsAg and HCV were 12.9%, 4.8% respectively, for commercial donors; 12.1% and 0.6% respectively, for replacement donors; 6.6%, and 1.6% respectively, for voluntary donors. However, the differences in the prevalences with regard to donor categories were not statistically significant (35).

On the other hand a study conducted by Afolabi et al. on transfusion transmissible viral infections among potential blood donors at blood bank of the University College Hospital in Ibadan, Nigeria. In those study 507 sera tested for antibody using ELISA Out of this, 30(5.9%) were positive for HBsAg, 7(1.4%) for HCV(36). Beside above two studies conducted by Shitu et al. on Seroprevalence of HBV Surface Antigenemia and HCV among Intending Blood Donors at Mother and Child Hospital, Akure, Nigeria indicate that the prevalence of Hepatitis infections

among the intending blood donors was 290(9.9%). HBsAg and anti-HCV were reactive in 7.4% and 2.1% of the study population respectively while co-infection was recorded in 0.4% (37).

Study conducted by Awadalla et al. on blood donors on risk factors of hepatitis C infections Egyptian donors, the result indicates that 16.8% of the studied sample was seropositive (38). and another study conducted by stokx et al. focus on Seroprevalence of transfusion-transmissible infections & evaluation of the pre-donation screening performance in Tete, Mozambique indicate that Seroprevalence of HBV and HCV infection was 10.6% (95% CI: 8.4-13.2%), 0.0% respectively. Prevalence of each infection was lower in voluntary than in replacement donors, but the differences were not statistically significant (39).

Another study conducted by Abou et al. on the Seroprevalence of Hepatitis B virus and Hepatitis C virus among blood donors in Darfur Sudan and in those study a total of 400 male blood donors were tested for the detection of HBsAg and anti-HCV antibodies, (6.25%) were found reactive for HBsAg and (0.65%) were reactive for anti-HCV antibodies (40).

Concerning hepatitis B and C virus different studies were done in Ethiopia in different parts of the countries at different time and one of those was study conducted by Gelaw et al. On the prevalence of HBV, HCV and malaria parasites among blood donors in Institution based cross-sectional study in Amhara and Tigray regional states at blood banks on Gondar, Dessie, Bahirdar and Mekele. And the overall prevalence of HBsAg, HCV anti-body and among the blood donors in the four blood banks was 6.2% (37/600) and 1.7% 10/600). Institutionally, the prevalence of HBsAg, was 4.7% (14/300) for Gondar College of Medical Sciences, 6% (6/100) for Bahir Dar Hospital, 3% (3/100) for Dessie and 14% (14/100) for the Mekele hospital blood banks. The prevalence of HCV anti-body was 2.3% (7/100) and 3% (3/100) for Gondar and Bahir Dar, respectively, while 0% (0/200) for Dessie and Mekele Hospital blood banks (21).

Another study conducted by Dessie et al on Seroprevalence of major blood-borne infections at Felege Hiwot referral hospital Northwest Ethiopia .In those study 324 blood donors( 283 males and 41 females) was included in study and out of which 152 (46.9%), 138 (42.6% ) and 34 (10.5% ) were commercial, replacement and voluntary donors respectively. Seroprevalence of

HBV and HCV was 25%, 13.3% respectively. The crude seroprevalence of major blood borne pathogens was significantly higher in commercial (56.6%) blood donors compared to voluntary (17.6%) and replacement blood donors (53.6%) at  $p=0.001$ . Among the co-infections HBV and HCV infections were found to be significantly co-existing in their study ( $p<0.05$ ) (22). As stated in this literature 56.6% donors were commercial due to this extremely high prevalence was observed in both viruses.

Similar study by Yemi et al. on Hepatitis B and C virus infections and their association with Human immunodeficiency in Jimma University specialized hospital Blood Bank found that the prevalence of HBV and HCV infection were 126 (2.1%) and 10 (0.2%) respectively. In that study none of HCV positive blood donors had co-infection with HBV or HIV (23).

In addition study conducted by Assefa et al. on HBV & HCV viral infections among blood donors in Bahir Dar, the seroprevalence rate of HBV infection was 4.11% where 95 (4.4%) out of 2177 males and three (1.45%) of the 207 females were having HBV infections. The overall prevalence rate of HCV infection in the study was 0.63% and all were males. Among 1356 commercial blood donors, 62(4.6%) for HBV and 10(0.7%) for HCV were seropositive (24).

## **2.2. Risk factors for Hepatitis B and C virus**

Both HBV and HCV has almost the same source transmission HBV transmitted through unsafe sexual contact, the transfusion of infected blood products, the use of contaminated needles in health care settings, and the sharing of injection equipment among people who inject drugs, mother to child (41).

Study conducted by Huang et al. on the prevalence and risk factors of hepatitis C show that the prevalence did not differ meaningfully by sex (Chi-square= 0.3094,  $p = 0.5780$ ). In above study indicated that there was a significant difference between educated and illiterate villagers with regard to HCV infection, but they found no difference with respect to the level of education attained by those who had been educated (primary school, middle school, or high school level); this proved that HCV seropositivity had no relationship with educational experience (31). Another study by Khan et al. on the prevalence of HCV among the young male blood donors

indicate that several factors contribute to increasing HCV prevalence such as lack of awareness regarding HCV transmission, inadequate diagnostic facilities & expertise in hospitals & public sector laboratories (33).

Study conducted by Awadalla et al. on risk factors of hepatitis C infections among blood donors demonstrates the relation between HCV test results and the socio-demographic data of the studied group and Shows that 15% of males and one quarter (25.1%) of females were positive. More than half (57.1%) of farmers were positive and more than one third of participants (39.6%) who had jobs related to blood exposure were positive as well. Nearly three quarters (71.1%) of illiterates were positive and all university graduated subjects were negative. Nearly one fifth (21.6%) of low socio-economic level were positive (38).

Study conducted by Abou et al. on the Seroprevalence of Hepatitis B virus and Hepatitis C virus in South Darfur, Sudan in blood donors clearly state associated factor and the highest percentage (30.8%) of HBV reacted samples were aged within the age group 19-24 and 37-42 for each. On the other hand the highest percentage (50%) of HCV reacted samples were aged within the age group 31-36 and for each (36.6%) was not aware for their condition (40).

Study conducted by Yemi et al on Hepatitis B and C viruses infections and their association with Human immunodeficiency in those study HBV infection by age group showed highest prevalence in the age group 40-44 years and lowest among the age group of forty five years or more 13 of 509 (4.5%) and 3 of 509 (0.9%) respectively. Females were less likely to be infected with HBV as compared to males. As compared to those in the age group less than 20 years, those with age group 20-24 years, 30-34 years and 35-39 years were twice and those with age group 40-44 years were four times at increased risk of HBV infection, respectively. HCV infection by age group also showed no evidence of infection among the age group less than 20 years, 20-24 years and in those 45 years or more, but higher prevalence was observed among the age group 30-34 years and 35-39 years, 3 of 957 (0.5%) and 4 of 509 (0.8%), respectively (23).

Study by Assefa et al. on HBV & HCV viral infections among blood donors in Bahir Dar, Ethiopia indicated that donors difference in proportions of seroprevalence of HBV 95(4.4%) in

male and 3(1.4%) in female. The highest seroprevalence of HCV was observed in blood donors aged greater than 45 years old (2.5%) followed by 18-25 years old donors (0.8%). However, age distribution and sero-prevalence of HBV was not significantly associated ( $\chi^2 = 7.3$ ,  $P=0.06$ ). In case of occupation of the blood donors the higher seroprevalence of HBV was observed in day laborers 62(4.6%) followed by farmers 28(3.8%), and students 4 (3.1%) (24).

study by Al-Waleedi et al. on the Prevalence of hepatitis B and C infections and associated factors in Aden City, Yemen show the prevalence of hepatitis B and hepatitis C was significantly lower among those with history of blood donations ( $P = 0.01$ ) and higher among those with a history of blood transfusion ( $P = 0.01$ ), dental treatment ( $P = 0.01$ ), cupping ( $P = 0.04$ ) and malaria infection ( $P = 0.04$ )(32).

Similarly Study by Awadalla et al. from shows the medically related risk factors for HCV transmission; all factors were significantly associated with HCV transmission. It was found that nearly half (48.4%) of those who had undergone surgical treatment were positive and nearly one third (35.2%) of circumcised subjects by traditional healer were positive. Nearly three quarters (72%) of subjects with history of blood transfusion were positive while nearly half (52.7%) of those subjected to a used needle were positive and 81% of subjects who had received parenteral anti-schistosomal treatment been positive and 30.1% subjects having had ear piercing using common tools were also positive (38).

Beside those study by Abou et al. on Seroprevalence of Hepatitis B virus and Hepatitis C virus among blood donors from Dar fur, Sudan show that different factors associated with HBV and HCV and their study result indicates those parenteral drug injections was (10%), razor sharing (13.3%), tattooing and surgical procedures were (3.3%) (40).

Study conducted by Awadalla et al. on risk factors of hepatitis C infections blood donors indicate 47.5% of drug abusers were positive (38). Similarly study by Abou et al. on the Seroprevalence of Hepatitis B virus and Hepatitis C virus among blood donors South Darfur, Sudan clearly state associated factor. From those study unprotected sexual activities (20%) was the most apparent predisposing risk factor for both HBV and HCV (40).

### 2.3. Hypothesis

- ✓ Given that the WHO estimated prevalence of HBV in Eastern Africa was 5-7% and HCV were 2.8%.
- ✓ The prevalence and of HBV and HCV viruses among volunteer donors were be no greater than 5-7% and 2.8% respectively.
- ✓ HBV and HCV infection among volunteer blood donors has no risk factors

# Chapter Three

## 3. Objective

### 3.1. General objective

- ✓ To assess prevalence and associated risk factors of HBV and HCV among volunteer blood donors in Arbaminch blood bank, SNNPR, Ethiopia, 2015.

### 3.2. Specific objective

- ✓ To determine the prevalence of HBV among Volunteer blood donors.
- ✓ To determine the prevalence of HCV among Volunteer blood donors.
- ✓ To identify associated risk factors related to HBV among volunteer blood donors.
- ✓ To identify associated risk factors related to HCV among volunteer blood donors.

## Chapter Four

### 4. Methodology

- 4.1. **Study Area:** Study was conducted at Arbaminch blood bank which is located in Arbaminch city administration, SNNPR, Ethiopia. Arbaminch is 500 km south of Addis Ababa the capital city of Ethiopia along the asphalt road konso to Jinka. It was named from forty springs that follow around the town. It is surrounded by Lake chamo and Abaya in the East and south east, chenchaworeda in the west and segen area zone in the south east and Arbaminch zuria woreda in the North. According to 2014/2015 SNNPR statistics bureau report Arbaminch city has total an estimated population of 108,955. It is sub divided into four sub cities, namely secha, seqela Abaya and Nech Sar. The blood bank was established in October 2013. On average the blood donor was ten, three hundred, four thousand per day, per month, per years respectively. It collects blood within 100km square area and collection site include Arbaminch, woliata sodo, Jinka and sawula town.
- 4.2. **Study design:** A cross sectional study design was used among volunteer blood donors.
- 4.3. **Study period:** The study was conducted from Feb 2015-Aug 2015.
- 4.4. **Source population:** All people who are 18-65 years of age & able to donate blood.
- 4.5. **Study population:** All volunteer blood donors 18-65 years of age who come to Arbaminch blood bank & Arbaminch blood bank collection site during the study period.
- 4.6. **Eligibility**
  - 4.6.1. **Inclusion criteria:** All age group from 18-65 years who were healthy and able to donate blood.
  - 4.6.2. **Exclusion criteria:** People whose hemoglobin level below 12mg/dl, current history of medication, recent history of operation, serious illness, weight < 45kg, people who refuse to give informed consent.
  - 4.6.3. **Identifying and approaching blood donor:** Donating blood is saving life therefore different communities were mobilized by aware the benefit of donating blood. Any donor who come to blood bank and fulfills inclusion & exclusion criteria was

offered the opportunity and both first time & repeated donor was included. Community mobilizer was briefly introducing the study to the donor and if donors would agree with study, they sign consent form.

#### 4.7. Variables

##### 4.7.1. Dependent variable

- Prevalence Hepatitis B and C virus

##### 4.7.2. Independent Variable

- age, sex, educational status, , income, awareness, occupational status, marital status, residence, blood transfusion, therapeutic drug injection, tattooing, razor and sharp material sharing, surgical procedure, sexual activities, drug injection.

#### 4.8. Operational definition

**Donor:** People who donate Blood

**Blood Bank:** A bank that give blood transfusion service

**Volunteer Blood Donor:** People who give blood without any payment

**Unsafe therapeutic injection:** Therapeutic injection given by traditional injection giver who is not trained formally as health professional (non health professional).

4.9. **Sample size calculation:** The sample size was determined by using single population formula by considering 95% Confidence interval assuming seroprevalence of major blood born infection among blood donor at Bahir Dar Felege Hiwot referral hospital, Ethiopia of hepatitis B and C among blood donors was (4.5%) with precession of 2.25% (24).

$$N = \frac{Z^2 /_2 p (1-p)}{d^2}$$

$$N = \frac{(1.96)^2 \times 0.045(1-0.045)}{(0.0225)^2}$$

$$N = \frac{3.8416 \times 0.1650}{0.00050625}$$

$$N = 326.11$$

$$N = 326$$

By assuming 10% non response rate, the final sample size was calculated as:

$$NF = \frac{n \times 10}{100} + 326$$

$$NF = \frac{326 \times 10}{100} + 326$$

$$NF = 358.6 \sim 359$$

Where

N= required sample size

$Z^2 /_2$  =critical value for normal distribution at 95% confidence interval

Which equals to 1.96 (Z value at alpha=0.05).

P= proportion of prevalence Hepatitis B and C Virus among blood donor (24).

$d^2$  =marginal error=2.55%

NF= final sample size

4.10. **Sampling procedure:** Mobilization of different parts of community (secondary school student, university community, religious organization, youth center) in Arbaminch, woliata sodo, Jinka and sawula town were conducted though the system that blood bank establish, beside those volunteer who come to blood bank without mobilization also included in this study. All volunteer blood donors who donate blood at Arbaminch during February 15,2015 to August 24, 2015 were included in the study and the total sample number of volunteer blood donors donating blood only once during the

study period. Full history, physical examination and screening of donors were performed and recorded for all volunteer blood donors to see their eligibility for donation. Volunteer blood donors who did not meet the criteria for blood donation stated in the inclusion criteria were excluded from the study.

#### 4.11. **Data collection method**

4.11.1. **Enrollment and data collection procedures:** Data on socio-demographic and socioeconomic variable, route associate variable, behavioral associated variables and for laboratory investigation were collected by structured questionnaire and questioners was numbered to identify those who have respond and or not. After donors agree to take part in the study, he or she sign a consent form, baseline information was collected. After fill all the questioners from volunteers, blood were drown by collecting bag.

4.11.2. **Specimen Collection and Processing:** From individual blood donor about 5ml of blood sample was collected from the collection bag using a sterile capped tube. The blood was centrifuged and plasma was separated and stored at 2-8°C until it was tested. Samples were brought to room temperature prior to testing.

4.11.3. **Laboratory test:** Each plasma sample was tested for HBsAg and anti-HCV antibodies using ELISA kits.

4.11.4. **Laboratory Testing Methods:** Laboratory sample for HBV and HCV were analyzed by Human HBsAg and anti-HCV by 3<sup>rd</sup> generation ELISA. For this study dialab ELISA kit was used which was manufactured by dialab production und vertrie bvon chemisch-techischen produkten und loborin strumenten Geselischaftm.b.H.

4.12. **Quality Assurance:** The questionnaire as component of the training was pre-tested in the study area to see the validity and completeness. The data collectors were regularly monitored to make sure for the reliability of data and for laboratory sample which was analyzed by ELISA, positive and negative controls were used for each reagent lot.

4.13. **Data Entry, storage and management:** After ensuring the completeness of the questionnaire the data were checked, were entered into Epi info version 3.5.1 cleaned and after all completed then transported and analyzed by SPSS 16 analysis.

- 4.14. **Data analysis:** A descriptive statistics were calculated to determine socio-demographic and socio-economic factors for any major differences in the study groups with regard to baseline information. The primary analyses were the outcome of laboratory test result as well as associated risk factors for HBV and HCV on volunteer donors. The differences in proportions of risk factors associated with the prevalence of HBV and HCV were analyzed by the Odd Ratio and 95% confidence interval. Significance levels were chosen at 0.05 levels with a two-tailed test.
- 4.15. **Ethical approval:** Ethical approvals for the study were obtained from the Addis Ababa university college of health science, school of allied health science department of laboratory sciences. In addition Ethical approvals were also obtained from SNNPR Health Bureau. Written informed consent, risk and benefit of the study were informed for donors, when donors were ready to participate in the study. To prevent the risk of back retrieval of confidential information like names of the donors, during data collection assigned code numbers was given by the investigators. Donors who were positive for HBV and HCV during study period, was counseled and linked to Arbaminch general hospital.
- 4.16. **Dissemination of Results:** The findings were presented to Addis Ababa University College of health science, Department of Allied health science school of medical laboratory science, SNNPR State Health Bureau, Arbaminch Blood Bank. The findings will also be presented at various seminars and workshops and expected to be disseminated to public through these organizations and also this paper will be sent to peer reviewed journals for publication.

## Chapter Five

### 5. Result

#### 5.1. Risk factors for HBV and HCV on volunteers blood donors

A total of 359 volunteer blood donors were included in this study, from those 197(54.9%) were male and 162(45.1%) were female. Their mean age was 22.57 years with SD 5.35. More than three fourth (80.2%) were less than 25 years old while majority, 85.8%,89.4% and 88.6%, were unmarried, urban and had degree and above respectively.

From study participants, 253 (70.5%) donated for the first time and 106(29.5%) donated for more than one times. Majority of participants, 353(98.3%) has no history of transfusion while 6 (1.7%) had history of transfusion and rest of route associated factors (Table 1).

**Table 1:** Risk factors for HBV and HCV on volunteers blood donors in Arbaminch blood bank from Feb-Aug 2015.

| Variable           |                | N (%)     |
|--------------------|----------------|-----------|
| Sex                | Male           | 197(54.9) |
|                    | Female         | 162(45.1) |
| Age                | 18-20          | 153(42.6) |
|                    | 20-24          | 135(37.6) |
|                    | 25-65          | 71(19.8)  |
| Marital status     | Unmarried      | 308(85.8) |
|                    | Married        | 51(14.2)  |
| Residence          | Rural          | 38(10.6)  |
|                    | Urban          | 321(89.4) |
| Educational status | 12             | 14(3.9)   |
|                    | TVET diploma   | 27(7.5)   |
|                    | Degree & above | 318(88.6) |
| Occupation         | Student        | 277(77.2) |
|                    | Employed       | 58(16.2)  |
|                    | Merchant       | 14(3.9)   |

|   |               |           |
|---|---------------|-----------|
|   | Others        | 10(2.8)   |
| Average monthly income                                    | <580          | 91(25.3)  |
|   | 581-1,300     | 203(56.5) |
|   | 1,301-4,000   | 46(12.8)  |
|   | 4,001-8,500   | 19(5.3)   |
| Knowledge about transmission                              | Yes           | 145(40.4) |
|   | No            | 214(59.6) |
| Donor status  | First         | 253(70.5) |
|   | Multiple      | 106(29.5) |
| History of Transfusion                                    | Yes           | 6(1.7)    |
|   | No            | 353(98.3) |
| Unsafe therapeutic drug injection                         | Yes           | 8(2.2)    |
|   | No            | 351(97.8) |
| Razor and sharp material sharing                          | Yes           | 29(8.1)   |
|   | No            | 330(91.9) |
| Exposure to surgical procedure                            | Yes           | 107(29.8) |
|   | No            | 202(70.2) |
|   | Not exposed   | 50(13.9)  |
| Tattoo, body or ear piercing or permanent make-up applied | Yes           | 172(47.9) |
|   | No            | 187(52.1) |
| Tooth extraction  | No extraction | 303(84.4) |
|   | Traditional   | 3(0.8)    |
|   | Modern        | 53(14.8)  |
| Circumcision condition                                    | Traditional   | 65(18.1)  |
|   | Modern        | 146(40.7) |
|   | Uncircumscd   | 145(40.4) |
| unprotected multiple heterosexual activity                | Yes           | 117(32.6) |
|   | No            | 242(67.4) |
| Inject able drug user                                     | Yes           | 6(1.7)    |
|   | No            | 353(98.3) |

## **5.2.Prevalence of HBV and HCV**

Prevalence of HBV among study participant was 4.7% while HCV was not detected. From 17 participants tested positive for HBV, 8 (47%) were males. The test positivity among male was 8/197 (4.1%) while among females 9/162 (5.6%) and more than three fourth participants tested positive were age less than 25.

## **5.3.Risk Factors associated with HBV and HCV**

As presented in above section, the prevalence of HBV was 17 (4.7%) among study participants. Only two variables had statistically significant association during both bivariate and multivariate analysis.

When positivity was compared among study participants based on average monthly income, participants earning 581-1,300 were 27.7% less likely to have infection than participants earning below 580 Birr per month. (OR= 0.277, 95%CI=0.096-0.805). From volunteer donors, 8(2.2%) were exposed to unsafe therapeutic drug injection and from these 3(37.5%) were positive for HBV. When compared to volunteers who were not exposed, exposed donors were at 14 times increased risk of HBV infection. (OR=14.443, CI=3.134-66.562)

The test positivity was slightly higher among female 9(5.6%) than males 8 (4.1%) but this was not statistically significant (OR=0.720, 95%CI=0.271-1.909). Regarding age group of study participants tested positive for HBV, more than three fourth of participants tested positive, 13 (76.5%), were age less than 25 but it was also not statistically significant(OR=2.047, 95%CI=0.616-6.805). Similarly, considering marital status of participants tested positive for HBV, test positivity was slightly higher among unmarried than married (5.9% Vs. 4.5%) but it was also not statistically significant (OR=0.762, 95%CI=0.211-2.751). About nine tenth (88.2%) of participants tested positive were from urban areas even though test positivity in relation to residence of volunteer donors tested was comparable, test positivity for rural dwellers was 2(5.3%) and urban dwellers was 15(4.7%) (OR=1.133, 95%CI=0.249-5.157).

Being educated (OR=0.777, 95%CI=0.099-6.117), being employed (OR=1.108, 95%CI=0.305-4.018), having knowledge about transmission (OR=1.255, 95%CI=0.454-3.474), frequency of blood donation status (OR=1.006, 95%CI=0.345-2.929), history of transfusion (OR=4.212,

95%CI=0.465-38.202), use of inject able drug use (OR=4.212, 95%CI=0.465-38.202), sharing sharp materials (OR=1.556, 95%CI=0.338-7.161), exposure to surgical operations (OR=0.490, 95%CI=0.138-1.743), having modern circumcision (OR=0.544, 95%CI=0.112-2.634), having unprotected sex (OR=0.955, 95%CI=0.121-7.556), having body makeup (OR=0.751, 95%CI 0.279-2.019) and traditional tooth extraction (OR=0.696, 95%CI=0.155-3.129) were also not statistically significant and this could be due to homogeneity of study population as majority of participants were students graduating from university.

After multivariate analysis, when positivity was compared among study participants grouped based on average monthly income, participants earning 581-1,300 were 32.2% less likely to have infection than participants earning below 580 Birr per month.(AOR= 0.322, 95%CI =0.108-0.961). Volunteer donors who exposed to unsafe therapeutic drug injection was 8(2.2%) and from those 3(37.5%) was positive for HBV. When compare to volunteers who not exposed 14(4%), exposed donors 11 times increased risk of HBV infection. (AOR=11.090, p=2.258-54.475)

**Table 2:** Risk factors association with Hepatitis B and C virus on volunteer Blood Donors in Arbaminch blood bank from Feb-Aug 2015.

| Variable           |           | No (%)    | Pos for HBsAg N (%) | Crude OR | 95% CI      | Adjusted OR | 95% CI |
|--------------------|-----------|-----------|---------------------|----------|-------------|-------------|--------|
| Sex                | Male      | 197(54.9) | 9(4.1)              | 1        |             |             |        |
|                    | Female    | 162(45.1) | 8(5.6)              | 0.72     | 0.271-1.909 |             |        |
| Age                | 18-20     | 153(42.6) | 9(5.9)              | 1        |             |             |        |
|                    | 20-24     | 135(37.6) | 4(3)                | 2.047    | 0.616-6.805 |             |        |
|                    | 25-65     | 71(19.8)  | 4(5.6)              | 1.047    | 0.311-3.521 |             |        |
| Marital status     | Unmarried | 308(85.8) | 14(5)               | 1        |             |             |        |
|                    | Married   | 51(14.2)  | 3(5.9)              | 0.762    | 0.211-2.751 |             |        |
| Residence          | Rural     | 38(10.6)  | 2(5.3)              | 1        |             |             |        |
|                    | Urban     | 321(89.4) | 15(4.7)             | 1.133    | 0.249-5.157 |             |        |
| Educational Status | 12        | 14(3.9)   | 1(7.1)              | 1        |             |             |        |

|                                   |     |                |           |         |        |              |        |              |
|-----------------------------------|-----|----------------|-----------|---------|--------|--------------|--------|--------------|
|                                   |     | TVET diploma   | 27(7.5)   | 1(3.7)  | 0.500  | 0.029-8.649  |        |              |
|                                   |     | Degree & above | 318(88.6) | 15(4.7) | 0.644  | 0.079-5.250  |        |              |
| Occupation                        |     | Student        | 277(77.2) | 13(4.7) | 1      |              |        |              |
|                                   |     | Employed       | 58(16.2)  | 3(5.2)  | 1.108  | 0.305-4.018  |        |              |
|                                   |     | Merchant       | 14(3.9)   | 0(0)    | 0.00   |              |        |              |
|                                   |     | Others         | 10(2.8)   | 1(10)   | 2.256  | 0.266-19.173 |        |              |
| Income                            |     | <580           | 91(25.3)  | 9(9.8)  | 1      |              |        |              |
|                                   |     | 581-1,300      | 203(56.5) | 6(3)    | 0.277  | 0.096-0.805  | 0.322  | 0.108-0.961  |
|                                   |     | 1,301-4,000    | 46(12.8)  | 2(4.3)  | 0.414  | 0.086-2.001  |        |              |
|                                   |     | 4,001-8,500    | 19(5.3)   | 0(0)    | 0.000  | 0.000        |        |              |
| Know about transmission           | Yes |                | 145(40.4) | 6(4.1)  | 1      |              |        |              |
|                                   | No  |                | 214(59.6) | 11(5.1) | 1.255  | 0.454-3.474  |        |              |
| Donor status                      |     | First donor    | 253(70.5) | 12(4.7) | 1      |              |        |              |
|                                   |     | Multiple donor | 106(29.5) | 5(4.7)  | 1.006  | 0.345-2.929  |        |              |
| History of Transfusion            | Yes |                | 6(1.7)    | 1(16.7) | 1      |              |        |              |
|                                   | No  |                | 353(98.3) | 16(4.5) | 4.212  | 0.465-38.202 |        |              |
| Injectable drug user              | Yes |                | 6(1.7)    | 1(16.7) | 1      |              |        |              |
|                                   | No  |                | 353(98.3) | 16(4.5) | 4.212  | 0.465-38.202 |        |              |
| Unsafe therapeutic drug injection | Yes |                | 8(2.2)    | 3(37.5) | 14.443 | 3.134-66.562 | 11.090 | 2.258-54.475 |
|                                   | No  |                | 351(97.8) | 14(4)   | 1      |              |        |              |
| Share razor and sharp materials   | Yes |                | 29(8.1)   | 2(6.9)  | 1      |              |        |              |
|                                   | No  |                | 330(91.9) | 15(4.5) | 1.556  | 0.338-7.161  |        |              |
| Surgical procedure                | Yes |                | 107(29.8) | 3(2.8)  | 1      |              |        |              |
|                                   | No  |                | 202(70.2) | 14(6.9) | 0.490  | 0.138-1.743  |        |              |
| Circumcision condition            |     | Modern         | 145(40.7) | 9(6.2)  | 1      |              |        |              |
|                                   |     | Traditional    | 65(18.1)  | 2(3.1)  | 0.54   | 0.112-2.634  |        |              |
|                                   |     | uncircumcised  | 149(41.5) |         | 4      |              |        |              |
| Unsafe multiple                   | Yes |                | 117(32.6) | 1(0.85) | 1      |              |        |              |

|  |             |           |          |            |             |
|--|-------------|-----------|----------|------------|-------------|
| heterosexual activity  | No          | 242(67.4) | 16(6.6)  | 0.95<br>5  | 0.121-7.556 |
| Tattoo, body or ear<br>piercing or<br>permanent make-up<br>applied | Yes         | 107(29.8) | 7(6.5)   | 1          |             |
|  | No          | 202(70.2) | 10(4.95) | 0.75<br>1. | 0.279-2.019 |
| Tooth extraction<br>condition                                      | Modern      | 53(14.8)  | 2(3.8)   | 1          |             |
|  | Traditional | 4(0.8)    | 0(0)     | 0.00       | 0.000       |

## Chapter six

### 6.1. Discussion

In this study, prevalence of HBV and HCV among volunteer donors was 4.7% and 0% consecutively. Lower HBV reported from previous study at Bahir Dar 4.11% (24) and in Jima University specialized hospital Blood Bank 2.1% (23). But higher HBV also reported from Northwest Ethiopia 25% (22), and Amhara and Tigray regional state 6.2% (21). This may be resulted from Blood bank adhere only with volunteer donors so that replacement and commercial not included. Both replacement donors (53.6%) and commercial (56.6%) donors have higher percentage compared to volunteer donors (22).

When the finding of this study compare with similar study in other countries, higher study reported from south Dar fur 6.25% (40), Tete Mozambique 10.6% (39), kano Nigeria 11.1% (35), Ibdan Nigeria 5.9%,(36), Akura Nigeria 7.4%(37), Quang Tri, Vietnam 11.1% (30). Lower finding also reported from Kathmandu Nepal 0.47% (27), Babylon Iraq 0.7% (28), Jordan 1.4%,(29),Gujarat India 0.68%,(34). Different geographical location, Socio cultural difference, dominant genotype, sub genotype and mutant existence may be possible factors. But the finding was comparable with finding of Aden city Yemen 5.1 %, ( 32).

Prevalence of HCV was zero; this may be due to changing of donors' from commercial and replacement donors to only volunteers donors.

Compare to this study, higher HCV study reported from Bahir Dar 0.63% (24), in Jima University specialized hospital Blood Bank 0.2% (23), Northwest Ethiopia 13.3% (22), and Amhara and Tigray regional state 1.7% (21). This may implies intervention was done from previous findings since blood Bank work though out the countries as well as shifting from replacement, commercial donors to only volunteer donors.

When the finding of this study compare with similar study in other countries, higher study reported from south Darfur 0.65% (40), kano Nigeria 1.8% (35), Ibdan Nigeria 1.4%, (36), Akura Nigeria 2.1% (37) Quang Tri, Vietnam 51.7% (30), Kathmandu Nepal 0.64% (27) Babylon Iraq 0.5% (28), Jordan 0.9% (29),Gujarat India 0.074% (34), Aden city Yemen 1.3% (32). Genetic diversity, socio-cultural may be factors. But the finding comparable with finding Tete Mozambique 0% (39)

Since in this study HCV infection was 0% and there was no co-infection between HBV and HCV. As the result HCV infection was infrequent in HBsAg positive volunteer donors. This finding was also similar with the study done in Amhara and Tigray Regional state (21).

In this study, significant association found between income status and HBV. Compared among study participants grouped based on average monthly income, participants earning 581-1,300 were 32.2% less likely to have infection than participants earning below 580 Birr per month.(AOR= 0.322, 95%CI =0.108-0.961). This may indicate that as income status increase peoples may easily take care from HBV associated factors. This was similar but higher by percentage to the finding in Jimma, Southwest Ethiopia on seroprevalence of HBsAg and its risk factors among pregnant Women whose income <500 Birr / month was 88.9%, (p<0.05) Even though in those study rapid chromatographic immunoassay test used (42).

Another significantly associated factor was use of unsafe therapeutic injection (AOR=11.09, CI=2.258-54.475) and the finding was in line with the study done among pregnant women in Bahir Dar City, North west Ethiopia, that showed significant association with unsafe therapeutic injection 15.9% (AOR = 5.65, 95% CI, 1.44-22.19) (43). There was another agreement that in developing countries, exposures to contaminated therapeutic injection equipment are common in many settings. Contaminated injections caused an estimated 21 million HBV infections worldwide in 2000, accounting for 32 percent of all new infections (9).

## **6.2. Limitation of the study**

Most factors tested for association with hepatitis infection were not found significant at 95% CI which could be due to homogeneity by age of study participants and this study was limited to investigate associated factors among heterogeneous population. In this study only HBsAg and anti HCV marker used for HBV and HCV detection by ELISA method.

## **6.3. Conclusions**

This study showed that the prevalence of HBV infections confirmed with positive test for HBsAg antibody among volunteers' blood donors in Arbaminch Blood Bank and the prevalence was 4.7%. Low monthly income and using unsafe therapeutic injection were related to HBV infection.

## **6.4. Recommendation**

### **WHO**

Since hepatitis worldwide problem, WHO should support minister of health by fundraising on hepatitis prevention and guide different aid organization work on hepatitis prevention.

### **Minister of Health**

Even though the prevalence of HBV and HCV were intermediate as per WHO 2012 regions status report, minister of health and regional health bureau should work hardly to handle infection and control spread below this level.

Strengthening health system on control of unsafe therapeutic injection givers may help in preventing and controlling disease propagation.

### **Health institution**

All Health institution should work on IEC (information education communication) activities on HBV infections to improve community awareness.

### **Blood bank**

Counseling for multiple donors should be strengthened to exclude donors based on previous test results.

Since blood bank mobilize community for blood donation, side by side work on activities of HBV infections prevention to improve community awareness.

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## 8.1. Annexes

### **Annex 1: Information, consent and Questionnaire**

#### **Information and Consent**

**Title of the project:** Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors in Arbaminch Blood Bank, SNNPR, Ethiopia

**Name of investigator:** Ayele Adato

**Name of the organization:** Addis Ababa University College of Health Sciences School of Allied Health Science Department of Medical Laboratory science

**Name of the Sponsor:** Addis Ababa University and SNNPR health bureau

**Introduction:** The information sheet and consent form prepared by the investigator with the aim of explaining the research project that you are asked to join by the group of research investigators. The main aim of this research project is to assess Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors in Arbaminch Blood Bank, SNNPR, Ethiopia. Decision on your involvement will be made by you and only you. The investigator includes 2 community mobilizer, 2 laboratory workers, 1 supervisor and 1 advisor from Addis Ababa University

**Purpose:** To assess Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors in Arbaminch Blood Bank, SNNPR, and Ethiopia and recommend possible interventions based on the finding.

**Procedure:** To assess Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors in Arbaminch Blood Bank, volunteer's blood donors are invited to participate in the project. If you are willing to participate in this project you need to understand and sign the agreement form. Then you will be requested to give response to some questions that will take few minutes (about 30 minutes) and then there will be blood pressure and weight measurement. All the responses given by you will be kept confidentially by using coding system whereby no one will have access to your response

**Risk:** By participating in this study you may feel that it has some discomfort especially on wasting your time (20-30 mints) to respond questions and during blood draw for laboratory detection of HBV and HCV but this may not be too much as you are one of the member of the communities, your response will help as important input to determine Prevalence and Associated

Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors. However there is no physical or psychological risk expected being involved in the study.

**Benefits:** If you participate in this study, you may not gain direct benefit but your participation will help us to assess Prevalence and Associated Risk Factors of Hepatitis B and C Virus among Volunteer Blood Donors and to take measures based on the finding

**Confidentiality:** Information about you will be collected without your name but a cod number assigned to it will be stored in a file and kept locked .Your personal information will only be used for the purpose of the study. Your response will be aggregated to yield summary data, but your individual response will not be reported

**Right of participants:** You have to know that your participation is largely based on your willingness and approval. There are questions to be answered by you .you are expected to answer all of the questions but You have the right to say “no” and not participate in the study (you can choose not to respond to some or all of the questions) . You have also a full right to withdrawal from this study at any time you wish without losing any of your right and without any penalty.

**Person to contact:** this research project will be reviewed and approved by the ethical committee of Addis Ababa University. If you want to know more information and ask any questions at any time you want you can contact with the following address.

1. Gebru Mulugeta (PhD fellow)Addis Ababa University. Mob. 0911757600

Email: gebrumulu@gmail.com

2. Ayele Adato(Bsc.) SNNPR regional health bureau, Tell 0462209098/ Mob.0912069184

Email: ayeleadatoka@gmail.com

At this time, do you have any questions about the study?

May I begin the interview now?

Yes [continues interviewing]

No [interviewer: end interview]

Name of interviewer\_\_\_\_\_

Start time\_\_\_\_\_

End time\_\_\_\_\_

I certify that I filled this questionnaire in accordance with the training I was given and instruction started in it. I have confirmed that information in it is correct.

Signed\_\_\_\_\_ Date\_\_\_\_\_

**Questionnaire****Id No.**-----

Risk factors for HBV and HCV on volunteer blood donors in Arbaminch blood bank from Feb-Aug 2015. **Direction:** Fill or use mark on box for response categories

| S. No | Questions                | Response of categories   | Remark |
|-------|--------------------------|--|--------|
| 101   | What is your age?        | _____year  |        |
| 102   | Sex?                     | 1. Male <input type="checkbox"/><br>2. Female <input type="checkbox"/>   |        |
| 103   | Ethnicity                | 1. Woliata <input type="checkbox"/><br>2. Gamo <input type="checkbox"/><br>3. Gofa <input type="checkbox"/><br>4. Ari <input type="checkbox"/><br>5. Amhara <input type="checkbox"/><br>6. others specify..... |        |
| 104   | Marital status?          | 1. Unmerried <input type="checkbox"/><br>2. Merried <input type="checkbox"/><br>3. Divorced <input type="checkbox"/><br>4. Widowed <input type="checkbox"/>  |        |
| 105   | Where you live?          | 1. Rural <input type="checkbox"/><br>2. Urban <input type="checkbox"/>   |        |
| 106   | Your educational status? | 1. Illiterate <input type="checkbox"/><br>2. 1-8 <input type="checkbox"/><br>3. 9-12 <input type="checkbox"/><br>4. TVET diploma <input type="checkbox"/><br>5. Degree & above <input type="checkbox"/>        |        |

|     |   |   |                   |
|-----|---|---|-------------------|
| 107 | Your occupation?  | 1. Employed <input type="checkbox"/><br>2. House wife/home activities <input type="checkbox"/><br>3. Daily laborer <input type="checkbox"/><br>4. Merchant <input type="checkbox"/><br>5. Farmer <input type="checkbox"/><br>6. Student <input type="checkbox"/><br>7. Jobless <input type="checkbox"/><br>8. Other Specify _____ |                   |
| 108 | What is your average monthly income of your house hold? | _____ETB  |                   |
| 109 | Have you ever heard about of HBV and HCV?               | 1. yes <input type="checkbox"/><br>2. No <input type="checkbox"/>   | If no go to Q.201 |
| 110 | Do you know how it is transmitted?                      | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>   | If no go to Q.201 |
| 111 | If yes please would you list some of them?              | 1. Unsafe sexual intercourse <input type="checkbox"/><br>2. Blood and Blood product <input type="checkbox"/><br>3. Use of sharp materials together <input type="checkbox"/><br>4. Other specify .....   |                   |

|     |  |  |                   |
|-----|--|--|-------------------|
| 112 | Have you ever had donate blood?                | 1. Yes <input type="checkbox"/><br>2. no <input type="checkbox"/>                  | If no go to Q.203 |
| 113 | If yes how many times did you donate blood?    | 3. Fist time <input type="checkbox"/><br>4. More than two <input type="checkbox"/> |                   |
| 114 | Do you have received blood and blood products? | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>                  | If no go to Q.205 |
| 115 | If yes how many times?                         | 1. Single <input type="checkbox"/><br>2. Multiple <input type="checkbox"/>         |                   |
| 116 | Have you ever had drug use drug?               | 1. Yes <input type="checkbox"/><br>2. no <input type="checkbox"/>                  |                   |

|     |   |   |                   |
|-----|---|---|-------------------|
| 117 | If yes is it that inject able drug ?  | 3. Yes <input type="checkbox"/><br>4. No <input type="checkbox"/>             |                   |
| 118 | Have you had exposed to unsafe any therapeutic injection?                     | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 119 | Have you had share razor & sharp materials together?                          | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 120 | Have you had a surgical procedure or been admitted to hospital?               | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 121 | Did you circumcised?  | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             | If no go to Q.211 |
| 122 | If yes traditional healer or modern?  | 1. modern <input type="checkbox"/><br>2. traditional <input type="checkbox"/> |                   |
| 123 | Do you have girl / boy friend?  | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             | If no go to Q.215 |
| 124 | Have ever had sex?  | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             | If no go to Q.215 |
| 125 | If yes have you had unprotected sexual contact with more than one girls/boys? | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 126 | Have you had a tattoo, body or ear piercing or permanent make-up applied?     | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 127 | Have you had a tooth extraction?  | 1. Yes <input type="checkbox"/><br>2. No <input type="checkbox"/>             |                   |
| 128 | If yes where?   | 1. Traditional <input type="checkbox"/><br>2. modern <input type="checkbox"/> |                   |

This is the end of the questionnaire. Thank you very much for taking time to answer these questions. We appreciate your help.

**8.2. Annex 2: Information, consent and Questionnaire Amharic version**  
**የመረጃ ማስገኛና የስምምነት ፎርም**

**የምርምር ፕሮጀክቱ ርዕስ :** በደቡብ ብሄር ብሄረሰቦችና ህዝቦች ክላሳዊ መንግስት በሚገኝ በአርባምንጭ ደም ባንክ ውስጥ የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭት ሁኔታና ተያያይጥነት ያላቸው ነገሮችን መዳሰስ

**የዋናው ተመራማሪው ስም:** አየለ አዳቶ

**የድርጅቱ ስም :** የአዲስ አበባ ዩኒቨርሲቲ የጤና ሳይንስ ኮለጅ በአላይድ ጤና ሳይንስ የላቦራቶሪ ትምህርት ቤት

**ወጪውን የሚሸው:** የአዲስ አበባ ዩኒቨርሲቲና የደቡብ ብሔር ብሔረሰቦችና ህዝቦች ክላሳዊ መንግስት ጤና ቢሮ

**መግቢያ:**

ይህ የመረጃና የውል ስምምነት የተዘጋጀበት አላማ በምርምር ፕሮጀክቱ እርስዎ እንዲሳተፉ በፕሮጀክቱ አባላት በሚጠየቁበት ወቅት ስለ ፕሮጀክቱ መረጃ በማግኘት እንዲብራራሎት ነው። የፕሮጀክቱ ዋና አላማ በደቡብ ብሄር ብሄረሰቦችና ህዝቦች ክላሳዊ መንግስት በሚገኝ በአርባምንጭ ደም ባንክ ውስጥ የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭት ሁኔታና ተያያይጥነት ያላቸው ነገሮችን መዳሰስ ሲሆን በጥናቱ የመሳተፍ ሆነ ያለ መሳተፍ ውሳኔው በእርሶና በእርሶ ብቻ የሚወሰን ነው። ይህ አጥኚ ቡድን በአርባምንጭ ደም ባንክ ውስጥ በሚሰሩ ሁለት የህብረተሰብ ቀስቃሽ ፣ ሁለት ላቦራቶሪ ባለሙያ አንድ የበላይ ተቆጣጣሪዎችና አንድ የአዲስ አበባ ዩኒቨርሲቲ መምህር በአማካሪነት ያካተተ ነው።

**የጥናቱ ዋና አላማ:** በደቡብ ብሄር ብሄረሰቦችና ህዝቦች ክላሳዊ መንግስት በሚገኝ በአርባምንጭ ደም ባንክ ውስጥ የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭት ሁኔታና ተያያይጥነት ያላቸው ነገሮችን መዳሰስ ሲሆን በሚገኘውም የጥናት ውጤትም ችግሩን ለመቅረፍ የሚያስችሉትን ስልቶችን ማመላከት ይሆናል ።

**አተገባበር:** የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭት ሁኔታና ተያያይጥነት ያላቸው ነገሮችን ለማጥናት እርሶዎ በፕሮጀክቱ ተሳታፊ እንዲሆኑ ተጋብዘዋል። በፕሮጀክቱ ለመሳተፍ ፈቃደኛ ከሆኑ ውሉ ሊገባዎትና ሊፈርሙ ይገባል። ከዚያም በመረጃ

ሰብሳቢዎች ጥቂት ደቂቃዎች (ሰላሳ) ለሚወስዱ ጥያቄዎች መልስ እንዲሰጡ በአክብሮት ይጠየቃሉ ፣ የደምግፍትና የክብደት ልኬትም ይደረግሎታል። ለእያንዳንዱ ጥያቄ ለሚሰጡት ምላሽ ማንም በማያገኘው መለያ ቁጥር ሚስጥራዊነቱ የተጠበቀ ይሆናል።

**ሊገጥም የሚችል ችግር/ አለመመቻት**

በዚህ ጥናት በመሳተፍዎ መጠነኛ አለመመቻት ማለትም የሰአት ብክነት (20-30 ደቂቃዎች) ና ደም ከክንዶ ስወሰድ የመርፈ መዎጋት ሊሰማዎት ይችላል ። ቢሆንም ግን የህብረተሰቡ አካል እንደመሆኖ መጠንና ና የሚሰጡት መረጃ የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭትሁኔተና ተያያይዥነት ያላቸው ነገሮችን ለማጥናት እንደግብአት ስለሚጠቅም የሚያጠፉት ጊዜ ቡዙ ላይሆን ይችላል። ስለሆነም በምርምር ፕሮጀክቱ በመካፈልዎ የሚደርስብዎ አካላዊም ሆነ ስለልቦናዊ ችግር የለም።

**ጥቅሞች**

ከዚህ ጥናት እርስዎ በቀጥታ ተጠቃሚ ላይሆኑ ይችላሉ። ነገር ግን የእርሶ መሳተፍ የሄፓታይቲስ ቢ ና ሲ ቫይረስ ስርጭትሁኔተና ተያያይዥነት ለማጥናትና በጥናቱም ውጤት መሰረት አስፈላጊውን የማስተካካያ እርምጃ ለመውሰድ ከፍተኛ እገዛ ያደርጋል።

**ሚስጥራዊነት**

የሚሰጡን ምላሽ የርሶ ስም ሳይጠቀስ የተለየ መለያ ቁጥር ተሰቶት በቁልፍ ተቆልፎ ይቀመጣል። ስም በመልስ መስጫው ወረቀት ላይ አይገለጽም የሚሰጡትንም መረጃ ከሌሎች ተሳታፊዎች ጋር በአንድ ላይ ተቀናብሮ የሚቀርብ እንጂ የእርሶ ምላሽ ለብቻውን አይቀርብም። በጥናቱ ለመሳተፍ ወይም እራስዎን ከጥናቱ የማግለል መብት በማንኛውም ሰዓት የተጠበቀ ነው።

**የተሳታፊዎች መብት**

በጥናቱ ለመሳተፍዎ የእርሶ ሙሉ ፍቃደኝነት ወሳኝ ነው ። ለሚጠየቁት ጥያቄዎችን ሁሉ ይመልሳሉ ብዬ ተስፋ አደርጋለሁ ። ነገር ግን ከሚጠየቁት ጥያቄዎች ለተወሰኑት አሊያ ለሁሉም መልስ ያለመመለስ መብት አለዎት። እንዲሁም ያለ ምንም ቅጣትና መብት መጓደል በፈለጉ ሰአት ጥናቱን የማቋረጥ ሙሉ መብት አለዎት።

**መረጃ ስለማግኘት**

ይህ የምርምር ፕሮጀክት በአዲስ አበባ ዩንቨርሲቲ ታርሞና ተክልሶ ይጸድቃል ። ተጨማሪ መረጃ ካስፈለግዎትና ማንኛውንም ጥያቄ በማንኛውም ሰዓትና ጊዜ መጠየቅ ስፈለጉ በሚከተሉት አድራሻዎች የፈለጉትን አካል ማነጋገር ይችላሉ።

1. አቶ ገብሩ ሙሉጌታ ፡ ከአዲስ አበባ ዩንቨርሲቲ ስልክ 0911757600

ኢ-ሜል: gebrumulu@gmail.com

2. አቶ አየለ አዳቶ ፡ ደቡብ ክልል ጤና ቢሮ ስልክ 0462209098/ 0912069184

ኢ-ሜል: ayeleadatoka@gmail.com

ጥያቄዎችን ከመጀመሪያ በፊት እኔን የሚጠይቁኝ ነገር አለ?

አሁን ጥያቄዎቼን መጠየቅ እችላለሁ?

አዎ.....ወደ ጥያቄ አይቻልም ያበቃል።

የጠያቂው ስም .....

መጠይቁ የተጀመረበት ሰዓት.....ደቂቃ.....

ያለቀበት ሰዓት.....ደቂቃ.....

የጠያቂው ቃል:-ይህንን መጠየቅ በላይ ላይ በተጻፈው መመሪያና ጥያቄ እንዲሁም በተሰጠኝ ሥልጠና መሰረት ሞልቻለሁ። በላይም ላይ የሰፈረው ትክክለኛ መሆኑን አረጋግጣለሁ።

ፊርማ ..... ቀን.....

**ስለጥናቱ መጠይቅ በተመለከተ**

የተሳታፊው መለያ ቁጥር-----

ከሂጋታይቲስ ቢ ና ሲ ቫይረስ ልዩጋልጡ የሚችሉ ነገሮችን መዳሰስ

መመሪያ: የሚሰጠው ምላሽ በጽሁፍ መሙላት/ በሳጥኑ ዉስጥ ምልክት መጠቀም

| ተ.ቁ | ጥያቄ          | በየክፍሉ-የተሰጠመልስ  | ምርመራ |
|-----|--------------|--|------|
| 101 | እድሜዎትስንትነው?  | _____ ዓመት  |      |
| 102 | ጾታ?          | 1. ወንድ <input type="checkbox"/><br>2. ሴት <input type="checkbox"/>  |      |
| 103 | ብሄር?         | 1. ወላይታ <input type="checkbox"/><br>2. ጋሞ <input type="checkbox"/><br>3. ጎፋ <input type="checkbox"/><br>4. አረ <input type="checkbox"/><br>5. አማራ <input type="checkbox"/><br>6. ሌላ ከሆኔ ይጻፉ.....  |      |
| 104 | የጋብቻ ሁኔታ?    | 1. ያላገባ(ች) <input type="checkbox"/><br>2. ያገባ(ች) <input type="checkbox"/><br>3. የፈታ(ች) <input type="checkbox"/><br>4. የመተባት(በት) <input type="checkbox"/>   |      |
| 105 | የምኖርያ አድራሻዎ? | 1. ገጠር <input type="checkbox"/><br>2. ከተማ <input type="checkbox"/>   |      |
| 106 | የት/ት ደረጃዎ?   | 1. ያልተማረ <input type="checkbox"/><br>2. 1-8 <input type="checkbox"/><br>3. 9-12 <input type="checkbox"/><br>4. ቴክኒክናሙያ ድፕሎማ <input type="checkbox"/><br>5. ድግርና ከዚያ በላይ <input type="checkbox"/> |      |

|     |   |  |                             |
|-----|---|--|-----------------------------|
| 107 | ሥራዎ ምንድን ነው?                                | 1. ተቀጣሪ <input type="checkbox"/><br>2. የቤት እመቤት <input type="checkbox"/><br>3. የቀን ሰራተኛ <input type="checkbox"/><br>4. ነጋዴ <input type="checkbox"/><br>5. ገበሬ <input type="checkbox"/><br>6. ተማሪ <input type="checkbox"/><br>7. ሥራ አጥ <input type="checkbox"/><br>8. ሌላ ከሆነ ይግለጹ _____ |                             |
| 108 | በአማካይ የቤተሰቦ ወራዊ ገቢ ሲንት ነው?                  | _____ የኢ.ዩ. ብር   |                             |
| 109 | ሰለጉበት በሽታ ወይም አይን ብጫ የሚያደርግ በሽታ ስምተው ያውቃሉን? | 1. አዎ <input type="checkbox"/><br>2. አልሰማሁም <input type="checkbox"/>   | መልሱ አልሰማሁም ከሆነ ጥያቄ 201 ይመለሱ |
| 110 | እንደት እንደምተላለፍ ያውቀዋሉ?                        | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>  |                             |
| 111 | የሚያወቁ ከሆነ የተወሰኑ የመተላለፍያ መንገድ ይዘርዝሩ?         | 1. በልቅ ግብረሥጋ ግንኝነት <input type="checkbox"/><br>2. በደምና ደም ውጤቶች <input type="checkbox"/><br>3. ስለታማ ነገሮችን በጋራ በመጠቀም <input type="checkbox"/><br>4. ሌላ ከሆነ ይግለጹ.....   |                             |

|     |                            |   |                            |
|-----|----------------------------|---|----------------------------|
| 112 | ደም ለግሰው ያወቃሉን?             | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>           |                            |
| 113 | ለግሰው ከሆነ ይህ ለስንተኛ ጊዜዎት ነው? | 1. ለመጀመሪያ ጊዜ <input type="checkbox"/><br>2. ከአንድ በላይ <input type="checkbox"/> |                            |
| 114 | ደምና የደም ውጤቶችን ወስደው ያውቃሉ?   | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>           | መልሱ አላውቅም ከሆነ ጥያቄ 204 ይመለሱ |
| 115 | ስንት ጊዜ?                    | 1. ለመጀመሪያ ጊዜ <input type="checkbox"/><br>2. ለብዙ ጊዜ <input type="checkbox"/>   |                            |

|     |   |  |                              |
|-----|---|--|------------------------------|
| 116 | ማንኛውም አይነት ሱስ የሚያሰዙ እጾችን ተጠቅመው ያውቃሉ?                              | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              |                              |
| 117 | ተጠቅመው ከሆነ በመርፌ የሚሰጡ እጾችን ነውን?                                     | 3. አዎ <input type="checkbox"/><br>4. አላውቅም <input type="checkbox"/>              |                              |
| 118 | ደህንነቱ ያልተረጋገጠ መርፌ የህክምና መድኃኒት ተወግተው ያውቃሉ?                         | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              |                              |
| 119 | ምላጪና ስለታማ ነገሮችን በጋራ ተጠቅመው ያውቃሉ?                                   | 1. አዎ <input type="checkbox"/><br>2. አያውቅም <input type="checkbox"/>              |                              |
| 120 | የቀዶ ጥገና ሕክምና ተደርጎሎታል፤ ሆስፒታል ተኝተው ታክመው ያውቃሉ?                       | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              |                              |
| 121 | ተገርዘዋል ወይ?  | 1. አዎ <input type="checkbox"/><br>2. አልተገረዘኩም <input type="checkbox"/>           | መልሱ አልተገረዘኩም ከሆነ ጥያቄ 211 ይሙሉ |
| 122 | ከተገረዙ በባህላዊ ወይስ በዘመናዊ ህክምና ነው?                                    | 1. በባህላዊ <input type="checkbox"/><br>2. በዘመናዊ <input type="checkbox"/>           |                              |
| 123 | የሴት/የወንድ ጓደኛ አሎት?   | 1. አዎ <input type="checkbox"/><br>2. የለኝም <input type="checkbox"/>               | መልሱ የለኝም ከሆነ ጥያቄ 215 ይሙሉ     |
| 123 | የግብረ ሥጋ ግኑኝነት ላይ አድርገው ያውቃሉን?                                     | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              | መልሱ አላውቅም ከሆነ ጥያቄ 215 ይሙሉ    |
| 125 | አድርገው ከሆነ ከአንድ በላይ ጓደኛ ጋር ነውን?                                    | 3. አዎ <input type="checkbox"/><br>4. አላውቅም <input type="checkbox"/>              |                              |
| 126 | ንቅላት ተነቅሰዋል፤ ሰውነቱን ወይን ምጅሮዎችን ተበስተዋል፤ ቋሚ የሆነ የሰውነት ማስዋቢያ ተደርጎሎታል? | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              |                              |
| 127 | ጥርስዎን አስወልቀው ያውቃሉን?   | 1. አዎ <input type="checkbox"/><br>2. አላውቅም <input type="checkbox"/>              |                              |
| 128 | አስወልቀው ከሆነ ያስወለቁት በባህላዊ ወይስ በዘመናዊ                                 | 3. በባህላዊ ህክምና <input type="checkbox"/><br>4. በዘመናዊ ህክምና <input type="checkbox"/> |                              |

**አመሰግናለሁ!**

**8.3. Annex 3: Blood donor enrollment form for sample collection.**

Name/code no. \_\_\_\_\_ City \_\_\_\_\_ subcity/region \_\_\_\_\_

Age \_\_\_\_\_ sex \_\_\_\_\_ zone \_\_\_\_\_ woreda \_\_\_\_\_ kebele \_\_\_\_\_

\_\_\_\_\_ H.no. \_\_\_\_\_ registration no. \_\_\_\_\_

| Date | Code no | Pack no. | Wt. | Hb | B/p | Hct | Vol. | Screed by | HCV | HBV | Type of donation | Remark |
|------|---------|----------|-----|----|-----|-----|------|-----------|-----|-----|------------------|--------|
|      |         |          |     |    |     |     |      |           |     |     |                  |        |
|      |         |          |     |    |     |     |      |           |     |     |                  |        |
|      |         |          |     |    |     |     |      |           |     |     |                  |        |

#### **8.4. Annex 4: ELISA test Principle, Procedures, Interpretation and Calculation of cut-off value**

For this study dialab ELISA kit was used which was manufactured by dialab production und vertrie von chemisch-technischen produkten und laborinstrumenten Gesellschaftm.b.H

**Test Principle for HBsAg:** it uses antibody sandwich ELISA method in which polystyrene microwell strips are pre-coated with monoclonal antibodies specific to HBsAg. Donor's serum or plasma sample is added to the microwells together with a secondary antibody conjugated with horseradish peroxidase (HRP) and directed against a different epitope of HBsAg. During incubation, the specific immune-complex formed in the case of presence of HBsAg in the sample, is captured on the solid phase. After washing to remove sample serum protein and unbound HRP-conjugate, chromogen solution containing tetramethyl benzidine(TMB) and urea peroxidase are added to the wells. In the presence of the antibody-antigen-antibody (HRP) sandwich immune-complex, the colorless chromogens are hydrolyzed by the bound HRP-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. Wells containing sample negative for HBsAg remain colorless. Every detail procedure will be followed according to manufacture instruction.

**Interpretation and calculation of cut-off value:** The result will be calculated by relating each sample optical density (OD) value to the cut-off value (CO) of the plate. If the cut-off reading is based on single filter plate reader, the result must be calculated by subtracting the blank OD value from the print report value of the sample control. In case the reading is based on dual filter plate reader, do not subtract the blank well OD from the print report values of the sample and control. Cut-off value (CO)= NCx2.1 (NC=the mean absorbance value for three negative control)

Negative result =  $S/CO < 1$

Positive result =  $S/CO \geq 1$

Borderline sample with absorbance to cut-off ratio between 0.9-1.0

**Principle for HCV:** Indirect ELISA assay for the detection of antibody to HCV in two-step incubation procedure. Polystyrene microwell stripes are pre-coated with recombinant, highly immune-reactive antigens corresponding to the core and non-structural regions of HCV. During

the first incubation step, anti-HCV specific antibodies, if present, will be bound to the phase pre-coated HCV antigens. The wells are washed to remove unbound serum proteins, and rabbit anti-human IgG antibodies (anti-IgG) conjugated to HRP is added. During the second incubation step, these HRP-conjugated antibodies will be bound to any antigen- antibodies complexes previously formed and the unbound HRP-conjugate is then removed by washing. Chromogen solutions containing TMB and urea peroxidase are added to the wells and in presence of the antigen-antibody-anti-IgG (HRP) immune-complex, the colorless chromogens are hydrolyzed by the bound HRP-conjugated to 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 antibody in the sample. Wells containing samples negative for anti-HCV remain colorless.

**Interpretation and calculation of cut-off value:** The result will be calculated by relating each sample optical density (OD) value to the cut-off value (CO) of the plate. If the cut-off reading is based on single filter plate reader, the result must be calculated by subtracting the blank OD value from the print report value of the sample control. In case the reading is based on dual filter plate reader, do not subtract the blank well OD from the print report values of the sample and control. Cut-off value (CO) = NC+2.1 (NC=the mean absorbance value for three negative control)

Negative result =  $S/CO < 1$

Positive result =  $S/CO \geq 1$

Borderline sample with absorbance  $OD \leq \text{cut-off} \times 2$  are considered borderline

Both kits as well as other resources available in the blood bank and blood bank permit to me to use for this search purpose.

## Declaration

I **Ayele Adato** do hereby declare that “*Prevalence and Associated Risk Factors of Hepatitis B and C virus among volunteer Blood donors in Arbamich Blood Bank.*” is entirely my original work, except where acknowledged, and that it has not been submitted before to any other University or institution of higher learning for the award of a degree.

Ayele Adato

Name

\_\_\_\_\_

Date of Submission

\_\_\_\_\_

Signature

This thesis report has been submitted for examination with the approval of the following supervisors:

Gebru Mulugeta

Name

\_\_\_\_\_

Date of Submission

\_\_\_\_\_

Signature

Place and date of submission:-Addis Ababa University College of Health Sciences, School of Allied Health Science Department of Medical Laboratory science September, 2015