SEROPREVALENCE AND DETERMINANTS OF TRANSFUSION TRANSMISSIBLE INFECTIONS AMONG VOLUNTARY BLOOD DONORS IN HOMABAY, KISUMU AND SIAYA COUNTIES IN WESTERN KENYA

BY

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DECLARATION

I declare that this thesis is my original work and has not been presented to any other University or Institution for a degree or any other award

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DEDICATION

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ABSTRACT

Transfusion transmissible infections (TTIs) especially, human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis (*Treponema pallidum)* are a constant threat to blood safety for recipients. Globally, about 1.6 million blood units are destroyed annually owing to TTIs seropositivity, of which 10% is discarded in sub-Saharan Africa. In Kenya, despite of a series of safety improvements in blood donations among them rigorous pre-donation screening and exclusion of high risk group from blood donation, a substantial amount of blood units of about 5.26% are still discarded annually owing to TTIs seropositivity, with greater majority coming from Homabay, Kisumu and Siaya counties in western Kenya. The objective of the current study was to assess the seroprevalence of HIV, HBV, HCV and syphilis and to establish the demographic and other risk factors driving TTIs seropositivity, exclusively in the category of voluntary donors. In across-sectional study, blood donors (n=1215) aged 16 - 65 years were recruited from a population of 15,480 using a systematic random sampling. A pre-donation questionnaire was used to collect data on demographic characteristic, medical history, and previous risk exposure. Samples were collected from units of blood donated; and tested at Regional Blood Transfusion Center (RBTC) of Kisumu for antigens or /antibodies to HBV, HCV, HIV-1 and 2 using enzyme linked immunosorbent assay (ELISA) while syphilis antibodies were tested using Rapid Plasma Reagin (RPR) test. Subsequently, all reactive samples were retested using chemiluminescent immunoassay to confirm reactive test results from ELISA and RPR tests. Seroprevalence distribution proportions in subcategories of variables were compared using Chi-square test for independence while logistic regression was used to determine the association between TTIs seroprevalence and various risk factors. All tests were two-tailed and a P-value < 0.05 was considered as statistically significant. Of the 1215 blood samples tested, 700(57.6%) were males and 515(42.4%) females (with a mean age of 19.04 ± 4.5). The overall TTIs seroprevalence was 114(9.4%), distributed among HIV, HBV, HCV and syphilis at 14(1.15%), 42(3.46%), 39(3.21%) and 19(1.56%), respectively. There were no significant differences in seroprevalence proportion distribution among the demographic variables tested. However, among the risk factors tested, high risk sex was significantly associated with higher odds of HBV infections (> 1 partner vs. 0-1 partner; Odd Ratio [OR] 2.60; 95% Confidence Interval [CI] 1.098 – 6.86; $p = 0.046$). In conclusion, a substantial percentage of blood donors still harbor transfusion transmissible infections despite recent safety improvements by the Kenya National Blood Transfusion Services (KNBTS) with greater majority cases caused by HBV infection arising from previous exposure to high risk sex. The findings are useful in informing blood donation safety improvements in the region by KNBTS agency. Consequently, promoting safe sex education in learning institutions and enhancing early uptake of HBV self testing with a subsequent vaccination would help reduce TTIs burden observed among blood donors.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency syndrome
BTS	-	Blood transfusion Services
BECs	-	Blood Establishment computerized system
CMIA	-	Chemiluminescent Micro particle Immunoassay
CDC	-	Center for Disease Control
CI	-	Confidence Interval
ELISA	-	Enzyme Linked Immunosorbent Assay
FRD	-	Family Replacement Donors
HBV	-	Hepatitis B Virus
HCV	-	Hepatitis C Virus
HIVAg/Ab	-	Human Immunodeficiency Virus Antigen/Antibody
JOOTRH	-	Jaramogi Oginga Odinga Teaching and Referral Hospital
KAIS	-	Kenya AIDS. Indicator Survey.
KDHS	-	Kenya Demographic Health Survey
KNBTS	-	Kenya National Blood Transfusion Services.
NACC	-	National AIDS Control Council
NBTC	-	National Blood Transfusion Center.
RLU	-	Relative Light Unit.
RPR	-	Rapid Plasma Reagin.
RBTC	-	Regional Blood Transfusion Center.
S/CO	-	Signal to the cut-off value
TTIs	-	Transfusion Transmissible Infections.
UNAIDs	-	United Nations Program on HIV/AIDS.
USA	-	United State of America
VNRBD	-	Voluntary Non-Remunerated Blood Donors
WHO	-	World Health Organization

DEFINITION OF TERMS

Beyond zero campaign – Initiative by the current first lady of Kenya, Margaret Kenyatta outlined in strategic framework towards control of HIV, maternal and child mortality in Kenya

Chemiluminescent Micro particle Immunoassay (CMIA) Techniques – Use of optic signals to quantify immune complex in assay.

Determinants of Transfusion Transmissible Infections (TTIs) –As used in this study includes; (1). Demographic characteristics such as age (2). Risk factors such as illicit drug use.

e-Progesa Blood Establishment Computerized System (BECs)- Is a vein to vein system that interface computer technology with automated blood screening equipment to generate results in real time with boosted efficiency

Family Replacement Donors (FRDs) – These are blood donors brought into the hospital by relatives of patients to donate blood specifically to replace units of blood given to a patient often for payment. Majority are known to have high risk exposure to TTIs.

Regional blood drive recruiter – A personnel within NBTS tasked with responsibility of booking dates for blood donation with heads of institution

Residual risk –Is the threat that remains after all efforts to identify risk have been made

Seroprevalence – Is the number of persons in a population who test positive for Transfusion Transmissible Infection (TTIs) mainly based on test done on blood sample.

Strata – A wider region under study represented in this study by counties.

Texts for life – A short text message platform launched in Kenya in 2014 to help KNBTS capture bio-data, notify and re-call regular blood donors.

Transfusion Transmissible Infections (TTIs) – These are pathogens found in blood, majorly HIV, HBV, HCV and syphilis and can be transmitted to recipient during blood transfusion.

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CHAPTER ONE

INTRODUCTION

1.1. Background

Blood transfusion plays an important role in the supportive care of medical and surgical patients but unsafe blood transfusion puts the patients at risk of acquiring transfusion transmissible infections (TTIs) (Jayaraman & Chelabi, 2010). Transfusion transmissible infections especially human immunodeficiency virus, syphilis, hepatitis B and C virus, are a constant threat to blood safety for the recipient, and more endemic in Africa, thus making donors in this region vulnerable to risk of exposure (Tessema *et al.*, 2010). Moreover, co-infection is also common due to similar routes of transmission (Muriuki, Gicheru, & Wachira, 2013), with prevalence varying with time and regions (Jehuda-Cohen, 2011). Infections with HIV compromise immunological status of a person, hepatitis B and C viral infections cause liver cirrhosis and hepatocellular carcinoma while infections with syphilis results in neonatal mortality (CDC, 2014), hence making the four TTI markers mandatory and irreducible minimum that must be tested in blood donations to achieve safety threshold (WHO., 2009).

Globally, about 1.6 million blood units are destroyed annually owing to TTIs seropositivity (WHO., 2011), with 10% reported in sub-Saharan Africa (Murphy, 2007), where risk of transfusion-transmitted HIV, HBV and HCV is estimated at 1.0, 4.3 and 2.5 infections per 1000 donations respectively, (Jayaraman & Chelabi, 2010). In Kenya, transfusion - related HIV transmission of 2% had been observed (Moore *et al*., 2001). Moreover, despite of recent safety improvements in blood donations by KNBTS such as stringent donor selection, enhanced haemovigilance through e-progesa blood computerized system (BECs), (KNBTS, 2015), and implementation of fourth generation p24 antigen and HIV antibody screening assays (Basavaraju

et al., 2010), a substantial amount of blood units estimated at 5.26% are still destroyed annually in the country owing to TTIs seropositivity (WHO-CDC, 2011). Furthermore, HIV, HBV, HCV and syphilis seropositive blood discards estimated at 2.6%, 3.9%, 2.2% and 0.5%, respectively, were reported earlier in Kisumu region under KNBTS covering Homabay, Kisumu and Siaya counties (NASCOP, 2005). The three counties experience the greatest burden of HIV and other co-infections in the region (NACC, 2016,), but also serve as major blood basket supplying most hospital in western Kenya based on their proximity to regional blood donor center of Kisumu and ease for transport during donations. To date, there is no published data on blood donation safety assessment from this region; hence this study sought to establish the seroprevalence of TTIs among voluntary donors in the region following a series of blood donation safety interventions.

Socio-demographic characteristics influence the distribution of TTIs among blood donors. In Kenya, National blood transfusion services (NBTS) rely mainly on young voluntary blood donors, particularly secondary schools, colleges and University students, majority in the age range of 15 - 24 years (Kimani *et al.*, 2011). Blood donations from school students are preferred over adult donors owing to lower HIV prevalence estimated at 1% compared to 6.6% prevalence recorded in adults aged 30 – 34 years (Kimani *et a*l., 2011). However, a study carried out in Kenya using stimmunology still detected a significant number of early pre-seroconversion of HIV carriers both among adults and teenage population (Mumo, Vansover, & Jehuda-Cohen, 2009). This study sought to establish the dominant demographic and other risk factors still playing a role in TTIs seropositivity recorded in the region.

1.2 Statement of the Problem

In regions with high burden of HIV, risk reduction of TTIs is threatened by the number of blood donors infected and the emergence of co-infections among donor population. In Kenya, risk of HIV infections due to blood transfusion is estimated at 2%, with overall TTIs seropositive blood discards of 5.26%. Furthermore, earlier studies in Kisumu region under KNBTS had shown that HIV, HBV, HCV and syphilis seropositive blood units of 2.6%, 3.9%, 2.2% and 0.5%, respectively, were discarded from blood donations for the year 2003. To date, there is no published data from the region on blood donation safety assessment. This study sought to establish the seroprevalence of TTIs in the region following a series of donation safety improvements.

Socio-demographic characteristics influence the distribution of TTIs among blood donors. Despite of blood collection exclusively from youthful voluntary donors, and rigorous pre-donation screening, a study carried out in Kenya using stimmunology still detected a significant number of early-preseroconversion of HIV carriers both in adults and teenage donor population. This study sought to establish the demographic and other risk factors still driving HIV, HBV, HCV and syphilis seropositivity among donors in the region.

1.3 Objective

1.3.1. General Objective

To assess the seroprevalence and determinants of TTIs among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya

1.3.2 Specific Objectives

1. To determine seroprevalence of HIV, HBV, HCV and syphilis among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya

2. To determine the demographic and risk factors associated with HIV, HBV, HCV and syphilis infections among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya.

1.3.3 Research Questions

1. What is the seroprevalence of HIV, HBV, HCV and syphilis among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya?
2. What are the demographic and risk factors still associated with seroprevalence of HIV, HBV, HCV and syphilis among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya?

1.4 Significance of the Study

A continuous assessment of seroprevalence of TTIs and the associated determinants in blood donations, especially in HIV high burdened regions, essentially provides accurate data on risk rates and guarantees safety of blood transfusions to the recipients. These findings are useful in informing blood donor selection improvement in the region by National Blood Transfusion Services. In addition, the study guides epidemiological surveillance of TTIs in the region and identified key intervention areas ideal for safety improvement.

CHAPTER TWO

LITERATURE REVIEW

2.1 Prevalence of TTIs among Blood Donors

2.1.1 Global Epidemiology of TTIs

Globally, about 1.6 million blood units are destroyed annually owing to TTIs seropositivity (Dhingra, 2013), (WHO., 2011), despite of adoption of WHO recommended mandatory screening for TTIs and blood collection exclusively from voluntary donors (WHO., 2009). A number of countries are making progress towards achieving both safety and blood supply by establishing nationally coordinated blood transfusion services with quality-assured testing protocols and blood collections exclusively from voluntary donors (WHO, 2015). Infections with HIV, hepatitis virus, syphilis and other infectious blood pathogens is reported to be lowest among voluntary blood donors as opposed to family replacement donors (FRDs) (WHO, 2015). In a global summit, it was reported that by the year 2008, about 45 countries collected less than 25% of their blood supply from voluntary donors with the rest coming from FRDs(WHO., 2010). In addition, 37% of all donation made from low income countries came from FRDs while thirty countries were still collecting blood from paid donors by 2008 (WHO., 2010). Moreover, it has also been estimated that, about 39 low income countries are yet to screen all blood donations for the four TTI markers, while 47% of the units collected are screened without quality assurance (WHO., 2011).

In low income countries, prevalence of HIV, HBV and HCV are estimated at 1.08%, 3.7% and 1.03%, respectively, (WHO., 2016), owing to their inability to shift completely from FRD, thus posing great challenge to the high rates of TTIs still reported in many regions (WHO, 2015). In the contrary, high income countries to date are experiencing lower prevalence of HIV, HBV and HCV estimated at 0.003%, 0.03% and 0.02%, respectively, (WHO., 2016). Moreover, risk of

acquiring HIV infections from a single unit of contaminated blood in high income countries is reported to be very low at 1 in 1.5 – 4.7 million units transfused, relative to 1 in 31,000 – 205,000 units transfused reported for HBV infections, and 1 in 2 – 3 million units transfused reported for HCV infections (Jayaraman & Chelabi, 2010), thus already achieving the zero tolerance target for TTIs in blood donations. In Islamabad, Pakistan, 94% of blood collection comes from FRDs while voluntary donors contribute only 6%, thus recording high prevalence of TTIs estimated at 14.3% with HBV and HCV infections reported at 3.9% and 8.3%, respectively, (Usman *et al.,* 2012). Meanwhile, a study of two rural communities in Vietnam reported prevalence of HBV and HCV among blood donors at 11.4% and 0.17%, respectively, (Le Viet & Nguyen., 2012).

2.1.2 Epidemiology of TTIs in Africa

In sub-Saharan Africa, blood safety remains a major public health concern because of high prevalence of TTIs and increased demand for transfusion (Tessema *et al.*, 2010), majorly due to anemia caused by malaria, pregnancy complication and malnutrition (Osaro & Charles, 2011). Moreover, a greater majority of voluntary donors in Africa are below 25years, and contributing about 38% of annual blood collection (WHO., 2010), of which nearly 10% are destroyed owing to TTIs seropositivity (Murphy, 2007). Co-infections with TTIs is also common due to similar route of transmission (Muriuki *et al*., 2013), with prevalence varying with time and region of study (Jehuda-Cohen, 2011). Moreover, serological early-HIV carriers within the donor population often remain undetected, as HIV-induced immunological window periods can span into months (Mumo *et al.*, 2009), while detection of acute and occult HBV and HCV infections in blood donors remain elusive during seronegative window periods (Husam-Has & Sting-Lansen., 2009). Studies have shown that incubation period following HBV exposure varies from 1-6 months and correlates with magnitude of inoculums (Webale *et al.,* 2015), while resolution

and outcome of infection is dependent on host immunity, age, gender, infection route and genotype (Webale *et al.,* 2015), thus resulting in more silent TTIs carriers fueling epidemic (Anyiwo clement, 2014) and variation in epidemiology that requires repeat testing several months later (Jehuda-Cohen, 2011).

The risk of becoming infected with HIV, HBV and HCV from blood transfusion in sub-Saharan Africa is 1.0, 4.3 and 2.5 infections per 1000 donations, respectively, (Jayaraman & Chelabi, 2010). In Bukavu, Democratic Republic of Congo (DRC), residual risk of HIV, HBV and HCV infection due to blood transfusion was estimated at 0.6, 7.9 and 3.1 per 1000 donation, respectively, (Kabinda & Bulabula, 2014). Thus, improving blood donation screening protocol for TTIs would ultimately eliminate or help reduce transmission of infections (Fathi-Abed & Al-Gani, 2011). In Ghana, syphilis seropositivity in blood donations was estimated at 13.5% (Ampofo *et al.,* 2002), relative to 9.1% detected in 252 first time donors of Cameroon (Mbaya & Takam, 2003). Meanwhile, in neighboring Ethiopia, HIV, HBV, HCV and syphilis seropositivity of 3.8%, 4.7%, 0.7% and 1.3%, respectively, was reported among blood donors (Tessema *et al*., 2010), relative to 4.3% (HBV) and 2.7% (HCV) seropositive detected among student donors in Egypt (El-Gilany & El-Fedawy, 2006). Similar studies among donors in Kano, Nigeria, reported 19% positivity for at least one TTIs while 21% had multiple infections with HIV, HBV, HCV and syphilis (Nwankwo & Imoru-Momodu, 2012). In Benin City, Nigeria, a study of 260 male voluntary donors detected TTIs seropositivity of 12.5% (Halim & Ajayi, 2000), relative to 24.0% seropositive reported among first time donors in Burkina Faso, of which 1.8% had serological evidence of multiple infection (Nagalo-Bolni & Marins., 2012).

2.1.3 Epidemiology of TTIs in Kenya

A study in Trans-Nzoia County, Kenya reported seroprevalence of HBV at 10.5% among febrile patients visiting health facilities (Demba & Mwau, 2013). Likewise, 56% prevalence of HBV was reported among outpatients attending three district hospitals in the towns of Mombasa, Kilifi and Malindi, Kenya (Hyams *et al.*, 1989), relative to 8.8% reported among asymptomatic nomads in Turkana, Kenya (Mutuma & Mbuchi, 2011). Moreover, a study involving pregnant women from the former Kenya six provinces estimated national prevalence of HBV at 9.3% (Okoth *et al.,* 2006), while co-infections with hepatitis B and C virus, among HIV-1 infected individuals in Nairobi was reported at 10.3% (Muriuki *et al.*, 2013), thus suggesting increased risk of dual infections in the general population of Kenya. Meanwhile, Kenya is among the countries reported to have shifted from family replacement donations (FRDs) to voluntary donations with all units collected screened 100% (KNBTS, 2011).

However, meeting the national demand of 400,000 units remain a big challenge as the organization can only meet 40% of the demand (NASCOP, 2005), with Kisumu region whose annual demand estimated at 50, 000 units collecting about 15, 480 units only (Kisumu-RBTC data, 2014 unpublished). Moreover, recent studies on blood donations from NBTS Kenya showed unstable annual prevalence of HIV range of 1.2% - 2.5% (Basavaraju *et al.*, 2010), relative to a subsequent report showing prevalence peak rates of HIV, HBV, HCV, and syphilis during the periods of 2006-2010 at 2.5%, 6.0%, 1.8% and 0.7% respectively (KNBTS, 2011), with HBV seroprevalence rising to a peak of 5.2% in 2011 (KNBTS, 2012). A study comparing voluntary blood donors with FRDs also reported 2.6% HIV seroprevalence among voluntary donors (Kimani *et al.*, 2011), while the overall blood discards in Kenya due to TTIs seropositivity is reported at 5.26% (WHO-CDC, 2011).

Meanwhile, earlier studies in Kisumu region which also represent Homabay, Kisumu and Siaya counties, reported prevalence peak of HBV, HCV and HIV among blood donors in the region at 3.9%, 2.2%, and 5%, respectively, (NASCOP, 2005), thus suggesting high risk of TTIs among donors in the region. Furthermore, a series of blood donation safety improvements have since been implemented in the recent past, among them, enhanced donor notification, retentions of safe seronegative donors, and deferral of seropositive through text for life initiatives (KNBTS, 2015). In addition, haemovigilance has also been improved through the implementation of e-progesa blood establishment computerized system (BECS), with enhanced donor selection exclusively from voluntary donors (KNBTS, 2015), and use of fourth generation p24 antigen and HIV antibody assays (Basavaraju *et al*., 2010). However, blood donation safety assessment has not been conducted in this region and published following those safety improvements.

2.2. Demographic Characteristic and Risk Factors among Voluntary Blood Donors

2.2.1 Demographics Characteristics of Voluntary Blood Donors

Demographic characteristics of blood donors such as age, gender, marital status, region and level of education influence the distribution of TTIs in the donor population (Kimani *et al*., 2011). For safe blood, NBTS rely mainly on young voluntary blood donors, particularly secondary schools, colleges and University student for donation (Mumo *et al.,* 2009), majority of whom are in the age range of 15 - 24 years (NASCOP, 2005). This fact is echoed in another study in Egypt, showing low prevalence of HBV and HCV among student population (El-Gilany & El-Fedawy, 2006). In terms of gender, male student donors in Egypt aged 17 -24 years recorded a high prevalence of HBV and HCV at 5.1% and 2.8%, respectively, compared to their female counterparts with 3.0% and 2.5%, respectively, (El-Gilany & El-Fedawy, 2006). In Kenya, voluntary donors aged 15 – 19 years experienced lower HIV prevalence of 1% compared to their counterpart aged 30 – 34 years who recorded prevalence of 6.6% (KNBTS, 2012). Studies in

Kenya have also shown that adults and adolescent aged of 15 – 24 years recorded low HIV prevalence of 0.9% compared to 1.4% prevalence reported in adults aged 25 – 34 years (NASCOP, 2014). Moreover, women aged 50 years and above recorded higher prevalence of HIV at 7% compared to 5.2% reported on male counterparts (NASCOP, 2014). However, despite of enhanced pre-donation selection from teenagers and young adults, majority being students in schools, a substantial amount of blood units are still discarded owing to TTIs seropositivity.

2.2.2 High Risk Sexual Behaviour

Multiple sexual partners and casual sex are drivers for TTIs positivity, and common among voluntary blood donors (Kimani *et al*., 2011). Studies have shown that, about 4.7% of voluntary donors in Kenya had multiple sexual partners of whom 2.6% of them tested HIV positive (Kimani *et al*., 2011). Moreover, local reports have also shown that men and women with more sexual partners experienced higher prevalence of HIV at 9.0% and 15.5%, respectively, while individuals with more lifetime sexual partners and being unmarried increases risk of acquiring HIV and other sexually transmitted diseases (Oluoch *et al.*, 2011). In a local study, about 66% of University students admitted engaging in sex or drug related risk behavior even after knowledge of their HIV status, with 42% engaging in both risk (Magu & Wanzala, 2012). More importantly, the three counties under study fall within the fishing lakeshore where multiple sexual partners are synonymous with fishing business (Kwena *et al.*, 2010), with majority participants interacting and intermingle with each other. Although NBTS have always excluded individuals with previous exposure to high risk sex from blood donation, local estimates still show increasing cases of TTIs seropositivity in blood donations from the region.

2.2.3 Blood Transfusion

Unsafe blood transfusions have historically contributed to a substantial burden of TTIs in sub-Saharan Africa (WHO., 2009). In Brazil, blood donors with transfusion history are 10 times more likely to test HCV positive (Brandao & Fuchs, 2002). And nearly three quarters (72%) of blood donors with history of blood transfusion tested positive for HCV in Egypt (Awadalla, Ragab, Nassar, & Osman, 2011). Likewise, pregnant women in Bahir city, northwest Ethiopia with history of blood transfusion were found to be 3.7 times more likely to test positive for HIV and HBV infections compared to their counterparts not transfused (Zenebe, Mulu, Yimer, & Abera, 2014). Similarly, pregnant women in the rural district of Cameroon with transfusion history were found to be 12.6 times more likely to test positive for HIV and HBV infections compared to their counterparts not transfused (Jean-Jacque & Jobert-Richie, 2015). In Kenya, about 2% of patients who received blood transfusion tested HIV positive (Moore *et al*., 2001), with a local study estimating HIV prevalence of 7% among donors with previous transfusion history (NASCOP, 2014) . Elsewhere, another local study reported higher rate of HIV infections, ranging from 6.8% - 9.6% among donors with history of blood transfusion (NASCOP, 2009). However, despite of stringent donor selection and exclusion from donations individuals with blood transfusion exposure in a period less than three months, substantial cases of TTIs seropositivity are still reported in donations.

2.2.4 Drug Use

Drug use is also a driver for TTIs (Webale *et al.*, 2015). In Egypt, studies have shown that 47.5% of drug abusers who donated blood tested positive for HCV infections (Awadalla *et al.*, 2011). In Kenya, drug users in Kisumu, Mombasa and Nairobi tested for HIV, HBV and HCV infections recorded prevalence of 11.4%, 4.4% and 5.9%, respectively, (Oyaro & Wylie, 2012). However, despite of rigorous selection, and a subsequent exclusion from blood donation all high risk

group, TTIs seropositive cases were still recorded in donations from this region, thus calling for safety assessment.

CHAPTER THREE

METHODOLOGY

3.1 Study Area

The study was conducted at Regional Blood Transfusion Center (RBTC) of Kisumu, situated at the outskirt of Kisumu town in the eastern shores of Lake Victoria, along Kisumu-Kakamega road, in Kisumu County (Appendix I). The three study sites, (Homabay, Kisumu and Siaya counties) experience the greatest burden of HIV in the county, estimated at 26.0%, 19.9% and 24.8% seroprevalence, respectively, (NACC, 2016,). In addition, the three counties form the major blood basket collecting approximately 15,480 blood units annually (Kisumu-RBTC data, 2014 unpublished), with Homabay, Kisumu and Siaya counties each contributing 4,260, 6,384 and 4, 836 blood units, respectively, owing to their proximity to the regional blood donor center, and ease for transport. Key health challenges in the three study sites are HIV/AIDS, Malaria, and pregnancy related hemorrhages (KNBTS, 2015), thus raising blood transfusion demand in many hospitals in the region.

3.2 Study Design and Population

This was a cross-sectional study in the reference population of voluntary donors in the regions of Homabay, Kisumu and Siaya counties in western Kenya. All voluntary blood donors of age range 16 – 65 years who underwent donor selection process and qualified as suitable donor as per the KNBTS selection protocol (Appendix II), were eligible to participate in the study.

3.3 Participants Recruitment and Consent Process

Permission to conduct blood donation and to recruit study participants was sought through institutions administration (Appendix III). Study participant were recruited among voluntary blood donors who presented themselves to donate blood during blood donation days. A brief health talk was provided during which a complete description of purpose of the study and

assurance of confidentiality were explained. Participants aged ≥ 18 years who qualified as suitable donors were approached and requested to provide informed written consent (Appendix IV), in order to participate in the study, while participants aged 16-17 years obtained informed written consent from their parents (Appendix V) before appending their signature to participate in the study; that is, their assent was obtained. All consenting participants were then provided with pre-donation questionnaire (Appendix VI) to fill their demographic details, medical history and any other information of previous risk exposure. Successful participants were then registered and blood samples collected.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion Criteria

Voluntary blood donors with; (i) hemoglobin ≥ 12.5gms/dl; (ii) body weight ≥ 50kgs; (iii) normal blood pressure and (iv) resident of the county under study. In addition, the participants must have signed an informed consent and/or assent and feeling well by the time of recruitment and registration.

3.4.2 Exclusion Criteria

(i) Previous blood donation in less than 3 months for males, or 4 months for females. (ii) Previous vaccination for HBV in less than 6 months. (iii) Family replacement donors (FRDs) and walk-in-donors visiting RBTC of Kisumu. (iv). All individuals with previous exposure to high risk contacts based on selection protocol and counselor's own assessment. (v) All donors who declined to sign a written consent were excluded.(vi) All individuals aged < 16 and > 65 years.

3.4.3 Sample Size Determination

The sample size was determined by Yamane formula. The choice for the formula was based on the fact that this was a proportion study on a large population; hence Yamane formula provides a

good representative sample size. The annual estimate of donor population for RBTC of Kisumu is 15, 480 (RBTC data, 2014 unpublished).

Formula:

$$n = \frac{N}{1 + (N \times e^2)}$$

n = Sample size

N = Estimated blood donor population (15,480)

1 = Constant

e = Precision level (0.05)

$$n = \frac{15{,}480}{1 + (15{,}480 \times 0.05^2)} = 389.9$$

3.4.4 Sample size adjustment

In order to detect difference in prevalence among the three counties of at least 10% with a significance level of 95% and test power of 90% given baseline overall prevalence of TTIs is 5.26%, a design effect of 2.98 was considered (Husam-Has & Sting-Lansen., 2009)

$$(389.9 \times 2.98) + \frac{10 \text{ X } 389.9}{100} = 11619 + 38.99 = 1200$$

Stratified sampling was applied to allocate study participants, proportionate to population of each county and institution

3.4.5 Determination of Sample Size per County

Homabay County (strata) $\frac{4260 \text{ X } 1200}{15480} = 330$

Kisumu County (strata); $\frac{6384 \text{ X } 1200}{15480} = 495$

Siaya County (strata): $\frac{4836 \text{ X } 1200}{15480} = 375$

3.4.6 Determination of sample size per institution

Example: Kirindo School in Homabay County with a population of 600 students

$$\frac{600 \quad X\ 330}{4260} = 46 \text{ participants.}$$

3.4.7 Sampling Procedure

The choice to include an institution in a study was based on previous blood donations and permission granted. To determine TTIs seropositivity in each county, stratified sampling was performed. To achieve equal distribution of ages and gender where donation response exceeded the calculated sample size, systematic random sampling of every second or third donor was applied in each institution. Study participants' distribution by institutions and sample size is included (Appendix VII).

3.5 Data Collection Process

After providing for the informed consent, qualified donors were given a pre-donation questionnaire to record their demographic details, social and medical history before samples collection.

3.6 Laboratory Techniques

3.6.1 Determination of Human Immunodeficiency Virus-1 and 2 using Sandwich ELISA Test

Determination of antigen or /antibody to HIV-1/2 was done using Vironostika^{R}HIVAg/Ab. test kit (Biomerieux SA, Microelisa system). This was done according to manufacturer's instruction. Briefly, 100µl of specimen diluents was dispensed into each test well; 50µl of serum sample or control was added and mixed using a micro shaker for 15 seconds then incubated at37°C for 60 minutes. The test was then washed six times with phosphate buffer; 100µl of TMB substrate was then added into each well and incubated at room temperature (15C°- 30°C) for 30 minutes in dark cabinet. Finally, 100µl of 1mol/L sulfuric acid was added to stop reaction, mixed and

absorbance read at 450 nm within 15 minutes. Cut-off value was obtained from mean of three negative controls plus factor 1.000. Test sample was positive if absorbance was ≥ cut- off value but negative if absorbance was < cut-off value.

3.6.2 Determination of Hepatitis B Virus using Sandwich ELISA Test

Hepatitis B surface antigen (HBsAg) was determined using Hepanostika HBsAg Ultra test (Biomerieux SA, Microelisa system). This was done according to the manufacturer's instruction. Briefly, 25µl of specimen diluents was dispensed into each test well; 100µl of sample or control was added and incubated at 37°C for 60 minutes. Using a multi-channel pipette, 50µl of HRP-conjugate solution was added and incubated at 37°C for 60 minutes. The test was then washed six times with phosphate buffer and 100µl of TMB substrate added and incubated in the dark cabinet at room temperature (15C° - 30°C) for 30minutes. There action was then stopped with 100 µl of 1mol/L sulfuric acid and absorbance read at 450 nm within 15 minutes. Cut-off value was then calculated from the mean of three negative controls plus factor 0.040.Test sample was positive if the absorbance was ≥ cut- off value but negative if absorbance was < cut-off value.

3.6.3 Determination of Hepatitis C Virus using Sandwich ELISA Test

Hepatitis C antibodies (Anti-HCV) were determined using Abbott Murex Anti-HCV (version 4.0) Elisa test (Murex Biotech SA (Pty) l.t.d).This was done according to the manufacturer's instructions. Briefly, 180µl of specimen diluents was dispensed into each test well and 20µl of sample or control was added, mixed and incubated at 37°C for 60 minutes. The test was then washed six times with phosphate buffer and 100µl of HRP-conjugate added then incubated at 37°C for 30 minutes. The test was washed again and 100µl of murex-substrate solution added, covered and incubated at 37°C for 30 minutes. The reaction was then stopped using 50 µl of 1mol/L sulfuric acid and absorbance read at 450 nm within 15 minutes. Cut-off value was

calculated from the mean of three negative controls plus factor 0.600.Test sample was positive if absorbance was ≥ cut- off value but negative if the absorbance was< cut-off value.

3.6.4 Determination of Syphilis using Rapid Plasma Reagin

Antibodies to reagin (syphilis) were determined using IMMUTREP^{R} RPR REF. (Omega diagnostics; Scotland, United Kingdom).This was done according to the manufacturer's instruction. Briefly, using a calibrated pipette, 50 µl of specimen or control was dispensed onto RPR card and spread to cover the entire ring surface. Using a dispenser bottle/needle, 16µl of RPR antigen was added onto the test specimen and rotated at 100 rpm for 8 minutes using automated rotor. Presence of black clumps (flocculation) was indicative of positive result.

3.6.5 Determination of HIV-1/2, HBV, HCV and Syphilis using a Fully Automated Chemiluminescent Micro Particle Immunoassay (CMIA) Technique (Abbott/Architect i 2000 SR USA).

Determination of HIV-1/2Ag.Ab, HBVsAg. Anti-HCV and Anti-*Treponema pallidum* (syphilis) was done using architect HIVAg/Ab Combo, Architect HBsAg. Qualitative II, Architect Anti-HCV and Architect syphilis TP, respectively. Briefly, a file for a specific assay obtained from *Architect j CD-ROM* was inserted and installed on the *Architect i 2000 SR system.* The reagent carrier was then loaded with Micro particles, acridinium-labeled conjugate, diluents, pre-trigger, trigger solutions and wash buffer according to the manufacturer instructions. Similarly, serum sample panels were also loaded into sample holder according to samples IDs. Sample processing was then initiated by pressing the run key on the processing keypad. Immediately, the Instrument & Control Technique (ICT) pipettor aspirated samples and micro particles into Reaction Vessels (RV), mixed and incubated for 18 minutes. The reaction mixture was then washed to remove unbound materials before acridinium-labeled conjugate was added and mixed and further incubated for 4 minutes before a second wash. A pre-trigger was then added, mixed and CMIA

optical system took background reading before a trigger solution was added to obtain activated reading. To obtain the final results for the analytes, the Architet i 2000 SR system calculated the cut-off value using the mean chemiluminescent signal (Relative Light Unit) from three replicates of calibrator. Results were determined based on the ratio of sample signal to the cut-off value (S/CO), (Relative Light Unit (RLU) to the cut-off for each specimen and control. Specimens with signal cut-off values less than 1.00 were considered non-reactive (Negative) while specimens with signal cut-off value ≥ 1.00 were considered reactive (positive). Samples with S/CO value in the range of 0.9 – 1.0 was classified as equivocal and were repeat tested using same protocol. Test result was ready in 30 minutes.

3.7 Validity and Reliability

For validation of conventional ELISA and CMIA test protocols, a subset of 10 samples randomly selected was re-analyzed at Huqas- laboratory, Nairobi, Kenya using similar techniques and results were concordant.

3.8 Data Management and Statistical Analysis

All information touching on participants' socio-demographics and test results were entered in data excel sheet and secured using secret password accessible to only study staffs. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Seroprevalence distribution proportions in subcategories of variables were compared using Chi-square test at p-value < 0.05. Logistic regression and estimates of odds ratio with their corresponding 95% confidence intervals was used to determine the association between TTIs seropositivity and various risk factors.

3.9 Ethical Consideration

Initial approval to conduct the study was provided by School of Graduate Studies (SGS) of Maseno University (Appendix VIII). Ethical approval of the study protocol was obtained from Ethical Review Committee (ERC) of Maseno University number MSU/DRPI/MUERC/00286/16 (Appendix IX), while institutional approval for the study was obtained from Institutional Review Board of Jaramogi Oginga Odinga Teaching and Referral Hospital number ERC.IB/VOL.1/254 (Appendix X). Written informed consent was obtained from each participant before enrolment. All study participants were provided with free health education on Transfusion Transmissible Infections (TTIs) including HIV, syphilis, hepatitis B and C, hygiene and nutrition. Arrangements were made to refer participants tested positive for any of the four TTIs markers to the comprehensive care centers at Jaramogi Oginga Odinga Teaching and Referral Hospital for treatment, care and support.

CHAPTER FOUR

RESULTS

4.1 Demographic Characteristics of Reactive and Non-Reactive Participants

Demographic characteristics of study participants are presented in table 4.1 below. A total of 1215 individuals were enrolled in this study comprising of 700 males and 515 females. Teenage participants (16-19yrs.) were more compared to adults aged ≥ 20 years (976vs. 239), manage 19.04. In addition, single (unmarried) participants were more compared to married (1165 vs. 50), while first time donors were the majority compared to repeat donors (900 vs. 315).

Table 4.1: Demographic characteristics of reactive and non-reactive participants

Characteristics	Non-reactive n(%)	Reactive n(%)
Age groups		
Teenage (16-19)	894(91.6%)	82(8.4%)
Adults ≥ 20 years	211(88.28%)	28(11.72%)
Gender		
Females	475(92.23%)	40(7.77%)
Males	630(90.0%)	70(10.0%)
Marital status		
Married	49(98.0%)	1(2.0%)
Single	1056(90.64%)	109(9.36%)
Number of donations		
First	813(90.33%)	87(9.76%)
Repeats	292(92.7%)	23(7.30%)
Counties		
Homabay	293(89.0%)	36(10.94%)
Kisumu	469(92.69%)	37(7.31%)
Siaya	343(90.26%)	37(9.74%)

Data shown are numbers (n) and proportions (%) of TTIs seronegative (1105) and seropositive (110) as distributed among demographics

4.2: TTIs Seroprevalence Distribution Proportion Indifferent Categories

TTIs seroprevalence distribution proportion among different categories is presented in Table 4.2 below. Of the 1215 voluntary blood donors recruited, 110(9.05%) individuals tested positive for at least one of the four TTIs, with co-infections detected only in 3(0.25%) individuals in a combination of HIV/HBV/HCV, HBV/HCV and HBV/Syphilis of 1(0.08%) each, of which, HBV was the predominant infection. There was no difference between adults aged ≥ 20 years and teenage donors (11.72% vs. 8.4%%; p = 0.180), males and females (10.0% vs. 7.77%; p = 0.076), as well as married and single (9.36% vs. 2.0%; p= 0.930). The overall seroprevalence of TTIs in the region was 114(9.4%), distributed among HIV, HBV, HCV and syphilis variables at 14(1.15%), 42(3.46%), 39(3.21%) and 19(1.56%), respectively.

Table 4.2: TTIs Seroprevalence Distribution in Different Categories.

Characteristics	n/1215	Non-reactive n(%)	Reactive n (%)	P –value
Counties				0.173
Homabay	329	293(89.06%)	36(10.94%)	
Kisumu	506	469(92.69%)	37(7.31%)	
Siaya	380	343(90.20%)	37(9.74%)	
Age groups				0.293
Teenage(15-19)	976	894(91.6%)	82(8.4%)	
≥ 20 years	239	211(88.28%)	28(11.72%)	
Gender				0.180
Female	515	475(92.23%)	40(7.77%)	
Male	700	630(90.0%)	70(10.00%)	
Marital status				0.076
Married	50	49(98.0%)	1(2.00%)	
Single	1165	1056(90.64%)	109(9.36%)	
Drug use				0.930
No	1203	1094(90.94%)	109(9.06%)	
Yes	12	11(91.67%)	1(8.33%)	
High risk sex				0.053
No	1152	1052(91.32%)	100(8.68%)	
Yes	63	53(84.13%)	10(15.87%)	
Number of donations				0.208
First	900	813(90.33%)	87(9.76%)	
Repeat	315	292(92.70%)	23(7.30%)	
Blood transfusion				0.399
No	1194	10.87(97.84%)	107(8.96%)	
Yes	21	18(85.71%)	3(14.29%)	

Data shown are numbers (n) and proportions (%); Difference in proportions distribution was compared using Chi-square test for independence. A p-value of < 0.05 was considered statistically significant. There were no significant differences in proportion distribution among the variables tested.

4.3 Determinants of HIV Seroprevalence in Blood Donors

Determinants of HIV seropositivity in blood donors is presented in Table 4.3 below. Analysis of demographic factors showed that, age groups (OR, 1.12; 95% [CI] 0.31-4.03; p = 0.863) and gender (OR, 1.33; 95% [CI] 0.44- 3.99; p = 0.613), had no association with HIV seropositivity. Furthermore, none of the pre-determined risk factors were associated with HIV seropositivity.

Table 4.3: Determinants of HIV seroprevalence in blood donors

Characteristics	HIV uninfected n(%) = 1201	HIV infected n(%)=14	OR(95% CI)	Pvalue
County				
Homabay	322(97.87%)	7(2.13%)	3.64(0.9-14.20)	0.062
Kisumu	503(99.41%)	3(0.59%)	ref.	
Siaya	376(98.95%)	4{1.05%)	1.78(0.40-8.02)	0.45
Age group years				
Teenager (16-19)	965(98. 87%)	11(1.13%)	ref.	
Adults ≥ 20	236(98.74%)	3(1.26%)	1.12((0.31-4.03)	0.863
Gender				
Female	510(99.03%)	5(0.97%)	ref.	
Male	691(98.71%)	9(1.29%)	1.33(0.44-3.99)	0.613
Marital status				
Married	50((100%)) 0(0.00%)		-	-
Single	1151(98.8%) 14(1.20%)			
Drug use				
No	1189(98.84%) 14(1.16%)		-	-
Yes	12((100%)	0(0.00%)		
High risk sex				
No	1139(98.87%)	13(1.13%)	ref.	
Yes	62(98.41%)	1(1.59%)	1.41(0.18-10.9)	0.741
No. donations				
First	888(98.67%)	12(1.33%)	ref.	
Repeat	313(99.37%)	2(0.63%)	0.47(0.10-2.12)	0.329
Blood transfusion				
No	1180(98.83%)	14((1.17%)	-	-
Yes	21(100%)	0(0.00%)		

Data shown are numbers (n) and proportions (%); HIV-1/2 human immunodeficiency virus 1 and 2; OR (95%), Odds Ratio at 95% Confidence interval; ref, Reference group; (-) denotes no analysis done due to lack of cases. None of the demographic and risk factors tested was associated with HIV seroprevalence.

4.4 Determinants of HBV Seroprevalence in Blood Donors

Determinants of HBV seropositivity in blood donors is presented in Table 4.4 below. Analysis of demographic factors showed that, age groups (OR, 1.47; 95% [CI] 0.33-2.97; p= 0.282), gender (OR, 1.49; 95% [CI] 0.78-2.86; p = 0.23), and marital status (OR, 1.79; 95% [CI] 0.2-13.26; p = 0.57), had no association with HBV seropositivity. However, in the analysis of pre-determined risk factors, high risk sex was significantly associated with higher odds of HBV infections (> 1 partner vs. 0-1 partner; Odd Ratio [OR] 2.60; 95% Confidence Interval [CI] 1.098 – 6.86; p = 0.046).

Table 4.4: Determinants of HBV seroprevalence in blood donors

Characteristics	HBV uninfected n(%) = 1173	HBV infected n(%) =42	OR(95% CI)	Pvalue
County				
Homabay	317(96.35)	12(3.65%)	1.09(0.51-2.31)	0.824
Kisumu	489(96.64%)	17(3.36%)	ref.	
Siaya	367(96.58%)	13(3.42%	1.02(0.49-2.12)	0.96
Age group				
Teenager (16-19)	945(96.82%)	31(3.18%)	ref.	
Above 20	228(95.4%)	11(4.60%)	1.47(0.73-2.97)	0.282
Gender				
Female	501(97.28%)	14(2.72%)	ref.	
Male	672(96.00%)	28(4.00%)	1.49(0.78-2.86)	0.23
Marital status				
Married	49(98.0%)	1(2.0%)	ref.	
Single	1124(96.48%)	41(3.52%)	1.79(0.2-13.26)	0.57
Drug use				
No	1161(96.51%)	42(3.49%)	-	-
Yes	12(100.0%)	0(0.00%)	-	-
High risk sex				
No	1115(96.79%)	37(3.21%)	ref.	
Yes	58(92.06%)	5(7.94)	2.60(0.98-6.86)	**0.046**
No. donations				
First	869(94.44%)	32(3.56%)	ref.	
Repeat	305(96.83%)	10(3.17%)	0.89(0.43-1.83)	0.75
Blood transfusion				
No	1153(96.57%)	41(3.43%)	ref.	
Yes	20(95.24%)	1(4.76)	1.4(0.18-10.73)	0.742

Data shown are numbers (n), and proportion (%); HBV, hepatitis B virus; ref, Reference group; OR (95%), Odds Ratio

at 95% Confidence interval: (-) denotes no analysis was done due to lack of cases. High risk sex was significantly associated with HBV seroprevalence.

4.5 Determinants of HCV Seroprevalence in Blood Donors

Determinants of HCV seropositivity in blood donors is presented in Table 4.5below. Analysis of demographic factors showed that age groups, (OR, 1.43; 95% [CI] 0.68- 2.97; p= 0.348 and gender, (OR, 0.95; 95% [CI] 0.50-1.810; p= 0.877) were not associated with HCV seropositivity. Moreover, none of the pre-determined risk factors were associated with HCV seropositivity.

Table 4.5: Determinants of HCV seroprevalence in blood donors

Characteristics	HCV uninfected n(%) = 1176	HCV infected n(%)= 39	OR(95% CI)	PValue
County				
Homabay	318(96.66%)	11(3.34%)	1.22(0.55-2.71)	0.633
Kisumu	492(97.23%)	14(2.77%)	ref.	
Siaya	366(96.32%)	14(3.68%)	1.34(0.63-2.97)	0.441
Age group				
Teenager (16-19)	947(97.03%)	29(2.97%)	ref.	
Above 20	229(96.32%)	10(3.68%)	1.43(0.68 - 2.97)	0.348
Gender				
Female	498(96.7%)	17(3.30%)	ref.	
Male	678(96.86%)	22(3.14%)	0.95(0.50-1.81)	0.877
Marital status				
Married	50(100%)	0(0.00%)		
Single	1126(96.65%)	39(3.35%)	-	-
Drug use				
No	1164(96.76%)	39(3.24%)	-	-
Yes	12((100%)	0(0.00%)		
High risk sex				
No	1116(96.87%)	36(3.13%)	ref.	
Yes	60((95.24%)	3(4.76%)	1.55(0.46-5.18)	0.476
No. donations				
First	869(73.9%)	31(3.44%)	ref.	
Repeat	307(97.46%)	8(2.54%)	0.73(0.33 - 1.61)	0.435
Blood transfusion				
No	1157(96.9%)	37(3.10%)	ref.	
Yes	19(90.48%)	2(9.52%)	3.29(0.74 - 14.65)	0.118

Data shown are numbers (n), and proportion (%); HCV, hepatitis C virus; ref. Reference group; OR (95%), Odds Ratio
at 95% Confidence interval; (-) denotes no analysis done dueto lack of cases. None of the demographic and risk factors tested was associated with HCV seroprevalence.

4.6: Determinants of Syphilis Seroprevalence in Blood Donors

Determinants of syphilis seroprevalence are presented in table 4.6 below. Analysis of demographic factors showed that, age groups (OR, 1.09; 95% [CI] 0.3-3.24; p=0.0879) and gender (OR, 1.27; 95% [CI] 0.5-3.24; p = 0.623) were not associated with syphilis seropositivity. Moreover, none of the risk factors were associated with syphilis seropositivity.

Table 4.6: Determinants of syphilis seroprevalence in blood donors

Characteristics	Syphilis uninfected n (%)=1196	Syphilis infected n(%) = 19	OR(95% CI)	Pvalue
County				
Homabay	323(98.18%)	6(1.82%)	2.33(0.6-8.33)	0.192
Kisumu	502(99.21%)	4(0.79%)	ref.	
Siaya	371(97.63%)	9(2.37%)	3.04(0.9-9.96)	0.066
Age group years				
Teenager (16-19)	961(98.5%)	15(1.5%)	ref.	
Above 20	235(98.33%)	4(1.67%)	1.09(0.3-3.24)	0.879
Gender				
Female	508(98.64%)	7(1.36%)	ref.	
Male	688(98.29%)	12(1.71%)	1.27(0.5-3.24)	0.623
Marital status				
Married	50(100%)	0(0.00%)		
Single	1146(98.37%)	19(1.63%)	-	-
Drug use				
No	1185(98.5%)	18(1.50%)	5.9(0.7-48.84)	0.095
Yes	11(91.67%)	1(8.33%))	ref.	
High risk sex				
No	1134(98.44%)	18(1.56%)	ref.	
Yes	62(98.41%)	1(1.59%)	5.9(0.7-48.84)	0.988
No. donations				
First	884(98.22%)	16(1.78%)	ref.	
Repeat	312(99.05%)	3(0.95%)	0.5(0.15-1.84)	0.317
Blood transfusion				
No	1175(98.41%)	19(1.59%)	-	-
Yes	21(100%)	0. (0.0%)		

Data shown are numbers (n), and proportion (%); OR (95%), Odds ratio at 95% Confidence interval; ref. Reference group; (-) denotes no analysis done due to lack of cases. None of the demographic and risk factors tested was associated with syphilis seroprevalence..

CHAPTER FIVE

DISCUSSION

5.1 Seroprevalence of HIV, HBV, HCV and Syphilis

The present study was set to determine the seroprevalence and determinants of HIV, HBV, HCV and syphilis among voluntary blood donors in Homabay, Kisumu and Siaya counties in western Kenya. Results established that, overall seroprevalence of TTIs among voluntary blood donors was 9.4%. Similar results have been reported in studies done in Ethiopia showing 9.5% seroprevalence (Tessema *et al.,* 2010), and in Benin, Nigeria showing 12.5% seroprevalence (Halim & Ajayi, 2000). However, different result were reported in some parts of Nigeria showing seroprevalence of 19.0% (Nwankwo & Imoru-Momodu, 2012), and in Burkina Faso showing seroprevalence of 24% (Nagalo *et al.*, 2012). This observation relates to HIV endemicity and intermediate endemicity of HBV and HCV in the region. In this study, overall TTIs seroprevalence in the three study sites was relatively higher compared to earlier reports of 5.26% national seroprevalence (WHO-CDC, 2011). This variation may be attributed to HIV endemicity experienced in the three study sites as compared to the rest of the country showing difference in HIV/STIs profile. Meanwhile, co-infection of 0.25% detected in the study population was comparable to 0.02% reported in a previous local study (Karuru, Lule, Joshi, & Anzala, 2005), and 0.8% reported in the neighboring Ethiopia (Tessema *et al*., 2010).

The HIV seroprevalence of 1.15% detected among blood donors is indicative of low seroprevalence and decreased susceptibility to HIV infections. Similar studies in DRC reported similar result of 1.1% seroprevalence (Kabinda & Bulabula, 2014). However, in Ethiopia, a relatively higher seroprevalence of 3.8% was reported (Tessema *et al*., 2010). These findings were comparable to the previous national estimates of 0.96% - 1.43% seroprevalence reported for the periods 2007-2010 (KNBTS, 2011)), and 0.5% – 1.5% seroprevalence for the periods

2011-2012 (KNBTS, 2012). Likewise, the result was also comparable to other national estimates of 1.2% -2.5% seroprevalence reported earlier in a local study (Basavaraju *et al.*, 2010). This study observation could be results of exclusion of family replacement donors (FRDs) from the study, and milestones of beyond zero campaign initiatives in the country. In contrast, the findings were relatively low compared to 2.6% national seroprevalence reported in a similar local study (Kimani *et al.*, 2011), and 2.6% seroprevalence reported from same study sites (NASCOP, 2005).

In this study, HBV seroprevalence of 3.46% detected among blood donors is indicative of intermediate endemicity and increased susceptibility to HBV infections. Similar results have been reported in Ethiopia showing seroprevalence of 4.7% (Tessema *et al.*, 2010), and in Egypt showing seroprevalence of 4.3% (El-Gilany & El-Fedawy, 2006). The findings were comparable to 3.9% seroprevalence reported earlier from the same study sites (NASCOP, 2005), but relatively higher compared to1.97% - 2.77% national estimates for the periods 2006 – 2010 (KNBTS, 2011). In contrast, these study findings were relatively lower compared to the national seroprevalence peak of 5.2% reported in the period 2011-2012 (KNBTS, 2012). Thus, it is evident from the study that, despite stringent donor selection exclusively from voluntary donors, implementation of fourth generation p24 antigen and HIV antibody screening assays, enhanced haemovigilance through e-progesa Blood Computerized System (BECs), retention and notification of safe seronegative donors through text for life initiatives, HBV infection remains a safety concern in blood donations from the region. The HCV seroprevalence of 3.21% detected among voluntary blood donors is indicative of intermediate endemicity and increased susceptibility to HCV infections. Similar studies reported relatively lower seroprevalence of 0.7% in Ethiopia (Tessema *et al.*, 2010), 2.7% in Egypt (El-Gilany & El-Fedawy, 2006), 0.7%

in Nigeria (Nwankwo & Imoru-Momodu, 2012), and 1.8% in Cameroon (Carole & Francoise, 2014), compared to this study results. The variation observed in HCV seroprevalence may be attributed to difference in geographical settings and study methodology adopted by different authors. In this study, HCV seroprevalence was relatively higher compared 0.79% - 0.99% national estimates for the period 2007 – 2010 (KNBTS, 2011), and 0 – 0.9% seroprevalence estimates for the period 2011-2012 (KNBTS, 2012). In addition, this study result was relatively higher compared 2.2% seroprevalence previously reported in the same study sites (NASCOP, 2005), Thus, it is evident from the study that HCV infection remains a challenge in blood donation safety, being a major contributor to many blood discards experienced in the region.

Syphilis seroprevalence of 1.56% detected among blood donors is indicative of low seroprevalence and decreased susceptibility to syphilis infection. Similar studies in Ethiopia reported similar results of 1.3% seroprevalence (Tessema *et al.,* 2010). However, different results were reported in Ghana showing seroprevalence of 13.5% (Ampofo *et al*., 2002), and in Cameroon showing 9.1% seroprevalence (Mbaya & Takam, 2003). Variation observed in seroprevalence may be attributed to difference in geographical setting. In this study, syphilis seroprevalence was similar to the national estimates of 0.15% - 0.28% (KNBTS, 2011), and 0.5% seroprevalence reported earlier in the same study area (NASCOP, 2005). This observation may be attributed to milestones of beyond zero campaign programs and enhanced pre- donation selection.

5.2 Demographic and Risk Factors of TTIs

In the analysis of demographic and risk factors, HBV infection was significantly associated with previous exposure to high risk sex. This may be explained by the low economic status initiating young adolescents to multiple sexual relationships, thus making them vulnerable to HBV and

other co-infections. The findings corroborate local studies that found sex for cash payment associated with HIV and other co-infections (NACC, 2016,). In contrast, different results were observed in Egypt showing that TTIs was not associated with high risk sex (Awadalla *et al*., 2011). In relation to age and gender subcategories, none was associated with any of the TTIs seroprevalence, although previous local studies had reported different results showing that adults' aged ≥ 20 years were more likely to get infected by HIV compared to young adolescents aged 10 – 19 years (NACC, 2016,). Moreover, females were more likely to test HIV positive compared to males (Kimani *et al*., 2011). The variation observed may be related to the difference in study population since voluntary donors is a low risk group compared to the general population. In relation to blood transfusion history, there was no association with any of the TTIs. However, a similar study in Egypt reported different results showing HCV seroprevalence of 72% among donors with transfusion history (Awadalla *et al*., 2011). Meanwhile, a previous local study had reported HIV transfusion transmission risk of 2% among recipients (Moore *et al.*, 2001). On the contrary, this study did not find any association between TTIs seroprevalence and blood transfusion history. Recent implementation of high quality screening assays and rigorous pre-donation screening of donors may have influenced reduction in transfusion risk experience before. From the study, previous exposure to illicit drug use was not associated with TTIs seroprevalence. However, different results have been reported in Egypt showing 47.5% of blood donors with drug use history testing HCV positive (Awadalla *et al.*, 2011).

5.3 Limitation of the Study

This study only used HBVsAg marker to detect infections of HBV without considering IgM and IgG antibodies to the core protein (HBcAb-Ig M & IgG) which are ideal for a complete and

accurate diagnosis of acute, occult and chronic infection stages of HBV (Webale *et al*., 2015), hence some cases may have been missed.

CHAPTER SIX

SUMMARY OF THE FINDINGS, CONCLUSIONS AND RECOMMENDATION

6.1 Summary of the findings

In this study, the overall seroprevalence of TTIs observed was higher among voluntary donors. In addition, seroprevalence of HBV and HCV was relatively higher compared to the seroprevalence of HIV and syphilis infections. HBV seropositivity was detected with higher frequency noted among voluntary blood donors with previous exposure to high risk sex.

6.2 Conclusion

1. The overall seroprevalence of TTIs was higher with HBV and HCV being the predominant infections while HIV and syphilis seroprevalence were lower
2. HBV seroprevalence was associated with previous exposure to high risk sex.

6.3 Recommendation from the Study

1. Promoting safe sex education in learning institutions and enhancing early uptake of HBV self testing with a subsequent vaccination would help reduce TTIs burden observed among blood donors.

6.4 Recommendation for future Studies

1. Future studies are suggested to quantify the residual risk of transfusion –associated syphilis resulting from low sensitivity and specificity of RPR assays, and evaluation of additional safety benefits that could be achieved if chemilumescent immunoassay was regionally implemented.

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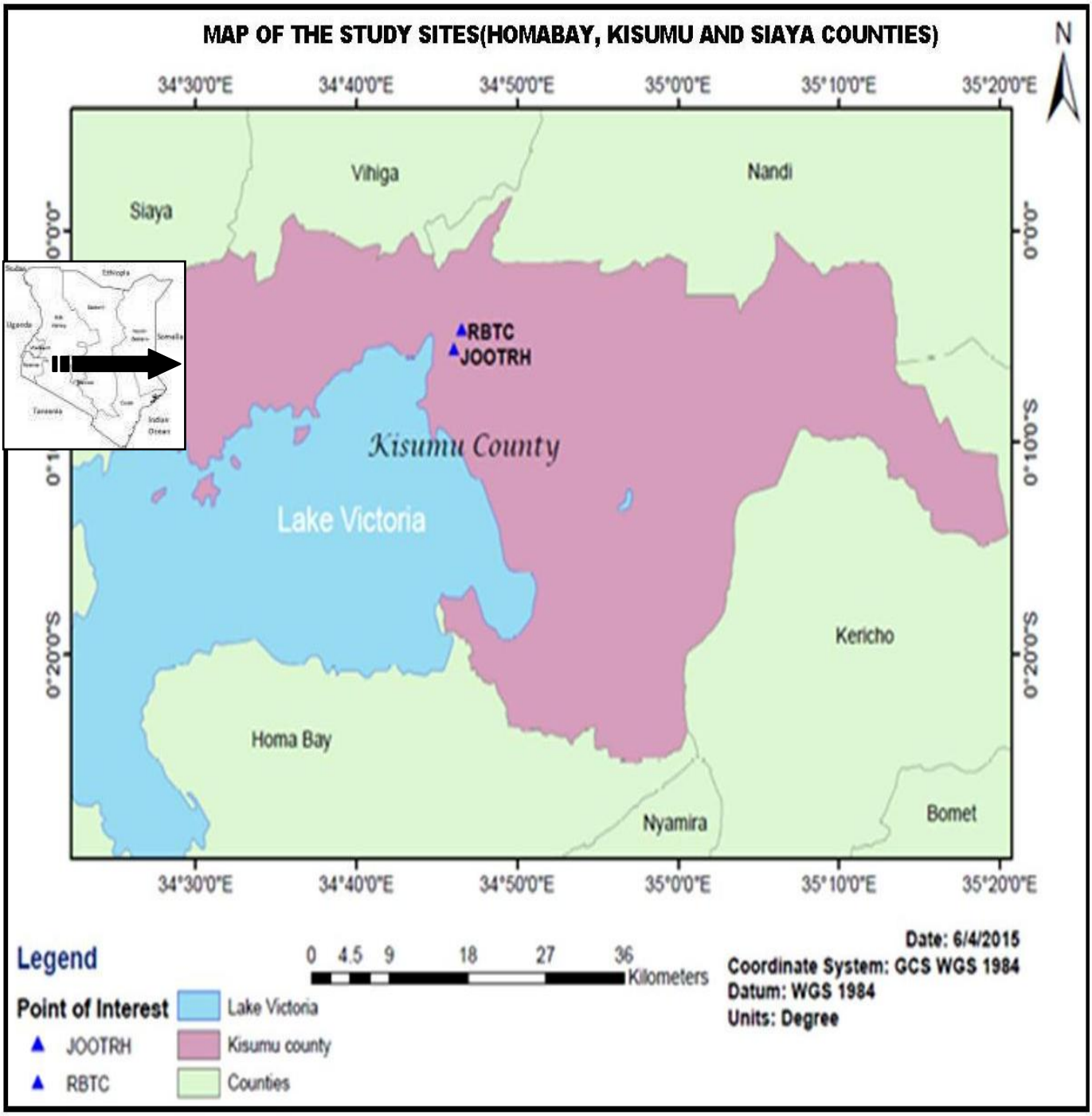
APPENDICES

Appendix I: The study Area Map



Appendix II: KNBTS donor recruitment and selection protocol

KENYA NATIONAL BLOOD TRANSFUSION SERVICE

Kenya National Blood Transfusion Service

It's safe and it saves.

STANDARD OPERATING PROCEDURE

Donor Selection

Document Number:	SOP CLN-001
Revision Number:	02
Effective Date:	June 2017
Controlled copy number:	14

	NAME	TITLE	SIGNATURE	DATE
Written By	Mercy Cherono	Donor Clinic Incharge –RBTC Nakuru		
Approved by	Dr J .Githaiga	Donor Services Manager-KNBTS		
	Charles R. Oliech	National Quality& Safety Manager – KNBTS		
Authorised By	Dr. Margaret Oduor	Head KNBTS		

1.32.3 Determining Preventive Action
KNBTS uses a defined process for determining the preventive action required to eliminate the cause(s) of potential problems.

1.32.4 Evaluating Preventive Action
KNBTS maintains processes for initiating needed preventive actions, applying controls to the involved processes, and evaluating the preventive actions taken to verify their effectiveness.

1.32.5 Quality monitoring
KNBTS maintain a process for identifying quality indicators to monitor the performance of selected procedures

1.32.6 Supporting Documents
Corrective and Preventive Action Process
Continual Improvement Process
Customer Care Process

2.0 Blood Donor Management

2.1 Mobilization and Recruitment of Blood Donors

KNBTS identifies communities of low risk blood donors who are voluntary non-remunerated for targeting as sources of safe blood. Donors are educated so that they understand the need for donating blood voluntarily and assuring them of personal safety and confidentiality in taking this action. KNBTS mobilizes donors through: having trained blood donor recruiters/organizers, distribution of IEC materials, conducting pre donation talk to different groups, establishing folk media groups to convey messages about blood donor recruitment, conducting open air campaigns, disseminating information during international and national events, initiating and supporting pre donor clubs among others.

KNBTS has a documented strategy to ensure it retains at least 10% repeat donors including: initiating and supporting post blood donor clubs, following up donors through telephone and mail, maintaining good relationship with blood donors, recognizing the outstanding contribution of blood donors by giving them badges, t-shirts, exercise books, pens etc. maintaining a register of all blood donors so that they can easily be tracked among others.

KNBTS collaborates with the surveillance team under the Ministry of Health department of disease surveillance to monitor emerging infectious diseases.

KNBTS does not offer incentives that discourage candid responses to donor eligibility criteria. Donors are only given donor cards on the first donation and certificates from the third donation.

2.3 Donor Selection Criteria

KNBTS has developed a donor selection criteria based on AfSBT standards, ministry of health and other applicable standards, epidemiological data of infectious diseases, risk behavior and local customs affecting safety of the donor or recipient.
KNBTS has identified medical consultants as per the SOP XXX for medical consultations and maintains records for the same.
KNBTS assists donor with disability like the dumb, blind and lame blood donors and also the illiterate donors and language barriers by donor registration personnel and/or donor clinic counsellor.

2.3.1 Donor Screening

KNBTS utilizes a donor medical questionnaire to gather information about risk factors to the donor or patient. The questionnaire is revised, updated every two years, used in a confidential manner and completed prior to all collections
KNBTS has an English version of the donor questionnaire (can be translated if need arises) which is completed to determine eligibility for donations

KNBTS conducts donor confidential interviews to determine donor suitability. For static clinics, it is done in a private room and the session is between the donor and the counsellor.

At mobile sites, donors are given general information in a group and specific interviews done one on one by the attending counsellors.

2.3.2 Donor Consent

KNBTS informs donors about donation procedures, potential adverse reaction and post donation care. The tests carried out on the tested blood, process for notification of abnormal results and information that may be released to a third party
Donors are allowed to give consent after full information has been given to them and any questions answered by the counsellor.
Donors who decline to consent are given appropriate information for future consideration.
Donor are also given information on confidential unit exclusion which can be done on site immediately after donation or later after the donor has left the donation station.

2.3.3 Donor Counselling

KNBTS confidentially notifies donors of their sero status through counseling and any other information that is obtained in their blood unit that is medically significant
When counselling services are not available, KNBTS has collaboration with other institutions to offer the same.

3.0 Collection of Blood from Donors.

10. Procedural Steps

10.1 Welcome donor/client

Confidentiality must be maintained at all times during this procedure.
Welcome the donor to the blood collection area in a friendly manner and confirm that they have come to donate blood.

If there will be a delay before the donation can be made, inform the donor of the likely waiting period. If the donor cannot wait, refer him/her to another suitable venue or time.

10.2 Predonation information/health talk

Provide blood donor with information on blood donation or heath talk before donation

10.3 Give donor questionnaire

Issue the donor with a questionnaire and ask them to complete personal details.

After the donor has filled in the questionnaire, confirm that all the questions have been answered and review the form with the donor.

If there are responses on the questionnaire that would not allow the donor to donate, refer the donor for counselling as per SOP on counselling

10.4 Conduct individual pre-donation counselling (Refer to SOP CLN 008)

Explain clearly the reasons why health screening is conducted and educate donor on the importance of giving correct information.

For new donors, carefully establish motive for coming to donate. For both new and repeat donors stress confidentiality and its limitations.

Explain procedure for blood donation to new donors. Establish what donor knows about safe blood donation, tests done, and requirements to be a blood donor.

10.5 Assess blood donor health and risk behaviour

Conduct health and risk behaviour assessment using donor questionnaire
Refer to Kenya Blood Transfusion Medical Guide . Accept or reject blood donor.

Does donor meet required criteria?

Yes - Proceed to step 10.6

No - Explain reason, counsel and educate donor whether they should donate again or not

10.6 Health Checks

The following health checks should be carried out:

Weight- Minimum acceptable weight is 50kgs

Blood Pressure- Acceptable ranges if blood donor is 30years or below 90/50 – 180/90 mmHg
Acceptable range for Blood donors above 30 years and above 90/50 – 180/100mmHg.

Haemoglobin Check using copper sulphate solution

Principle - This method estimates the haemoglobin content of blood by using specific gravity. If the specific gravity of blood is higher than that of the copper sulphate solution; the drop will sink within 15 seconds. Minimum acceptable HB for donation is 12.5g/dl.

Explain procedure to donor. Clean the middle finger or (finger preferred by donor) thoroughly with 70% Methylated spirit. Do not blow or use dry cotton wool to dry the finger.

Open new lancet/autoclix and hold firmly the prepared finger between the counsellor's thumb and the index finger to support the donor's finger. Prick the side of the finger, apply firm pressure on the donor's finger but do not squeeze. Fill capillary tube up to ¾ by submerging one end in the drop of blood. Avoid drawing air bubbles into the capillary tube.

Allow a single drop of blood to freely fall into copper sulphate solution by holding the tube about1cm above the surface of the solution. Observe the drop for 15 seconds and see whether it sinks.

Dispose of lancet and capillary tube into biohazard container. Place a small piece of cotton wool into the puncture site and instruct donor to hold between punctured finger and thumb to arrest bleeding.

NB-Do not put more than 25 drops in one vial (50mls) of copper sulphate in a universal bottle. Copper sulphate of specific gravity1.053 corresponds to haemoglobin of 12.5g/dl

10.7 Does donor pass haemoglobin screening test?

Yes - If the drop of blood falls through the solution within 15 seconds, the donor has passed the test. Tick on the space provided on donor questionnaire. Give donor questionnaire and direct to registration area

NO - If the drop does not sink within 15 seconds, explain to donor what it means to fail copper sulphate test. Reassure donor, counsel and defer.

10.8 Handling of deferred donors

Always use simple language which the donor understands. Do not rush donor. Respond to donors questions professionally and empathetically.

Explain the dangers associated with taking blood from an unsuitable donor either from a recipients or donors perspective. Ensure donor is satisfied before he/she leaves.

Inform the donor if there is need to come again and thank donor for his/her effort
Record reason for deferral on donor questionnaire form

Appendix III: Official Blood donor recruitment letter
FRM CLN/04 **Version 1.0**

The Regional Blood Drive recruiter

Blood Donation Center of Kisumu

P.O Box 9282

Kisumu

Dear Sir/Madam.

RE: REQUEST FOR PERMISION TO CONDUCT BLOOD DRIVE IN YOUR INSTITUITION

The ministry of Health through the National Blood Transfusion Services (NBTS) is mandated to source for and make available safe and adequate blood for transfusion to needy cases in the country. In western Kenya, this exercise is done through the Regional Blood Transfusion center (RBTC) of Kisumu. The NBTS works with voluntary blood donors to donate blood towards this cause.

The RBTC of Kisumu therefore request you kindly to allow us mobilize and sensitize the students in your institution on the date……to donate blood. Blood donation is absolutely voluntary, safe and saves life. The entire exercise involves health education on who qualifies to donate, transfusion transmissible infections that are tested in blood and how donors are notified of their results, benefits of donation and the overall time for the exercise.

We look forward for your kind gesture and hope for greater partnership with your institution in saving lives of Kenyans.

Yours Faithfully

Regional Blood Drive Recruiter

Name…… ……Sign…….Date……

FOR Institutions official approval

Name of Institution
Sub. County
Population of the Institution
No. of pre-registered donors (if any)
Proposed arrival time
Name of institution contact/responsible officer
Postal address
Telephone number
E-mail address
Comment (Approved/not approved reason)

Principle's name……Sign……..….Date……..

Appendix IV: A Consent form for adults aged ≥ 18 years
FRM CLN/03 **Version 1.0**

TTIs SEROPREVALENCE STUDY CONSENT TO TAKE PART IN RESEARCH FOR ADULTS AGED ≥ 18 YEARS

Introduction: Hello, my name is George Calleb Onyango. I am conducting a study to determine the prevalence and risk factors of Transfusion Transmissible Infections (TTIs) majorly HIV, HBV, and HCV and syphilis among the voluntary blood donors in the region of western Kenya. You are invited to take part in this study because you are a voluntary blood donor. This form tells you why this research study is being done. Please read and decide whether to join the study or not.

Investigators: The principle investigator in this study is George C. Onyango; co-investigators are Dr. Lilian Ogonda and Dr. Bernard Guyah all from Maseno University. A study team will be working with investigators. The study period is one year.

Objective of the study: The purpose of this study is to find out the magnitude of TTIs among our potential voluntary blood donors. The results obtained will help us review our current donor selection criteria and formulate new strategies that will improve adequacy and safety of blood to the local recipients.

Study location: The study will be done at RBTC in Kisumu and NBTC Nairobi while blood samples will be collected from schools and colleges in Homabay, Kisumu and Siaya.

Anticipated benefit: Participation in this study is free. Refreshments would however be provided to all those who donate a unit of blood. All donors will also get donors card showing blood group. Results of TTIs will be provided on an individual request.

Risk and discomfort: Drawing blood during blood donation will be accompanied by a small amount of pain and bleeding that is short lived and may cause minor discomfort. Occasionally

mild dizziness and sweating may also follow a blood donation. You do not have to take part in the study if you do not wish to do so. You do not need to give any reason of refusing.

Compensation: No compensation is provided for. First aid will however be provided to those with minor adverse events. You are not obliged to participate and can withdraw from the study at any time. No special treatment is provided to study participants.

Voluntary participation: Your participation in this study is voluntary. If you choose not to participate; you will still be our potential donor and will continue to get our services. Please be assured that the test results obtained will not be linked to any names or identifications.

Sample type, amount and time: Overall, 15 minutes is enough for donor selection, bleeding and recovery. About 6mls of blood samples will be collected from the single unit of blood you donate. Long Elisa test will be used to detect the presence of Human Immunodeficiency Virus, Hepatitis B, Hepatitis C virus and *syphilis* in the blood. A minimum of 1, 215 participants will be registered for the study.

Follow-up schedule: All donors who test positive for any of the TTIs will be notified appropriately for further counseling and referral to medical care. The visiting date shall be communicated to the head of school or college.

Confidentiality: Every effort will be made to keep your study records confidential. Any information about you will be reported anonymously. If you think that you were harmed because of this study, contact the Principle or co-Investigators on the contact provided bellow.

I consent: By signing my name below, I confirm the following:

I have read this consent document. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed.

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

Principal Investigator..... Signature.....Date.....

Contacts: Bellow is some key contacts

For any question or concern about research study or study related injuries, contact George C. Onyango on 0720775249 or director of RBTC-Kisumu Reuben Anyango on 0721804268 or visit him in the office.

For questions pertaining to your right, contact the secretary, Maseno University, Ethics Review Committee, Private bag, 0722203411; 0721543976;muerc-secretariate@gmail.com

Appendix V: A Consent form for participants aged 16 – 17 years

FRM CLN/04 **version 1.0**

TTIs SEROPREVALENCE STUDY CONSENT TO TAKE PART IN RESEARCH FOR PARTICIPANTS AGED 16 – 17 YEARS

INTRODUCTION

You are being asked to take part in medical research, also called a study. This study is looking at what may put people in Homabay, Kisumu and Siaya in western Kenya at risk of getting the HIV, HBV, HCV virus and syphilis. This study does not focus on people who are already infected with TTIs. Instead, it looks at healthy, uninfected men and women who are 16 to 65 years old.

The research is being done by Calleb Onyango as principle investigator. About 1215 people will be asked to take part in the study.

PURPOSE OF THE RESEARCH: The purpose of this study is to find out the magnitude of TTIs among our potential voluntary blood donors. The results obtained will help us review our current donor selection criteria and formulate new strategies that will improve adequacy and safety of blood to the local recipients.

WHO WILL TAKE PART

To be in this research, you must be living in Homabay, Kisumu or Siaya, be between the ages of 16 and 65 and feeling well and healthy.

TAKING PART IS YOUR CHOICE

Because you are a minor, you will need two things before you can be in this study.

1. Your parent's or legal guardian's permission and 2. Your assent. Your parent or guardian must give permission for you to be in the study. But, if you do not want to be in the study, you do not have to sign this assent. Without your assent, you will not be included in the study. It is

important for you to know from your parent or guardian that he/she has allowed you to take part in the study.

WHAT WILL HAPPEN IN THE RESEARCH

We will ask you to answer questions about yourself. We will also ask you basic questions about your sexual partners. These questions will be asked on a questionnaire. This will help keep your information private. You will be shown how to answer the questions in the questionnaire. You can ask a staff person for help at any time.

We will also ask you to have a medical examination. The examination requires some medical tests. These medical tests include tests for hemoglobin, blood pressure and weight. You will be asked to donate one unit of blood from where 6mls of blood sample will be collected and used to test HIV, HBV, HCV, syphilis and blood group. Your blood will only be used for research purposes.

IF YOUR RESULTS SHOW YOU HAVE HIV, HBV, HCV OR SYPHILIS

If your blood tests results show you have any of the above diseases, we will help link you to support and medical services you might need. The soonest we can give you the results of your blood test is at least two weeks during our donor notification program. At that visit**,** we will give you the results of your TTIs test and other medical tests.

RISKS AND/OR DISCOMFORTS

You may not feel that this study is directly helpful to you.

You may feel pain when blood is taken from your arm. You may bruise, feel dizzy, or get light-headed. There is a small chance of an infection where the blood is taken from. Clinical staff will use proper procedures to lessen this risk.

You may find it hard to answer questions. Some may make you feel embarrassed or uncomfortable.

You may be afraid to get your HIV, HBV, HCV or syphilis test results. You may be embarrassed that others will find out that you have been tested. You may worry that your HIV test results will be made known to other people.

People in your community, including your family, may learn that you are taking part in this study. They may not be pleased that you are doing so.

BENEFITS

This study can help show if you do not have HIV, HBV, HCV or syphilis

You will also know your blood group and get donor card

It can link you to other health facilities for treatment of some illnesses.

It will tell you about what causes HIV, HBV, HCV, and syphilis and how to prevent spreading them.

It may help you to change behaviors that may put you at risk for TTIs infection.

Your community may learn more about TTIs because you have taken part in this study.

PRIVACY: All information you give will be kept private by the study staff. No one else will be told your answers to questions or results of medical tests. Findings from this study will use information from everyone who took part. It will not focus just on your answers and medical test results.

You will be given a special study number. This number will be used on all your study records. Your name will not be on any of these records. Your name and personal information will only be used to reach you. It will not be included in any reports.

Overall findings from this study will be shared with the Kisumu community. Nothing about you specifically will be included in these findings.

YOUR RIGHTS TO REFUSE TO TAKE PART IN THE RESEARCH OR LEAVE THE RESEARCH: You may choose to take part in this study or you can choose not to take part in it. If you choose not to take part, your participation in blood donation will still continue and we shall still recognize you as our potential blood donor with KNBTS.

STORAGE OF BLOOD FOR FUTURE TESTING: Some of the blood taken from you in this study may be used for tests that will not be done until the study has ended. This blood will be stored securely. Only a very small number of study staff will have access to it. If this blood is used this way, your name and personal information will not be linked to it. You may take part in the study even if you decide not to have your blood stored.

PROBLEMS OR QUESTIONS

For any question or concern about research study or study related injuries, contact George C.Onyango on 0720775249 or director of RBTC-Kisumu Reuben Anyango on 0721804268 or visit him in the office.

For questions pertaining to your right, contact the secretary, Maseno University, Ethics Review Committee, Private bag, 0722203411; 0721543976;muerc-secretariate@gmail.com

Do you have any questions?

STATEMENT OF ASSENT

I have read and /or had this form read to me. I understand the purpose of the research. All the procedures have been explained to me and my questions have been answered.

☐*I agree to be in the research.*

☐*I **do not** agree to be in the research.*

I understand that some of my blood will be stored for future medical testing.

☐*I agree to have my blood stored and used for future testing.*

☐*I **do not** agree to have my blood stored and used for future testing.*

Participant Name: (Print)		Participant signature:		Date:	
Witness's Name: (Print)		Witness's Signature:		Date:	

I have explained the purpose of this research to the volunteer. To the best my knowledge, he/she understands the purpose, procedures, risks and benefits of this research.

☐*I have verified that permission for study participation was granted by the parent or legal guardian of this participant.*

Investigator's or designee's Name: (Print)		Investigator's or designee's signature:		Date:	

Appendix VI (a): Blood donor Questionnaire

KENYA NATIONAL BLOOD TRANSFUSION SERVICE

Donation Number

DONOR QUESTIONAIRE

Clinic Venue ---------- **County** ---------- **Clinic Code:** ------ **Donor Number** ----------

SECTION 1: DAILY BLOOD DONOR REGISTRATION& SCREENING FORM (Donors please complete this section below)

Surname: _____ **Other Names:** _____ _____ **GENDER:** F / M

Student Number/ National ID Number: _____ **Date of Birth:** ------/------/----- **(dd/mm/yy)**

Marital Status: *(Mark in appropriate box)*	Single	Married	Divorced/Separated	Widowed

Contact Details: Postal Address (where you would like to receive your correspondence)

Code

Home phone number: ---------- **Cell phone number:** ----------

Email: ---------- Residence (county) ----------

Level of education: None/ Primary/ Secondary/ Tertiary Occupation: .....

When did you last donate Blood? ..... **Blood Group:** .....

SECTION 2: HEALTH QUESTIONNAIRE	**Circle the appropriate answer**
1. Are you feeling well and in good health today?	Yes/No
2. Have you eaten in the last 6 hours?	Yes/No
3. Have you ever fainted?	Yes/No
In the past 6 months have you:	
4. Been ill, received any treatment or any medication?	Yes/No
5. Had any injections or vaccinations (immunizations)?	Yes/No
6. Female Donors: Have you been pregnant or breast feeding?	Yes/No
In the past 12 months have you:	
7. Received a blood transfusion or any blood products?	Yes/No
Do you have or have you ever had:	
8. Any problems with your heart or lungs e.g. asthma?	Yes/No
9. A bleeding condition or a blood disease?	Yes/No
10. Any type of cancer?	Yes/No
11. Diabetes, epilepsy or TB?	Yes/No
12. Any other long term illness Please Specify	Yes/No

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Appendix VI(b): Blood Donor Questionnaire

KENYA NATIONAL BLOOD TRANSFUSION SERVICE

SECTION 3: RISK ASSESSMENT QUESTIONNAIRE

The lives of patients who receive your blood are totally dependent on your honesty & frankness in answering the questions below. Your answers will be treated in a confidential manner. Circle the appropriate answer.

In the past 12 months have you:	
1. Received or given money, goods or favours in exchange for sexual activities?	Yes/No
2. Had sexual activity with a person whose background you do not know?	Yes/No
3. Been raped or sodomized?	Yes/No
4. Had a stab wound or had an accidental needle stick injury e.g. injection needle?	Yes/No
5. Had any tattooing or body piercing e.g. ear piercing?	Yes/No
6. Had a sexually transmitted disease (STD)?	Yes/No
7. Live with or had sexual contact with someone with yellow eyes or yellow skin?	Yes/No
8. Had sexual activity with anyone besides your regular sex partner?	Yes/No
Have you ever:	
9. Had yellow eyes or yellow skin?	Yes/No
10. Injected yourself or been injected, besides in a health facility?	Yes/No
11. Used non-medical drugs such as Marijuana, Cocaine etc?	Yes/No
12. Have you or your partner been tested for HIV?	Yes/No
13. **Do you consider your blood safe to transfuse to a patient?**	Yes/No

SECTION 4: DECLARATION (Please read this before you complete the form with your name and signature below)

I declare that I have answered all the questions truthfully and accurately.

I understand that my blood will be tested for HIV, Hepatitis B & C, and Syphilis and the results of my tests may be obtained from the National Blood Transfusion Service.

I understand that should any of the screening tests give a reactive result, I will be contacted by use any communication medium(s) to send me **important information**. Such medium(s) shall include but not limited to e-mail, post office, mobile telephone and/or fixed telephone, and offered counseling to make an informed decision about further confirmatory testing and management.

I hereby give consent to KNBTS to use the contact details provided in this form to communicate to me as the need may be.

I understand the blood may be used for scientific research, main objective being to improve the safety of the blood supply to patients.

I consent to give blood; I understand that it may be used for transfusion for the benefit of others.

Signature: ---------- **Date:** ----------

For Official Use:

Weight (kg)	Hb >12.5g/dl	BP	Pulse

Donor is Accepted	
Yes	No

Report:

Name of Nurse / Counselor: ---------- **Date:** ----------

Low Volume	> 1 Venepuncture	Hematoma	Faint		
			Mild	Moderate	Severe

Time Needle In		Time Needle Out	

Report:
Name of Phelotomist **Date**

Appendix VII: Study participants distribution

DISTRIBUTION OF STUDY PARTICIPANTS BY COUNTY AND INSTITUTIONS

COUNTY	SCHOOLS	POPULATION	DONORS REGISTERED	STUDY PARTICIPANTS	% PARTICIPANTS
HOMABAY	ST. INNOCENT GIRLS	430	45	31	7.2%
	MAWEGO GIRLS	380	48	35	9.2%
	LIGISA MIXED	460	51	46	10%
	AGORO MIXED	350	43	39	11.1%
	NYANGIELA MIXED	300	35	30	10%
	LALA MIXED	450	46	28	6.2%
	KOBALA MIXED	300	40	11	3.7%
	OTHORO MIXED	480	37	33	6.9%
	LUORA MIXED	450	30	28	6.2%
	ORERO BOYS	900	86	13	1.4%
	COLLEGES				
	MTC -KENDU ADVENT.	180	51	15	8.3%
	CHURCH/CAMP				
	MAWEGO SDA	200	20	20	10%
			TOTAL	**329**	
KISUMU	**SCHOOLS**				
	RIDORE MIXED	430	42	29	6.7%
	ALAWA MIXED	390	38	33	8.5%
	ST. RITA MIXED	600	72	54	9.0%
	DR. ALOO MIXED	530	38	19	3.6%
	NYAKACH GIRLS	1500	76	53	3.6%
	KISUMU GIRLS	1200	183	79	6.6%
	ST. PETER KONIN	300	31	20	6.7%
	WITHUR MIXED	530	63	56	10.6%
	ACHEGO GIRLS	400	43	28	7.0%
	COLLEGES				
	KMTC-KISUMU	1200	64	26	2.2%
	MASENO UNIV.	10,000	225	27	0.27

	NYABONDO MTC	200	34	11	5.5%
	CHURCH/CAMPS				
	SPORTSGROUND	1000	45	26	2.6%
	PEFA MIGOSI	600	62	10	1.7%
	PIPELINE KENYA	100	21	5	5%
	JCC CHURCH	700	36	11	1.6%
			TOTAL	**506**	

DISTRIBUTION OF STUDY PARTICIPANTS BY COUNTY AND INSTITUTIONS

COUNTY	SCHOOLS	SCHOOL POPULATION	DONORS REGISTERED	STUDY PARTICIPANTS	% PARTICIPANTS
SIAYA	NYAMIRA GIRL	1137	72	45	4.0%
	MAJANGO MIX	350	68	43	12.3%
	SAWAGONGO	800	77	8	1.0%
	NYAMBARE	360	43	24	6.7%
	UGENYA HIGH	500	47	19	3.8%
	BAR-KOWINO	550	56	24	4.4%
	MITIRO MIX	440	64	33	7.5%
	GOT-ABIERO	580	49	23	4.0%
	RARIEDA MIX	670	78	36	5.4%
	RAMBA BOYS	1140	125	33	2.9%
	MAKASEMBO	600	57	29	4.8%
	NDIGWA	550	69	39	7.1%
	COLLEGES				
	BONDO TTC	800	71	14	1.8%
	CHURCH/CAMP				
	SAGAM MEDICAL	120	45	10	8.3%
			TOTAL	**380**	

Appendix VIII: Initial Approval of study Protocol by SGS Maseno

MASENO UNIVERSITY
SCHOOL OF GRADUATE STUDIES

Office of the Dean

Our Ref: MSC/PH/00164/2014

Private Bag, MASENO, KENYA
Tel:(057)351 22/351008/351011
FAX: 254-057-351153/351221
Email: sgs@maseno.ac.ke

Date: 15th February, 2016

TO WHOM IT MAY CONCERN

RE: PROPOSAL APPROVAL FOR GEORGE CALLEB ONYANGO— MSC/PH/00164/2014

The above named is registered in the Master of Science Programme of the School of Public Health and Community Development, Maseno University. This is to confirm that his research proposal titled *"Seroprevalence and Determinants of Transfusion Transmissible Infections among Voluntary Blood Donors in Western Kenya"* has been approved for conduct of research subject to obtaining all other permissions/clearances that may be required beforehand.

Prof. P.O. Owuor
DEAN, SCHOOL OF GRADUATE STUDIES

16 FEB 2016

Appendix IX: Ethical Approval of study protocol by MUERC

MASENO UNIVERSITY ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221

Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

FROM: Secretary - MUERC

DATE: 21th April, 2016

TO: George Calleb Onyango
PG/MPH/PH/ 00164/2014
Department of Public Health
School of Public Health and Community Development
Maseno University
P. O. Box, Private Bag, Maseno, Kenya

REF: MSU/DRPI/MUERC/00286/16

RE: Seroprevalence and Determinants of Transfusion of Transmissible Infections among voluntary Blood Donors in Western Kenya, Kenya. Proposal Reference Number: MSU/DRPC/MUERC/00286/16

This is to inform you that the Maseno University Ethics Review Committee (MUERC) determined that the ethics issues raised at the initial review were adequately addressed in the revised proposal. Consequently, the study is granted approval for implementation effective this 21th day of April, 2016 for a period of one (1) year.

Please note that authorization to conduct this study will automatically expire on 20th April, 2017. If you plan to continue with the study beyond this date, please submit an application for continuation approval to the MUERC Secretariat by 21th March, 2017.

Approval for continuation of the study will be subject to successful submission of an annual progress report that is to reach the MUERC Secretariat by 21th March, 2017.

Please note that any unanticipated problems resulting from the conduct of this study must be reported to MUERC. You are required to submit any proposed changes to this study to MUERC for review and approval prior to initiation. Please advice MUERC when the study is completed or discontinued.

Thank you.

DIRECTORATE OF RESEARCH PUBLICATION & CONSULTANCIES 21 APR 2016 MASENO UNIVERSITY

Yours faithfully,

Dr. Bonuke Anyona,
Secretary,
Maseno University Ethics Review Committee.

Cc: Chairman,
Maseno University Ethics Review Committee.

Appendix X: Institutional Review Board of JOOTRH protocol clearance

MINISTRY OF HEALTH

Telegrams: "MEDICAL", Kisumu
Telephone: 057-2020801/2020803/2020321
Fax: 057-2024337
E-mail: ercjootrh@gmail.com
When replying please quote

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL
P.O. BOX 849
KISUMU

Ref: ERC.1B/VOL.I/254

Date 1st, April 2016

Dear Caleb,

The JOOTRH ERC (ACCREDITATION NO. 01713) has reviewed your protocol entitled '***Seroprevalence and determinants of transfusion transmissible infection among voluntary blood donors in Western Kenya***' and found it ethically satisfactory. You are therefore, permitted to commence your study immediately. Note that this approval is granted for a period of one year (April 1, 2016 to April 1, 2017). If it is necessary to proceed with this research beyond the approved period, you will be required to apply for further extension to the committee.

Also note that you will be required to notify the committee of any protocol amendment(s), serious or unexpected outcomes related to the conduct of the study or termination for any reason.

Finally, note that you will also be required to share the findings of the study in both hard and soft copies upon completion.

The JOOTRH ERC takes this opportunity to thank you for choosing the institution and wishes you the best in your endeavours.

Yours sincerely,

NANY W. MAKUNDA,
For: **SECRETARY –ERC,**
JOOTRH – KISUMU.

JOOTRH ETHICS & REVIEW COMMITTEE
P. O. Box 849 - 40100
KISUMU