PREVALENCE DETERMINATION AND TREND ANALYSIS OF MAJOR TRANSFUSION TRANSMISSIBLE INFECTIONS AMONG BLOOD DONORS IN NAIROBI REGIONAL BLOOD TRANSFUSION CENTRE

BY

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DECLARATION

I hereby declare that this research report is my original work, which has not been forwarded to any institution for the award of a degree.

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DEDICATION

I take this time to dedicate this paper to the statistical fraternity and my university guiding team.

Much dedication to my lovely family and friends.

ACKNOWLEDGEMENT

I wish to acknowledge the efforts made by my supervisory team who ensured that all the materials in here are of substance concerning research and analysis. Thanks to the Regional Blood Transfusion Centre (RBTC) staff and its administration for allowing me to use their data in coming up with the said analysis.

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ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
CDC	Centre for Disease Control
CMIA	Cheminiluminsence Microparticle Immune Assay
FRBD	Family Replacement Blood Donor
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
KNBTS	Kenya National Blood Transfusion Service
KRCS	Kenya Red Cross Service
NASCOP	National AIDS and STI Control Programme
PCP	Pneumocystis Carinii Pneumoniae
RBTC	Regional Blood Transfusion Centre
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infections
TTIs	Transfusion Transmissible Infections
VNRBD	Voluntary Non-Remunerated Blood Donor
WHO	World Health Organization

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ABSTRACT

Background: Blood is one of the therapeutic products for terminal ailments and most medical emergencies in hospital situations involve blood transfusion as utmost remedy, however, it has the risk of transfusion-transmissible infections (TTIs) such as Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C Virus (HCV) and Syphilis.

Objective: This study was undertaken to determine the prevalence of, trends of and sociodemographic characteristics associated with TTIs among blood donors from the Regional Blood Transfusion Centre at Nairobi.

Design and site: This study used a retrospective cross-sectional analytical design based on the secondary analysis of blood donors' data between July 2017 and June 2018 obtained from the RBTC database at Nairobi.

Methods: Information on 17,193 blood donors were obtained from the RBTC database at Nairobi. The statistical analysis involved the use of generalized linear models, with Poisson regression and log-link function. The p-values were calculated at < 0.05 and adjusted prevalence ratios did at 95% confidence intervals. Time trends were developed to demonstrate the changes, if any, in the prevalence of TTIs. The autoregressive integrated moving-average process was developed to detect changes in the prevalence of TTIs.

Results: Only 515 (3.0%) blood donors were seropositive for at least one TTI. The prevalence of HIV was 0.49%; HBV, 1.29%; HCV, 0.61%; Syphilis, 0.65%. Multivariate analysis showed that students had a prevalence that was almost 100% lower than and 3.7 times greater than that of people in business ($p<0.001$) for each of HIV, HBV, and HCV, and for syphilis respectively. Similarly, rural, slum and urban blood donors had a prevalence of HIV, HBV and HCV that was almost 100% lower than that of blood donors in college ($p<0.001$). Subsequently, moderate oscillation periods occurred. Time series revealed that TTIs prevalence fluctuates with no evidence of seasonality but instead random walks with uncorrelated white noise process with mean for HIV, HCV, syphilis, and zero-mean for HBV.

Conclusion: The TTIs prevalence was considerably high and fluctuated with time. The data supports robust blood donor selection, serological screening and blood supply monitoring.

CHAPTER ONE

1. INTRODUCTION

1.1 Background

Kenya is categorized as a country with a concentrated epidemic of TTIs in its population. This poses a greater risk in the blood and blood component consumption by a patient who has no option other than being transfused for the reprieve of their medical conditions. This is reflected in the assumption that every transfusion carries a risk to the patient[1]. Although many lives are saved through transfusion, still the dangers posed by these pathogens still are endangering the population and are hence worrying. The Kenya Red Cross Service (KRCS) and Kenya National Blood Transfusion Service (KNBTS) have implemented considerable efforts to supply the safe blood and blood products according to increasing demand. Trend analysis may be valuable in understanding the appropriate plan for further improved safe blood supply[2]. The study was aimed at determining the prevalence of, trends of and sociodemographic characteristics associated with TTIs among blood donors from RBTC at Nairobi

During the transfusion, there are many pathogens, which may contaminate the process thus posing a more challenge than the positive effect. On this notice then the WHO recommends that every country or region that conducts blood transfusion for its citizens develop a system, which looked into how to achieve and maintain, secure and safe programmes for the blood products. Kenya through the initiative of the ministry of health in accordance with WHO came up with a system that would then take responsibility for the blood programmes in the year 2001 [3]. This led to the formation of the Kenya National Blood Transfusion Service with its office in Nairobi, which also served as head office acting as administration and technical services. Then progressively spread its branches to other parts of the country. It was to ensure safe and adequate blood free of TTIs

was available to its citizens. Since its inception, it has tried to put measures in place to reduce the seroprevalence of TTIs in collected blood and it has been observing the varying proportion of these parameters (TTIs). To curb these unpredicted trends then the ministry of health came up with measures such as developing national standards, Kenya guidelines on blood and its products, appropriate use of this product as well as hemovigilance in its consumption sites.

The Kenyan country consumption of blood and blood components range up to approximately 600,000units of blood per year, but the country was able to collect 155,000 units of blood in the year 2012 [3]. Of these, the majority comes from school going students and university/college students. The national programme in charge of blood in any country as per the WHO requirement is to concentrate on voluntary non-remunerated donors than family replacement donors. This has been attributed to the fact that voluntary donors have reduced risk due to their health-seeking behavior and they donate to any patient as compared to a family replacement who pose a danger of transmitting various infections to patients [4].

1.2 Statement of the Problem

Transfusion has been a routine medical therapy to alleviate terminal and emergency situations, though, the after transfusion, effect of TTIs transmission has been reported in some individuals yet they were transfused with screened blood. The best sensitive testing by use of Fluoresces and Elisa methods of blood from low-risk areas will reduce the chances of transmitting the virus at the window period. There is a question of whether collection blood from specific areas and screening with different types and methods have effects on the safety of transfusion.

1.3 Justification

The research aimed at determining the changes of TTIs prevalence for blood donors to allow efficient distribution of safe blood wherever it is needed. It also aimed at finding ways of reducing

resource wastage depending on how much blood is collected and discarded because of being infected with various TTIs. To overcome this mode of TTIs transmission, the RBTC ensures careful donor selections by use of previous infection burden, quality-controlled blood donor screening, and competent personnel are in place as ways of prevention.

1.4 Hypothesis

1.4.1 Null Hypothesis

The transfusion transmissible infections prevalence have remained constant over time at Regional Blood Transfusion Centre, Nairobi.

1.4.2 Alternative Hypothesis

The prevalence of transfusion transmissible infections has changed over time at the regional blood transfusion Centre, Nairobi.

1.5 Objectives

1.5.1 General Objectives

To determine the prevalence of, trends of and sociodemographic characteristics associated with transfusion transmissible infections among blood donors from (Regional Blood Transfusion Centre (RBTC) at Nairobi.

1.5.2 Specific Objectives

i) To determine the overall TTI prevalence among blood donors in RBTC Nairobi.

ii) To determine the disaggregated prevalence of transfusion transmissible infections between July 2017 and June 2018 among blood donors from RBTC at Nairobi.

iii) To assess the trends of the transfusion transmissible infections between July 2017 and June 2018 among blood donors from RBTC at Nairobi.

iv) To determine the effect of sociodemographic characteristics of the blood donors from RBTC at Nairobi who tested positive for transfusion transmissible infections between July 2017 and 2018.

1.6 Study questions

i) What is the overall and disaggregated prevalence of transfusion transmissible infections between July 2017 and June 2018 among blood donors from RBTC at Nairobi?

ii) What is the trend of the transfusion transmissible infections between July 2017 and June 2018 among blood donors from RBTC at Nairobi?

iii) What are the effects of sociodemographic characteristics of the blood donors from RBTC at Nairobi who tested positive for transfusion transmissible infections between July 2017 and 2018?

CHAPTER TWO

2. LITERATURE REVIEW

2.0 Introduction

This chapter presents a review of literature on the transfusion transmissible infections (TTIs). It also provides an overview of the prevalence of these TTIs in Kenya and other countries as well as the historical perspectives of HIV including the modes of transmission.

2.1 Overview

Blood transfusion is one of the key pillars in the attainment of safe and quality healthcare of the Kenyan citizens as stipulated in the millennium development goals (KMDG). Blood transfusion is a therapeutic procedure that is lifesaving with millions of patients around the globe being beneficiaries. Blood transfusion was known to be applicable in the early 1930s through the physician William Harvey who tried and transfused some dogs after depleting its body and then re-transfusing it with blood from another dog. It started being used on many occasions until it gained popularity in the 1950s.

WHO recommends that prior to blood transfusion procedure; thorough screening is carried out on the units. This is for reasons that the tissue in itself is potential to transmit bloodborne pathogens, which are either viral, bacterial or parasitic in nature depending on the regional distribution.

All known TTIs share a common route of entry hence their mode of transmission is more or less the same. This may range from but not limited to sexual contact, exposure to infected blood and blood components, sharing of contaminated sharp objects(needles, sharpeners), intravenous drugs use, vertical transmission (mother-to-child) [5]. The knowledge of the distribution of these pathogens among blood donor population gives the prevalence of all the TTIs that needs to be

assessed prior to selection of low-risk donors and thus assures/asserts the safety of the unit donated. This is made easy by knowledge of TTIs distribution in respect to various variables such as geographical, age, marital status, occupation, the health status of the blood donor, and type of donor (first/repeat) among many others.

The effects of these pathogens once they gain access to the body cells, they cause various harmful projections. These are some of the known associations of long-term morbidity and mortality due to complications like liver cirrhosis and hepatocellular carcinoma for infections with HBV and HCV. These viral pathogens infect the liver and its cells [6]. HIV virus has the ability to infect the immune cells of the body such as T helper cells (specifically CD4+ T cells), macrophages and dendritic cells. This weakens the body system (AIDS) making the body vulnerable to many other opportunistic infections [7].

The distribution of the various TTI in the African continent have proved to be significant and the African Journal has tasked every country to make its own estimates of the prevalence to have better projections on curbing the increase. The prevalence of these TTIs in Nigeria in the year 2015 of HIV, HBV and HCV was 6.2%, 10% and 1.5%respectively whereas the SYPHILLIS antibody prevalence was 0% [8]. In another study conducted in Ethiopia, the prevalence for HBsAg, HCV, HIV, & Syphilis antibodies were 10. 9 %, 0.4 %, 0.1 % and 0.1 % respectively [9].

In western Kenya, a study on HIV, HBV, HCV, and syphilis reported the disaggregated seroprevalences of 2.4%, 3.1%, 2.3%, and 1%, respectively among blood donors of the RBTC at Kisumu [10]. A similar TTIs study reported an overall seroprevalence of 9.4%, and for HIV was 1.15%, HBV 3.46%, HCV 3.21% and syphilis 1.56% in three counties in western Kenya – specifically Kisumu, Homabay and Siaya [11].

Voluntary donors are those who donate willingly with no any intention as to who the blood unit will help, they are not coerced but present themselves to blood donation sites, whereas family replacement donors are the ones who at a given time and situation present themselves because either one of their relatives or next of kin or friend needs blood. The FRD is said to be having a high risk of the TTIs transmission [12]. From the study conducted by Kimani et al. [12], in the year 2011, the findings showed specific TTIs prevalence of HIV, hepatitis B, and Syphilis as 1.7%, 4%, and 0.7%, respectively. Though that is within the KNBTS TTIs prevalence, they are different from what the general population is like.

The map below shows some of the KNBTS head office and its satellites in the country.

From the geographical point of view, some TTIs are distributed along some regional lines thus propelling those regions to concentrate on the thorough screening of donors during selection as well as during sample testing. In most cases, the low-risk group is usually the best target depending on the understanding of the vulnerability they are prone to, as well as the likelihood of them having reduced chances of being contaminated with TTIs pathogens.

2.2 **Transmission Mode.**

2.2.1 Human Immunodeficiency Virus (HIV)

The risk of contracting the HIV virus, which causes AIDS, has been attributed to various behaviors and characters within the population. These range from sexual intercourse between male and female with suspected cases, injecting drug abuse, homosexual among others. The virus transmission is via anybody fluid from a positive person who poses the risk. This can also be through blood transfusion and other infusions. The understanding of the virus is key in the medical fraternity in targeting the mediums involved and their biological genetical make-ups.

HIV is a Ribonucleic acid (RNA) virus that uses the enzyme reverse transcriptase to produce DNA from the RNA template, thus it is classified as a retrovirus. The viral DNA intermediate can become incorporated into the host cell's DNA structure leading to chronic infection of the cell in a form that is undetectable to the immune system. The first case was reported in 1981 when cases of 'Pneumocystis Carinii Pneumoniae (PCP)' in homosexual men in California, USA were described. One month later, 26 cases of unusually aggressive Kaposi's sarcoma in homosexual men, some of whom also had PCP were reported in New York United States of America (Gordon C.G. *et-al*, 2001).

By the end of 1982, it was clear that an outbreak of a new acquired immune deficiency syndrome had occurred according to "centers for disease control". In 1884, the transmissible agent was

identified by the international committee on taxonomy of viruses and named it “Human Immunodeficiency virus type 1 (HIV-1)”.

2.2.2 HBV

Hepatitis disease, which leads to the inflammation and necrosis of the liver cells, is caused by among many varieties of the Hepatitis family’s infection. More serious and most common being the hepatitis b virus which is a DNA. It was discovered by Blumberg and Alter [13] in Australia. HBV virus affects all ages of the human population randomly depending on the route of entry and the category they belong. The prevalence of hepatitis is generally high with HBV compared to other family but it is taken to be less serious because it has a vaccine, unlike other hepatitis family. The Hepatitis B virus can be passed from person to person through various modes [14]. The most common ones being getting into contact with blood and other body fluids, which are contaminated, with the virus.

The virus can also be transmitted from mother-to-child (perinatal transmission) in endemic areas; other transmission routes include saliva, menstrual, vaginal and seminal fluids. Both sexual (heterosexual and homosexual) are at risk if one partner is infected with the virus. The statistics generally indicates the reduced number of infection in young compared to the adult.

Globally it's estimated that more than 350 million people are carriers of HBV [15]. This led to the introduction and use of the hepatitis b virus vaccine due to the chronic state the viral disease develops. Mostly the population which develops the chronic state are those who are infected at early stages in life [15]. The distribution of the disease is less than 0.1% in some parts of northern Europe, Australia and Northern America, but it goes high in parts of southern America and

southern Europe up to 5%: the prevalence goes higher to 20% in other regions like Africa, Asia, and Pacific [16].

2.2.3 HCV

Hepatitis C is a viral infection that is caused by the Hepatitis virus that is an RNA virus in the family Flaviviridae. The virus usually infects the liver causing various liver disorders. This includes cancer in the hepatocells called “hepatocellular carcinoma”, some malignant cells called lymphomas. The virus reproduces via replication that takes place in the liver cells through various steps. The particulate matter of the virus is called the virion. It is estimated that each infected cell produces fifty (50) virions (virus particles) daily. The virus also replicates in the peripheral blood mononuclear cells causing immunological disorders, which are common in the chronically infected HCV patients.

The HCV virus is a blood-borne with very low risk of sexual or vertical transmission. Due to this transmission mode, the groups at risk include recipient of blood-products and hemodialysis patients and injectable drug users. The estimated population infected with the virus globally is 71 million people. This causes an annual death of 399,000 persons mostly due to liver cirrhosis and hepatocellular carcinoma [17]. Treatment is by use of anti-retroviral drugs, which cure up-to 95% of infected persons. This reduces the risk of death from liver cancer and cirrhosis. There is no current vaccine for hepatitis C.

The HCV prevalence according to WHO is 2.3% in the Mediterranean and 1.5% in the European Regions. However, it is reduced in other parts of the world to as low as 0.5% -1.0%.
It is estimated that in 2015, there was a new infection of HCV of 1.75 million (globally 23.7 new cases per 100,000*)* according to the lancet pathologist gastro-enterologist department.

2.2.4 Syphilis

This bacterial infection is transmitted through contact with contaminated body fluid. It is sexually transmitted by the bacteria called Treponema Pallidum. It is common in sexually active people, but can also be transmitted through blood transfusion. It causes chancre disease and can extend to causing neurological disorder “neurosyphilis” dismembers the central nervous system.[14]. The WHO estimates that there are about 12 million new cases that occur every year [14].

The severity of this bacterial infection in human beings is of big concern to health workers.
The pathophysiology of the infection due to Treponema Pallidum brings worries as it affects major body systems. This needs to be reduced as much as possible and be eradicated from society. This is made possible by assessing the statistics in terms of the trends and the predisposing factors and ways of stopping it from spreading.

2.3 Models for binary outcome

2.3.1 Logistic Regression.

The logistic regression has been extensively used for studying the association between a binary outcome variable and exposure variables while adjusting for covariates. This method utilizes the logit link to yield odds ratio (OR) estimates for measuring association. The utility of the OR in epidemiological research has been interrogated for many years [18] mostly for cross-sectional studies [19] and prospective studies [20,21]. The OR sufficiently estimates the risk or prevalence ratio (PR) when the outcome is rare in all exposure and confounder categories [21] however it overstates the risk ratios or PRs in non-rare outcomes. While conversion procedures are available for OR to risk ratios, their applicability is not direct when it entails covariates adjustment [22].

2.3.2 Log-Binomial Regression.

Numerous studies have supported the utilization of log-binomial regression as the favourite technique in comparison to logistic regression, for cross-sectional or prospective studies with common binary outcomes [23–26].. This model, just like logistic regression, assumes a binomial distribution of outcome. However, it applies a log link in place of a logit link function ordinarily used logistic regression. The log-binomial regression model coefficients maybe used for direct estimation of PRs in data from cross-sectional studies and risk ratios in prospective studies [27]. Although this model can yield narrower confidence intervals (CIs) given that the smaller estimated standard errors (SEs), convergence problems can occur.

2.3.3 Poisson Regression/Modified Poisson Regression

Poisson regression is also applicable in analysis of data from cross-sectional studies having binary outcomes [23] and produces accurate estimates of the PR and is a favoured alternative to logistic regression, as the PR it provides is easier to interpret and communicate. For binary data, the use of Poisson regression is because the standard generalized linear models (GLM) parameterization of its mean is of the similar form as the log-binomial model [24]. Therefore, the model and the association measure have the similar form like in log-binomial regression but the outcome is assumed to follow a Poisson distribution. Even so, the problem with Poisson regression is that it provides too wide CIs [23] since its errors over-estimates the binomial errors in non-rare outcomes. Therefore, for binary data, the Poisson model produces conservative estimates, that is, the regression model tends to be less likely statistically significant.

To address the aforesaid limitation, Zou [28,29] suggested a modified Poisson regression framework in which the information sandwich estimator is used for getting robust variance estimates to the error misspecification. The Zou's [28] modified Poisson model works just like the

simple Poisson model apart from that to adjust for model heterogeneity, it estimates robust standard errors for the model coefficients and is more conservative. The two models, the Poisson and modified Poisson regression methods for binary data have no need of data modification and are simply executed via the glm function in the R software.

Comparative studies, more so Yelland et al.'s [30] work, found both log-binomial and modified Poisson models to perform well generally considering bias, coverage and type I error. However, modified Poisson regression model, unlike log-binomial, was found not prone to problems of convergence. In analysis of relative risks (RR), Sutcliffe et al. [31] used Poisson regression with robust variance and was functionally appropriate but when log-binomial was applied, it failed to converge.

Reyes-Urueña et al. [32] determined correlates of blood-borne infections using a Poisson regression with robust variance. The reasons Reyes-Urueña and colleagues provided for using Poisson model instead of logistic regression was the high prevalence of infections and that it enables estimation of PRs, as well as with their 95 % CIs. Among the notable TTI prevalence studies is the Hernández-Arriaga et al. [33] that applied modified Poisson regression model and has further motivated this study.

CHAPTER 3

3. METHODOLOGY

3.0 Introduction

In this Chapter, the information on how the objectives of the study were achieved is presented. The Chapter particularly describes the design of the study as well as the setting, the population, sample size calculation and justification, ethical considerations and data management. It also provides information on study variables and the statistical analysis plan and the statistical methods that were employed.

3.1 Study area

The study was carried out at Regional Blood Transfusion Centre (RBTC) in Nairobi, Kenya situated at National Public Health Laboratory Services compound, within Kenyatta national hospital grounds. The RBTC conducts blood drives within Nairobi and its environments. The RBTC collects blood units and samples from voluntary non-remunerated blood donors, makes various blood components, and stores these units in their cold-room then dispatches the same units to the hospitals in Nairobi (both private and public) and its environment. The screening of these samples is done at the KNBTS national testing laboratory.

3.2 Ethical considerations

This research study was presented for review and ethical clearance from Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH-UoN ERC) and approval was given (approval number P881/12/2018) (Appendix A). Additional administrative permission to use the RBTC database was obtained from KNBTS management. This study used previously collected (secondary) data and no participants were engaged at any stage, as such, a waiver for the

necessity to acquire consent from blood donors was sought from the KNH-UoN ERC, as well, as part of ethical clearance. To guarantee the confidentiality of blood donors, the data was anonymized by use of codes for de-identification purposes. De-identification ensured the names or any blood donors identifiers are not collected and involved in the data analysis. The information obtained from the study was kept confidential and only intended for the research purpose.

3.3 Scope of the study

The main scope was to provide a reference basis for determining the real reasonable status of the TTI seroprevalence. This was of help in interpreting the results reliably for informing purposes. The target was records of TTIs screened results of donors who voluntarily donated blood between the July 2017 and June 2018 and whose results were entered in the available result registers that are stored within the Kenya National Blood Transfusion Service Nairobi Region. This made a monthly trend for 12months. (Annual trend).

3.4 Assumption of study

Since this is a retrospective study, the data was accessed at the KNBTS national office, the assumption was that the data was of high integrity and that the KNBTS staff co-operated to the success of the study. This was by aiding in the data access from the database (retrieval of donor information from registers and results registers). The data varied in terms of TTIs positivity in relation to various collection/donation points. The description also varied in relation to time since donors and sites are different. The time series was of interest, as their assessment aided in describing the behaviour.

3.5 Study design and population

The study design was a retrospective cross-sectional involving getting data from records of adult donors who had consented and donated blood at the RBTC Nairobi.

The sample size that was used was calculated from a formula for the estimation sample size of a single population proportion [34].

$$Sample\ size = \frac{{Z_{1-\alpha/2}}^2\ P(1-P)}{d^2}$$

Where $Z_{1-\alpha/2}$ = 1.96, the standard normal variate at 5% type 1 error (p<0.05). P is 9.4% [11] and is the expected proportion in population-based on previous studies and d is the margin of error.

$$Sample\ size = 827 = \frac{1.96^2 * 0.094(1-0.094)}{0.02^2}$$

Sero-epidemiological studies in Kisumu Regional Blood Transfusion Centre reported HIV seroprevalence of 2.4%, HBV of 3.1%, HCV at 2.3%, and syphilis at 1% [10] with a sample size of 2046. Similarly, another sero-study in western Kenya, in Kisumu and Siaya counties, found the overall TTIs seroprevalence of 9.4%, HIV 1.15%, HBV 3.46%, HCV 3.21% and 1.56% for syphilis [11] working with a sample size of 1215 voluntary.

In any case, the overall TTIs seroprevalence of 9.4% is used as in Onyango et al. [11], there would still be concerns with power and point prevalence when generalized to the entire blood donor population. So for greater power of the analysis and determination of prevalence of the infections, all (n = 17,193) blood donors' records were reviewed at Regional Blood Transfusion Centre at Nairobi from July 2017 to June 2018 since this study was assessing period reports with four TTIs, a census-type of sampling was adopted to avoid power loss (e.g., Kimani et al. [12]).

3.6 Study variables

The dependent variables of this study were HIV, HBV, HCV and Syphilis test result, while the independent variables in this study included age, gender, locality, and occupation, type of donor (first/repeat), education level and marital status. All these were assessed to find on the attributes

of each specific infection prevalence. The variables, which have more than two levels, were categorized to include all possible combinations and to have their impact felt.

3.7 Inclusion and exclusion criteria

The data was collected from blood donors who meet the laid down qualification for a suitable blood donor as per the Kenya national blood transfusion guidelines. The only data that was used w that of a donor who had all his/her fields in the register updated.

Inclusion criteria:

a. Only those donors within the age bracket of (16 to 65years) among others prescribed variables.
b. Only medically fit as assessed by the selection criteria
c. Only those donors with weight above 50 kilograms
d. Only those donors who had finished three months since their last donation period

Exclusion criteria:

Exclusion criteria were that all those donors who had not met the qualification criteria of becoming a suitable blood donor. Also excluded were all blood donors with some fields in the register incomplete.

a. The under 16 years were not accepted
b. Pregnant and breastfeeding females were not accepted
c. Those above 65 years were excluded
d. Records of medically ill donors with known history were excluded

3.8 Data source and management

Information on the data intended for analysis was from two areas. The first one being the testing laboratory registers which had the prerequisite TTIs prevalence as per their management. While the second one was from the clinical (donor clinic registers) area which has the demographic factors that were aiding in coming up with final analysis and conclusions. This was then analyzed by the use of a package of R software with relevant coding.

The output from the statistical package used was assessed and the significance of parameters in relation to the p-value of <0.05 taken as significant. The results were concluded as per the outcome and shared with relevant authorities as per ethical requirements of each independent variables and find their effects on the dependent variable. This information is to be then interpreted using the relevant model (general linear mixed model). Time series analysis was employed to show the behaviour and projections at various time points. The correlational association between variables were compared using chi-square. Then a specific variable was discussed and its influence on the trend impact clarified. This was again compared with the specific TTIs that are affected due to a single variable or multiple infections.

3.9 Data Analysis and presentations

The data were analyzed using the R Core Team [19]. The information on 17,193 blood donors were obtained from the RBTC database at Nairobi and the categorical variables that include gender, age, location, occupation and donor type described as frequencies and as percentages (proportions) as well as the prevalence distribution, that is, the percentages of blood donors who test positive for HIV, HBV, HCV and syphilis (Table 1).

The second step entailed statistical analysis using GLM, with Poisson regression and log-link function with a robust variance. The p-values were calculated at < 0.05 and adjusted PRs did at 95% confidence intervals. Bivariate and multivariate analyses with comparisons by gender, age, location, occupation and donor type to demonstrate which category has a lower (or higher) infection of HIV, HBV, HCV and syphilis and what significance levels (Table 2, 3, 4 and 5). Poisson regression, by definition, is specified by the use of the generalized linear model with the following notation:

$$g(\mu_i) = \eta_i = \beta_0 + \beta_1 x_1 + \cdots + \beta_2 x_2 = x'\beta$$

Where g is the canonical link function and $g(\mu_i) = \eta_i$ is the mean response. The canonical link function for μ_i is the logarithm, which implies that the exponential function has to be applied to the linear model to revert to the original scale.

$$y_i \sim Poisson\ (\mu_i)$$

$$\log(\mu_i) = \beta_0 + \beta_i x_i$$

$$\mathrm{E}[y_i] = \exp(\beta_0 + \beta_i x_i)$$

Time trends were developed to demonstrate the changes in the prevalence of TTIs and presented as graphs. A time series model of the autoregressive moving-average process was developed to detect changes in the prevalence of HIV, HBV, HCV, and syphilis using data collected between June 2017 and June 2018 (Table 8 and 9) expressed in general terms as:

$$\hat{y}_t = \mu + \rho * \sum_{i}^{p} y_{t-1} + \theta * \sum_{i}^{q} \varepsilon_{t-1} + \varepsilon_t$$

Where $\hat{y}_t$ is the outcome in question at time t (months), ρ is the autocorrelation parameter and θ is the moving average parameter while ε_t is white noise $\varepsilon_t \sim i.i.d.N(0, \sigma^2)$

Declining (or increasing or stable) trends in HIV, HBV, HCV, and syphilis risk in RBTC at Nairobi established using time series model.

Additionally, the Wald chi-square test was used to test for significance of specific predictor variables. Whether they add some impact to the model. This test can be used for many models including those with a binary or continuous outcome.

3.10 Result dissemination

At the end of the study period and analysis of the data, the outcome is to be disseminated to relevant authorities who are directly or indirectly involved with the source and control of the data.

CHAPTER FOUR

4. RESULTS

4.1 The overall and disaggregated prevalence of transfusion transmissible infections

In a period of 12 months (July 2017 to June 2018), a total of 17,193, asymptomatic blood donors were screened at RBTC, Nairobi. The majority of the blood donors were males (55.8%). Most of the study participants were young and were in the age category 16–20 (29.1%) followed closely by category 21–25 (28.1%). The mean age is 27.62 ±0.158 (age range 16 to 65 years).

Only 515 (3.0%) blood donors were seropositive for at least one TTI. The disaggregated prevalence of TTI markers were: HIV, 0.49%; HBV, 1.29%; HCV, 0.61%; Syphilis, 0.65%. The data for the specific TTI markers and the prevalence distribution by sociodemographic characteristics for all the blood donors are illustrated in Table 1.

Table 1: Prevalence distribution of transfusion transmissible infections by sociodemographic variables among blood donors of RBTC at Nairobi, July 2017 to June 2018.

Variable	HIV		HBV		HCV		Syphilis	
	R No (%)	NR No (%)	R No (%)	NR No (%)	R No (%)	NR No (%)	R No (%)	NR No (%)
Overall prevalence	85 (0.49)	17108 (99.51)	222 (1.29)	16971 (98.71)	105 (0.61)	17088 (99.39)	112 (0.65)	17081 (99.35)
Gender								
Female	37 (0.22)	7559 (43.97)	83 (0.48)	9458 (55.01)	40 (0.23)	7556 (43.95)	41 (0.24)	7555 (43.94)
Male	48 (0.28)	9549 (55.54)	139 (0.81)	7513 (43.7)	65 (0.38)	9532 (55.44)	71 (0.41)	9526 (55.41)
Age in years								
16–20	9 (0.05)	4987 (29.01)	19 (0.11)	4977 (28.95)	14 (0.08)	4982 (28.98)	13 (0.08)	4983 (28.98)
21–25	17 (0.1)	4816 (28.01)	51 (0.3)	4782 (27.81)	31 (0.18)	4802 (27.93)	28 (0.16)	4805 (27.95)
26–30	7 (0.04)	1372 (7.98)	19 (0.11)	1360 (7.91)	9 (0.05)	1370 (7.97)	12 (0.07)	1367 (7.95)
31–35	13 (0.08)	2057 (11.96)	35 (0.2)	2035 (11.84)	9 (0.05)	2061 (11.99)	13 (0.08)	2057 (11.96)
36–40	11 (0.06)	1103 (6.42)	22 (0.13)	1092 (6.35)	12 (0.07)	1102 (6.41)	13 (0.08)	1101 (6.4)
41–45	16 (0.09)	1583 (9.21)	31 (0.18)	1568 (9.12)	16 (0.09)	1583 (9.21)	20 (0.12)	1579 (9.18)
45+	12 (0.07)	1190 (6.92)	45 (0.26)	1157 (6.73)	14 (0.08)	1188 (6.91)	13 (0.08)	1189 (6.92)
Location								
College	16 (0.09)	3661 (21.29)	42 (0.24)	3636 (21.15)	24 (0.14)	3654 (21.25)	24 (0.14)	3654 (21.25)
Rural	13 (0.08)	1237 (7.19)	24 (0.14)	1226 (7.13)	16 (0.09)	1234 (7.18)	8 (0.05)	1242 (7.22)
School	8 (0.05)	4849 (28.2)	19 (0.11)	4838 (28.14)	11 (0.06)	4846 (28.19)	11 (0.06)	4846 (28.19)
Slum	1 (0.01)	327 (1.9)	5 (0.03)	323 (1.88)	3 (0.02)	325 (1.89)	1 (0.01)	327 (1.9)
Urban	47 (0.27)	7031 (40.89)	132 (0.77)	6947 (40.41)	51 (0.3)	7028 (40.88)	68 (0.4)	7011 (40.78)
Occupation								
Employed	31 (0.18)	4793 (27.88)	77 (0.45)	4747 (27.61)	40 (0.23)	4784 (27.83)	40 (0.23)	4784 (27.83)
Business	11 (0.06)	1811 (10.53)	32 (0.19)	1790 (10.41)	12 (0.07)	1810 (10.53)	19 (0.11)	1803 (10.49)
Student	24 (0.14)	8553 (49.75)	61 (0.35)	8516 (49.53)	35 (0.2)	8542 (49.68)	36 (0.21)	8541 (49.68)
Unemployed	19 (0.11)	1950 (11.34)	52 (0.3)	1917 (11.15)	18 (0.1)	1951 (11.35)	17 (0.1)	1952 (11.35)
Donor Type								
1=First-time	58 (0.34)	8595 (49.99)	149 (0.87)	8504 (49.46)	66 (0.38)	8587 (49.94)	70 (0.41)	8583 (49.92)
2=Repeat	27 (0.16)	8513 (49.51)	73 (0.42)	8467 (49.25)	39 (0.23)	8501 (49.44)	42 (0.24)	8498 (49.43)

The proportions of blood donors who were seropositive for HBV, syphilis, HCV, and HIV TTIs were 42.4% (222/515), 21.4% (112/515), 20.0% (105/515), and 16.2% (85/515), respectively

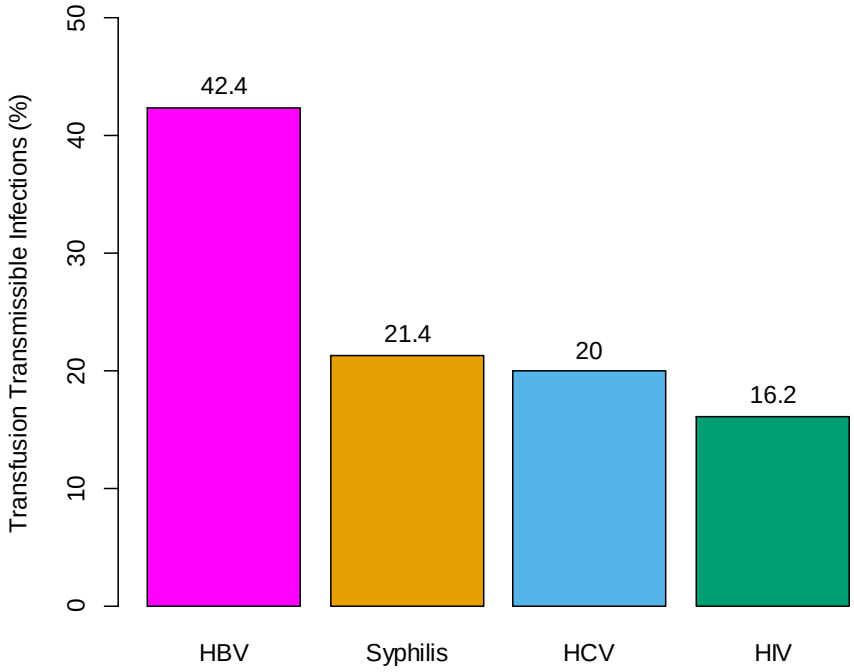

Figure 1: Percentages of transfusion transmissible infections among seropositive

On the prevalence of co-infections in this study, 9 (0.052%) of all the blood donors or 1.75% of the infected blood donors were co-infected with two TTIs. Out of these most of them were attributed to both HIV-HCV and HIV-Syphilis, each at 33.3%. One (11.1%) blood donor was co-infected with HIV-HBV, HBV-HCV and HBV-Syphilis were 11.1% each case (Table 2). There were neither HCV-Syphilis nor more than two pathogenic agents involved as HIV-HBV-HCV, HBV-HCV-Syphilis, HCV-Syphilis-HIV, and HIV-HBV-HCV-Syphilis coinfections.

Table 2: Prevalence of co-infections of transfusion transmissible infections among blood donors of RBTC at Nairobi, July 2017 to June 2018

Co-infections	Frequency	Percentage
HIV-HBV	1	11.1
HIV-HCV	3	33.3
HIV-Syphilis	3	33.3
HBV-HCV	1	11.1
HBV-Syphilis	1	11.1
Total	9	100

4.2 The effect of sociodemographic characteristics of the seropositive blood donors.

Majority of those seropositive (n=515) were males consisting of 61.7% (318) and 24.3% (125) were in the 21–25 age category. Among the seropositive, the mean age was 33.46 years, the median age was 34 and the ages ranged from 16–64 years. The greatest proportion of the seropositive donors were first-time donors were 65.8% (339), were mostly urban residents (56.7%), and were employed (35.5%). The descriptive sociodemographic characteristics of the seropositive blood donors are shown in Table 3.

Table 3: Sociodemographic characteristics of the RBTC at Nairobi blood donors who tested positive for transfusion transmissible infections between July 2017 and June 2018.

Variable	n = 515	%
Gender		
Female	197	38.3
Male	318	61.7
Age in years		
16–20	55	10.7
21–25	125	24.3
26–30	46	8.9
31–35	68	13.2
36–40	57	11.1
41–45	83	16.1
45+	81	15.7
Location		

College	104	20.2
Rural	60	11.7
School	49	9.5
Slum	10	1.9
Urban	292	56.7
Occupation		
Employed	183	35.5
Business	72	14.0
Student	154	20.9
Unemployed	106	20.6
Donor Type		
1=First-time	339	65.8
2=Repeat	176	34.2

4.2.1 Factors associated with HIV seropositivity

From the bivariate regression model, gender, age, occupation, location, and donor type were not associated with seropositivity of HIV since the prevalence was not significantly greater (or less) than the reference groups ($p > 0.05$) (Table 4).

The results of the multivariate analysis showed that the males had a prevalence of HIV that was 20% lower than in females but not statistically significant ($p = 0.283$). A unit increase in age of blood donors predicted no increase in the prevalence of HIV ($p = 0.858$). On occupation, students had a prevalence of HIV that was almost 100% lower than that of people in business ($p<0.001$). The blood donors from rural, slum and urban areas had a prevalence of HIV that was almost 100% lower than that of blood donors in college ($p<0.001$). Furthermore, school blood donors and repeat donors had a prevalence of HIV that was 9% greater and 9% lower than the college and first-time donors but not statistically significant ($p=0.833$ and $p=0.661$) respectively (Table 5).

4.2.2 Factors associated with HBV seropositivity

Bivariate analysis of HBV showed that none of the variables considered were statistically significant ($p > 0.05$) (Table 4). However, as shown in Table 5, multivariate analysis demonstrated that student blood donors had a prevalence of HBV that was almost 100% lower than that of people in business ($p<0.001$). Rural, slum and urban blood donors had a prevalence of HBV that was almost 100% lower than that of college blood donors.

4.2.3 Factors associated with HCV seropositivity

HCV bivariate analyses were not statistically significant. The multivariate analysis revealed that student blood donors had a prevalence of HCV that was almost 100% lower than that of people in business ($p<0.001$). Rural, slum, and urban blood donors had a prevalence of HCV that was about 100% ($p<0.001$) lower than that of college blood donors (Table 5) similar to the previous analyses from the HBV model.

4.2.4 Factors associated with syphilis seropositivity

Multivariate regression model demonstrated that student blood donors had a prevalence of syphilis that was 3.7 times greater than that of people in business ($p<0.001$). Moreover, urban blood donors had a prevalence of Syphillis that was 5.15 times greater than that of college blood donors, and all statistically significant ($p<0.001$) (Table 5).

Table 4: Bivariate analysis of the transfusion transmissible infections based on the sociodemographic characteristics of RBTC at Nairobi blood donors who tested positive for infections between July 2017 and June 2018.

Variable	**P-values (n = 515)**			
	HIV (n = 85)	**HBV (n = 222)**	**HCV (n = 105)**	**Syphilis (n = 112)**
Gender: Male	0.2723	0.726	0.9704	0.6863
Age (years)	0.6687	0.0983	0.2206	0.378

Age group (years)				
16–20	Comparison group			
21–25	0.6256	0.43811	0.92545	0.8550
26–30	0.8753	0.48452	0.48594	0.7761
31–35	0.6929	0.06968	0.09091	0.5418
36–40	0.6858	0.65702	0.58210	0.9172
41–45	0.6652	0.73853	0.38802	0.9506
45+	0.8060	0.02403	0.24808	0.2703
Occupation				
Business	Comparison group			
Employed	0.7486	0.7285	0.3633	0.43519
Student	0.9527	0.4855	0.3053	0.62080
Unemployed	0.6449	0.5491	0.9562	0.09345
Location				
College	Comparison group			
Rural	0.3087	0.9614	0.6044	0.1432
School	0.8810	0.8503	0.9313	0.9313
Slum	0.6590	0.5274	0.6105	0.3864
Urban	0.8651	0.4051	0.2046	0.9652
Donor type=Repeat	0.6096	0.5932	0.4705	0.3993

Table 5: Multivariate analysis of the transfusion transmissible infections based on the sociodemographic characteristics of RBTC at Nairobi blood donors who tested positive for infections between July 2017 and June 2018.

Variable	**Prevalence ratio (95% CI) and p-values (n = 515)**			
	HIV (n = 85)	**HBV (n = 222)**	**HCV (n = 105)**	**Syphilis (n = 112)**
Gender: Male	0.8 (0.54, 1.2) 0.283	1.03 (0.84, 1.27) 0.764	1.01 (0.71, 1.44) 0.938	1.09 (0.76, 1.55) 0.638
Age (years)	1 (0.98, 1.03) 0.858	1.01 (1, 1.02) 0.137	0.98 (0.96, 1.01) 0.221	0.99 (0.97, 1.02) 0.562
Occupation				
Business	Comparison group			
Employed	1.13 (0.6, 2.14) 0.706	0.95 (0.69, 1.3) 0.735	1.28 (0.71, 2.31) 0.405	0.83 (0.51, 1.33) 0.438
Student	0.0000037 (0, 0) * < 0.001	0.0000015 (0, 0) * < 0.001	0.0000035 (0, 0) * < 0.001	3.7 (2.24, 6.12) < 0.001
Unemployed	1.18 (0.59, 2.36) 0.639	1.12 (0.81, 1.56) 0.479	0.91 (0.47, 1.74) 0.766	0.64 (0.35, 1.17) 0.147

Location				
College	Comparison group			
Rural	0.0000044 (0, 0) * < 0.001	0.0000012 (0, 0) * < 0.001	0.0000051 (0, 0) * < 0.001	3.18 (1.35, 7.49) 0.008
School	1.09 (0.49, 2.44) 0.833	1 (0.65, 1.55) 0.988	0.89 (0.46, 1.73) 0.74	0.95 (0.5, 1.84) 0.887
Slum	0.000002 (0, 0) * < 0.001	0.0000015 (0, 0) * < 0.001	0.0000055 (0, 0) * < 0.001	2.46 (0.35, 17.5) 0.367
Urban	0.0000033 (0, 0) * < 0.001	0.0000014 (0, 0) * < 0.001	0.000003 (0, 0) * < 0.001	5.15 (3.26, 8.13) < 0.001
Donor type: Repeat	0.91 (0.59, 1.39) 0.661	0.95 (0.76, 1.18) 0.63	1.09 (0.76, 1.57) 0.642	1.19 (0.83, 1.7) 0.342

4.3 The trends of the transfusion transmissible infections

Figure 2 shows the prevalence of TTIs from July 2017 to June 2018. The HIV prevalence was 0.75% in July 2017 and increased in the second month (August 2018) registering a 0.98% prevalence. A gradual decline and a considerable decrease were witnessed in January 2018 (the 7th month) with prevalence at 0.14%. This low level was not sustained to the end of the period and regular variations were observed as well; as the last month (June 2018) demonstrated 0.37% prevalence.

These kind of observations in HIV trend were not so different with the rest of the TTIs as very sharp decline and gradual increases were regularly observed for HBV, HCV, and syphilis from July 2017 to June 2018. The observational plots in Figure 2 indicate a severe oscillation period, especially for HBV followed by mild oscillation periods of prevalence for all the TTIs. Subsequently, moderate oscillation periods occurred. In addition, a dramatic elevation in TTI prevalence appeared in April 2018.

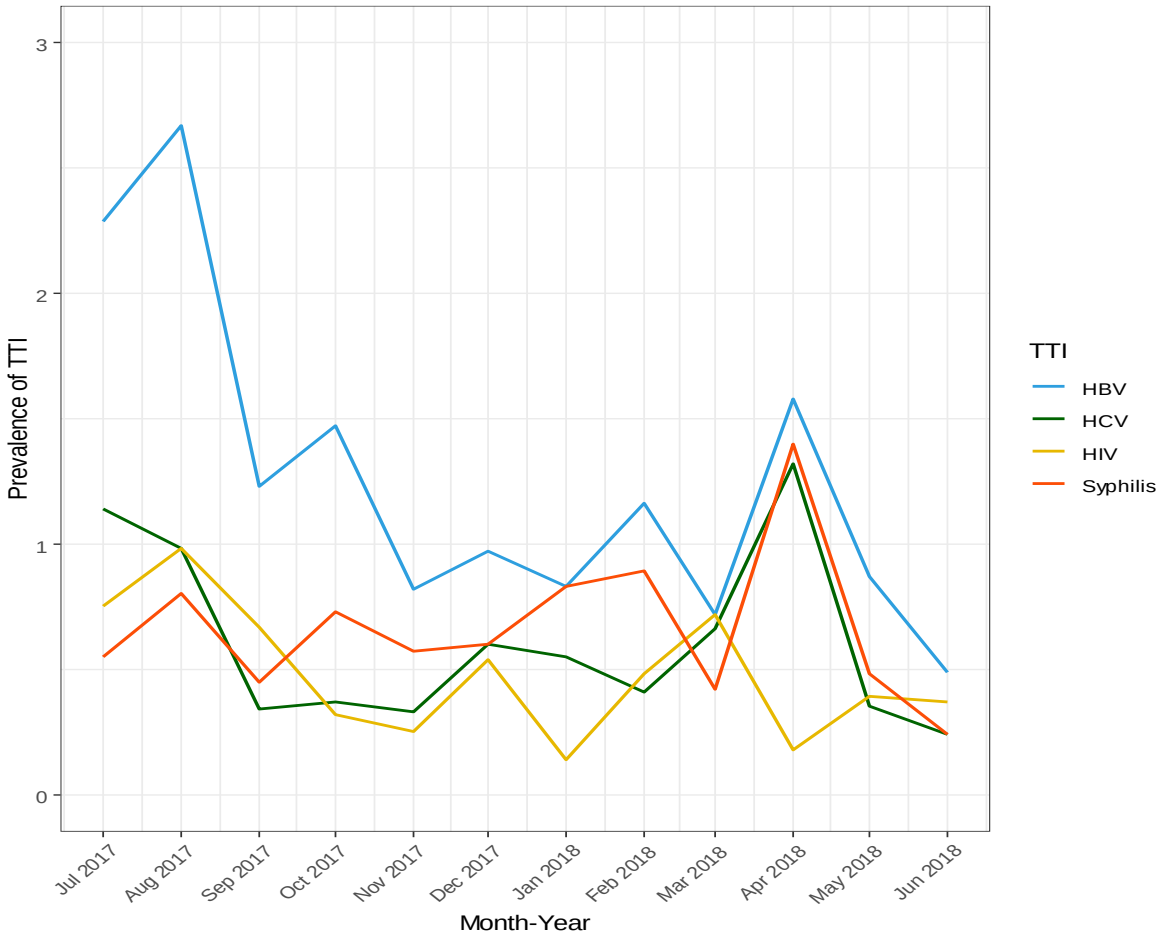

Figure 2: Time series plot of prevalence of transfusion transmissible infections (TTI) RBTC, Nairobi from July 2017 to June 2018.

4.3.1.1 The ACF and PACF plots and model fitting

According to Figures 5–8, the ACF and PACF plots do not demonstrate positive correlation at higher or lower lags but appears to be mostly white noise processes of their corresponding linear relations. This is because they don't exceed the blue marked line depicting the confidence interval of the ACF and PACF. This shows that differencing may not be required to make the series stationary. However, ADF tests show that a differencing of order two, apart from three for HCV data, is required at least from the sense of the statistically significant tests shown in Table 7.

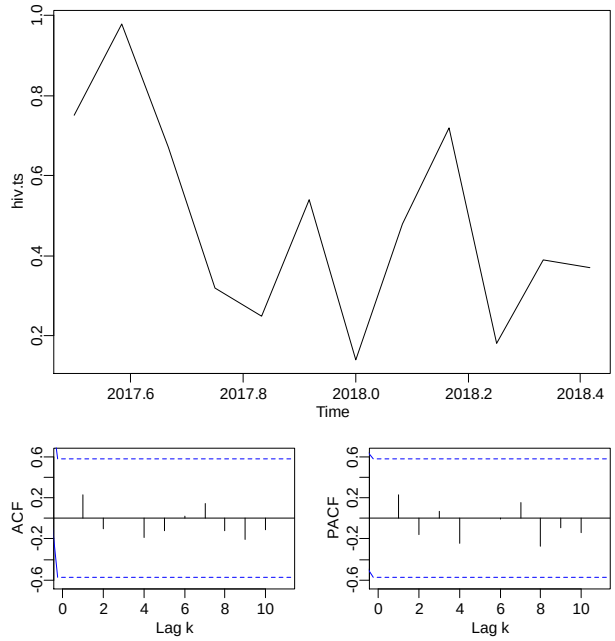

Figure 3: HIV time series, ACF and PACF plot

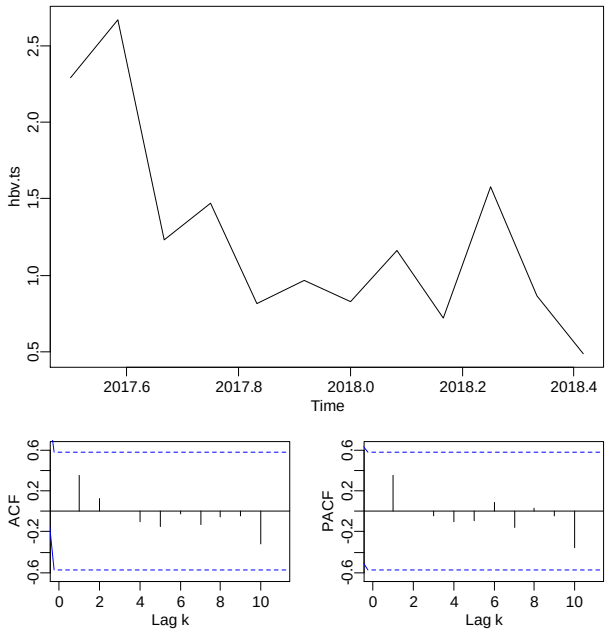

Figure 4: HBV time series, ACF and PACF plot

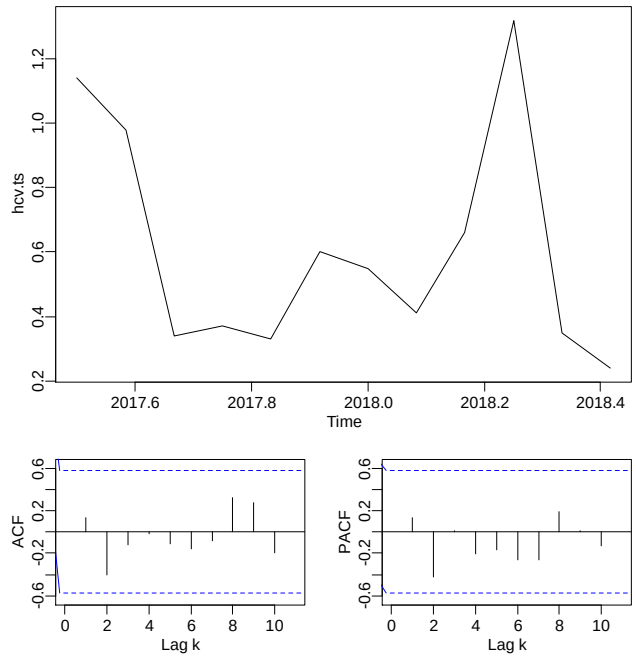

Figure 5: HCV time series, ACF and PACF plot

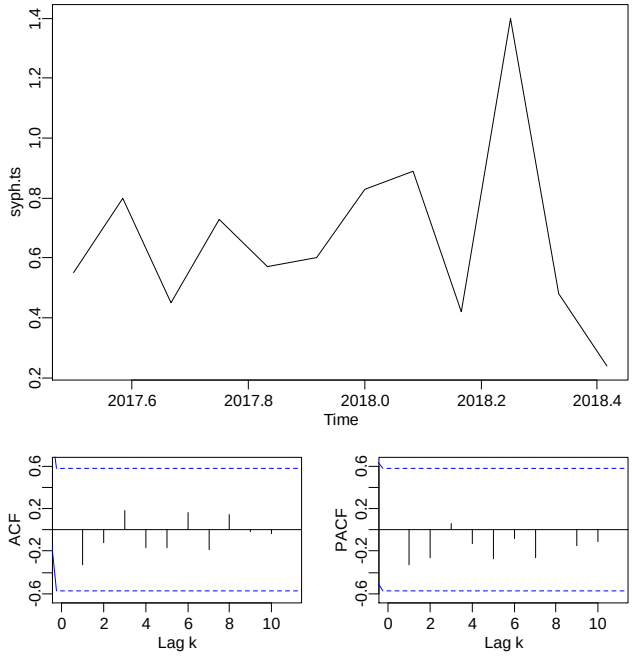

Figure 6: Syphilis time series, ACF and PACF plot

Figure 9 – 12 shows the ACF and PACF for the differenced series. These plots were made guided by Augmented Dickey-Fuller test results (Table 7). Qualitatively, the plots were characterized by lags that cut off. Apparently, the ACFs and PACFs for HIV and HCV don't exceed the confidence intervals same for HBV and Syphilis. The HIV series needed differencing twice, however, the ACF and PACF plots suggest that the series was ARIMA (0,2,0). HBV and syphilis required ARIMA (1,2,1) both due to the cutting off after first lag in both plots for the TTIs. The HCV is simply white noise (differenced thrice as portrayed by ADF in Table 7).

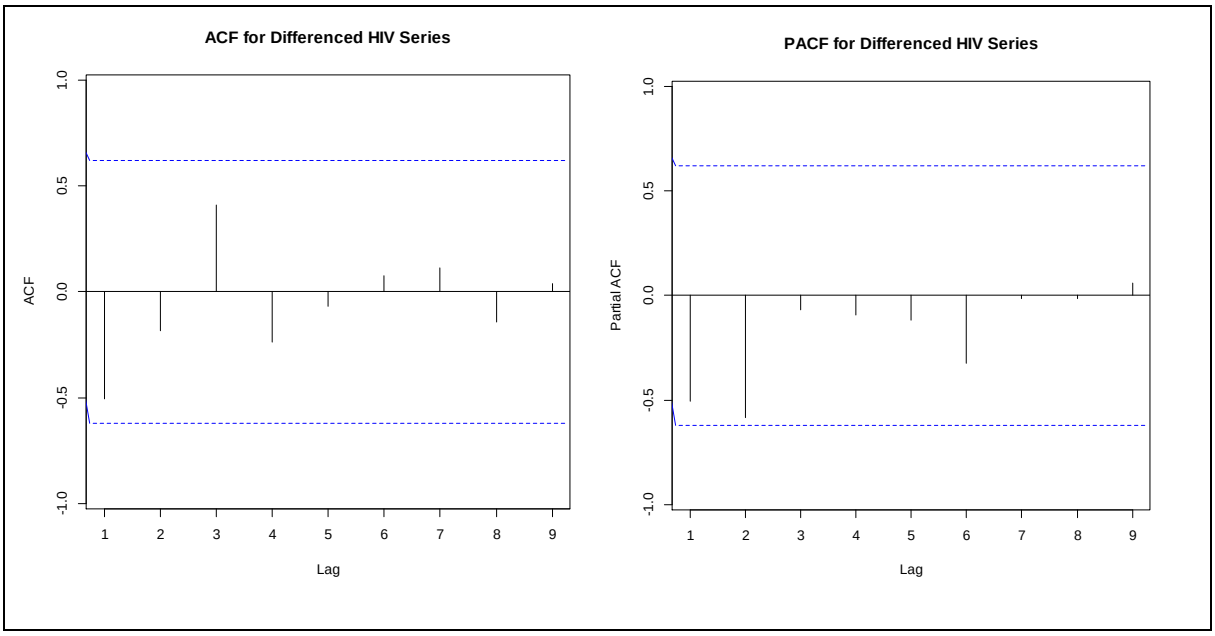

Figure 7: Behaviour of ACF and PACF plots for HIV

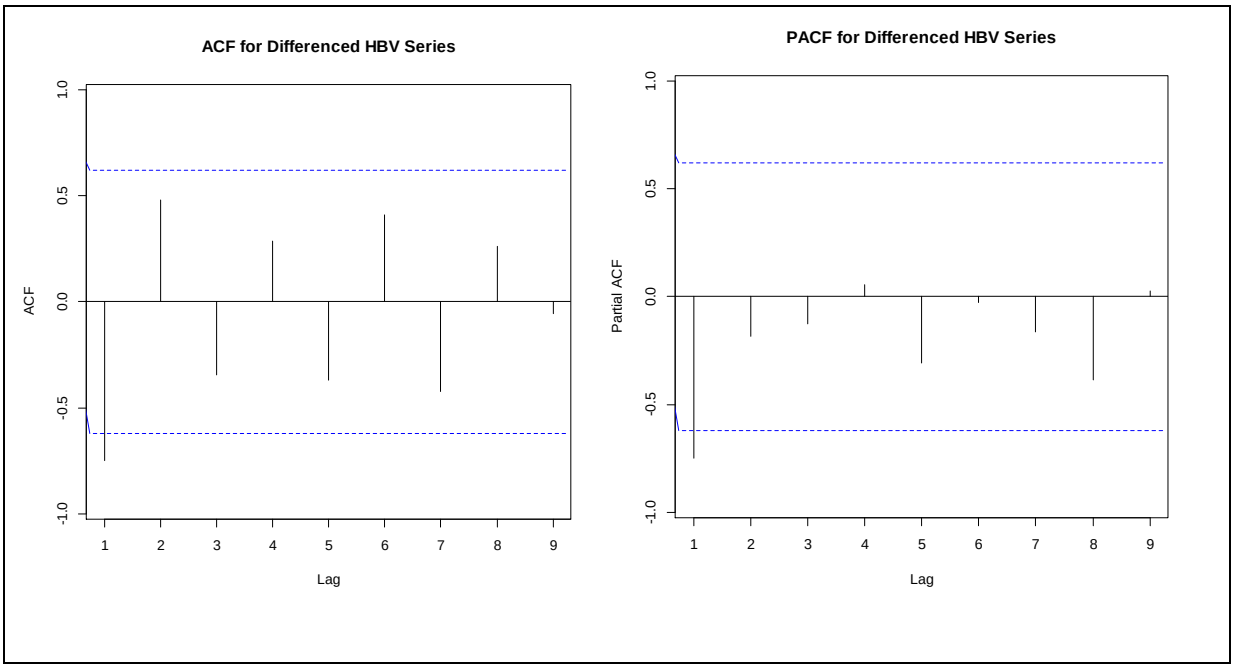

Figure 8: Behaviour of ACF and PACF plots for HBV

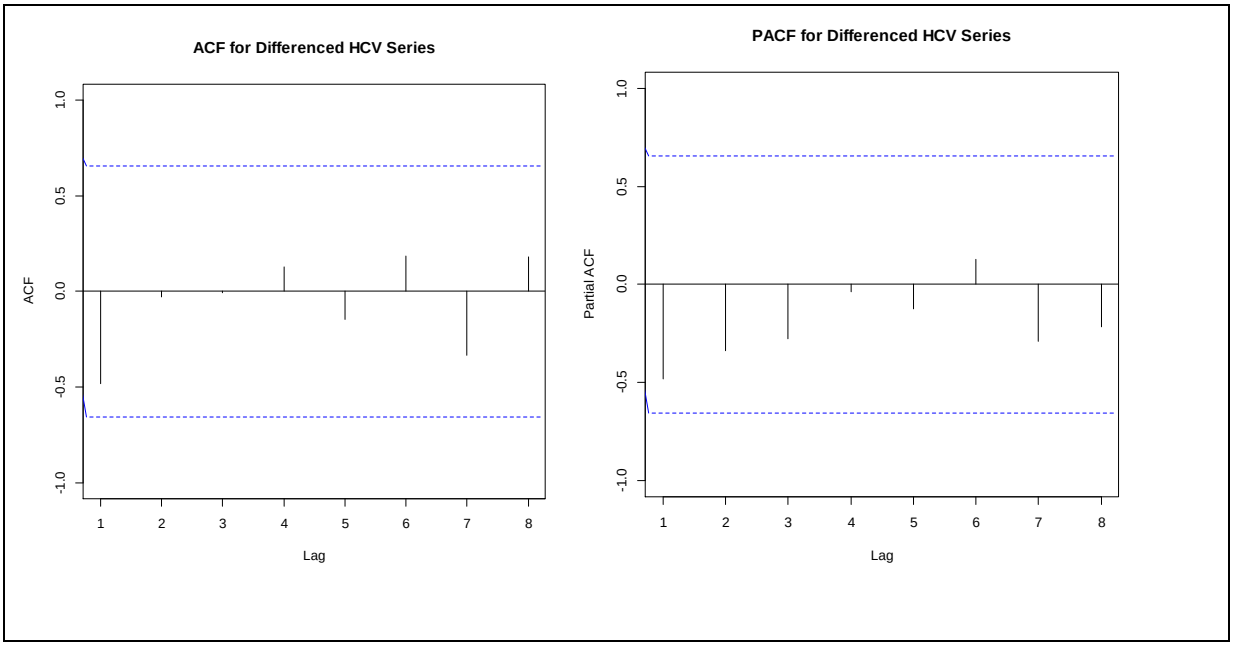

Figure 9: Behaviour of ACF and PACF plots for HCV

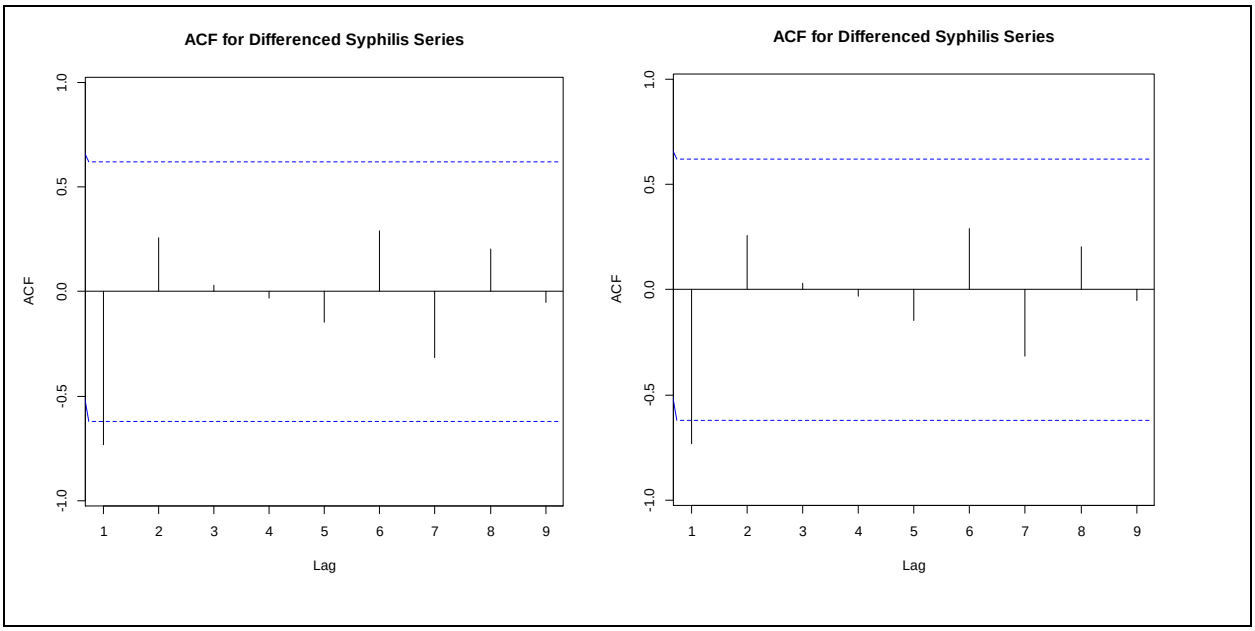

Figure 10: Behaviour of ACF and PACF plots for Syphilis

The TTI models fitted are shown in Table 8. The table below also shows the goodness of fit approaches for decision making, that is, Akaike information criterion (AIC) values and Bayesian information criterion (BIC) values. Even so, the AIC and BIC are considerably large.

The models appear to be good fit pending statistically significant MA co-efficient and low AIC. The p-values for the autoregressive (AR) process is very small and therefore confirms that AR estimate is statistically significant. However, the moving average coefficients were not statistically significant and $p<0.005$.

Table 6: Time series models for transfusion transmissible infections in RBTC, Nairobi blood between July 2017 and June 2018.

HIV							
Models	**Parameter**	**Coefficient**	**Standard Error**	**T-value**	**P-value**	**AIC**	**BIC**
ARIMA(0,2,0)	Constant	0	–	–	–	17.50052	17.8031
HBV							
ARIMA (1,2,1)	AR(1)	-0.80002	0.24358	-3.2845	0.001022	23.83814	24.74589
	MA(1)	-0.31957	0.50808	-0.6290	0.529371		
HCV							
ARIMA (0,3,0)	Constant	0	–	–	–	30.88965	31.08688
Syphilis							
ARIMA (1,2,1)	AR(1)	-0.51442	0.25009 -	-2.0569	0.03969	19.50999	20.41774
	MA(1)	-1.00000	0.51993	- 1.9233	0.05444		

4.3.1.2 Checking for the model with least AIC and BIC – model auto fitting

By use of ARIMA notations, the models illustrated in Table 7 can be respectively expressed as:

HIV: $\hat{y}_t = 0.482500 + y_{t-1} + \varepsilon_t$

HBV: $\hat{y}_{t-1} + \varepsilon_t \sim$ iid WN (0,0.4028)

HCV: $\hat{y}_t = 0.607500 + y_{t-1} + \varepsilon_t$

Syphilis: $\hat{y}_t = 0.663333 + y_{t-1} + \varepsilon_t$; where ε_t are random uncorrelated errors across time.

Table 7 indicates that the auto-fitted model for HBV prevalence is an ARIMA (0, 1, 0) series which as well could be differenced once to be an ARMA (0, 0). These auto-fitted HBV model predicts no change from the current monthly prevalence time point to the subsequent time point, since previous HBV prevalence values would give no information about the future values of prevalence: $\hat{y}_t = y_{t-1} + \varepsilon_t$. Therefore is a random-walk-without-drift model as such. For HBV, the error term is an independent and identically distributed (iid) white noise (WN) process with mean zero and variance σ^2. The fitted model has no constant (or the mean) or simply the mean is zero.

For the HIV, HCV, and syphilis, the next prevalence value in the series is taken as the mean (μ) annual trend in the TTI data and is dependent on the white noise (uncorrelated errors). Table 7 shows that HIV, HCV and syphilis all have an ARIMA (0, 0, 0) series model. The models are a random-walk-with-drift processes, and have a prediction equation taken as: $\hat{y}_t = \mu + y_{t-1} + \varepsilon_t$. Suggesting that the monthly prevalence values are drifting.

Table 7: Auto fitted time series models for transfusion transmissible infections in RBTC, Nairobi blood between July 2017 and June 2018.

HIV							
Models	**Parameter**	**Coefficient**	**Standard Error**	**T-value**	**P-value**	**AIC**	**BIC**
ARIMA(0,0,0)	Constant	0.482500	0.070929	6.8026	<0.00001	4.36712	5.336934
HBV							
ARIMA(0,1,0)	Constant	0	–	–	–	23.21418	23.61208
HCV							
ARIMA (0,0,0)	Constant	0.607500	0.097946	6.2024	<0.00001	12.11303	13.08285
Syphilis							
ARIMA (0,0,0)	Constant	0.663333	0.082835	8.0078	<0.00001	8.091584	9.061397

4.3.1.3 Model Validation

The auto fitted model was evaluated by looking at the ACF and PACF plots for residuals. According to Figure 13, the models were correctly specified given that there were no autocorrelations. The model fitted by auto ARIMA shown in Figure 13 have all their respective coefficients statistically significant (Table 9). The models also have lower AIC and BIC when compared with the models fitted manually (Table 8) and therefore due to parsimony, the models fitted manually can be rejected and fail to reject the auto fitted model

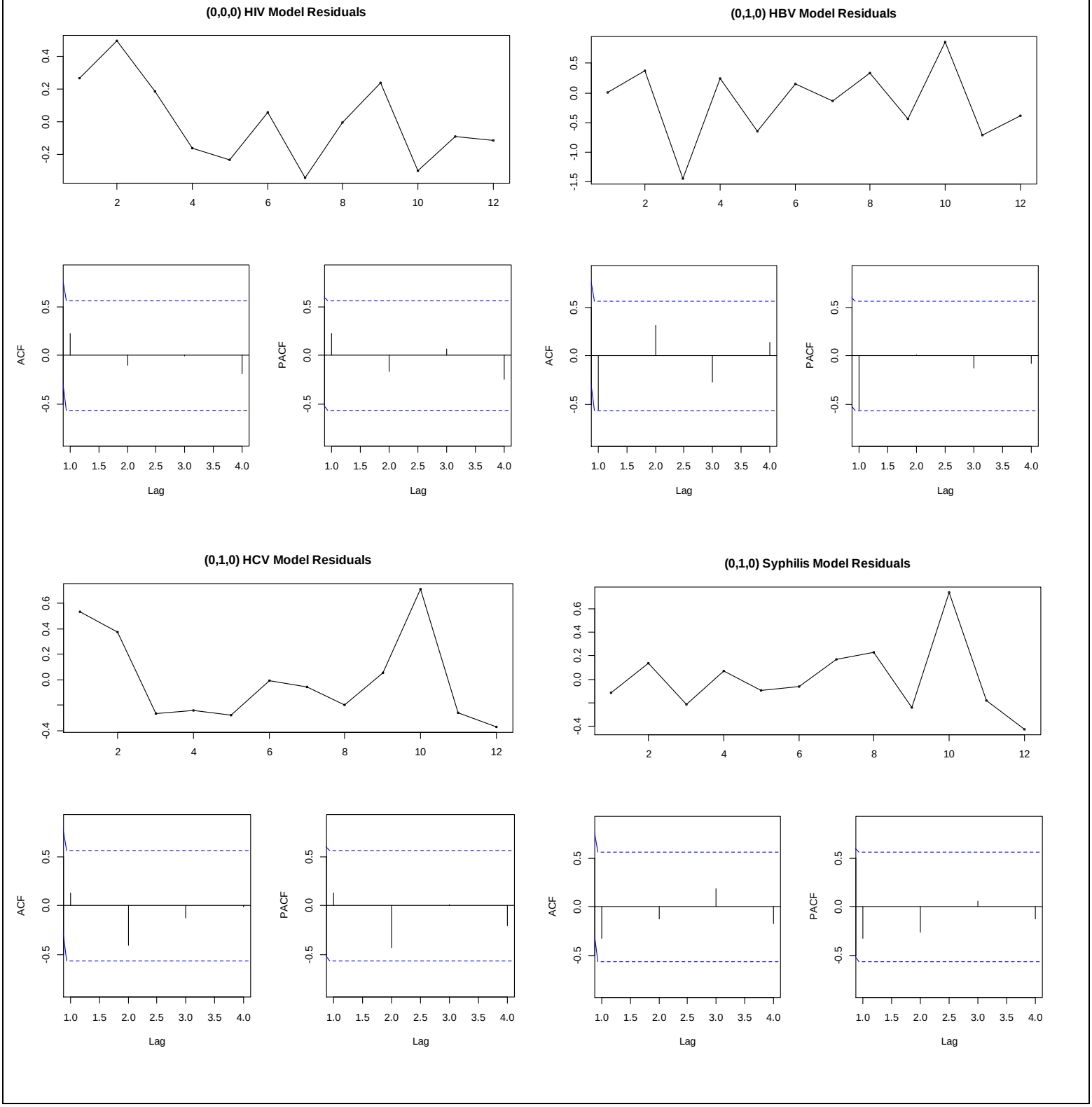

Figure 11: Evaluation of ACF and PACF plots for model residuals for TTIs

CHAPTER FIVE

5 DISCUSSION AND CONCLUSIONS

5.1 Discussions

The objective of this study was to determine the prevalence of, trends of and sociodemographic characteristics associated with transfusion transmissible infections among blood donors from Regional Blood Transfusion Centre (RBTC) at Nairobi between the July 2017 and June 2018. Out of 17,193 blood donors, 515 (3.0%) were seropositive for at least one TTI. The TTI specific prevalence was 0.49% for HIV, 1.29% for HBV (the highest prevalence), 0.61% for HCV and syphilis, 0.65%. Previous seroprevalence surveys have reported 2.6% among voluntary blood donors in Kenya [36], 9.4% in three counties of western Kenya [37]. The TTI-type prevalence found in this study is also quite comparable to values from studies in Kenya [10,36,37] and in Nigeria, West Africa, a prevalence of 0.9% [38].

Of the blood donors TTI seropositive, 61.7% were males. It appears males were disproportionately affected as similar disparity has been reported in Kenya [37], however, it's also possible that this could be attributed to their access to blood transfusion services. Importantly, previous studies have indicated the high seropositivity among females [39]. Equally, a higher proportion (65.8% of all the 515 seropositive blood donors) of TTI seropositivity was among first-time donors compared to repeat donors. This differences could be due to altruistic behaviour of the repeat donors [40].

On the prevalence of TTI co-infections, 9 (0.052%) of all the blood donors or 1.75% of the infected blood donors were co-infected with two TTIs. This prevalence is lower than that reported from an Eritrean retrospective study that found at least 3.6% co-infections with at least one pathogen and 0.1% multiple infections [41] and 2.4% in North Ethiopia [42]. The co-infections could be due to

epidemiological synergism (syndemicity) of the TTI [43,44]. This kind of endemicity has been reported by Shiferaw et al. [45] in Ethiopia and also corroborated by a study in Equatorial Guinea which equally found coinfections of which HBV-syphilis was the most common [46].

This study revealed that students had a prevalence of most of the TTIs that was almost 100% lower than that of people in business ($p<0.001$). Similarly, the blood donors from rural, slum and urban areas had a prevalence of HIV that was almost 100% lower than that of blood donors in college ($p<0.001$). Comparable findings have been reported in Ethiopia [47]. These low prevalence values could be because of Nairobi being a city and therefore most blood donors identify as urban and possibly due variations in the levels of awareness in the categories. This study, therefore, presents an opportunity for the promotion of awareness of blood safety issues.

The prevalence of TTIs was characterized by increase, gradual decline, and severe oscillation and moderate periods, with a dramatic elevation in TTI prevalence happening in April 2018. This trend is not new, a study in Ethiopia showed similar trends [47].

The data presented in this study is a sequence of observations (time series). Given that the inherent characteristics of a time series are the correlation of the sequence of observations, an autoregressive integrated moving average (ARIMA) parametric models employing ACF and PACF were used in model building and auto fitting. Auto fitting of ARIMA achieved parsimony. ARIMA models have been used widely in trend analysis, for instance in malaria studies [48], modeling syphilis incidence [49], and in TTIs [50]. In this study, there was no evidence of seasonality from the autocorrelation analyses but white noise.

The auto-fitted model for HIV, HCV and syphilis are all ARIMA (0, 0, 0) series: The HIV model: $\hat{y}_t = 0.482500 + y_{t-1} + \varepsilon_t$, the HCV:$\hat{y}_t = 0.607500 + y_{t-1} + \varepsilon_t$, and Syphilis:

$\hat{y}_t = 0.663333 + y_{t-1} + \varepsilon_t$. The models show that the mean step size is some non-zero value μ, therefore it is a random-walk-with-drift process, with prediction equation of the form $\hat{y}_t = \mu + y_{t-1}$. It also implies that that the errors are uncorrelated over time. Therefore, the prevalence values are drifting. More succinctly, in these models, the next value in the series is taken as the non-zero mean (μ) annual trend in the TTI data and is dependent on the white noise.

From the auto-fitted model, the HBV model is an ARIMA (0, 1, 0) series, which with differencing once, come to be an ARMA (0, 0), and this is random, uncorrelated, noise. These auto-fitted HBV model simply predicts no change from one prevalence time point (month) to the subsequent time point, as past HBV data gives no information about the values of future prevalence: $\hat{y}_t = y_{t-1} + \varepsilon_t$. More specifically, the HBV model is a random-walk-without-drift model as such it assumes that, for HBV prevalence at the current month, the time series simply takes a random step away from its past reported prevalence value, with steps whose prevalence mean value is zero. Therefore, HBV: $y_{t-1} + \varepsilon_t \sim \text{iid WN}(0, 0.4028)$ is simply an independent and identically distributed (iid) white noise (WN) process with zero means (0) and variance σ^2.

5.2 Limitations

Given that this study was a retrospective (secondary analysis) design, it did not take into account all the correlates of risk associated with these blood pathogens, hence the possibility of introducing bias or residual confounding. The time span was short hence few data points were available for time-domain analysis. The resource required for such study to be a true reflective was huge, thus limited scope area coverage.

5.3 Conclusions

The data from this study shows that the prevalence of TTIs among blood donors at the RBTC, Nairobi between the July 2017 and June 2018 is still considered high. Apart from the effect of other TTIs, the greatest risk to blood safety is HBV as evidenced by the substantial proportion among the seropositive blood donors. The prevalence of TTIs is not constant but alternates between periods of severe spikes and gradual decline. Multivariate analysis showed that students had a prevalence that was almost 100% lower than and 3.7 times greater than that of people in business ($p<0.001$) for each of HIV, HBV, and HCV, and for syphilis respectively. Similarly, rural, slum and urban blood donors had a prevalence of HIV, HBV and HCV that was almost 100% lower than that of blood donors in college ($p<0.001$).

5.4 Future research

The results of this study need to be replicated in large population-based studies. Robust population-based studies would determine the correlates of risk of TTI infections and causality.

Future retrospective studies should involve a longer period of time, possibly five or more years to have a better look into the past and forecast the future. Modeling approaches such as exponential smoothing methods, seasonal auto-regressive integrated moving average, and Prais Winsten Regression methods need to be considered.

5.5 Recommendations

The data from this study supports prioritization of thorough blood donor selection, serological screening and blood supply monitoring at all levels of care in Kenya. Consistent prevention strategies need to be put in place for awareness among Kenyans and targeted sensitization to those disproportionately affected.

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APPENDICES

APPENDIX A: WORK PLAN

TIME ACTIVITY	August/September 2018	October 2018	June 2019	August 2019	October/November 2019
Proposal development					
Proposal presentation					
Data collection					
Data analysis					
Thesis presentation					

APPENDIX B: BUDGET

ITEM	SPECIFICATION	COST
Collection of secondary data.	500*3PAX*5 DAYS	75000
Stationary and printing services	2 RIMS+TONER	10000
ERC FEE	ONCE	2000
Data entry	500*2PAX*8DAYS	8000
Transport	300*4PAX*8DAYS	96000
Miscellaneous		5000
Airtime		5000
Total		47100

APPENDIX C: ETHICAL APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 21 MAY 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Ref: KNH-ERC/A/187

21st May, 2019

Philip Masese Sagini
Reg. No.W62/ 89049/2016
UNITID
College of Health Sciences
University of Nairobi

Dear Philip

RESEARCH PROPOSAL: PREVALENCE DETERMINATION AND TREND ANALYSIS OF MAJOR TRANSFUSION TRANSMISSIBLE INFECTIONS AMONG BLOOD DONORS IN NAIROBI REGIONAL BLOOD TRANSFUSION CENTRE (P881/12/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 21st May 2019 – 20th May 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, UNITID, UoN
Supervisors: Dr. Anne Wang'ombe, Dr.Nelson Onyango

APPENDIX D: KENYA NATIONAL BLOOD TRANSFUSION QUESTIONAIRE.

DONOR QUESTIONARE

Donation Number

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

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 counselling 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 Phlebotomist: ---------- Date: ----------