SAFETY PROFILE AND ANALYSIS OF FIRST-TIME AND REPEAT BLOOD DONORS IN NATIONAL BLOOD TRANSFUSION CENTRE, NAIROBI CITY COUNTY, KENYA

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DECLARATION AND APPROVAL

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Declaration

This thesis is my original work and has never been presented for any academic award in any institution.

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Approval

This thesis is being submitted with our approval as university supervisors

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DEDICATION

I dedicate this work to my wife Rachael Rombo and Tegwemich for their unconditional love, sacrifices, and constant support which have inspired me throughout my academic journey.

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ABSTRACT

Blood safety remains a major challenge in Africa's healthcare systems. The WHO's 2001 regional strategy emphasized strict screening to prevent transfusion-transmitted infections, a major risk in resource-limited settings. Kenya struggles to ensure a safe and sufficient blood supply due to inconsistent donor turnout, limited funding, and varied health risks. This study examined blood safety practices and risk factors at the Nairobi Regional Blood Transfusion Centre using a cross-sectional descriptive design. A total of 369 voluntary donors aged 18–65, both first-time and repeat, were selected through convenience sampling. Data collection involved ELISA and rapid tests for HIV, hepatitis B and C, and syphilis, alongside questionnaires on health habits and demographics. Data were analysed using SPSS version 23, applying chi-square tests and logistic regression. Hepatitis B had the highest prevalence (2.0%), with other infections below 1%. The findings support improved screening technologies and policy development to enhance blood safety in Kenya.

Keywords: Blood safety, blood donors, transfusion-transmitted infections, sub-Saharan Africa.

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LIST OF ABBREVIATIONS AND ACRONYMS

ABO	-	A, B & O Blood group systems
AfSBT	-	African Society for Blood Transfusion
BTS	-	Blood transfusion service
CMV	-	Cytomegalovirus
HBV	-	Hepatitis B virus
HCV	-	Hepatitis C virus
HIV	-	Human Immune-deficiency Virus
HTLVs	-	Human T-cell leukaemia-lymphoma virus
ISO	-	International Organization for Standardization
KNBTS	-	Kenya National Blood Transfusion Services
MoH	-	Ministry of Health
PLHIV	-	People living with HIV
Rh	-	Rhesus
SDRD	-	Specialized Donor recruitment departments
SLMTA	-	Strengthening Laboratory Management Toward Accreditation
TTI	-	Transfusion transmitted infections
WHO	-	World Health Organization
WNV	-	West Nile virus

CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Blood transfusion services are necessary in healthcare because they provide safe and sufficient blood for patients who need it. In Kenya, as in many low- and middle-income countries, blood donor centers rely primarily on voluntary, non-remunerated donations from healthy individuals. So, it is necessary to keep donated blood safe to protect both the donors and the people who receive it Abdella et al., 2020). To maintain this safety, donor centers implement a layered system of safeguards like the use of detailed health history questionnaires, physical examinations, and laboratory testing to screen for transfusion-transmissible infections like HIV, hepatitis B virus, hepatitis C virus, and syphilis because they are the main tools used to improve efforts to stop infectious diseases from spreading through blood transfusion.

In Africa, as Hughes et al. (2021) indicates, the risk of spreading infections is still a big issue, mainly in places like Kenya that lack many resources. Transmitting diseases through unscreened or inadequately screened blood remains a significant threat in public health sector. Because of this risk, Akpan & Njar (2023), state that healthcare systems that are already struggling with limited resources, money and staff must deal with even more challenges. In Kenya, as Candotti et al. (2021) posits, the situation is compounded by consistent screening and follow-up challenges, especially in rural and high-demand urban areas like Nairobi.

The type of donor, whether they are giving blood for the first time or have given before, is a major factor in blood safety. Research by Omaish et al. (2024) reveals that in many low- and middle-income countries like Kenya, approximately 80% of donors are first-time donors of which majority of them may not realize how healthy they are or if they have ever come into contact with TTIs. As a result, there is a higher chance that

infected blood will be given to someone receiving a transfusion. Consequently, since the study aims to examine the occurrence of transfusion-transmitted infections among both first-time and repeat donors, Salah et al. (2025) claim that is ideal to understand these infection trends as doing so will help to improve the safety profile of Kenya's blood supply and guide targeted interventions in donor education and screening.

Equally important in understanding (TTIs) are the socio-demographic characteristics of blood donors. Factors like age, gender, education, occupation, and income level can influence an individual's risk of infection or likelihood of engaging in high-risk behavior. Therefore, this study aims to provide evidence that can guide more effective strategies for recruiting, screening, and retaining low-risk donors by comparing these characteristics between first-time and repeat donors. This supports the second objective of the study: to assess how donor characteristics relate to blood safety.

In addition to infection screening and donor profiling, it is vital to protect the health and well-being of donors as doing so will ensure availability of safe and sustainable blood supply. Blood donation centers must ensure that donors, especially repeat ones are not adversely affected by frequent donations. Health concerns like fatigue or anemia can arise if proper monitoring is not done. Therefore, evaluating the current safety measures and donor care practices is necessary. This aligns with the third objective: to assess the safety and well-being of both first-time and regular donors at the Kenya National Blood Transfusion Centre in Nairobi.

In addition to the above discussed points, systemic challenges also impact blood safety in Kenya. O'Brien et al. (2021) claim that health systems in many low-income countries struggle with limited funding, low public awareness, and weak donor education programs. As a result, these systems often rely on high-risk or one-time donors while failing to build a base of low-risk, voluntary repeat donors. It is thus of

great importance to encourage donations from repeat donors who have been screened and found to be low-risk as this can significantly improve blood safety. In support of this, O'Brien et al. (2023) found that repeat donors generally have a lower TTI prevalence than first-time donors an aspect that make them even more reliable source of safe blood.

1.2 PROBLEM STATEMENT

Blood safety continues to be a major public health issue in Kenya. This is because Kenya depends too much on first-time donors who account for nearly 80% of all blood donations. These donors are more likely to carry TTIs like HIV and hepatitis than repeat donors (WHO, 2020; Mwai et al., 2021). Despite this risk, the Kenya Blood Transfusion and Transplant Service has yet to develop a comprehensive understanding of the health and behavioural differences between first-time and repeat donors. It also lacks sufficient data on how negative donor experiences affect the likelihood of future donations (Muthoni et al., 2022). Oluoch et al. (2021) posits that these knowledge gaps make it difficult to implement targeted recruitment and retention strategies that are intended to build a safe, and consistent donor base. As a result, Kenya continues to fall short of the target set by World Health Organization of achieving a fully voluntary, regular, and non-remunerated blood donation system (WHO, 2016).

1.3 PURPOSE OF STUDY

This study investigates the prevalence of TTIs among first-time and repeat blood donors at the Kenya National Blood Transfusion Service in Nairobi. It also seeks to assess the safety of donated blood and explore the factors that influence individuals' decisions to donate blood.

1.4 OBJECTIVES OF THE STUDY

1.4.1 BROAD OBJECTIVE

To assess the safety and health characteristics of both first-time and repeat blood donors at the National Blood Transfusion Centre in Nairobi.

1.4.2 SPECIFIC OBJECTIVES

1. To examine the occurrence of transfusion-transmitted infections in blood samples from both first-time and repeat blood donors in Nairobi.
2. To analyse the socio-demographic characteristics of first-time and repeat blood donors and how these traits relate to the safety profile of donated blood at the Kenya National Blood Transfusion Centre.
3. To evaluate the safety measures and well-being of first-time and repeat blood donors in Nairobi, Kenya.

1.5 RESEARCH QUESTIONS

This study intended to answer the below stated research questions:

1. What is the socio-demographic characteristics of first-time and repeat blood donors at the Kenya National Blood Transfusion Centre in Nairobi City?
2. What is the prevalence of transfusion-transmissible infections (TTIs) among first-time and repeat blood donors in Nairobi, Kenya?
3. How do the safety profiles and well-being of first-time and repeat blood donors compare at the Kenya National Blood Transfusion Centre in Nairobi City?

1.6 SIGNIFICANCE OF STUDY

This study plays a critical role in supporting the Kenya National Blood Transfusion Service (KNBTS) to achieve its strategic goal of 100% voluntary, non-remunerated blood donations, which is a vital accreditation standard set by the Africa

Society for Blood Transfusion. Currently, about 80% of Kenya's blood donors are first-time donors who present a higher risk of transfusion-transmissible infections (TTIs) like HIV, hepatitis B and C. This overreliance on new donors significantly challenges the ability to maintain a safe, stable, and sustainable blood supply. The study addresses these challenges by providing an in-depth analysis of first-time versus repeat donors' safety profiles and health characteristics at the National Blood Transfusion Centre in Nairobi. Additionally, it explores key socio-demographic factors and the prevalence of TTIs among different donor groups, and offer critical insights into donor behaviors, health risks, and patterns of blood donation.

The findings from this study will support the Kenya National Blood Transfusion Service and health policymakers in designing better strategies for recruiting and retaining low risk donors. Doing so will help to enhance blood safety and lower the rate of transfusion-transmissible infections in the donated blood supply. In addition to that, the research will also help shape more inclusive donor outreach programs by identifying gaps in donor representation across different demographic groups.

Understanding the factors that encourage or discourage people from donating blood will be essential in developing supportive policies that make donors feel appreciated and motivated to return. Besides that, the study results will guide improvements in donor screening, counseling, and selection processes. Strengthening these areas will aid in reducing the likelihood of TTIs entering the national blood supply. In the end, the study intends to offer insights that will help to protect recipients, improve the efficiency of blood transfusion services, and build public confidence in the national blood donation system.

1.7 SCOPE OF STUDY

The study focused on individuals residing within the selected catchment areas and who had somehow donated blood at the Kenya National Blood Transfusion Service centers in Nairobi or participated in outreach blood drives organized by the center. This scope was defined to ensure that the donor population reflected the broader demographics of Nairobi. The study aimed to produce findings that are both reliable and relevant for improving donor services in the region and that is why data was collected from a wide range of voluntary donors within the KNBTS's area of operation.

1.8 STUDY LIMITATION AND DELIMITATIONS

Delimitations

This study was carried out at the National Blood Transfusion Centre in Nairobi City. The research focused on both first-time and repeat donors attending the facility. These population was drawn from a diverse cross-section of individuals with variations in age, occupation, and educational background. Nairobi was selected as the study site due to its high volume of blood donors, convenient accessibility, and the presence of sufficient infrastructure and resources to facilitate thorough and reliable data collection.

Limitations

The study did not include donors from other RBTCs (Kisumu, Mombasa, Nakuru, Embu, and Eldoret) or pilot centers nationwide. As a result, findings may not fully reflect donors' characteristics or safety profiles in other regions. Additionally, logistical constraints limited the ability to conduct longitudinal follow-up on donor return rates, and self-reported data may have introduced bias in health and behavioral responses.

1.9 ASSUMPTIONS OF THE STUDY

The study assumed that the participants were willing to donate blood from an altruistic drive and were not coursed or motivated by other unstated factors, that are not captured and which would make them involuntarily donate blood.

1.10 OPERATIONAL DEFINITIONS OF KEY TERMS

Anaemia: Is a state where the body's physiological demands exceed the available number of red blood cells or their ability to carry oxygen.

Blood Bank: It is a database or record maintained by a blood transfusion centre that stores information on donated blood.

Blood Donation: It is the process giving out blood to be used by other people to manage a health condition.

Blood Donors: They are people that donate their blood to be used by other people who are in need of it.

Blood: It is a fluid that circulates through the veins and arteries and deliver oxygen, nutrients, and other vital components to the body tissues.

National Blood Transfusion Service: This is the body mandated to collect and distribute blood within a country.

Regular donor- are individuals who donate blood consistently over time, often following a routine schedule.

Repeat donors- are individuals who have donated blood more than once, though not necessarily at regular intervals.

S**creening**: It is a medical procedure used to screen blood for infectious diseases such as HIV, Syphilis, Hepatitis B, and Hepatitis C or to determine an individual's blood type.

Voluntary Non-Remunerated Blood Donors: they are blood donor who voluntarily donates blood without expecting any compensation or reward.

CHAPTER TWO: LITERATURE REVIEW

2.1 INTRODUCTION

This chapter provides a critical evaluation of existing literature on transfusion-transmitted infections among blood donors with a particular focus on Nairobi, Kenya. The review looks at recent studies from both the region and around the world to help understand the current situation, spot patterns, and find gaps in what is known. It focuses on how common transfusion-transmitted infections are, the role of donor characteristics, differences between new and regular donors, and the challenges with current testing methods.

2.2 OCCURRENCE OF TTI IN BLOOD DONORS

Transfusion-transmitted infections remain a significant public health concern worldwide especially in low- and middle-income countries. According to Alhazemi (2023), TTIs like Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and syphilis are infections transmitted from donor to recipient via blood transfusion. Even with new screening tools and better education for donors, these infections still endanger the safety of blood transfusion. As Alhazemi (2023) observes, Sub-Saharan Africa, including Kenya, bears a disproportionate burden due to higher disease prevalence and structural limitations like inadequate screening infrastructure and irregular donor recruitment strategies.

TTIs are still preventing Kenya from maintaining a safe and adequate supply of blood. A recent study by Onyango et al. (2024) revealed a persistent prevalence of TTIs among blood donors in Nairobi. These scholars attributed this trend to urban HIV rates, insufficient public health education, and the underreporting of high-risk behaviors by donors. The National AIDS Control Council (2018) reported Nairobi's HIV prevalence at 6.1 a value that is considerably higher than the national average of 4.8%, thereby

increasing the likelihood of HIV-positive donations, particularly during the window period when infections remain undetectable by standard screening.

Other Sub-Saharan countries are not exempted from this trend. In Sierra Leone, for instance, Nsekuye et al. (2023) found that replacement donors demonstrated higher infection rates than voluntary non-remunerated donors. This aligns with findings from Tapko and Tagny (2021), who argue that replacement donors often feel pressure to donate to relatives, potentially leading to incomplete disclosure of health histories and circumvention of screening protocols. In Tanzania, Mwambe et al. (2022) reported an 11.7% overall TTI prevalence among blood donors with HBV being the most common. The authors attributed these findings to limited pre-donation counseling and insufficient public awareness of high-risk behaviors. Similar concerns were echoed in Uganda, where Kasule et al. (2023) found HCV and HBV to be most prevalent among first-time donors. This statistic thus shows the need for these nations to improve their initial screening protocols.

While these studies offer valuable insights, many treat the donor population as homogenous and fail to disaggregate data by donor history. This is a critical oversight. First-time donors, lacking previous screenings and potentially unaware of deferral criteria, are at higher risk of harboring TTIs especially during the early stages of infection. Conversely, repeat donors who have undergone previous screenings and donor education tend to present a lower risk profile. For instance, Owusu et al. (2021) reported a TTI prevalence of 3.9% among repeat donors in Ghana, compared to 12.4% among first-time donors demonstrating the value of disaggregating donor data for more targeted risk mitigation.

Kenyan evidence further advocates the need for refined analysis. The Kenya Tissue and Transplant Authority (2023) highlighted the necessity of tracking donor

categories to enhance blood safety. However, most Kenyan public health surveillance efforts still report aggregate data without differentiating between first-time and repeat donors. This gap limits the ability to design targeted interventions. Although previous studies have shed light on the prevalence of TTIs in Sub-Saharan Africa, there are still gaps in localized urban analyses, donor-type-specific risk profiles, and longitudinal monitoring of intervention outcomes (Kumari et al., 2020). This study thus addresses these gaps by looking at Nairobi's blood donors, separates data for first-time and repeat donors and studies social and time-related trends to help design better transfusion safety measures.

2.3 DONOR CATEGORY AND RISK PROFILE

The category of blood donors whether first-time, repeat, or replacement is a pivotal determinant of risks associated with transfusion-transmitted infection. Around the world, studies have found that first-time blood donors are more likely to have TTIs than repeat donors. This disparity is attributed mainly to limited awareness, inadequate self-screening, and inexperience among first-time donors (Kumari et al., 2024). Abebe and Marga (2021) highlight that first-time donors may be unaware of or fail to disclose behaviors that elevate infection risk like recent unprotected sex, multiple sexual partners, or new tattoos. In contrast to this, repeat donors are generally more familiar with donation guidelines, benefit from prior health screenings, and often participate in educational interventions. These reasons as Muli et al. (2024) assert enable them to represent a comparatively lower-risk group.

The above distinction is confirmed by evidence from Sub-Saharan Africa. In Uganda, Kabiru et al. (2022) reported a TTI prevalence of 7.4% among first-time donors, compared to 3.1% among repeat donors. They believed this was because repeat donors kept using the services and learned more about health. Similarly, Nwogoh et al.

(2023) in Nigeria found that first-time donors were nearly twice as likely to test positive for hepatitis B (HBV) and hepatitis C (HCV) as repeat donors making all of them to stress on the importance of conducting routine pre-donation counseling as it helps in mitigating infection risks.

In Ethiopia, a large cross-sectional study by Tesfaye et al. (2023) and Mojtaba Azadbakht et al. (2021) found that 85% of all recorded TTI cases occurred among first-time donors, particularly for infections like HIV and syphilis. These findings align with data from Ghana, where Boateng et al. (2024) documented a significantly lower TTI risk among repeat donors. These scholars linked these findings to ability of effective compliance with screening protocols and safer lifestyles.

The reasons and actions of donors are often quite different depending on their category. Alabi et al. (2023) argue that first-time donors often donate under pressure for instance to help a friend or family member rather than from intrinsic motivation. These reasons in most cases tend to compromise the disclosure of risky behaviors. Unlike first-time donors, those who give more than once tend to donate willingly and with altruism which are linked to safer ways of donating.

According to Kamau et al. (2023), Nairobi's donor base includes a high proportion of students, informal sector workers, and unemployed youth groups. These groups are often associated with higher sexual risk behaviors. A related study by Chege and Maina (2023) found that first-time donors under 25 were twice as likely to test positive for HIV than older, repeat donors. These findings show that age, donor experience and TTI vulnerability are related.

As Salah et al. (2025) observe, repeat donors often participate in organized donation events with standardized procedures, whereas first-time donors particularly replacement donors frequently respond to emergencies. Because saving a relative is

urgent, these donors may not be fully examined and might hide any risk factors that could disqualify them. Barton et al. (2023) caution that such dynamics heighten the risk of undetected TTIs, as replacement donors may intentionally withhold risky behavior information.

Technology can limit how well infections are found. Although nucleic acid testing (NAT) offers enhanced sensitivity for early-stage infections, Tulel et al. (2024) report that its availability in Kenya is limited to high-capacity facilities like Kenyatta National Hospital. Most blood banks depend on serological testing which is not very sensitive during the window period and can be risky when testing new or emergency donors.

Despite global and regional evidence, Kenyan literature especially in Nairobi seldom differentiates between first-time, repeat, and replacement donors. Few studies incorporate behavioral and sociodemographic variables that could explain the variations in TTI prevalence by donor category. Moreover, replacement donors remain under-researched as a distinct, high-risk group, further impeding the development of evidence-based donor management strategies.

This study aims to fill these gaps by conducting a comparative analysis of TTI prevalence and risk factors among first-time, repeat, and replacement blood donors in Nairobi. By integrating sociodemographic and behavioral dimensions, the findings will support the design of targeted interventions, including tailored counseling protocols, improved donor follow-up, and differentiated screening strategies. These outcomes are expected to enhance the overall safety and reliability of the blood supply in Nairobi's dynamic urban context.

2.4 SOCIODEMOGRAPHIC TRAITS OF BLOOD DONORS

Sociodemographic factors significantly influence the prevalence and distribution of transfusion-transmitted infections among blood donors. Characteristics like age, gender, education level, marital status, and occupation have consistently been associated with variations in infection rates because they represent broader behavioral, social, and economic determinants of health.

Al-Mohani et al. (2024), in a comprehensive study carried out in Ethiopia, reported that male blood donors exhibited a higher overall prevalence of TTIs (8.2%) compared to females (5.6%). This gender disparity was evident among younger donors aged 18–25, a cohort that is characterized by increased engagement in high-risk sexual behaviors and lower utilization of preventive health services (Maulide Cane et al, 2021). The study suggests that young male donors should receive special education and behavioral guidance because they are more likely to be at risk of contracting TTIs.

Likewise, Mremi et al. (2020) analyzed Tanzanian blood bank data. They identified a significantly elevated prevalence of infections like syphilis and hepatitis B virus (HBV) among unemployed donors and those without formal education. The findings indicate that people with more education are less likely to get infected as they are more aware, seek medical help and take preventive steps. This result stresses the importance of socioeconomic factors in determining who gets exposed to TTIs and supports including educational outreach in blood donation campaigns.

In Uganda, Melku et al. (2021) explored the relationship between educational attainment and infection prevalence. These scholars established a clear association between low education levels and increased HIV and HBV rates among donors. The study attributed these outcomes to limited knowledge of transmission routes and prevention measures among less-educated individuals. They also identified lack of

educational as a critical barrier to achieving safe and sustainable blood supplies in resource-limited contexts. Their conclusion aligns with broader public health literature linking sociodemographic vulnerability to infectious disease susceptibility.

Kenyan research has provided further insights into these dynamics. Muli et al. (2023) investigated TTI prevalence among Nairobi blood donors and found a significant correlation between age and HBV infection among males aged 20–29. The study highlighted this demographic as a priority group for enhanced screening and behavioral intervention. However, their analysis did not address other key variables like education, marital status, or occupation. Thus, this study leaves gaps in understanding the full range of sociodemographic risk factors within Nairobi's donor population.

Njenga et al. (2022), in a broader nationwide assessment of Kenyan blood donors, observed that female donors had lower prevalence rates of HIV and syphilis compared to their male counterparts. Even so, women were less likely to donate again which suggests that gender differences may exist in both infection rates and how long people continue to donate. The research also found that employment status and whether someone lives in a city or town play a big role in donation frequency and infection risk. These findings suggest that donor recruitment and management should be adapted to different places.

Akoth (2021) focused on sociodemographic predictors of TTIs in Nairobi and found that unmarried donors exhibited higher infection rates. This was linked to behavioral risk factors associated with singlehood, including multiple sexual partnerships. However, education and occupation remained underexplored in this study, further emphasizing the need for localized and comprehensive research to understand these variables' interplay fully.

Despite the growing body of literature that link sociodemographic traits to TTI prevalence, a notable gap remains in studies that comprehensively examine the roles of age, gender, education, marital status, and occupation within the urban context of Nairobi. Many existing studies either concentrate on isolated variables or aggregate data from diverse regions, including rural areas thus limiting the specificity and applicability of their findings for Nairobi's complex urban population. This study addresses these limitations by systematically examining the sociodemographic traits of first-time and repeat blood donors in Nairobi and their association with TTI status. The disaggregated analysis aims to generate context-relevant evidence to inform tailored donor recruitment, retention, and risk-reduction strategies in Kenya's urban settings.

2.5 TESTING METHODS IN BLOOD SERVICE

Ensuring the safety of transfused blood is vital because it helps to reduce the risk of transfusion-transmitted infections like HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis. The effectiveness of screening technologies measured by their sensitivity, specificity, and timeliness as Mbanya et al. (2022) indicates is critical to achieving this goal. In Kenya and most Sub-Saharan African countries, serological assays remain the predominant screening method due to their affordability and accessibility. However, Wanjiru et al. (2024) claim that antibody/antigen-based methods have limitations especially during the early “window period” when these markers are undetectable.

Various studies highlight the advantages and trade-offs of existing tools. Wahome et al. (2022) evaluated enzyme-linked immunosorbent assays (ELISA) and rapid diagnostic tests (RDTs) in Kenya. She noting that while ELISA is more sensitive, it requires advanced lab infrastructure and longer turnaround times. In contrast, RDTs deliver quick results and are better suited for low-resource, and decentralized settings.

In Turkana County, Omondi et al. (2023) observed that RDTs enabled near real-time screening with a reported efficacy of 99.2%, which make them valuable in remote regions. However, the authors cautioned that variations in diagnostic accuracy across RDT brands limit their reliability.

Concerns about RDT consistency have been echoed by the Kenya Tissue and Transplant Authority (KTTA, 2023). KTTA has highlighted the absence of standardized quality control and confirmatory testing across blood collection centers. In urban areas like Nairobi, Onyango et al. (2024) warned that low-sensitivity tests could result in false negatives an element that poses significant risks to blood safety. Conversely, Singogo et al. (2023) flagged the issue of false positives which contribute to unnecessary donor deferrals and blood wastage. Both studies emphasized that the lack of systematic confirmatory testing undermines screening reliability, especially in smaller facilities.

Similarly, Nucleic acid testing has emerged as a gold standard in blood screening due to its ability to detect viral nucleic acids and reduce the diagnostic window period. In South Africa, Mahlangu et al. (2022) reported a 70% reduction in transfusion-transmitted HIV and hepatitis cases following NAT implementation. Similarly, Adebayo et al. (2023) found that NAT detected TTIs missed by serological tests in one out of every 1,000 blood donations in Nigeria thus reinforcing its value in high-risk environments.

Despite its advantages, infrastructure and cost challenges limit adaption of NAT in Kenya. The Nairobi Regional Blood Transfusion Centre (2023) estimated that fewer than 40% of the city's blood banks consistently use NAT or comparable molecular methods. Tulel et al. (2024) reported that rural hospitals rely on RDTs and basic ELISA tests due to resource constraints an aspect that further leads to uneven safety standards and persistent TTI risks.

Emerging technologies like multiplex serological assays which can detect multiple pathogens simultaneously have shown promise. In a Mombasa pilot, Wanjiru et al. (2024) documented a 30% reduction in testing time and increased lab throughput during blood drives. However, limited data on their cost-effectiveness and operational efficiency, particularly in Nairobi, presents a critical evidence gap.

Global best practices, including World Health Organization (2022) recommendations, advocate for tiered screening algorithms that combine RDTs for initial triage with ELISA and NAT for confirmatory testing. These approaches aim to balance cost, sensitivity, and operational feasibility. However, effective implementation relies on robust data regarding local TTI prevalence and donor profiles. Biwot et al. (2025) emphasized that technology alone is insufficient as successful outcomes require trained personnel, consistent reagent supply, and strict protocol adherence. Their audit revealed that advanced tools are often underutilized in peripheral centers and these further compromises blood safety.

While existing literature details the strengths and weaknesses of various screening technologies, de Oliveira Garcia Mateos et al. (2021) indicate that it lacks Nairobi-specific evaluations that align these tools with local epidemiology and donor characteristics. This study addresses that gap by assessing the efficacy, limitations, and cost-effectiveness of blood screening technologies within Nairobi. It will also explore the feasibility of implementing integrated screening algorithms, considering infrastructure, human resources, and donor safety. Therefore, this study aims to provide actionable recommendations to strengthen screening protocols and enhance transfusion safety in urban Kenya by contextualizing the findings within Nairobi's healthcare system.

2.6 SAFETY MEASURES ON BLOOD DONORS

Donor safety and well-being are essential pillars of an effective blood transfusion system, as they influence the quality of donated blood, donor retention, and overall sustainability. While international literature offers substantial insights into blood donors' safety practices and health outcomes, research focusing on these aspects in Kenya; particularly in Nairobi remains fragmented.

Jiang et al. (2024) investigated the prevalence and severity of adverse reactions among different donor groups. The research shows that first-time donors are more likely to experience dizziness, nausea, hematoma and vasovagal syncope than donors who have given blood before. Supporting this, Wakoli (2024); Cwinyaai (2024) examined donor reactions in four Ugandan regional hospitals and reported that 17.6% of first-time donors experienced adverse events post-donation, compared to 6.3% of repeat donors. The reason for these reactions was that people felt more anxious and didn't know what to expect during donation.

When donor monitoring is not consistent in Africa, these issues are made even more difficult.

Navarro and Cuella (2025) explored donor care systems in Morocco in their study, and their findings reveal that pre-donation counseling and post-donation follow-up are often poorly implemented in overcrowded urban centers. In Nairobi, Wambua (2024) documented post-donation observation practices and similarly found irregular adherence to established safety protocols, increasing the likelihood of missed delayed reactions.

Biwot et al. (2025) evaluated pre-donation screening procedures in six Kenyan transfusion facilities. Their research showed that blood pressure and hemoglobin were regularly tested, but the team did not pay much attention to donor anxiety and fear of

needles. This is echoed by Klinkenberg et al. (2021), whose research indicates that psychological readiness strongly influences donor experiences and future behavior, particularly for first-time donors.

Li and Jiang (2025) carried out a study on psychological barriers to donation in East Asia, revealing that over 40% of first-time donors felt fearful or anxious about the procedure. Their research shows that such emotions make it more likely for donors to have negative experiences and less likely to give again. Even though there is not much data on this in Nairobi, people often report that youth and newcomers share these same fears.

Physiological safety concerns, especially iron depletion among frequent donors, also require attention. Mantadakis et al. (2022) researched ferritin levels in Greece, and their findings reveal that frequent donors are at risk of iron deficiency anemia. Nyamu (2024) performed a study at Kenyatta National Hospital in Nairobi and reported that 7.42% of donors were anemic, most repeat female donors. However, their findings reveal that iron supplementation was inconsistently administered.

A related study by Mvere et al. (2023) in Zimbabwe highlighted the lack of routine iron monitoring in public donation centers.

Donor motivation also plays a role in safety outcomes. Barton et al. (2023) researched the differences between replacement and voluntary donors in Kenya. Their findings reveal that replacement donors, often under pressure to support relatives, are more likely to withhold critical health information, leading to increased incidences of transfusion-transmissible infections and post-donation complications.

Singogo et al. (2023) assessed the implementation of Kenya National Blood Transfusion Service (KNBTS) guidelines in three counties. Some centers used modern technology and followed up with donors, but others had no basic system for caring for

donors after their blood was taken. As a result, long-term monitoring of donor safety is reduced and donors may not return.

Innovations like “walking blood banks,” piloted in Turkana County, also raise safety concerns. Wahome et al. (2022) reviewed the diagnostic protocols used in these models, and their findings reveal a reliance on rapid diagnostic tests, which are less sensitive than nucleic acid testing (NAT). This increases the risk of transfusion-transmitted infections in emergency contexts. Despite WHO’s recommendation to adopt NAT (2023), Kenya faces adoption challenges due to limited funding and infrastructure.

Importantly, most studies in Kenya do not disaggregate data by donor type an aspect that limits a nuanced understanding of the different safety needs of first-time and repeat donors. Moreover, long-term health outcomes both psychological and physical are rarely tracked, which hinders the development of tailored interventions and support systems.

While existing research has addressed general donor safety, there is limited comparative evidence focusing on first-time versus repeat donors in Nairobi. This study addresses that gap by comparing their safety and well-being outcomes. It also investigates the adequacy of donor care protocols and follow-up practices, aiming to provide evidence-based recommendations for improving donor retention and safeguarding health in urban Kenyan contexts.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter describes the research methodology used in the study, including the study location, target population, sample size, and the approach for determining the sample size. It also covers the criteria for participant selection, sampling methods, data collection tools, laboratory procedures, and the tests performed. Data management was also explained in this section and again data analysis and presentation will be featured. The section concludes by highlighting the ethical consideration procedures.

3.2 STUDY DESIGN

This study employed a cross-sectional descriptive research design to assess the factors influencing blood donation. Blood specimens were collected from voluntary donors at selected blood collection sites in Nairobi. The descriptive cross-sectional approach was deemed appropriate as it facilitated the collection of real-time data and fresh insights into blood donation trends, associated challenges, and potential risks. This design offered a snapshot of critical issues which allowed for a deeper understanding of donor characteristics, the prevalence of transfusion-transmitted infections, and barriers to blood donation within the study population.

In such descriptive research, the outcomes of interest were clearly defined, with appropriate procedures established for their independent measurement, supported by a detailed profile of the target population. To ensure a comprehensive analysis, the study integrated both qualitative and quantitative research approaches. This methodological choice aligns with the positivist research paradigm, which advocates for selecting methods best suited to the research problem. Additionally, multiple methodologies were applied at different stages of the study to enhance the reliability, validity, and depth of the findings.

3.3 STUDY AREA

This study was conducted in Nairobi, the capital city of Kenya and the largest urban center in East Africa. With a population exceeding 3.1 million (Kenya National Census, 2009), Nairobi presents a high and consistent demand for blood due to its numerous hospitals, referral centers, and frequent medical emergencies such as road accidents, childbirth complications, and chronic illnesses. Nairobi was strategically selected as the study site due to its robust infrastructure supporting blood transfusion services. It hosts the headquarters of the Kenya National Blood Transfusion Service (KNBTS) and the Regional Blood Transfusion Centre (RBTC), both of which play a central role in coordinating blood donation drives, screening and testing blood samples and distributing blood units to health facilities within the city and surrounding regions. This made it an ideal location in terms of logistical efficiency and institutional support for data collection and analysis.

The presence of both permanent and mobile blood donation centers across Nairobi enabled easy access to a diverse pool of blood donors, including both first-time and regular donors. This diversity enhanced the quality and reliability of the data collected, allowing for a comprehensive understanding of voluntary blood donation behaviors. Moreover, the proximity of laboratory testing facilities managed by RBTC ensured timely and accurate analysis of samples, further strengthening the study's credibility.

3.4 STUDY POPULATION

This study targeted a population of all first-time and repeat blood donors at Nairobi Regional Blood Transfusion Centre consisting of both the walk-ins at the static site and outreach activities during blood drives organized by this Centre within the month of April to June 2023.

3.5 SAMPLE SIZE DETERMINATION

The study's population sample comprised all individuals who donated blood at the Nairobi Regional Blood Transfusion Centre over a two-month period (April to June 2023). Due to uncertainty about the accessible population size, Cochran's (1977) formula for determining sample size was used to calculate an appropriate number for inferential analysis. $= \frac{Z^2 p(1-p)}{e^2}$

Where

n = sample population size necessary to determine the population to donate

z = z tabular value at 95% confidence level (1.96)

p = It's the proportion of either first-time or repeat blood donors

e= error margin of 2 %

n= $\frac{1.96^2 * 0.04(1-0.04)}{0.02^2}$

$n = 369$ Donors

A sample of 369 adults was selected through purposive sampling at collection centres in Nairobi within a period of 3 months from April to June 2023.

3.6 INCLUSION AND EXCLUSION CRITERION

3.6.1 INCLUSION CRITERIA

- The study included three types of voluntary blood donors: first-time donors, repeat donors, and regular donors who met the Kenya National Blood Transfusion Service (KNBTS) screening guidelines. First-time donors are individuals donating blood for the first time. Repeat donors are those who have donated more than once but do so irregularly and regular donors are individuals who donate blood frequently and consistently over time.
- Participants were required to be between 18 and 65 years old with a minimum body weight of 50 kg.

- Additionally, only individuals who provided informed consent were included in the study.

3.6.2 EXCLUSION CRITERIA

- The study did not include donors who were postponed based on the KNBTS screening criteria.
- People under the age of eighteen and those over sixty-five were not allowed to participate in the study.
- Participation was also prohibited for anyone weighing less than 50 kilograms.
- Those who declined to take part in the research

3.7 SAMPLING TECHNIQUE

A consecutive purposive sampling method was employed in this study. This approach as Ahmad & Wilkins (2024) explains involves intentionally selecting all individuals who meet predefined inclusion criteria and presenting themselves consecutively over a set period until the required sample size is reached. In this case, first-time and repeat voluntary blood donors who satisfied the Kenya National Blood Transfusion Service (KNBTS) eligibility criteria were included. Unlike random sampling, where participants are selected by chance, consecutive purposive sampling focuses on continuously recruiting relevant and available participants. This method is useful when the target population is easily accessible at a specific site and aims to gather rich, and context-specific data.

In practice, every eligible donor who came to Nairobi Regional Blood Transfusion Centre (RBTC) or participated in mobile blood drives during the study period was assessed for eligibility. Those who met the inclusion criteria and gave informed consent were enrolled consecutively, without gaps or time-based restrictions,

until the sample size was achieved. This non-probability sampling method was well-suited for the study's qualitative and descriptive aims, as it ensured a reliable flow of relevant participants and provided a broad understanding of donor characteristics and behaviors within the Nairobi region.

3.8 DATA COLLECTION INSTRUMENTS

Demographic data was obtained through structured questionnaires with individuals donating blood. The research analysed the prevalence of transfusion-transmissible infections and evaluated the safety of both donors and transfused blood among first-time and returning donors in Nairobi, Kenya.

3.9 PRE-DONATION QUALITY CONTROL MEASURES

Quality control measures performed on the Blood Donor: The prospective blood donor underwent health checks guided by the blood donor questionnaire and physical examination was done when the examiner saw the need in cases of swellings, skin infection. In this study the identity of the blood donor was confirmed as required by the donor screening SOP.

- Product Quality Checks: Blood bags were checked for
    - Expiry date
    - Confirmation of storage presence of moistened bags
    - Confirmation of kinks in the tubing’s
    - Confirmation of leakage
    - Confirmation if the unique identifier is captured in the blood bag
    - Confirmation of the availability of blood clips
- Puncture Site Cleaning: The antecubital fosa region was disinfected in a circular motion twice from inside out using isopropyl alcohol 70%. Needle was inserted bevel up

- Sample Collection: First, collecting blood into a plain tube, followed then by with EDTA (a chemical that prevents clotting).
- Documentation: Making sure all forms are fully and correctly filled out and double-checked before processing.

Blood sample

1. A 2–6 millilitres of blood from the sample pouch were transferred into a properly labelled red-top plain test tube
2. An additional volume of 2–6 millilitres of blood was drawn from the sample pouch vein into a vacutainer containing EDTA.
3. Samples were then labelled with unique donor ID to assure confidentiality
4. Blood samples were then packed into a blood transport box layered with Ice packs and temperatures monitored using data loggers and transported to the laboratory

3.9 LABORATORY TEST PROCEDURES

The collected blood samples underwent the laboratory tests provided below.

These tests were carried out by the designated study personnel at the KNBTS National Testing Laboratory in Nairobi under my supervision. Capillary blood drawn from the finger was used to estimate haemoglobin levels using the HaemoQ HB estimation machine. The cut-off for blood donation was 12.5 g/dL; any donor with Hb levels below this was excluded from donation as per the exclusion criteria.

3.9.1 TESTING QUALITY CONTROL

STANDARDIZATION AND OPTIMIZATION

To ensure reliability and consistency of test results, the following quality control measures were observed:

- Instrument Calibration was performed every 28 days or whenever a new reagent lot was introduced.
- Internal Quality Controls (Abbott Architect controls) were routinely run for HIV, HBV, HCV, and Syphilis using reagent lot series 694, 680, and 690.
- Reagent Management**:** All reagents used were within their expiry dates and stored between 2–8°C as per manufacturer guidelines.
- External Quality Assessment (EQA): Conducted through One World Accuracy, covering HIV, HBV, HCV, and Syphilis, with all results successfully passing assessment.
- Equipment Maintenance**:** Included routine cleaning of probes and running system error checks on the Abbott Architect machine.
- Rechecking of Results**:** All reactive TTI samples were retested, and 10% of negative samples were randomly rerun to validate consistency.
- Environmental Monitoring**:** Room temperature and refrigerator storage conditions were tracked daily using log sheets and monitoring charts.

3.9.2 POST-TESTING QUALITY CONTROL MEASURES

Verification and Confirmation of TTI Results: All transfusion-transmitted infection (TTI) results were verified and confirmed by a qualified second party to ensure accuracy and reliability.

- Results Documentation**:** Verified results were transcribed into the official results form **(**FRM LAB-24**)** for standardized reporting.
- Data Security and Storage**:** All documentation was securely stored and password-protected under the supervision of the Quality Assurance (QA) lead.
- Post-Test Safety Protocols**:** Appropriate safety measures were observed at the workbench following testing. This included decontamination using 70% isopropyl alcohol and equipment flushing with Tween 20.
- Serum Archiving**:** Serum samples were archived at –80°C to preserve sample integrity for future reference or reanalysis.

3.9.3 TRANSFUSION TRANSMISSIBLE INFECTION TESTING

The Chemiluminescence Immunoassay (CLIA) technique was used to screen for HIV, HBV, HCV, and Syphilis, which are among the most common and serious Transfusion Transmissible Infections (TTIs). These infections pose significant risks to blood safety and patient health especially if not detected early. CLIA is preferred due to its high sensitivity, specificity, and speed thus making it ideal for modern automated platforms like the Abbott Architect i2000SR (Arcot et al., 2022).

- For HIV**,** the Abbott Architect i2000SR detects both HIV-1 and HIV-2 antibodies as well as the p24 antigen using a combined Ag/Ab test. This enables detection of both early and late-stage infections thus making it easy to reduce risks associated with transfusion. The WHO (2023) affirms CLIA's effectiveness in early detection.
- For Hepatitis B Virus (HBV), the system identifies Hepatitis B surface antigen (HBsAg) and detect low viral loads and distinguish acute from chronic infections (Massarweh et al., 2021).

- For Hepatitis C Virus (HCV)**,** CLIA detects HCV antibodies and identify both current and past infections with high specificity and reduced false negatives (Liu et al., 2024).
- For Syphilis, CLIA identifies antibodies against *Treponema pallidum*, and help detect both acute and chronic infections even in asymptomatic donors.

3.9.4 INTERNAL QUALITY CONTROL PROCEDURES

Internal quality control was essential to ensure accurate and reliable test results. For hemoglobin estimation, quality control materials with known low and high HB levels were used daily to confirm analyzer performance. For chemiluminescence testing, IQC was performed at the start of each batch using manufacturer-supplied positive and negative controls. These controls validated the reagents and the instrument's performance. If control results deviated from expected ranges, testing was paused, and corrective actions like reagent replacement or re-running calibration were taken. All IQC activities were documented, reviewed, and archived regularly as part of quality assurance protocols.

3.9.5 BENEFITS OF CHEMILUMINESENCE

Chemiluminescence Immunoassay (CLIA) is highly recommended for screening transfusion-transmissible infections (TTIs) because it is more sensitive and specific than traditional methods like ELISA and rapid diagnostic tests (RDTs). According to Bolton et al. (2020), it can detect very small amounts of antigens or antibodies and help to identify infections like HIV, HBV, HCV, and Syphilis at an early stage, an element that improves blood safety.

CLIA is also fast and efficient, especially when using high-throughput machines like the Abbott Architect i2000SR. This is useful in busy blood transfusion centers

where results are needed quickly to release safe blood for use. The system can test many samples at once and produce results in a short time (Yang et al., 2020).

Another benefit is that CLIA has a low risk of false positives, which protects regular blood donors from being wrongly excluded. This ensures that more safe donors remain in the pool, helping maintain an adequate blood supply (Van Buren, 2021). Lastly, CLIA systems like the Architect i2000SR are fully automated and thus tend to reduce human error and improve accuracy. They are also scalable, an aspect that makes them ideal for large testing facilities.

3.9.6 SOP FOR HEMOGLOBIN, SCREENING AND MEDICAL CHECKS

Hemoglobin Medical Check (HB Test)

Before blood donation, hemoglobin levels were assessed using the Hemocue 201+ analyzer to ensure donor eligibility and safety. The device was checked daily for functionality and calibrated using the manufacturer-supplied standard. A finger prick was performed using a sterile lancet after cleaning the site with 70% isopropyl alcohol in a circular motion. The first drop of blood was wiped away, and the second was collected into a Hemocue cuvette, which was then inserted into the analyzer. Hemoglobin values were recorded and assessed against acceptable ranges. Donors with hemoglobin levels below the acceptable threshold were deferred to prevent harm and advised on appropriate nutritional or medical intervention.

HB Ranges and Gender Differentiation

Acceptable hemoglobin levels vary by gender. For males**,** the normal range is 13.5 to 17.5 g/dL**,** and for females**,** it is 12.5 to 15.5 g/dL. However, the minimum cut-off for eligibility to donate blood was set at 12.5 g/dL for both genders, and the upper limit was 18g/dl according to national blood transfusion guidelines (African Society for Blood

Transfusion, 2023). Donors falling below this limit were not allowed to proceed with donation and were provided with guidance on improving their health status.

HIV, HBV, HCV, and Syphilis Testing Procedures

Donor blood was screened for Transfusion-Transmissible Infections (TTIs) using Chemiluminescent Immunoassay (CLIA) technology via the ARCHITECT i1000SR analyzer. The tests included: HIV 1/2 Antigen/Antibody Combo (4th generation), HBsAg for Hepatitis B, Anti-HCV for Hepatitis C, and Syphilis testing through RPR (Rapid Plasma Reagin), with TPHA confirmation for reactive samples. All testing was conducted under strict biosafety standards, and each batch of testing was validated through quality control procedures. These tests ensured that only safe blood was used for transfusion purposes, thereby protecting recipients from infections.

Supervisory Role in Testing Process

As the individual in charge of the screening program, I supervised all aspects of the testing and screening procedures. I oversaw the team of laboratory assistants and phlebotomists to ensure adherence to standard operating procedures. My responsibilities included verifying proper donor screening, overseeing sample labeling and processing, interpreting test results, and confirming the accuracy of documentation. I also ensured all quality assurance protocols were observed and resolved any discrepancies in results or testing procedures. My leadership was central to maintaining the integrity of the donation process and upholding safety standards.

Internal Quality Controls for Chemiluminescence

For the ARCHITECT i2000SR platform, the HIV Ag/Ab Combo Assay used an S/CO ratio cutoff of 1.00. A sample with an S/CO less than 1.00 was interpreted as non-reactive, while a result equal to or greater than 1.00 was considered reactive and required repeat or confirmatory testing. The HBV HBsAg Qualitative II Assay based its

result on the sample's RLU compared to a cutoff RLU of 0.05 IU/mL, which corresponds to the WHO standard. Samples with an RLU below this cutoff were non-reactive; those meeting or exceeding it were considered reactive and required confirmation using HBsAg neutralization or HBV DNA testing.

The Anti-HCV assay used the same S/CO threshold of 1.00 as the HIV test. Results below 1.00 were non-reactive, while those equal to or above were reactive and required confirmation with HCV RNA PCR or RIBA. Similarly, the Syphilis TP Assay followed the S/CO ratio of 1.00. Samples below this value were non-reactive, while those above or equal to it were reactive and needed confirmatory testing using treponemal or non-treponemal methods such as FTA-ABS or RPR.

To ensure assay reliability, internal control requirements were also enforced. The positive control was expected to yield a COI or S/CO ratio of ≥3.00, while the negative control had to be <0.25. If either control failed to meet these limits, the assay was invalidated, and no patient samples were reported until corrective actions were completed.

Table 1: Quality control performance Table

Batch ID	Marker	Control/Sample ID	Type	Replicate #	Expected Result	Observed Result	Operator	QC Status
BATCH-2023-06-01	HIV Positive Control	PC-LOT694	Positive Control	2	Positive	Positive	C.Rombo	Pass
BATCH-2023-06-01	HIV Negative Control	NC-LOT456	Negative Control	1	Negative	Negative	C.Rombo	Pass
BATCH-2023-03-04	HBV Positive control	PC-LOT680	Positive Control	2	Positive	Positive	C.Rombo	Pass
BATCH-2023-04-05	HBV Negative Control	NC-LOT456	Negative Control	1	Negative	Negative	C.Rombo	Pass
BATCH-2023-11-03	HCV Positive Control	PC-LOT690	Positive Control	2	Positive	Positive	C.Rombo	Pass
BATCH-2023-11-03	HCV Negative Control	NC-LOT456	Negative Control	1	Negative	Negative	C.Rombo	Pass
BATCH-2023-08-02	Syphilis Positive Control	PC -Lot 691	Positive Sample	2	Positive	Positive	C.Rombo	Pass
BATCH-2023-08-02	Syphilis Negative Control	NC-Lot 689	Negative Control	1	Negative	Negative	C.Rombo	Pass
BATCH-KBTTS HIV003	Known HIV Sample Control	KPCHIV	Known Sample	1	Positive	Positive	C.Rombo	Pass
BATCH-KBTTS HBV 004	Known HBV Sample Control	KPC HBV	Known Sample	1	positive	Positive	C.Rombo	Pass
BATCH-KBTTS HCV 006	Known HCV Sample Control	KPCHCV	Known Sample	1	positive	Positive	C.Rombo	Pass
BATCH-KBTTS SYP 001	Known Syphilis Sample Control	KPC SYP	Known Sample	1	positive	Positive	C.Rombo	Pass

NB- The equipment read the optical densities of samples and controls and results were given out qualitatively

3.10 DATA MANAGEMENT

3.10.1 DATA COLLECTION PROCEDURE

The data collection process was structured to support the study's objectives through the use of three primary methods: laboratory assays, structured questionnaires, and donor deferral logs. To achieve Objective 1; laboratory assays were conducted using the Abbott Architect i2000SR analyzer, which utilizes the Chemiluminescence Immunoassay (CLIA) technique to test for HIV, HBV, HCV, and syphilis. Blood samples were collected from the brachial vein and blood collection units of both first-time and repeat donors. For Objective 2; structured questionnaires were administered during the donor screening process. These questionnaires gathered essential information on age, sex, education level, occupation, donation history, and personal health practices. To fulfill Objective 3; haemoglobin levels were assessed using capillary blood from a finger prick and analyzed with a HaemoCue HB analyzer. Donors with haemoglobin levels below 12.5 g/dL were deferred according to national guidelines. Additionally, donor deferral logs were used to document any adverse reactions experienced during or after donation and to record general observations of donor wellness. This multi-method approach ensured accurate, reliable, and comprehensive data collection aligned with the study's goals.

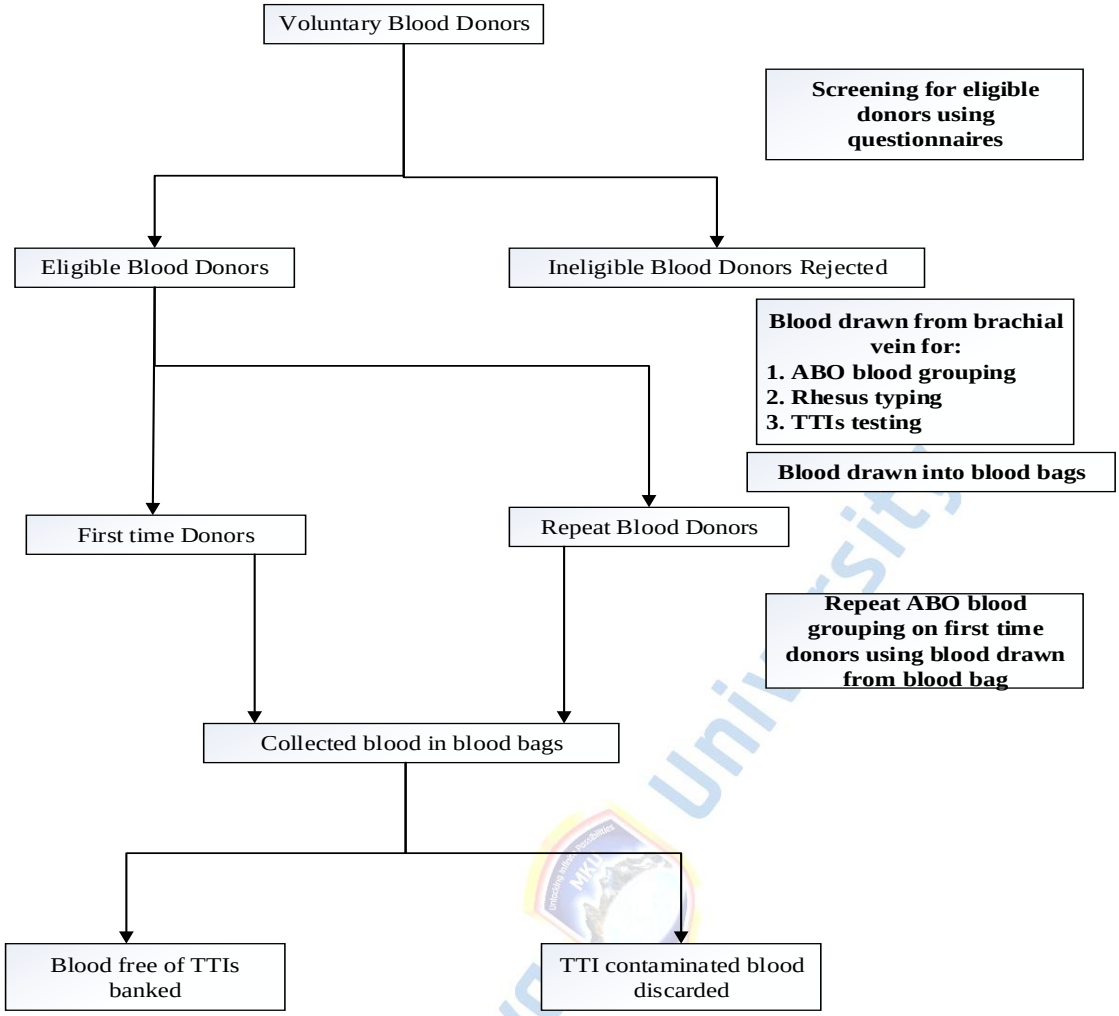

FIGURE 3.1: FLOW CHART OF THE STUDY (FROM KENYA NATIONAL BLOOD TRANSFUSION SERVICE) NB -REGULAR DONORS ARE CAPTURED UNDER REPEAT BLOOD DONORS

3.10.2 DATA PROTECTION

The collected data was handled with strict adherence to the principles of confidentiality, security, and legal compliance. Data protection measures followed the guidelines outlined in the Data Protection (Compliance and Enforcement) Regulations, 2021, and the Data Protection Act No. 24 of 2019.

To ensure confidentiality, each donor was assigned a unique identification number, and all records were anonymized. Donor information was securely stored in password-protected digital databases and physical documents were kept in lockable cabinets. Donors also provided individual informed consent prior to participation.

The data storage and analysis infrastructure incorporated multiple layers of security. This included the use of encrypted drives for on-site storage, secure cloud-based backups performed daily, and restricted access to authorized personnel only. All electronic systems used in the study were protected by strong passwords to ensure that access to sensitive information was tightly controlled.

3.11 DATA ANALYSIS AND PRESENTATION

Hemoglobin estimation was performed using the Haemcue Hb-201 analyzer. And data was analyzed using the SPSS software package version 23 to ensure a structured approach that aligned with the specific objectives of the study. To address the first objective, which focused on examining the occurrence of transfusion-transmissible infections (TTIs) like HIV, HBV, HCV, and syphilis among donors, the prevalence rates were calculated and expressed as percentages and proportions. The distribution of TTI-positive cases among first-time and repeat donors was compared using the Chi-square test to enable essay identification of any significant differences between these groups. These findings were presented using tables to provide a clear visual summary of infection rates.

For the second objective, which involved analyzing the socio-demographic characteristics of blood donors, variables including age, gender, occupation, location, and donor type were summarized through frequencies and percentages. To explore differences in these characteristics between first-time and repeat donors, the Chi-square test was applied to categorical data, while the Mann-Whitney U test was used for continuous data that did not meet the normality assumption. This approach facilitated a detailed understanding of how donor demographics relate to the safety profile of donated blood.

The third objective focused on evaluating the safety measures and well-being of donors. Haemoglobin levels and other continuous safety indicators were summarized using means and standard deviations. An independent t-test was used to compare these variables between first-time and repeat donors, with non-parametric tests employed when data distributions were not normal. Throughout the analysis, results were displayed in tables to enhance clarity and support interpretation thus providing a comprehensive presentation of the study's findings.

3.12 ETHICAL CONSIDERATIONS

This study strictly adhered to ethical research standards and obtained all necessary approvals and permits prior to data collection. Ethical clearance was granted by the Mount Kenya University Ethical Review Committee (Approval Reference: MKU/ISERC/2748). Subsequent research authorization was obtained from the National Commission for Science, Technology and Innovation (NACOSTI) under license number 174990**.**

Permission to access blood donation sites and laboratory facilities was officially granted by the Kenya Tissue and Transplant Authority (KTTA)**,** formerly Kenya National Blood Transfusion Service, under Reference Number: KTTA/EXT/CORR/22/VOL.III (110)**.**

All participants were informed about the purpose and procedures of the study, and informed consent was obtained using the approved form **(**FRM CLN 001, Version 5**).** Donors voluntarily agreed to participate in the study, which included completing a structured questionnaire and undergoing biomedical testing. Confidentiality was assured through the use of anonymized unique IDs and password-protected digital records.

Qualified laboratory personnel conducted all biomedical tests in accordance with national standards, and quality control procedures were followed to ensure the accuracy

and reliability of results. Donors were informed of their blood group and the results of TTI screening after all confirmatory testing was completed, in line with national blood donation protocols. As a gesture of appreciation, donors were offered refreshments and thanked for their participation and life-saving contribution through voluntary blood donation.

CHAPTER FOUR: RESEARCH FINDINGS AND DISCUSSION

4.1 INTRODUCTION

This study assessed TTIs, donor demographics, and safety outcomes among 369 voluntary donors at the Nairobi Regional Blood Transfusion Centre. HBV had the highest prevalence at 2.0%, while HIV and HCV were each at 0.54%, and syphilis at 0.27%. Most donors were aged 18–25 (51.8%), male (52.0%), and students (59.3%). First-time donors were more often male (54.7%), while repeat donors had a slightly higher proportion of females (51.4%). Urban areas contributed the highest share of donors (40.9%). Adverse donor reactions were more frequent among first-time donors (22.0%) compared to repeat donors (11.8%), with the majority being mild (93.7%). Notably, return rates were lower among first-time donors who experienced reactions (30.0%) than those who did not (47.3%). These findings point to the need for enhanced HBV screening, targeted youth education, and improved donor care to support safer, more sustainable blood donation practices.

4.2 RESULTS OBJECTIVE 1: TRANSFUSION-TRANSMITTED INFECTION PREVALENCE

To assess transfusion-transmitted infections prevalence from samples of first-time and repeat donors in Nairobi, Kenya

Transfusion-transmitted infections prevalence

Table 2: Prevalence of transfusion-transmitted infections across donor types

Characteristic	Donor Type 1		Donor Type 2		Total
	(n)	(%)	(n)	(%)	
HIV					
Negative	190	99.48	177	99.4	367
Positive	1	0.52	1	0.56	2
Syphilis					
Negative	190	99.48	178	100.0	368
Positive	1	0.52	0	0	1
HBV					
Negative	187	97.91	174	97.75	361
Positive	4	2.09	4	2.25	8
HCV					
Negative	190	99.48	177	99.44	367
Positive	1	0.52	1	0.56	2
Total positives	7	-			
Total	191		178		369

The table presents the prevalence of transfusion-transmitted infections (TTIs) among first-time (Donor Type 1) and repeat (Donor Type 2) blood donors in Nairobi, Kenya. A

total of 369 participants were included in the study, with 191 (51.8%) being first-time donors and 178 (48.2%), being repeat donors. 0.52% of first-time donors and 0.56% of repeat donors tested positive for HIV, while 1 first-time donor (0.52%) tested positive for syphilis and 1 for repeat donors. Four first-time donors (2.09%) and four repeat donors (2.25%) tested positive for HBV. 0.52% of first-time blood donors and .56% of repeat donors tested positive for HCV.

4.3 RESULTS OBJECTIVE 2: SOCIODEMOGRAPHICS

To assess the Socio-Demographic factors of first-time and repeat blood donors in Kenya National Blood Transfusion Service, Nairobi.

Characteristic			**Donor Type 1**		**Donor Type 2**	
Age	N	(%)	(n)	(%)	(n)	(%)
<18	79	21.4%	43	54.4	36	45.6
18-25	191	51.8%	93	48.7	98	51.3
26-34	58	15.7%	34	58.6	24	41.4
35-43	30	8.1%	15	50	15	50
44-52	7	1.9%	5	71.4	2	28.6
>52	4	1.1%	1	25	3	75
Total	369		191	-	178	-
Gender						
Male	192	52.03	105	54.69	87	45.31
Female	177	47.97	86	48.59	91	51.41
Total	369	-	191	-	178	-
Location						
College	85	23.04%	41	48.23	44	51.76
School	133	36.04	71	53.38	62	46.61
Urban	151	40.92	79	52.31	72	47.68
Total	369	-	191	-	178	-
Occupation						
Business	24	6.50	17	70.83	7	29.16
Employed	107	28.99	51	47.66	56	52.34
Student	219	59.34	112	51.14	107	48.86
Unemployed	19	5.14	11	57.89	8	42.11
	369	-	191	-	178	-

Table 3: Sociodemographic characteristics of the participants

1: The majority of blood donors were in the age category 18-25(51.8%), followed by those under 18 (21.4%). Male constituted more donors (52.03% vs 47.97%) than female while donors from urban settings where the majority (40.92%) compared to those in colleges and schools. By occupation, majority of donations were from students (59.3%). (The age range of the participants is from 18 to 57 years and the mean age of the participants is 24.14 years.

2: The majority of donors in both Donor Type 1(first-time) and Donor Type 2 (Repeat/Regular) are in the 18-25 years age group, with 48.7% and 51.3% respectively. The second largest age group for both donor types is < 18 years, with Donor Type 1 at 54.4 % and Donor Type 2 at 45.6% of the age group.

3: Donor types across age groups: The table highlights the distribution of donor types across different age groups. Donor Type 1 is more prevalent among younger donors (<18 and 18-25), while Donor Type 2 is more prevalent among older donors (26-34 and 35-43). This suggests that Donor Type 1 may be more representative of younger donors, while Donor Type 2 may be more representative of younger donors and older donors.

4: Donor Types across Gender indicate that male participants are more represented among first-time donors (Donor Type 1), accounting for 54.9% of this group. In contrast, female participants are more represented among repeat donors (Donor Type 2), accounting for 51.2% of this group.

5: Urban locations had a higher representation of first-time donors and repeat donors (52.31%, 47.68% followed by School (53.38%, 46.61%)

6: Students constituted the majority among first time and repeat donors (51.14%, 48.86%), followed by those employed (47.66%) for first time donors and (52.34%) for repeat donors.

SOCIO DEMOGRAPHIC CHARACTERISTICS IN BLOOD DONORS

Age

Table 4: Contribution of age demographic within Donor types

Age Group	N	Within Age group (%)		Within Donor Type (%)	
		Donor Type 1 (n=191)	Donor Type 2 (n=178)	Donor Type 1 (n=191)	Donor Type 2 (n=178)
<18	**79**	54.43	45.57	22.51	20.22
18-25	**191**	48.70	51.31	48.69	55.05
26- 34	**34**	58.62	41.37	17.80	13.48
35-43	**15**	50	50	7.85	8.42
44-52	**5**	71.4	28.6	2.62	1.12
>52	**1**	25	75	0.52	1.69

1. Among donors' age category18-25 years, had the highest contribution within Donor Pool with Donor Type 2 also contributing more at 55.05% overall, compared to Donor Type 1's 48.69%.
2. Age category <18 years followed in overall donor pool contribution with almost equal measure at 22.51% within donor type 1 and 20.22% within donor type 2 category respectively

Gender

Table 5: Contribution by gender demographic within Donor types

Gender	Within Gender (%)		Within Donor Type (%)	
	Donor Type 1 (n=191)	Donor Type 2 (n=178)	Donor Type 1 (n=191)	Donor Type 2 (n=178)
Female	48.59	51.41	45.03	51.12
Male	54.69	45.31	54.97	48.88

The overall contribution to each donor type: females make up 45.03% of Donor Type 1 and 51.12% of Donor Type 2. While Males, In terms of contribution to each donor type, account for 54.97% of Donor Type 1 and 48.88% of Donor Type 2.

4.4 RESULTS OBJECTIVE 3: SAFETY OF BLOOD DONORS

To examine how safe first and repeat blood donors are in Nairobi, Kenya

Table 6: Blood Donor Adverse reaction and Haemoglobin levels

Characteristic	**Total Donors (n)**	**Adverse Reactions (n)**	**Adverse Reaction Rate (%)**	**Average Haemoglobin Level (g/dL)**	Statistical Analysis
Total Donors	369	63	17.1	13.5	$\chi^2 = 8.03$, df = 1, p = 0.0046
First-Time Donors	191	42	22.0	14.2	
Repeat Donors	178	21	11.8	12.8	
Adverse Reaction Types					
- Mild Symptoms		59	93.7 (of total ARs)		
- Severe Symptoms		4	6.3 (of total ARs)		
Return Rate After Adverse Reaction					
- First-Time Donors with AR	42	13	30.0		$\chi^2 = 5.24$, df = 1, p = 0.022
- First-Time Donors without AR	149	0	47.3		
- Repeat Donors with AR	21	1	2.8		

1. The total adverse reaction rate that was recorded stood at 17.1%, with a higher rate of 22.0% for first-time donors and 11.8% for repeat donors.

2. Mild symptoms accounted for 93.7% of adverse responses, whereas severe symptoms were less frequent (6.3%).

3. First-time donors who had negative reactions had a 30.0% return rate, whereas those who did not had a 47.3% return rate. Only 2.8% of repeat donors experienced negative reactions.

4. All donors had an average hemoglobin level of 13.5 g/dL. The average for first-time donors was higher at 14.2 g/dL, whereas the average for repeat donors was lower at 12.8 g/dL.

4.5 DISCUSSION OBJECTIVE 1: ASSESSMENT OF TTI PREVALENCE

Table 2: Discussion of Prevalence of transfusion-transmitted infections across donor types

Characteristic	Donor Type 1		Donor Type 2		Total
	(n)	(%)	(n)	(%)	
HIV					
Negative	190	99.48	177	99.4	367
Positive	1	0.52	1	0.56	2
Syphilis					
Negative	190	99.48	178	100.0	368
Positive	1	0.52	0	0	1
HBV					
Negative	187	97.91	174	97.75	361
Positive	4	2.09	4	2.25	8
HCV					
Negative	190	99.48	177	99.44	367
Positive	1	0.52	1	0.56	2
Total positives	7	-	6	-	13
Total	**191**		**178**		**369**

This study found no statistical difference in transfusion-transmissible infection (TTI) rates between first-time and repeat blood donors at the Kenya National Blood Transfusion Centre (KNBTC). Specifically, the prevalence of Hepatitis B virus (HBV); the most common TTI observed was nearly identical between first-time donors (2.09%)

and repeat donors (2.25%), with a p-value of 1.0 indicating no significant difference. These results suggest comparable infection risks across donor types, challenging the common assumption that repeat donors inherently carry lower TTI risks.

The observed numerical differences in infection rates likely reflect random variation rather than systematic divergence. This interpretation is supported by the limited number of positive cases (only 13 total), which reduces the statistical power to detect subtle differences. Consequently, the findings underscore the importance of extensive and sensitive screening to accurately characterize TTI risks, aligning with recommendations by Puerto-Meredith et al. (2023), who highlight that fewer positive samples limit detection of true prevalence differences.

When compared with Mohammed et al. (2022), who reported a higher HBV prevalence among first-time donors (4.7%) compared to repeat donors (1.7%) in southern Ethiopia, Aliyo et al. (2021) study's findings differ notably. This discrepancy may reflect regional variations in infection dynamics, donor selection criteria, or differences in healthcare infrastructure and public health interventions. While Mohammed et al.'s study supports the idea of reduced risk in repeat donors, the present study's equivalence between groups calls for a critical re-evaluation of the assumption that repeat donors are categorically safer**.**

The strength of this study lies in its focus on voluntary, non-remunerated donors in an urban African context, which is less represented in existing literature. Most comparative studies focus on family-replacement or paid donors, who have higher infection risks (Singogo et al., 2023; Zezai et al., 2020). By highlighting similar TTI rates in both donor groups within a voluntary donor framework, this study provides valuable evidence supporting the effectiveness of Nairobi's donor recruitment strategies and the safety of voluntary donation models.

Furthermore, this study adds novel insight into the urban context of blood safety in Kenya, complementing rural-focused studies like Nsekuye et al. (2023), which reported higher TTI prevalence in rural settings. The equivalence in infection risks between donor types in Nairobi suggests urban healthcare infrastructure, donor education, and access to screening facilities may reduce infection risks more effectively.

PREVALENCE OF TTIS

HIV

This study revealed a low overall prevalence of HIV among blood donors at the Kenya National Blood Transfusion Centre in Nairobi, with 0.52% of first-time donors and 0.56% of repeat donors testing positive. While the prevalence appears slightly higher among repeat donors, the difference not statistically significant

When compared with previous studies across sub-Saharan Africa, these findings reflect a more favorable HIV profile in this Nairobi urban cohort. Higher HIV prevalence rates have been reported in studies from Malawi, Zambia (Zezai et al., 2022), and Tanzania (Mremi et al., 2021)**.** Variations in donor recruitment strategies can partially explain these differences. In countries where family-replacement or paid donors constitute a larger proportion of the donor pool, HIV prevalence tends to be higher. In contrast, Nairobi's heavy reliance on voluntary, non-remunerated donors, who are typically at lower risk, likely contributes to the lower HIV rates observed. This supports the World Health Organization's (2021) recommendation that blood services prioritize voluntary donors to improve transfusion safety.

However, previous research like Nsekuye et al. (2023)**,** reported substantially higher HIV prevalence in rural Kenyan settings, pointing to systemic geographic inequities in healthcare access, education, and screening infrastructure. This urban-focused study, therefore, adds valuable data on blood safety in a better-resourced

context but highlights the need for national strategies to improve rural blood safety and expand access to screening and education.

Critically, some earlier studies lacked the diagnostic sensitivity achieved in this research**.** Many relied on rapid diagnostic tests or basic ELISA kits, which may underestimate true HIV prevalenc**e** due to lower sensitivity, especially in early or latent infections. In contrast, this study utilized chemiluminescent assays with clearly defined quantitative cut-off values, enhancing the reliability and accuracy of HIV detection. This methodological strength represents a significant improvement over many previous approaches and adds to the scientific rigor of the findings.

Although the overall HIV prevalence is low, the presence of HIV-positive cases among repeat donors raises important concerns. Repeat donors are typically assumed to be safer due to prior screening and behavioral counseling. The presence of HIV in this group, therefore, challenges the assumption that repeat donation alone guarantees low risk and suggests the possibility of post-donation seroconversion, behavioral changes, or testing errors in earlier donations. This emphasizes the importance of continuous surveillance, routine post-donation follow-up, and regular re-evaluation of donor eligibility criteria and screening protocols**.**

The novelty of this study lies in its combination of high-quality laboratory diagnostics with a stratified analysis of first-time and repeat donors**,** offering a more granular and updated understanding of HIV prevalence in Nairobi's donor population. By providing disaggregated data, the study helps identify subtle but meaningful patterns that may otherwise be masked in aggregate statistics. Additionally, the urban Kenyan context**,** where donor recruitment is structured and predominantly voluntary, provides a benchmark for the region's best practices in blood safety**.**

From a scientific and public health standpoint, these findings serve as a call to maintain vigilance even in high-performing centers. Although the risk of HIV transmission through transfusion in Nairobi appears low, "low" is not "zero." The study reaffirms that screening systems must evolve with changing epidemiological patterns, and public health authorities must continue to invest in safer recruitment strategies, pre- and post-donation counseling, and more sensitive screening tools like nucleic acid testing (NAT) to detect early infections.

SYPHILIS

This study found an exceptionally low prevalence of syphilis among blood donors at the Kenya National Blood Transfusion Centre, with only one case (0.52%) detected among first-time donors and none among repeat donors. This suggests that syphilis is nearly eliminated among regular blood donors in this urban setting, indicating the effectiveness of repeated screening and donor education in reducing transmission risk over time.

Compared to findings from other sub-Saharan African countries, where syphilis prevalence among donor's ranges from 1% to over 5% (Zezai et al., 2020; Mremi et al., 2021), the Nairobi data shows a marked improvement. Higher rates in countries like Zimbabwe and Tanzania are often associated with family-replacement or paid donors, who tend to have higher exposure to risk factors like unprotected sex or limited access to STI screening. In contrast, Nairobi's emphasis on voluntary, non-remunerated donors likely contributes to this reduced burden an aspect that align with WHO guidelines on safe blood donation practices (WHO, 2021).

Earlier studies have either lumped syphilis together with other TTIs or used qualitative or less sensitive screening methods, thus limiting the specificity and reliability of their findings. In contrast, this study applied quantitative chemiluminescent

assays, which offer greater sensitivity and defined thresholds for positivity hence ensuring accurate detection of even low-level infections.

The absence of syphilis in repeat donors reinforces the importance of donor retention and regular health checks. In contrast, the detection in a first-time donor underscores the limitations of pre-donation questionnaires, which may fail to capture recent high-risk behaviors or asymptomatic infections. This suggests a need for enhanced screening tools and risk education, especially for new donors. Scientifically, the finding adds valuable urban data on the near-elimination of syphilis in a well-managed blood donor population, and demonstrate the effectiveness of current screening and donor management strategies. It also highlights the potential to use repeat donor programs as a model for reducing other sexually transmitted infections in similar resource-limited settings.

Hepatitis B (HBV)

This study identified Hepatitis B virus (HBV) as the most prevalent transfusion-transmissible infection (TTI), with nearly identical positivity rates among first-time (4.09%) and repeat donors (4.25%)**.** Despite over 97% of donors in both groups testing negative, the detection of four positive cases in each group points to a consistent and unresolved HBV transmission risk across donor types.

Globally, higher HBV prevalence is typically reported among first-time donors. For example, Tognon et al. (2020) reported a 38.4-fold higher risk in first-time donors in Sierra Leone, and Wahome et al. (2022) found 1.7 times higher odds among Kenyan first-time donors. These findings reinforce the protective role of repeated screening. In contrast, countries like Iran report much lower prevalence, such as 0.68% in first-time and 0.21% in repeat donors (Vasmehjani et al., 2020), likely due to differences in HBV endemicity, immunization coverage, and health system strength**.** O'Brien et al. (2024**)**

also emphasized the global challenge of HBV among first-time donors, especially where screening and vaccination remain limited.

However, the similar HBV rates observed in both donor groups in this Nairobi study are striking and concerning. They challenge the widely accepted assumption that repeat donors are inherently lower risk. This anomaly as Zheng et al. (2022) claim may reflect gaps in post-donation counseling, possible occult or undetected chronic infections, or insufficient deferral and follow-up systems. It also raises concerns about screening sensitivity, especially regarding early-stage or latent HBV infections.

Unlike earlier studies that focused primarily on prevalence in first-time donors, this study reveals a critical blind spot in the blood safety system: the overreliance on donor history as a proxy for safety. This finding highlights the need for enhanced HBV detection strategies, including nucleic acid testing (NAT) or more sensitive antigen-antibody assays. It also highlights the importance of expanding HBV vaccination to cover new donors and active repeat donors who may have missed earlier immunization campaigns.

Educational interventions targeting behavioral risks, improved pre-donation screening protocols, and routine follow-up for previously positive or borderline cases should be prioritized. Additionally, policymakers must recognize that donor repetition alone does not guarantee safety and adjust strategies accordingly.

This study's strength lies in its direct comparison of HBV rates between donor types using reliable quantitative screening and its urban Kenyan context. TTI trends have often been generalized without detailed differentiation. Scientifically, it contributes new, actionable insights into HBV transmission risks in blood donation systems. It has implications for transfusion safety policies, public health education, and screening technology implementation particularly in resource-limited, high-endemicity

regions like sub-Saharan Africa.

Hepatitis C(HCV)

This study identified a very low prevalence of Hepatitis C (HCV) among blood donors in Nairobi, with 99.48% of first-time donors and 99.44% of repeat donors testing negative. The observed HCV positivity was 0.52% in first-time donors and 0.56% in repeat donors, amounting to just two confirmed cases in each group. These figures reflect the effectiveness of current pre-donation screening protocols, which appear successful in limiting HCV transmission risk through transfusion.

The findings are consistent with global trends indicating the rarity of HCV among donor populations. For instance, Josephson et al. (2022) reported only 166.56 HCV-positive cases per 100,000 first-time donors highlighting the generally low HCV burden among screened individuals. Similarly, Kasraian et al. (2021) found even lower pooled prevalence rates in Iran 0.43% for first-time and 0.28% for repeat donors suggesting that regional differences, donor behaviors, and diagnostic sensitivities significantly influence reported prevalence. These comparisons affirm the Nairobi center's performance as aligned with global best practices, albeit with slightly higher local rates possibly reflecting differing epidemiological contexts or resource limitations.

However, a noteworthy and somewhat counterintuitive finding from this study is the slightly higher HCV prevalence among repeat donors, which diverges from patterns in the literature where repeat donors consistently show lower infection rates due to repeated screening and cumulative risk reduction. This anomaly may reflect gaps in donor follow-up systems, the possibility of HCV acquisition between donations, or occult chronic infections that evade standard serological detection. The asymptomatic nature of HCV could allow infected individuals to donate again without detection if not monitored rigorously.

Although the number of HCV-positive cases in this sample is small and limits statistical power, the persistence of HCV even at low levels demands vigilance**.** It shows the importance of continuous technological and procedural improvements, including adopting nucleic acid testing (NAT)**,** which can detect low-level viremia or early-stage infections. Additionally, donor education on HCV transmission pathways, particularly injection-related or high-risk sexual behaviors, remains crucial in both donor recruitment and retention strategies.

Unlike hepatitis B, no vaccine exists for HCV. This thus make prevention and early detection the only viable tools to combat its spread. Therefore, regular post-donation surveillance and data-driven risk assessment tools are necessary, especially for repeat donors (Tsega et al., 2024). The detection of HCV in this donor group suggests that current assumptions about donor safety based solely on repeat status may need to be reconsidered in Nairobi and similar urban African settings.

The scientific contribution of this study lies in its detailed stratification of HCV prevalence by donor type, an area often underexplored in sub-Saharan African literature. It offers evidence-based insights into the persistence of transfusion-transmissible infections in ostensibly low-risk groups and reinforces the importance of sustained investments in blood safety infrastructure**.** The unexpected detection of HCV among repeat donors is a call to enhance follow-up protocols**,** tighten deferral policies**,** and upgrade testing strategies to maintain a safe and reliable blood supply.

Implications of TTI prevalence among blood donors

The low rates of transfusion-transmissible infections (TTIs) among blood donors in Nairobi suggest that maintaining a safe blood supply is achievable. However, the detection of infections like hepatitis B and HIV shows that continuous screening and preventive measures are still necessary to uphold safety standards (Dei-Adomakoh et

al., 2021). Notably, the difference in infection rates between first-time and repeat donors highlights the need for tailored strategies that address the specific risks and needs of each group. First-time donors showed higher rates of infection, which could be due to lower awareness of medical risks or lack of prior screening experience.

To reduce the risk of TTI transmission, it's important that first-time donors receive proper education on how to identify and disclose risk factors. TTIs found in the donor population also reflect broader public health trends, offering valuable insight into the spread of infections within the community. Monitoring these patterns helps health authorities identify at-risk groups and design more effective prevention campaigns. Improving pre-donation counselling and donor education encourages honesty and awareness, ultimately strengthening the safety and reliability of the entire blood donation system.

4.6 DISCUSSION OBJECTIVE 2: SOCIO-DEMOGRAPHIC CHARACTERISTICS

4.5.1 Discussion 1: Table 2: Discussion Socio-demographic Characteristics of the participants

Characteristic			**Donor Type 1**		**Donor Type 2**	
Age	N	(%)	(n)	(%)	(n)	(%)
<18	79	21.4%	43	54.4	36	45.6
18-25	191	51.8%	93	48.7	98	51.3
26-34	58	15.7%	34	58.6	24	41.4
35-43	30	8.1%	15	50	15	50
44-52	7	1.9%	5	71.4	2	28.6
>52	4	1.1	1	25	3	75
Total	369		191	-	178	-
Gender						
Male	192	52.03	105	54.69	87	45.31
Female	177	47.97	86	48.59	91	51.41
Total	369	-	191	-	178	-
Location						
College	85	23.04%	41	48.24	44	51.76
School	133	36.04	71	53.38	62	46.62
Urban	151	40.92	79	52.32	72	47.68
Total	369	-	191	-	178	-
Occupation						
Business	24	6.5	17	70.83	7	29.17
Employed	107	29%	51	47.66	56	52.34
Student	219	59.3	112	51.14	107	48.86
Unemployed	19	5.14	11	57.89	8	42.10
	369	-	191	-	178	-

There was no significant difference in age distribution between donor types (Type 1: 51.8%, Type 2: 51.3%; $p = 0.54$), indicating similar age profiles across groups. Overall, most blood donors in Nairobi are young adults aged 18–25, consistent with findings by Suemnig et al. (2023), Romero-Domínguez et al. (2021), and Eltewacy et al. (2024). This youth dominance is linked to better health, greater awareness, and easier access to donation sites, making young donors ideal for regular blood donation Dorle et al., (2020). Youth-focused blood drives are thus common and effective globally Moore et al., (2023).

Unlike many studies that focus narrowly on youth donors, this study stresses the need to expand recruitment to older donors, who remain underrepresented but are important for long-term blood supply sustainability. Previous research often generalizes findings from high-income or homogeneous populations and lacks detailed age-stratified analysis relating donor age to infection risk. The cross-sectional design also limits trend interpretation over time.

While younger donors typically have lower transfusion-transmissible infection (TTI) risk (Puerto-Meredith et al., 2023), age alone does not guarantee safety. Comprehensive screening for all ages is essential. These findings highlight the need for inclusive recruitment and education strategies targeting all age groups to maintain a diverse and stable donor pool. This study's novelty lies in its local, age-stratified focus on donor safety in Kenya, challenging assumptions that youth-dominated donor pools are inherently safer.

GENDER

This study found a nearly balanced gender ratio among new blood donors, with males slightly predominating (52.03%) and no significant difference between donor types (Type 1: 55.0%, Type 2: 48.9%; $p = 0.32$). This contrasts with many previous studies in sub-Saharan Africa that report a strong male dominance, often with women constituting less than 30% of donors (Ibrahim et al., Mremi et al., 2021; Asamoah-Akuoko et al., (2023). Such earlier findings attribute lower female participation to physiological barriers like anemia and iron deficiency, alongside socio-cultural factors limiting women's donation opportunities (Silva Carlos & Rodrigues, 2024).

Unlike broad national data in prior research, this study's urban focus reveals a shifting donor profile toward greater gender balance, possibly due to improved awareness and targeted interventions in urban settings. However, Sundararajan et al. (2021) studies often fail to capture these localized dynamics or consider the potential impact of urbanization on reducing barriers for female donors.

The findings highlight the importance of a universal recruitment strategies that address physiological and socio-cultural constraints. The relatively balanced gender ratio challenges prevailing assumptions of male predominance, indicating evolving donor demographics in Nairobi and similar contexts. This study contributes valuable, recent data that can guide inclusive policies ensuring safe and equitable blood donation opportunities for both men and women.

LOCALITY

This study found that most donors were young and urban-based, with 51.8% aged 18–25 years and 40.92% residing in city settings. However, the difference in donor location was not statistically significant ($p = 0.66$), indicating that urban versus non-urban residence did not strongly influence donor characteristics or infection prevalence in this sample. These finding challenges common assumptions that urban residency may increase the risk of transfusion-transmissible infections (TTIs) due to factors like population density or lifestyle differences.

The overall prevalence of TTIs was low but persistent, with notable differences observed between first-time and repeat donors, and a nearly equal gender distribution. Interestingly, repeat donors showed a slightly higher prevalence of hepatitis C virus (HCV) infections, which contrasts with trends reported by Kasraian et al. (2021) where repeat donors generally have lower TTI prevalence due to prior screening and risk education. This divergence suggests gaps in follow-up protocols or undetected chronic infections among repeat donors, which is significant given that repeat donors are usually considered a safer blood source. Additionally, the near-equal gender ratio found in this study contrasts with Ibrahim et al., (2021); Eltewacy et al., (2024) reports that show male predominance in donor populations, a difference possibly influenced by local demographic or cultural factors unique to Nairobi.

Previous studies often suffer from limitations such as focusing narrowly on either first-time or repeat donors without direct comparisons, or relying on regional data that may not reflect the unique dynamics of urban centers like Nairobi. Some also report prevalence changes without clarifying baseline values or temporal trends, which is problematic for cross-sectional designs that capture only a single point in time. These

issues limit the understanding of nuanced donor risk profiles and challenge the assumption that repeat donors uniformly have lower infection risks.

A key strength of this study lies in its stratification of donors by type, location, and gender, allowing a more granular analysis of TTI prevalence. The urban setting provides a unique context for understanding donor characteristics in a major African city, which can differ substantially from rural or national averages. The identification of an unexpected higher HCV prevalence among repeat donors highlights a critical area for intervention that has not been widely reported.

OCCUPATION

This study found that the majority of blood donors were young, with students making up nearly 60% of the donor population. This is consistent with previous research of Mappala et al., (2023); Kiwanuka et al., (2024); and Suemnig et al., (2023) which indicate that younger individuals especially students, are the most active donors, likely due to better health, greater awareness, and easier access to donation sites. Employed donors constituted the next largest group, while unemployed individuals accounted for a small fraction, aligning with earlier Murtagh & Katulamu (2021) studies that suggest socioeconomic barriers limit donation rates among the unemployed. Although the difference in donor occupation was not statistically significant ($p = 0.16$), this finding still provides valuable insight into the occupational distribution of donors in this urban African context.

Previous studies often generalized donor populations without detailed occupational stratification, but this study's focus on occupation and age offers a more granular understanding of demographic patterns and how they relate to transfusion-transmissible infection (TTI) risks. The heavy reliance on young student donors raises concerns about the sustainability of the blood supply if other occupational groups

remain underrepresented. This indicates the need for targeted recruitment strategies aimed at employed and unemployed populations to diversify the donor base, which can enhance both blood safety and supply stability.

The study is scientifically significant because it contributes to a more nuanced understanding of donor demographics and the implications for blood safety programs. By highlighting occupation-related donor patterns and potential recruitment gaps, it provides important guidance for improving donor diversity and reducing TTI risks in resource-limited urban settings Although the p-value indicates a lack of strong statistical significance, the occupational trends observed are meaningful for informing policy adjustments and enhancing blood donation strategies.

4.6.1 DISCUSSION 2: DONOR TYPES AND DEMOGRAPHIC

Table 7: *Discussion Sociodemographic characteristics of the participants p-value (α=0.05)*

Characteristic			**Donor Type 1**		**Donor Type 2**	
Age	N	(%)	(n)	(%)	(n)	(%)
<18	79	21.4%	43	54.4	36	45.6
18-25	191	51.8%	93	48.7	98	51.3
26-34	58	17.8 %	34	58.6	24	41.4
35-43	30	8.1%	15	50	15	50
44-52	7	1.9%	5	71.4	2	28.6
>52	4	1.1%	1	25	3	75
Total	369		191	-	178	P value -0.54
Gender						
Male	192	52.03	105	54.69	87	45.31
Female	177	47.97	86	48.59	91	51.41
Total	369	-	191	-	178	-P Value 0.32
Location						
College	85	23.04%	41	21.47	44	24.72
School	133	36.04	71	37.17	62	34.83
Urban	151	40.92	79	41.36	72	40.45
Total	369	-	191	-	178	P Value-0.66
Occupation						
Business	24	6.5	17	8.90	7	3.93
Employed	107	29%	51	26.70	56	31.46
Student	219	59.3	112	58.64	107	60.11
Unemployed	19		11	5.76	8	4.49
	369	-	191	-	178	P value 0.16

4.6.2 AGE DISTRIBUTION AMONG DONOR TYPES

The age distribution of blood donors reveals distinct trends between first-time and repeat donors. A large proportion of first-time donors were found to be younger, with 48.69% aged between 18 and 25 years, and 22.51% under 18 years. This trend aligns with previous findings that associate youth participation with factors such as educational outreach, awareness campaigns, and peer influence prevalent in academic institutions. Among repeat donors, the majority also fell within the 18–25 age group (55.05%), followed by 13.48% in the 26–34 age range. These results indicate that while younger individuals are the most active in initiating donation, a proportion of them continue to donate consistently over time. The presence of older repeat donors suggests that age may be linked to increased donor commitment and long-term engagement. Similar patterns have been reported in studies by de Oliveira et al. (2021) and Priyono et al. (2021), which emphasize the strong participation of younger age groups and the sustained contribution of older, experienced donors. Understanding these trends is important for designing age-appropriate recruitment and retention strategies to maintain a stable blood supply.

4.6.2.1 IMPLICATION OF SOCIODEMOGRAPHIC PARAMETERS

The fact that first-time and return donors are separated by age demonstrates how socioeconomic status influences blood donation behavior. Younger donors may have different aims and challenges than older donors with more experience (Ibrahim et al., 2021; Suen et al., 2020). According to Romero-Domínguez et al. (2021), younger donors may be motivated by immediate rewards or learning opportunities. In contrast, older donors may feel responsible for their community or the potential for improved health.

Understanding age differences is essential for developing effective hiring and retention strategies. For example, adverts targeting younger contributors should emphasize education and expertise through school and university networks. Efforts to retain elderly donors, on the other hand, may emphasize the value of long-term commitment, health benefits, and regular check-ups.

4.6.2.2 IMPLICATION OF TRANSFUSION-TRANSMISSIBLE ILLNESSES

Transfusion-transmissible diseases are more common among older and younger donors. Younger donors, who are more likely to be first-time donors, may have lower rates of TTIs because they are healthier and engage in less risky behaviors. Studies (Shrivastava et al., 2023; Chaurasia et al., 2024; Cisneros-García et al., 2023) indicate that diseases such as hepatitis B and C are less prevalent in younger individuals than in older individuals. However, elderly repeat donors may be more susceptible to TTIs since they have been exposed to them more frequently and have health conditions that make them more sensitive (Alharazi et al., 2022). To ensure the safety of the blood supply, it is necessary to determine the prevalence of TTI among various groups of donors. Different age groups may have different dangers that must be considered when checking.

4.6.2.3 IMPLICATION OF BLOOD DONOR AND TRANSFUSION SAFETY

The general safety of blood donations is also affected by the age difference between first-time and repeat donors. Younger people donating blood for the first time are less likely to suffer adverse outcomes or become ill, which would prevent them from contributing. Since this group is less likely to experience long-term issues, keeping them safe and healthy can be crucial. However, even though we depend on older repeat donors to maintain a steady donation pool, they might also have higher health problems.

These donors may have health conditions that prevent them from donating blood or endanger their blood safety.

One can select donors and ensure that the blood supply is secure and functional for all by looking at the safety characteristics of these two donor groups. Determine the age range of both new and returning blood donors to understand their actions' motivations better. This knowledge is vital in finding and keeping donors, lowering the risk of TTIs, and keeping the blood supply safe. Donor programs for blood businesses can work better and last longer if they pay attention to different age group's specific needs and traits.

4.6.2.4 GENDER DIFFERENCE IN DONOR TYPES

It was clear that men and women who gave blood for the first time and those who did it again were not the same. Most people in the first-time donor group (Donor Type 1) were guys (54.69%). On the other hand, 51.41% of repeat donors (Type 2) were women, which means that women like to help more. Men are more likely than women to give blood for the first time or again (Brunson et al., 2022; Niazkar et al., 2020). Men and women were the main types of first-time and return donors. This shows how gender is an important sociodemographic factor that affects blood donation habits. Norms, problems, and reasons for giving blood may differ for men and women (Griffin et al., 2021; Duh et al., 2021). This might help explain the different kinds of donors. Men may be more inclined to donate blood for the first time due to societal standards of bravery.

However, because they care more or have had positive experiences donating blood, women might be more inclined to do so repeatedly (Ou-Yang et al., 2017). The data provides a wealth of information about the types of people who give blood for the first time and again in Nairobi, Kenya. Gender is a significant factor. These strategies can help attract and retain both male and female donors. It is necessary to consider and

address the disparities in blood donation practices between men and women. This will enhance public health and the effectiveness of donor programs.

Impact on Blood Transfusion-Spread Infections (TTIs)

These differences between men and women may also impact the prevalence of transfusion-transmitted infections (TTIs) among donors. Certain TTIs, such as hepatitis B and C, are more or less common in men and women. Understanding the gender distribution of the various donor types is crucial to determining how this may impact the number of TTIs. Screening and prevention programs tailored to each donor and recipient are created after this information is obtained. Because of these activities, both groups have a decreased risk of infection.

Implications for the safety of blood donors and transfusions

The differences in the appearance and feelings of men and women are significant regarding the safety of blood donors and the quality of the blood donated. Men and women differ in hemoglobin levels, body weight, and pre-existing medical conditions. Because of these differences, it's not safe for everyone to give blood. Being aware of the variations between male and female blood donors can help improve the selection process, which will protect the safety and reliability of the blood supply.

Differences Between First-Time Donors and Repeat Donors

Studies show that students are the most common donor group, accounting for 59.34% of first-time donors and 48.86% of repeat donors. This highlights schools and universities as key settings for successful blood donor recruitment. Employed individuals make up the second-largest group, representing 28.99% of initial donors and 52.34% of repeat donors. These figures suggest that workplaces also serve as strong platforms for encouraging consistent blood donation.

In contrast, business owners and unemployed individuals are significantly underrepresented. They comprise only 5.14% of the donor pool, with just 42.11% returning for repeat donations. Several studies have examined the link between occupation and donor behavior, showing that work structure, income stability, and daily routines can shape donation habits (Lu et al., 2022; Gorleer et al., 2020; Lin et al., 2018; Tsega et al., 2024).

Sociodemographic factors such as education, job type, and income level play a major role in influencing both first-time and repeat donation patterns. Understanding these differences can help tailor recruitment and retention strategies. For instance, schools and workplaces should remain key focus areas, while targeted outreach efforts may be needed to engage business owners and unemployed individuals who may face unique barriers to participation.

4.6.3 DISCUSSION 3: DISCUSSION CONTRIBUTION OF AGE DEMOGRAPHIC WITHIN DONOR TYPES

Table 8: Discussion Contribution of age demographic within donor Types

Age Group	Within Age group (%)		Within Donor Type (%)	
	Donor Type 1 (n=191)	Donor Type 2 (n=178)	Donor Type 1 (n=191)	Donor Type 2 (n=178)
<18	54.43	45.57	22.51	20.22
18-24	48.60	51.40	45.55	51.69
25-31	53.85	46.15	10.99	10.11
32-38	55.10	44.90	14.14	12.36
>38	56.52	43.48	6.81	5.62

AGE DIMENSION IN OVERALL DONOR POOL WITHIN DONOR TYPES

This cross-sectional study explored the prevalence of age distribution and donor type among blood donors, revealing several key findings. The most significant contributor to the donor pool was the 18–24 age group, particularly within Donor Type 2, which accounted for 51.69% of all donations in that category. This suggests a high willingness or ability to donate blood among young adults, possibly due to better physical health, increased awareness through youth-centered campaigns, or successful recruitment strategies tailored to this demographic. In comparison, Donor Type 1 reported a 45.55% contribution from the same age group, slightly lower than the 56.22% contribution from the 25–49 age group within that donor type. This indicates an age-dependent variability between donor types, likely influenced by structural, operational, and engagement differences.

The second-highest donor group comprised individuals under the age of 18. This group showed a relatively balanced distribution across both donor types (Donor Type 1 = 22.51%**,** Donor Type 2 = 20.22%), unlike the sharper disparities observed in older age groups. This uniformity suggests that outreach and educational initiatives targeting minors often involving schools, community programs, and parental influence have been effective across organizational lines (Wahome et al., 2022). It also indicates a promising opportunity to cultivate a donor culture early, potentially leading to higher retention in adulthood.

When compared to previous studies, the present findings provide important context. Vermeulen (2022) reported that 58% of donors in South Africa were aged 30 and above, and Vuhahula et al. (2023) found 69.6% of Tanzanian donors were aged 35 or older. In contrast, Okuthe et al. (2022) noted that 47% of Kenyan donors were aged 19–21. These regional differences show how cultural, socioeconomic, and policy

environments affect donation trends. However, many of these studies lack a detailed breakdown of donor types or how organizational models influence age-specific engagement, which limits cross-study comparability.

A key strength of this study is based on its comparative analysis of age cohorts across different donor types which offers a more nuanced understanding of blood donor dynamics. Unlike previous research that often treats donors as a homogenous group, this study distinguishes between organizational donor models, revealing age-specific preferences and participation trends. Doing so provides actionable insights for improving donor retention and tailoring recruitment strategies.

This study's novelty and scientific value stem from its differentiated approach to understanding blood donation behavior by age and donor type. This study expands the understanding of how recruitment, organizational structure, and demographic targeting may impact donation rates by introducing a dual-donor type framework This layered analysis can inform national and regional strategies for increasing voluntary blood donation, especially among younger age groups with a high potential for long-term donor retention.

4.6.4 DISCUSSION 4: DEMOGRAPHIC CONTRIBUTION BY GENDER

Table 9: Discussion Contribution by gender demographic within Donor types

Gender	Within Gender (%)		Within Donor Type (%)	
	Donor Type 1 (n=191)	Donor Type 2 (n=178)	Donor Type 1 (n=191)	Donor Type 2 (n=178)
Female	48.59	51.41	45.03	51.12
Male	54.69	45.31	54.97	48.88

GENDER DIMENSION IN OVERALL DONOR POOL WITHIN DONOR TYPES

The current investigation found a relatively balanced gender distribution across donor types, with female donors comprising 45.03% of Donor Type 1 and 51.12% of Donor Type 2, while male donors made up 54.97% of Donor Type 1 and 48.88% of Donor Type 2. While these differences are not statistically significant, they reflect subtle gendered preferences shaped by recruitment strategies or social influences. Donor Type 2 had a little more women than men donating blood. This might be because the campaigns to encourage donation focused on community and helping others which are messages that often connect well with women. On the other hand, Donor Type 1 had more men donating, which could be because of cultural ideas about men being stronger or because the messages used to encourage donation spoke more to men.

The near-equal engagement of both sexes is an encouraging sign as it indicates an inclusive donor environment. This contrasts with broader African trends where male dominance in blood donation is persistent. For example, in Sokoto, Nigeria, men accounted for over 99.4% of donations (Li & Jiang, 2025); in Pakistan**,** female

participation was under 1% (Bukhari et al: Bhatti et al, 2022); and in Burundi**,** 77% of donors were men (Ntawuyamara et al., 2024). These disparities are typically rooted in sociocultural norms, health misconceptions, and logistical barriers that disproportionately affect women.

Compared to such studies, our findings demonstrate a notable deviation, suggesting that gender parity is possible when donor programs are consciously inclusive. The differences in our results point to the potential success of targeted efforts such as educational campaigns and safe, accessible donation sites in promoting female involvement.

This study challenges the generalized notion that male dominance in blood donation is universal across African contexts. Instead, it highlights the importance of localized program design that reflects the unique dynamics of each donor population. Furthermore, the results as Greffin et al. (2021) backs up suggest that donor type preference is not inherently gendered, but may be more influenced by other demographic or psychosocial factors like age, occupation, or motivational triggers.

The scientific value and novelty of this study is based on its dual analysis of gender distribution across differentiated donor types, a perspective that is not commonly addressed in prior literature. While most studies report aggregate gender figures, this research disaggregates donor types to uncover subtle behavioral trends thereby providing richer insights for tailoring blood donor recruitment and retention strategies.

4.7 DISCUSSION OBJECTIVE 3: SAFETY OF BLOOD DONORS

SAFETY OF BLOOD DONORS AMONG FIRST AND REPEAT BLOOD DONORS

Table 11: Blood Donor Adverse reaction and Haemoglobin levels

Characteristic	**Total Donors (n)**	**Adverse Reactions (n)**	**Adverse Reaction Rate (%)**	**Average Haemoglobin Level (g/dL)**
Total Donors	369	63	17.1	13.5
First-Time Donors	191	42	22.0	14.2
Repeat Donors	178	21	11.8	12.8
Adverse Reaction Types				
- Mild Symptoms		59	93.7 (of total ARs)	
- Severe Symptoms		4	6.3 (of total ARs)	
Return Rate After Adverse Reaction				
- First-Time Donors with AR	42	13	30.0	
- First-Time Donors without AR	149	0	47.3	
- Repeat Donors with AR	21	1	2.8	

Safety of Blood Donors Among First-Time and Repeat Donors

This study highlights the critical safety differences between first-time and repeat blood donors, revealing that first-time donors experience significantly higher rates of adverse reactions (22.0% vs. 11.8%; $\chi^2 = 8.03$, $P < 0.0046$). This finding aligns with

Sabina et al. (2023), who also observed greater complication rates in new donors (60.5% vs. 39.5%). The higher incidence of adverse events among first-time donors is likely linked to anxiety, unfamiliarity with the donation process, and physiological stress.

Importantly, experiencing such adverse reactions substantially decreases the likelihood of first-time donors returning to donate again, a trend supported by Biswas et al. (2019). These results underscore the need for enhanced pre-donation counseling, reassurance during donation, and thorough post-donation care to improve donor experience and retention. Compared to previous studies, this research provides robust, locally relevant data that emphasize the vulnerability of first-time donors and the direct impact of their safety on the sustainability of the blood supply. By quantifying these safety concerns in an urban African context, the study offers valuable insights for targeted interventions aimed at minimizing adverse reactions and fostering a more reliable donor pool.

Hemoglobin Levels and Donors' Health

This study found that first-time blood donors had significantly higher average hemoglobin (Hb) levels (14.2 g/dL) compared to repeat donors (12.8 g/dL). This reflected the physiological impact of frequent donation on donor health. This difference is consistent with earlier findings by Kandasamy et al. (2020), who identified low Hb as the leading cause of donor deferral, and Kiss et al. (2015), who reported iron deficiency anemia as a consequence of repeated donations without adequate iron replenishment.

However, some regional studies like that of Njenga et al. (2022) in Kenya and Robaina- Tulel et al. (2024) in Eldoret show higher average Hb levels. These studies emphasize on geographic and nutritional factors that tend to influence hemoglobin profiles. The variability across locations, as seen also in Okuthe et al. (2022), highlights

the need for context-specific donor eligibility criteria based on local hemoglobin baselines.

Importantly, this study links these physiological differences with donor experience and retention: first-time donors not only had higher Hb but also reported more post-donation complications (22.0%) than repeat donors (11.8%), with vasovagal reactions being the most common and mild adverse reactions dominating the profile. The lower return rate among first-time donors experiencing adverse reactions (30.0%) compared to those without such events (47.3%) suggests that even mild complications can significantly affect donor willingness to donate again. This behavioral dimension complements previous studies like Ashraf & Malik (2023) and Brunson et al. (2022), which highlighted vasovagal reactions as a primary cause of adverse experiences.

This study's strength is based on its holistic approach that integrates physiological data, adverse event monitoring, and behavioral outcomes to provide a comprehensive view of donor health risks and retention factors in the Kenyan context. It also highlights gender-specific vulnerabilities like slower hemoglobin recovery in female donors due to menstrual blood loss. It therefore aligns with findings from Mast et al. (2020).

The novel contribution of this research is its potential to inform national blood safety policies by recommending routine iron supplementation, adjusting eligibility criteria to regional hemoglobin norms, and developing targeted education and retention interventions focused on first-time and frequent donors. This integration of biological, psychological, and contextual factors advances understanding of donor safety and sustainability in resource-limited urban settings.

CHAPTER 5: SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 SUMMARY

This study looked at the safety and health characteristics of first-time and repeat blood donors at the National Blood Transfusion Centre in Nairobi. The goal was to help improve how donors are recruited and retained safely. The study focused on three key areas:

1. **Transfusion-Transmitted Infections (TTIs)**
    - Some blood samples tested positive for infections like HIV, Hepatitis B, and Hepatitis C.
    - First-time donors had more infections than repeat donors, making them less safe as blood sources.
2. **Donor Background (Socio-demographic Information)**
    - First-time donors were mostly younger and less informed about blood donation.
    - Repeat donors were often older, better educated, and had a better understanding of the donation process.
3. **Donor Safety and Well-being**
    - First-time donors reported more side effects like dizziness and fainting.
    - Repeat donors were more comfortable and had fewer problems after donation.

5.2 CONCLUSION

Each conclusion is based on the specific study objective;

1. **Objective 1 – TTIs**
    - First-time and repeat donors have no difference in infection risk hence adherence to strict screening protocol in both.

- Apparent elevated hepatitis B virus prevalence may have been a random occurrence

2. **Objective 2 – Donor Background**
    - Sociodemographic like Age, occupation, gender, and location are not associated with the country not meeting its blood needs.
    - Younger donors appeared to dominate both blood donor types.
3. **Objective 3 – Donor Safety and Well-being**
    - First-time donors face more health challenges during and after donation.
    - Repeat donors feel more confident and have better physical responses.
4. **Policy Use**

- The findings can help the Ministry of Health and other partners improve donor recruitment strategies, training, and safety procedures.

5.3 RECOMMENDATIONS

The following actions are suggested based on the study's results and objectives;

For Objective 1 – TTIs

- Use better testing methods like nucleic acid testing (NAT) to detect infections early (Tulel et al., 2024).
- Introduction of donor screening criteria that will reduce incidence of Hepatitis B virus amongst voluntary blood donors

For Objective 2 – Donor Background

- Create a universal awareness campaign targeting donor population
- Provide clear information on safe donation practices and benefits.

For Objective 3 – Donor Safety

- Offer pre-donation counseling to first-time donors t
- Train staff to identify and assist donors who may experience side effects.

- Give post-donation support and follow-up to improve the donor experience.

For Policy and Planning

- Use this study to shape national blood safety policies.
- Focus on long-term programs that promote safe donation, regular donor follow-up, and health checks.
- Partner with community organizations and healthcare facilities to improve public trust and awareness**.**

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APPENDICES

APPENDIX I: BLOOD DONOR QUESTIONNAIRE

REPUBLIC OF KENYA

Kenya Tissue and Transplant Authority

DamuKE
The Kenya Blood Banking Management System

KENYA TISSUE AND TRANSPLANT AUTHORITY (KTTA)
BLOOD DONOR QUESTIONNAIRE

Name of Blood Establishment:		Affix/write Donation Number here
Blood Establishment Code:		

Donation site: _____ **County:** _____ **Donor Number:** _____

SECTION 1: DONOR INFORMATION (To be completed by the donor)

Surname	Other Names	Gender (F/M/Other/Prefer not to disclose)

Next of kin name: _____

Unique Identifier (Student No. /ID No./PP No.): _____ **Date of Birth:** _____ DD / MM / YY

Status: (Mark in appropriate box): Single/Married /Separated /Divorced /Widowed/Widower /Prefer not to disclose

Cell Phone No.	Email	Residence (County)

Level of Education: (Mark in appropriate box): None/ Primary/ Secondary/ Tertiary/ other

Occupation: (Mark in appropriate box): Employed/ Self-Employed/ Unemployed/ Student

When did you last donate blood?	Number of previous donations:_____
☐ Never donated: 3 months 6 months 12 months ☐ More than 12 months	

SECTION 2: ELIGIBILITY QUESTIONNAIRE (Please fill in truthfully and accurately- your answers will be treated with utmost confidentiality- tick where appropriate)

1	Are you feeling well today?	Yes / No
2	Have you eaten in the last 6 hours?	Yes / No
3	Have you ever fainted within the past one year?	Yes / No
4	Are you pregnant or lactating	Yes / No
5	Have you traveled in the last 14 days outside your usual area of residence?	Yes / No
6	Are you on any regular medication, antibiotics, analgesics e.g. Aspirin, any other?	Yes / No
7	In the last 3 months have you had any tattooing or body piercing e.g. ear piercing?	Yes / No
8	In the last 3 months have you had sexual activity with a person whose health status you do not know?	Yes / No
9	In the last 3 months have you had a vaccination	Yes / No
In the past 6 months have you:		
10	Had surgery or medical treatment	Yes / No
11	Received Blood or Blood Products	
Have you ever:		
12	Had Hepatitis or yellow eyes?	Yes / No
13	Been exposed to suspected case of Covid-19 in the last 14 days?	Yes / No

SECTION 3: DECLARATION & CONSENT (Please read this before you sign the form)

i.	I declare that I have filled in all the information required in this form truthfully and accurately.
ii.	I declare that I will also answer truthfully and accurately to any other questions that may be asked of me, for purposes of verifying my eligibility to donate blood.
iii.	I consent to give blood; I understand that if found to be safe, it may be used for transfusion for the benefit of others.
iv.	The undersigned hereby releases the Kenya Tissue and Transplant Authority, its agents or employees, as well as any other users and exhibitors of said pictures, from any and all claims, demands, accountings and causes for which the aforesaid videotape, testimonial, motion picture, digital images, or photograph likeness may be used pursuant to this consent and general release. It is also my understanding that i will receive no compensation for my likeness and testimonial.
v.	I understand that whatever blood I donate will be screened for HIV, Hepatitis B & C, and Syphilis and the results of my tests may be obtained from the Kenya Tissue And Transplant Authority by myself.
vi.	I understand that should any of the screening tests give a reactive result, I will be contacted by use of any communication medium(s), to send **me important information and or to offer me counselling to make an informed decision** about further confirmatory testing and management. Such medium(s) shall include but are not limited to e-mail, post office, mobile telephone and/or fixed telephone.
vii.	I hereby give consent to KTTA to use the contact details provided in this form to communicate to me as the need may be.
viii.	I understand the blood may be used for scientific research, main objective being to improve the safety of the blood supply to patients. I further understand that this will be done in an anonymized manner, so as to not to reveal Personal Identifiable Information (PII), that may be linked directly to me No ☐ Yes ☐

Donor Signature: _____ **Date:** _____

SECTION 4: FOR OFFICIAL USE

a. Donor Screening Report

Weight (kg)	Hb >12.5g/dl	BP	Pulse	Temp (°C)		Donor is Eligible	
						Yes	No
Donor Deferred (Y/N)	**Brief reason for deferral**						
Type of donor (Replacement/ Voluntary/ Autologous)			**Type of Donation (Normal / Apheresis)**				

Name of Nurse / Counselor:_____**Date:**_____**Sig** _____

b. Donation outcome & post donation adverse events: (Yes or no)

Underweight Unit (Y/N)	Underweight Unit (Y/N)	> 1Venipuncture (Y/N)	Hematoma (Y/N)	Fainting (Y/N)	Nausea (Y/N)
Vomiting (Y/N)	**Headache (Y/N)**	**Convulsion (Y/N)**	**Incontinence of urine/stool (Y/N)**		

Time Needle In		**Time Needle Out**		**Volume donated (ml)**		**Bag Type**	

SECTION 5: NOTIFICATION

Reported by:_____**Date:**_____ **Sign:**_____

APPENDIX II: KENYA BLOOD TRANSFUSION AND TRANSPLANT SERVICE APPROVAL

MINISTRY OF HEALTH
STATE DEPARTMENT FOR MEDICAL SERVICES
KENYA BLOOD TRANSFUSION AND TRANSPLANT SERVICE

Telegrams: "MINHEALTH". Nairobi
Telephone: Nairobi 0794 655 629
Email : info@ktta.go.ke
When replying please quote:

KBTTS
NPHLS GROUNDS
P.O. Box 29804-00202
NAIROBI

Ref. KTTA/ EXT/CORR/22/VOL. III (110)

Date: 22nd June, 2023

Mr. Charles Rombo Oliech
Mount Kenya University
NAIROBI.

Dear Mr. Oliech,

REF: APPROVAL TO CONTINUE RESEARCH PROJECT – CHARLES ROMBO OLIECH (MMLS/43079'/2016)

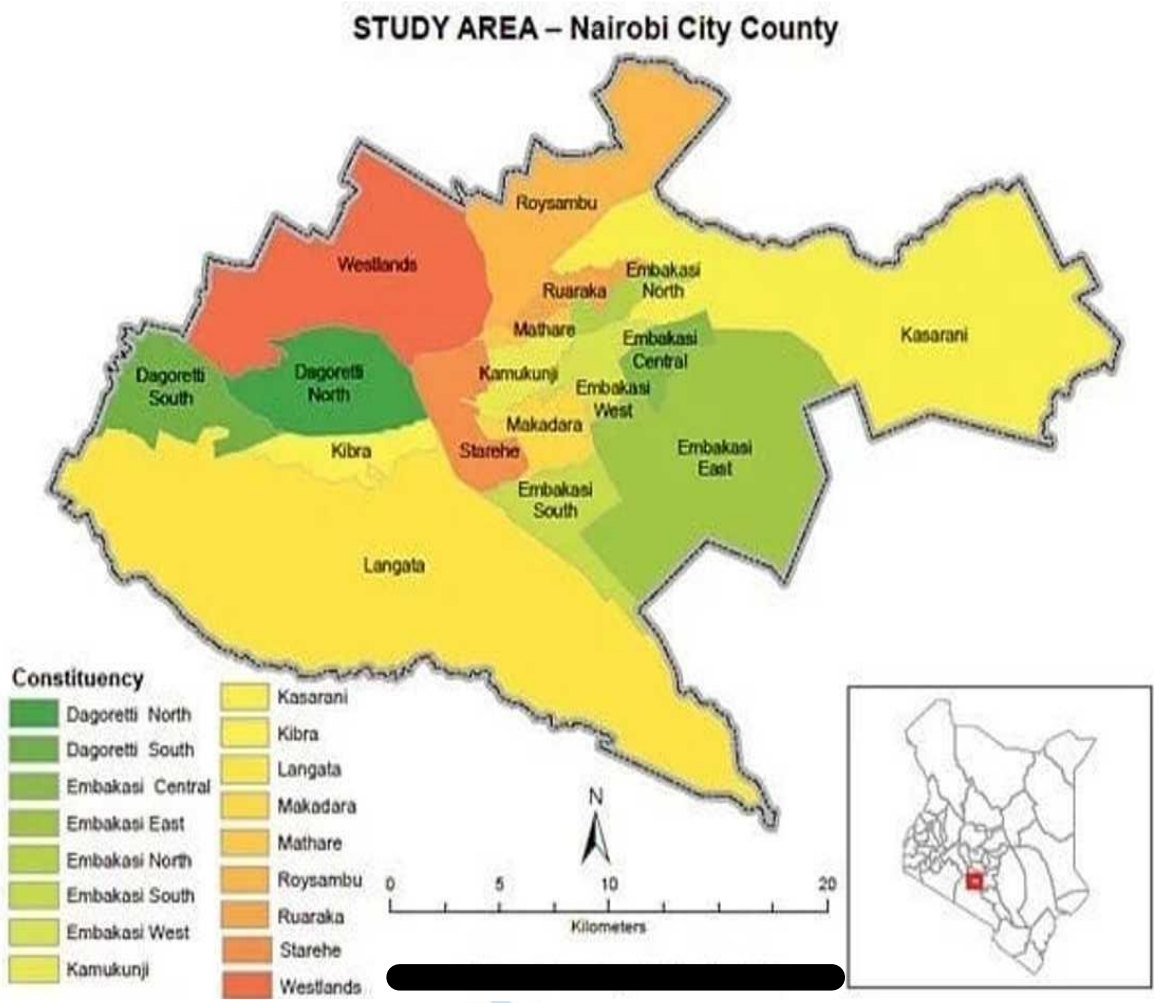
The Kenya Blood Transfusion and Transplant Service (KBTTS) is a mandated with ensuring a safe, sustainable, and adequate supply of blood and blood products, as well as overseeing ethical transplant practices across Kenya. Our mission is to enhance public health through efficient donor mobilization, screening, and adherence to global standards in transfusion and transplant services. We continuously support research initiatives that contribute to improved policies and practices in these critical areas.

We acknowledge receipt of your request dated 15th June 2023, seeking approval to continue your research project titled *"Analysis of the Health Characteristics of New and Repeat Blood Donors in Kenya."* After reviewing your submission, including the attached NACOSTI approval (Ref: 174990), we are pleased to grant you full authorization to proceed with your study. Your research aligns with our mandate to promote safe and sustainable blood donation practices, and we commend your dedication to identifying strategies that encourage frequent donor participation.

This approval is granted with the expectation that you will adhere to ethical guidelines set by NACOSTI and other relevant health research policies, maintain compliance with data protection laws, and ensure confidentiality of donor information. Additionally, we request that you submit periodic progress updates to KBTTS for monitoring purposes.

Dr. Wakwabubi M. N
Ag. CHIEF EXECUTIVE OFFICER

APPENDIX III: STUDY AREA OF NAIROBI COUNTY



APPENDIX IV: MOUNT KENYA UNIVERSITY APPROVAL

Mount Kenya University

REF: **MKU/ISERC/2748**

Date: 25 April 2023

TO: **CHARLES ROMBO OLIECH**

REG: **MMLS/43079/2016**

Dear Sir/Madam,

RE: COMPARATIVE ANALYSIS OF THE HEALTH CHARACTERISTICS OF NEW AND REPEAT BLOOD DONORS IN KENYA NATIONAL BLOOD TRANSFUSION SERVICE, NAIROBI

This is to inform you that **Mount Kenya University** has reviewed and approved your above research proposal. Your application approval number is **1776.** The approval period is **25/04/2023 - 24/04/2024.**

This approval is subject to compliance with the following requirements;

i. Only approved documents including informed consents, study instruments, MTA will be used
ii. All changes including amendments, deviations and violations are submitted for review and approval by **Mount Kenya University**
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **Mount Kenya University** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to **Mount Kenya University** within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions
vi. 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
vii. Submission of an executive summary report within 90 days upon completion of the study to **Mount Kenya University**

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

The Chairman
Mount Kenya University
Ethics Review Committee
P. O. Box 342 - 0100, Thika

Dr. Peter G. Kirira
Chairman, Mount Kenya University ISERC

Main Campus, General Kago Road, P.O. Box 342-01000 Thika.

APPENDIX V: NACOSTI APPROVAL

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **174990**

Date of Issue: **18/May/2023**

RESEARCH LICENSE

This is to Certify that Mr.. Charles Rombo Oliech of Mount Kenya University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: ANALYSIS OF THE HEALTH CHARACTERISTICS OF NEW AND REPEAT BLOOD DONORS IN NAIROBI, KENYA for the period ending : 18/May/2024.

License No: **NACOSTI/P/23/25937**

174990

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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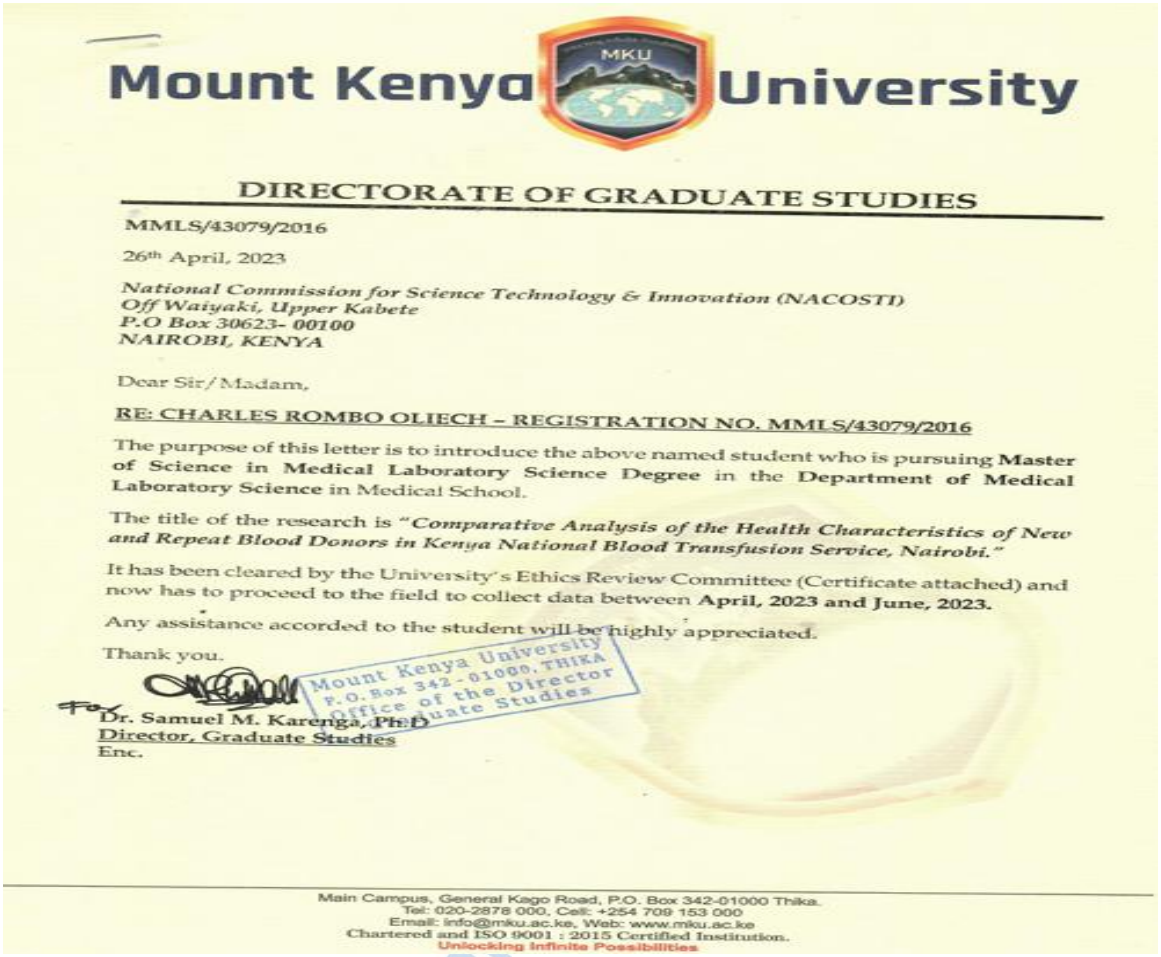
See overleaf for conditions

APPENDIX VI: LETTER OF INTRODUCTION



Mount Kenya University

DIRECTORATE OF GRADUATE STUDIES

MMLS/43079/2016

26th April, 2023

National Commission for Science Technology & Innovation (NACOSTI)
Off Waiyaki, Upper Kabete
P.O Box 30623- 00100
NAIROBI, KENYA

Dear Sir/Madam,

RE: CHARLES ROMBO OLIECH – REGISTRATION NO. MMLS/43079/2016

The purpose of this letter is to introduce the above named student who is pursuing **Master of Science in Medical Laboratory Science Degree** in the **Department of Medical Laboratory Science** in Medical School.

The title of the research is ***"Comparative Analysis of the Health Characteristics of New and Repeat Blood Donors in Kenya National Blood Transfusion Service, Nairobi."***

It has been cleared by the University's Ethics Review Committee (Certificate attached) and now has to proceed to the field to collect data between **April, 2023 and June, 2023.**

Any assistance accorded to the student will be highly appreciated.

Thank you.

Mount Kenya University
P.O. Box 342-01000, THIKA
Office of the Director
Graduate Studies

for **Dr. Samuel M. Karenga, PhD**
Director, Graduate Studies
Enc.

Main Campus, General Kago Road, P.O. Box 342-01000 Thika.
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APPENDIX VII: STANDARD OPERATING PROCEDURE; MANAGEMENT OF ADVERSE REACTION IN A DONOR

KENYA NATIONAL BLOOD TRANSFUSION SERVICE

Kenya National Blood Transfusion Service

It's safe and it saves.

STANDARD OPERATING PROCEDURE

Management of adverse reactions in a donor

Document Number:	**SOP LAB**
Revision Number:	**00**
Effective Date:	
Controlled copy number:	

	NAME	TITLE	SIGNATURE	DATE
Written By	Zahra Mohamed	I/C Donor Clinic; Nairobi RBTC		
Reviewed by	Joseph Mirereh	Blood Donor Service Manager		
	Charles Rombo	National Quality & Safety Manager-KNBTS		
Authorised By	Dr. J. Githaiga	Head KNBTS		

1. Purpose: To provide a procedure for management of adverse reactions of the blood donors.
2. Scope: The procedure shall be used during blood donation to address any adverse reactions in the immediate post donation period.
3. Responsibilities: Lab technologist/Technicians/Nurses
4. Materials and Reagents:

Oral medication.

i. Analgesic tablets
ii. Calcium and vitamin C tablets
iii. Electrolyte replacement fluid

Injection

- Epinephrine (Adrenaline)
- Atropine sulphate
- Pheniramine maleate
- Diazepam
- Glucocorticosteroid
- Glucose (Dextrose 25%)
- Furosemide
- Metoclonopromide
- Prochlorperazine maleate
- Sodium bicarbonate
- Glucose saline(sodium chloride and Dextrose 500 ml)

Antiseptics

i. Salvon
ii. Hydrogen peroxide
iii. Tincture benzoine
iv. Mercurochrome

Miscellaneous

i. Bandages/dressings
ii. Band aids
iii. Anti-histaminic cream
iv. Oxygen cylinder

v. Heparin and benzyl nicotinate ointment
vi. Smelling salt –spirit of ammonia
vii. Analgesic balm
viii. Tongue depressor
ix. Disposable syringes and needles 22g
x. Clinical thermometer
xi. Infusion jet
xii. Paper bag

5. Records

Type	Retention Period	Location
Adverse Reaction Records	10	Donor Clinic

6 Safety Precautions

- Use appropriate protective clothing when handling samples i.e. gloves, lab coats etc.
- Any spillage of human material should be handled according to the organization's procedure on handling bio-hazardous spills.
- General laboratory safety guidelines must be observed at all times.

7. Procedural Steps

Vasovagal syndrome

i. Raise the feet and lower the head end
ii. Loosen tight clothing (belt, tie etc.)
iii. Ensure adequate airway
iv. Check pulse and blood pressure

v. Apply cold compresses to the forehead and back

vi. Administer inhalation of spirit of ammonia if needed.

vii. The donor should respond by coughing which will elevate the blood pressure.

viii. If there is bradycardia and hypotension

I. Administer injection. Atropine 1 ml IM, if bradycardia continues for more than 20 minutes.

II. Administer IV normal saline or dextrose saline infusion if hypotension is prolonged.

Convulsions.

i. Keep the head tilted to the side, prevent the tongue bite

ii. Keep the airway patent by inserting a tongue blade or gauze between the teeth.

8 References: Technical Manual of American Association of blood banks 13TH edition

1999. Page 99-100.

Introduction to Transfusion Medicine Z.S Bharucha & D.M. Chouhan 1st Edition 1990, page 101-102.

9 Revision History

Revision No.	Review Date	Reviewer Title/ Name	Reviewer Initials	Summary of Changes	Next Scheduled Review Date
00	18th March 2018	BDS,NQ&S, ICT Managers	JM CRO	New document	March 2020

APPENDIX VIII: STARNDARD OPERATING PROCEDURE VENEPUNCTURE

Kenya National Blood Transfusion Service

It's safe and it saves.

STANDARD OPERATING PROCEDURE

Performance of Venepuncture

Document Number:	**SOP CLN 003**
Revision Number:	**02**
Effective Date:	**April 2018**
Controlled copy number:	

	NAME	TITLE	SIGNATURE	DATE
Written By	Darline Kidiavai	Donor Clinic In charge-RBTC Eldoret		
Reviewed by	Joseph Mirereh	Blood Donor Services Manager - KNBTS		
	Charles R.Oliech	National Quality Manager-NBTS		
Authorised By	Dr. J. Githaiga	Head KNBTS		

1. **Purpose:** To provide procedure on how to perform Venepuncture

2 **Scope:** To be used in the donor clinic sections from time the need goes in to until acceptable blood volume is collected in the bag (s) i.e.350-**450mls**

3 **Responsible:** Authorised personnel in the blood collection clinic that are assigned to the collection of blood donations are responsible for all the activities described in this procedure.

4 **Materials and equipment's required:**

Specimen tubes.

Donation Identification Numbers.

Scissors.

Plastic artery forceps.

Blood collection scale.

Tourniquet.

Disinfectant solution.

Swabs.

Cotton wool.

Plasters.

Personal protective equipment.

6. **Definitions:** NIL

7. **References:** AABB Technical Manual 14th Edition

National Standards for Blood Transfusion Service in Kenya 1st Edition 5.5.2

WHO guidelines on good phlebotomy practice latest edition

AFSBT standards

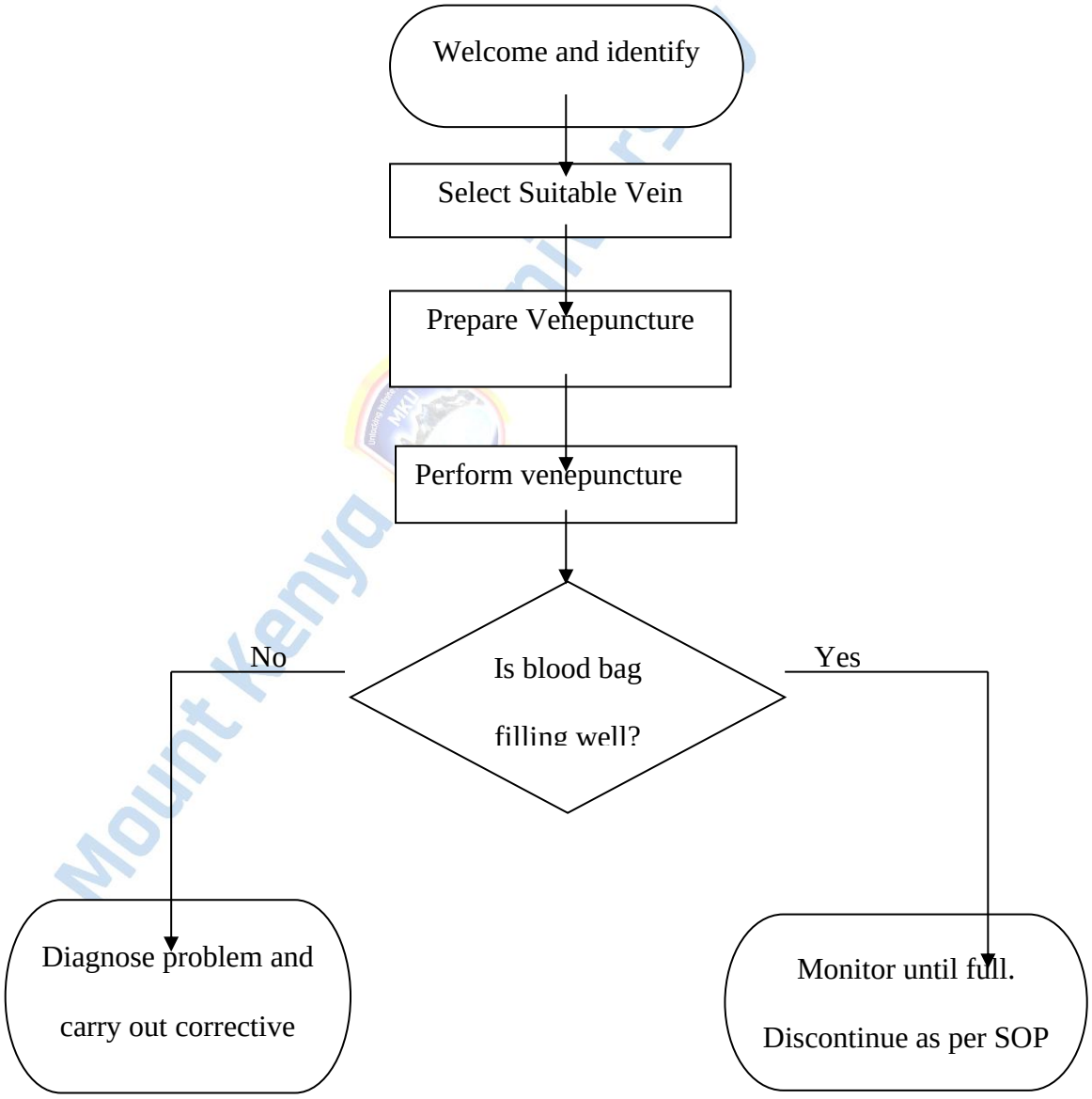
8. **Records:**

Type	**Retention Period**	**Location**
Blood Donor questionnaire FRM CLN – 01	10 years	Archive
Blood donation session analysis Report Form FRM CLN-3	10 years	Archive

Safety Precautions

All blood should be treated as if it is infectious. The general precautions to be followed are described in the Safety Manual

9. Flow Chart



10. Procedural Steps

10.1 Welcome and identify the donor

The phlebotomist must wear gloves throughout the donation procedure. Gloves must be changed after each donor, or if there are any obvious signs of blood contamination or physical damage to the gloves.

Receive the blood bag and the questionnaire from the donor as you welcome him/her to donation couch. Check the identity of the donor by asking them to repeat their name and date of birth. Resolve any discrepancies before proceeding.

Check the blood bag that is to be used for the collection:

Check that the bag has not expired.

Check that the bag has not leaked.

Check that the needle cover is correctly in place.

Check that the anticoagulant and the preservative solution (if present) are clear and colourless

Check that the Donation Identification Number on the blood bag and on the Medical History Form correspond.

If the blood bag fails any of these checks it must NOT be used. Report the problem to the in-Charge and obtain a replacement blood bag.

10.2 Select Suitable Vein

Check both hands and identify suitable vein that is free from lesions and infection. Apply tourniquet approximately 4cm above the venepuncture site and tighten sufficiently to distend the veins.

Give the donor a sponge ball and ask him/her to squeeze it firmly to make the veins more prominent.

Examine and palpate the antecubital fossa with pads of the 3 middle fingers to differentiate the anatomical structures and to find out the direction and quality of vein.

Select a vein that has adequate tissue support for retention of the venepuncture needle.

10.3 Prepare Venepuncture Site

Clean the venepuncture site using readymade alcohol pads. Clean the venepuncture site three times using a circular motion starting in the centre and moving outwards.

Ensure that the skin is in contact with the disinfectant for at least 30 seconds. Allow the arm to air-dry for at least 30 seconds. Do NOT touch the site after disinfection.

10.4 Perform venepuncture

If you are using Blood Mixer go to step 10.4.1

If you are using manual technique go to 10.4.2

10.4.1 Venepuncture using Genesis Blood Mixer

Put blood bag into the blood mixer tray.

Clamp tubing and place blood bags on a receiver below the used arm.

Place your forehand below the venesection site and use the thumb to stretch or tighten the donor's skin.

Remove the cover from the blood bag needle and quickly inspect the needle for defects. If the needle is damaged, do NOT use the blood bag.

Report the defect to the in-Charge and obtain a replacement blood bag.

Hold the needle at the hub approximately at an angle of 30 - 45° resting your knuckles on the donor's arms to steady your hand.

With the bevel-up, swiftly pierce the skin of selected vein at point of entry. Penetrate the vein wall and push the needle approximately 1cm inside the lumen.

Press 'start' button on the blood mixer and watch the flow of blood and if the flow is not satisfactory adjust the needle slightly.

Secure the needle to the donor's arm using a tape. Loosen the tourniquet slightly and make sure blood donor is comfortable.

Indicate time needle in on the donor questionnaire

Encourage blood donor to open and close hand slowly and gently. Then proceed to 10.5.

10.4.2. Manual Technique

Place your forehand below the venesection site and use the thumb to stretch or tighten the donor's skin.

Remove the cover from the blood bag needle and quickly inspect the needle for defects. If the needle is damaged, do NOT use the blood bag. Report the defect to the in-Charge and obtain a replacement blood bag.

Hold the needle at the hub approximately at an angle of 30 - 45° resting your knuckles on the donor's arms to steady your hand.

With the bevel-up, swiftly pierce the skin of selected vein at point of entry. Penetrate the vein wall and push the needle approximately 1cm inside the lumen.

Unclamp the tubing and ensure blood is flowing into the pack. Secure the needle to the donor's arm using micropore.

Loosen the tourniquet and make sure blood donor is comfortable.

Indicate time needle in on the donor questionnaire.

Gently mixed the blood every 1 minute

Encourage blood donor to open and close hand slowly and gently.

10.5 Is Blood bag filling well?

Yes - Obtain a full pack of approximately 450mls i.e. 515 - 595grams. Discontinue blood donation as per SOP CLN 005

NO- Check for kinks on tubing, check needle position and take corrective action. Continue with blood donation until pack is full.

If not successful (if blood donor has stayed for more than 15 minutes despite the corrective actions), reassure donor, Discontinue blood donation as per SOP CLN 005.

During the collection period observe the donor for sweating, pallor or complaints of feeling faint; development of a haematoma at the site of phlebotomy; and changes in the blood flow that may indicate that the needle has shifted and needs to be re-positioned.

11.0 Revision History

Revision No.	**Review Date**	**Reviewer Title/Name**	**Reviewer Initials**	**Summary of Changes**	**Next Scheduled Review Date**
00	July 2009	NQ&SM	CRO	New document	July 2011
01	Sept 2013	NQ&SM	CRO	Logo, Scope, Approval and Responsibility	Sept 2015
02	March 2018	BDS Manger NQ&SM	JM CRO	Procedural steps adjusted	March 2020

APPENDIX IX: STANDARD OPERATING PROCEDURE ABBOTT ORDERING AND RUNNING DONOR SAMPLES USING THE ARCHITECT SYSTEM

)

It's safe and it saves.

Standard Operating Procedure

Ordering and running donor samples using Architect system

Document Number: SOP LAB 028

Revision Number: 02

Effective Date:

Controlled copy number:

	NAME	TITLE	SIGNATURE	DATE
Written By	Alice Mbui	Deputy Quality Manager-KNBTS		
Approved By	Rachel Githiomi	Head, Technical Services-KNBTS		
	Charles Rombo	Quality and Safety Manager- KNBTS		
Authorised By	Dr. J. Githaiga	Head, KNBTS		

1.0 Purpose

This document describes the steps taken when testing all blood donations for TTIs, i.e. HIV, Anti-HCV, HBs Ag, and Syphilis.

2.0 Scope

This procedure applies to KNBTS laboratory using Architect i2000 SR to screen donor samples

3.0 Principle

The procedure involves Chemiluminescent Microparticle Immunoassay (CMIA). Combination of assay diluent, paramagnetic particles, (conjugate-for HBsAg only) with the analyte present in the sample results to formation of a complex. Washing and addition of an acridinium labelled conjugate (for HIV, HCV and SYPHILIS) leads to further complex formation. Addition of pre-trigger and trigger to the reaction mixture results into a chemiluminescent reaction which is measured as a Relative Light Units (RLUs). A direct relationship exists between the amount of the analyte in the sample and the RLUs detected by the Architect system optics. The presence or absence of the analyte in the sample is determined by comparing the chemiluminescent signal in the reaction to the cut off signal determined from a previous assay calibration

4.0 Responsibilities

Trained staff operating the equipment

5.0 Performance Characteristics:

5.1 **HIV:**

5.1.1 **Sensitivity:** 100%

5.1.2 **Specificity:** 99.89% **;** with a 95% confidence interval of 99.68% to 99.98%

5.2 **HBV**

5.2.1 **Sensitivity:** 100%

5.2.2 **Specificity:** 99.91% **;** with a 95% confidence interval of 99.78% to 99.97%

5.3 **HCV**

5.3.1 **Sensitivity:** 100%

5.3.2 **Specificity:** 99.60% **;** with a 95% confidence interval of 99.45% to 99.71%

5.4 **SYPHILIS**

5.4.1 **Sensitivity:** 100%

5.4.2 **Specificity:** 99.94% **;** at 95% confidence interval of 99.83% to 99.99%

6.0 Type of sample: Serum or plasma

7.0 **Patient Preparation:** Donor undergoes pre-donation counselling as per Sop CLN 008

8.0 **Type of container and additives:** Samples are collected in red top vacutainer or in ETDA vacutainer

9.0 Required Equipment, Reagents and Materials

9.1 Architect I 2000 SR analyzer

9.2 Centrifuge

9.3 Reagent kits,

9.4 Carriers, trays,

9.5 Samples cups,

9.6 Pipettes,

9.7 Gloves,

9.8 Waste containers,

9.9 Distilled water,

9.10 Concentrated wash buffer

9.11 Pre-trigger

9.12 Trigger solution,

9.13 Reaction vessels,

9.14 Sample cups

9.15 Printer and printing papers

10.0 Abbreviations and Definitions

10.1 Abbreviations

CAR- Corrective Action Request form

IQC- Internal Quality Control

SID- Sample Identity

RSH- Robotic Sample Handler

RLU-Relative Light Unit

S/CO-Signal /Cut Off

11.0 Record and related documents

11.1 Records

Type	Retention Period	Location
RESULT PRINT OUTS	2 months	Laboratory
	10 years	Archive
Control print outs	1 year	Laboratory
	10 years	Archive

11.2 **Related Documents**

11.2.1 SOP LAB 020 on calibration, configuring of Controls and preparation, loading of new reagent bottles and Supplies

11.2.2 SOP LAB 025 on Preparation of samples for analysis with Architect.

11.2.3 SOP LAB 058 on verification and release of results

11.2.4 SOP LAB 043 Electronic Entry of results into eprogessa

12.0 Safety Precautions

- Observe safety measures when handling the equipment

• Treat all human material as potentially infectious.

• Use appropriate protective clothing when handling samples i.e. gloves, lab coats etc.

• Any spillage of human material should be handled according to the organization's procedure on handling bio-hazardous spills.

• General laboratory safety guidelines must be observed at all times.

13.0 Calibration procedures

13.1 The user will calibrate reagents whenever new lots are received using the provided lot calibrators

13.2 This will be done as per SOP LAB 020

13.3 Pipettor probes will be calibrated as needed; reference will be made to online equipment user manual on probe calibration steps.

13.4 Calibration results will automatically be printed at the end of the process

14.0 Procedure

14.1 **Pre-testing preparation**

14.1.1 Estimate the quantity of the samples to be tested. Consider also samples from Regional and satellite centres

14.1.2 Verify that the machine is in Ready status

14.1.3 Verify the status of on board reagents and supplies

14.1.4 Verify that the quantities of reagents/Supplies on board are sufficient. If not sufficient, load additional reagents in accordance with the procedure for loading and unloading reagents. Replenish supplies as needed.

14.1.5 Perform daily/weekly maintenance in accordance with the procedure for Performing daily/weekly maintenance

14.1.6 Select the two READY icons on both the Processing Module and Robotic Sample Handler graphics and press RUN.

14.2 **Preparation of Materials and samples**

14.2.1 Prepare samples in accordance with the procedure for Preparation of samples for analysis with Architect.

14.2.2 Verify the Sample integrity and acceptability using SOP on Preparation of samples for analysis with Architect. ***Note: For optimum results, observe the specimen integrity prior to running the sample on the system.***

14.2.3 Verify that the serum and plasma specimens are free of:

14.2.3.1 Particulate matter

14.2.3.2 Fibrin

14.2.3.3 Red blood cells

14.2.3.4 Bubbles

14.3 **Run controls**

14.3.1 Arrange 10 sample cups in two sample carriers- 5 cups in each.

14.3.2 In to the cup on position 1 of the first carrier, dispense at least 1 ml of HIV negative control.

14.3.3 Into cups in position 2, 3 and 4, dispense HIV positive control 1, 2 and 3 respectively

14.3.4 In to position 5, dispense HBV Negative control

14.3.5 In to sample cup in position 1 of the second carrier, dispense at last 1 ml of HBV positive control

14.3.6 Into sample cups in position 2, 3, 4 and 5, dispense at least an ml of HCV negative control, HCV positive control, Syphilis negative control and syphilis positive control respectively.

14.4 **Create control orders**

14.4.1 Access the sample order screen on the Computer by following the following steps:

14.4.2 Select Orders from the icon bar at the top of the screen, and then select *single analyte* from the menu bar-The control list is displayed

14.4.3 Enter sample carrier ID , tab and enter position

14.4.4 From the list of test panel, select HIV

14.4.5 Check (tick) all the levels (negative and the three positives)

14.4.6 Click on add order at the bottom of the screen. Position 5 will be highlighted on the screen

14.4.7 Select HBV from the test panel

14.4.8 Check HBV negative control level

14.4.9 Click on add order

14.4.10 Repeat steps 14.4.3 to 14.4.6 for the second carrier

14.4.11 Create test orders for HCV negative and positive control followed by Syphilis negative and Positive control in that order

14.4.12 Click on add orders at the bottom of the screen

14.4.13 Load the two carriers in position one and two of the priority bay

14.4.14 Testing will commence

14.4.15 Review QC results and print the sheet and sign it and keep records.

14.4.16 Make sure that Controls are performed and are within acceptable WESTGARD RULES

14.5 **Loading Samples in the Carrier**

14.5.1 Prepare the number of carriers required depending on the workload (number of samples to be tested)

14.5.2 Place the sample in the sample carrier so that bar codes are visible in the sample bar code label window

14.5.3 Ensure that the sample cups and/or tubes are pushed completely down into the sample carriers and are not tilted. If bar coded samples are used, ensure that the bar code is visible in the sample bar code window

Note: Make sure to apply safety precautions when handling samples

14.6 **Ordering Samples**

14.6.1 Access the sample order screen on the Computer by following the following steps:

14.6.2 Select Orders from the icon bar at the top of the screen, and then select patient order from the menu bar-The patient order screen displays

14.6.3 Select Single patient

14.6.4 Using the Barcode scanner, scan the carrier ID into the Carrier ID position

14.6.5 SELECT the specimen position P, the carrier and Scan the sample ID

14.6.6 For Donor samples, proceed to step 9.4.3.5

14.6.7 For SAMPLES OF PATIENT, go to detail and put his complete address and identification.

14.6.8 Select the desired assay from the Assays list (e.g. HBs Ag qual) or select the "TTI PANEL"

14.6.9 Click on *Add Order*

14.7 **Loading Samples into the bays**

14.7.1 Verify the indicators below the routine bay farthest to the left are both off, which indicates the bay is available.

14.7.2 Place the carrier tray with the starting SID sample in front of the bay farthest to the left and align the tray with the alignment guides.

14.7.3 Push the carrier tray into the bay until the green indicator illuminates.

14.7.4 Repeat with additional trays (if needed) using the next bay to the right, until all samples in the batch are loaded.

Note: Do not leave empty spaces between samples as they will be identified as an invalid sample with error message 0120

14.8 **Running Samples**

After loading samples onto the RSH and initiating a run:

1. RSH carrier transport moves to the first carrier as determined by prioritization and picks it up, the RSH indicators turn amber
2. The carrier transport moves the carrier to the RSH bar code reader where the carrier ID and sample ID(s) are read and then the carrier returns to its original location.
3. The RSH indicators blink green when all samples within the routine or priority bay are aspirated. If you add or rerun tests for a sample before it is unloaded, the indicators for the bay change back to amber while the sample is re-aspirated.
4. After the sample is loaded, the sample handler moves the sample to the aspiration location
5. Carriers in the priority bay are processed first in the order they were inserted
6. Carriers in the routine bay are then processed in the order they were inserted

14.9 Observe error codes for any exception which may appear and handle it as required. Refer to the on board manual for identity and reason for exceptions.

14.10 **Reviewing results on screen and repeat positives**

14.10.1 Review finished results by accessing the results module on the machine

14.10.2 Repeat in duplicate reactive samples by selecting the reactive result and pressing RERUN if the sample is still on board. If the sample is not on board. Reorder as a single order and do it twice.

14.11 **Printing Results**

14.11.1 Select and print all the reactive results

14.11.2 Select all results and release. Results will automatically be printed.

14.11.3 Handle results in accordance with procedure for handling donor results

14.12 **Unloading Samples**

14.12.1 Remove the sample carriers from the machine

14.12.2 Recap the samples

14.12.3 Remove the sample tubes/Cups from the sample carrier and return them in the racks

14.13 Quality control procedures

14.13.1 Run QC once daily when the machine is in use

14.13.2 Use the commercially provided IQC materials

14.13.3 Reject any IQC result that falls outside 3 SD

14.13.4 Rerun the unacceptable IQC prior to running the donor samples

14.13.5 The LJ chart is plotted in the system

14.13.6 Print and review charts at the end of the month

14.14 Disposal of samples and other biohazard materials

14.14.1 Dispose remaining samples and used sample cups in accordance with the procedure for Waste management

14.14.2 Dispose all wastes in accordance with the procedure for waste management.

14.14.3 Clean and decontaminate the working surface as per the procedure for decontamination of working surfaces

15.0 Interferences

15.1 Light, Particulate matter

15.2 Fibrin, Red blood cell, Bubbles, Over diluted samples

15.3 Samples with obvious bacterial contamination

16.0 **Principle procedure for calculating results**: Results are calculated by the analyser as follows : Cutoff (CO) =Calibrator 1 mean RLU (Relative light unit)x 0.20

S/CO = Sample RLU/ CUTOFF RLU

Th cut off RLU is stored for each reagent lot calibration

17.0 **Biological reference intervals**: Not applicable

18.0 **Reportable interval of examination results**: Not applicable

19.0 **Instructions for determining quantitative results when a result is not within the measurement interval**: Not applicable

20.0 **Critical Values**: Not applicable

21.0 **Laboratory clinical Interpretation**:

21.1 Samples with S/CO values less than 1.00 are considered non reacted and reported as Negative

21.2 Samples with S/CO values greater than or equal to 1.00 are considered reactive by the Architect (HIV or HBV or HVC or Syphilis) assay; and are reported as reactive.

22.0 **Potential sources of variation**: Not applicable

23.0 **References**:

23.1 Abbott ARCHITECT® System Operations Manual (PN 201837-110) MAY, 2017

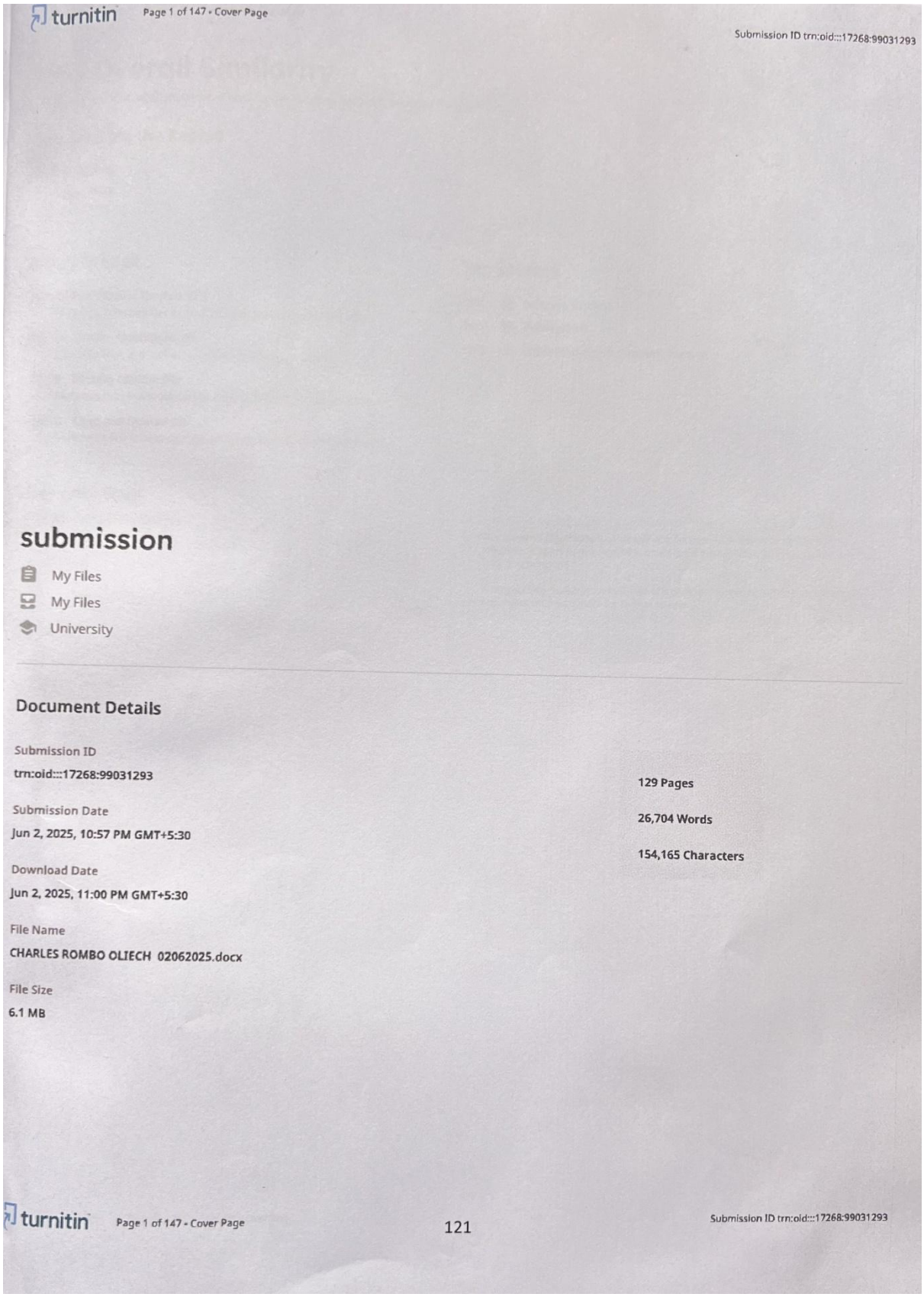
23.2 Abbott Reagent Package Inserts

24.0 **Revision History**

Revision No.	Revision Date	Reviewer	Reviewer Initials	Summary of Changes	Next Scheduled Review Date
00	7th Feb 2015	NQ&SM	CR	New document	
01	May 2017			Title Changed (deleted the word assay), Principle reviewed, Edited procedural steps 9.6,Added table for record retention, References	
02	April 2019	Judy N	JN	Aligned SOP to requirements of ISO 15189:2012/5.5.3	April 2021

APPENDIX X: TURNITIN REPORT

WITH REFERENCE



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