MALARIA PREVALENCE AND DIAGNOSTIC PERFORMANCE OF RAPID DIAGNOSTIC TEST VERSUS MICROSCOPY AMONG FEBRILE PATIENTS AT KIGOROBYA HOSPITAL, HOIMA DISTRICT, UGANDA

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ABSTRACT

This study investigated the prevalence of malaria and the diagnostic performance of Abbott rapid diagnostic tests (RDTs) compared to microscopy among adolescent and adult febrile patients attending Kigorobya Community Hospital. Malaria remains a major public health challenge in Uganda, particularly in rural endemic settings where accurate and timely diagnosis is essential for effective case management. The study aimed to determine malaria prevalence among patients with acute undifferentiated fever aged 12 years and above and assess the concordance between Abbott malaria RDTs and microscopy. A descriptive cross-sectional study nested within the SPIRIT study was conducted from April to December 2024. Secondary data were extracted from the RED Cap database for 213 eligible participants. Malaria diagnosis was performed using both Abbott malaria RDTs and microscopy blood smear tests. Data were analyzed using SPSS version 26, and diagnostic performance measures including sensitivity, specificity, positive predictive value, negative predictive value, and Cohen's kappa were computed. The overall malaria prevalence was 34.7% by microscopy and 34.3% by RDT. The highest malaria prevalence was observed among participants aged 19–34 years. The Abbott malaria RDT demonstrated excellent diagnostic performance, with sensitivity of 98.65%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 99.29%. There was nearly perfect agreement between RDT and microscopy results ($\kappa = 0.990$, $p < 0.001$). The findings demonstrate a high burden of malaria among adolescent and adult febrile patients in this setting and confirm that Abbott malaria RDTs are highly reliable compared to microscopy. The study recommends continued use of Abbott malaria RDTs in resource-limited settings and strengthening malaria control interventions targeting high-risk populations.

DECLARATION

I, Ogwang Joel hereby declare that this thesis on 'malaria prevalence and diagnostic performance of rapid diagnostic tests versus microscopy among febrile patients at Kigorobya Community Hospital, is my original work and has never been submitted to any university or higher institutions of learning for any award.

23/03/2026

Sign Date

APPROVAL

We hereby declare that we have reviewed the thesis titled: “Malaria prevalence and diagnostic performance of rapid diagnostic tests versus microscopy among febrile patients at Kigorobya Community Hospital” submitted by Joel Ogwang. To the best of my knowledge and belief, the thesis is an original piece that conforms to the guidelines and standards set by Uganda Christian University.

I therefore recommend that this thesis be accepted in fulfillment of the requirements for the award of Master’s degree in Public Health.

Sign 

Prof. Anou Dreyfus

Date…24.03.2026

Sign 

Prof. Robert K. Basaza

Date 23/03/2026

DEDICATION

I dedicate this dissertation to my beloved mother, whose strength, resilience, and unwavering commitment shaped my life and made this achievement possible. Following the loss of my father, she courageously embraced the role of a single parent, providing guidance, support, and care with remarkable determination.

Her sacrifices, perseverance, and steadfast belief in the value of education have been a constant source of inspiration throughout my academic journey. This work stands as a testament to her enduring love, encouragement, and the values she instilled in me.

I am deeply grateful for her unwavering support, without which this accomplishment would not have been possible.

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Table 2 List of abbreviations and acronyms

AUF	Acute Undifferentiated Fever
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
CRF	Case Report Form
DHIS	District Health Information System
HMIS	Health Management Information System
HRP2	Histidine-Rich Protein 2
IDI	Infectious Diseases Institute, Makerere University
IPC	Infection Prevention and Control
ITNs	Insecticide-Treated Bed Nets
MOH	Ministry of Health
NPV	Negative Predictive Value
pLDH	Plasma Lactate Dehydrogenase
PPV	Positive Predictive Value
REC	Research Ethics Committee
RDTs	Rapid Diagnostic Tests
UCU	Uganda Christian University
UZH	University of Zürich, Switzerland
WHO	World Health Organization

Table 3 Operational definitions

Acute undifferentiated fever	A fever of sudden onset, usually lasting less than two weeks, that presents without specific clinical features pointing to a clear diagnosis.
Concordance	The level of agreement between malaria RDT results and microscopy results, measured using Cohen's kappa coefficient and other statistical tests.
Febrile patient	Any patient who presented with a temperature of ≥38.0°C or reporting a history of fever within the past 2 weeks.
Malaria case	Any febrile patient aged 12 years and above who tests positive for malaria by either microscopy or RDT.
Malaria prevalence	The proportion of febrile patients at Kigorobya Community Hospital who tested positive for malaria using a rapid diagnostic test (RDT) and or blood smear test.
Microscopy (Blood smear test)	A laboratory method for diagnosing malaria by examining stained blood smears under a microscope to detect Plasmodium parasites. This served as the gold standard for comparison where available.
Rapid diagnostic test for malaria	A point-of-care test used to detect malaria antigens in a patient's blood. A positive RDT result indicates the presence of Plasmodium falciparum or other malaria species antigens.
Submicroscopic malaria infection	The presence of malaria parasites in an individual's blood that are not detectable by

	conventional light microscopy but are detectable using more sensitive molecular diagnostic techniques such as polymerase chain reaction (PCR).

CHAPTER 1: GENERAL INTRODUCTION

1.1 Background of the study

Acute undifferentiated fever is a common presentation among patients visiting healthcare facilities, constituting a significant reason for medical consultations, particularly in regions where infectious diseases are prevalent (D'Acremont et al., 2014). It is often symptomatic of a range of conditions, including malaria, which remains one of the leading causes of morbidity and mortality in tropical and subtropical regions (World Health Organization - WHO, 2023). The accurate diagnosis of malaria is crucial not only for effective clinical management but also for implementing appropriate public health interventions (WHO, 2023). Timely identification and treatment of malaria can significantly mitigate its complications and reduce its transmission within communities, especially among vulnerable populations such as adolescents and adult (Kpagoi et al., 2023; Wegener et al., 2022).

The World Health Organization has identified Uganda as one of the countries with the highest malaria burden globally, with Plasmodium falciparum being the predominant species responsible for the majority of cases (Maniga et al., 2022).

In terms of economic impact, malaria poses a significant financial burden on Uganda's health system and economy. A recent analysis estimated that malaria cost Uganda approximately $577 million USD in 2021, which represents about 1.4% of the country's Gross Domestic Product (GDP)(Snyman et al., 2025). This economic burden arises from direct costs associated with treatment and prevention, as well as indirect costs related to lost productivity due to illness and mortality (Fogang et al., 2022). The healthcare system bears a substantial portion of these costs, particularly as antimalarial treatments are often provided free of charge for children under five years old (ibid). The economic implications of malaria extend beyond healthcare costs, affecting household incomes and overall economic productivity, thereby perpetuating a cycle of poverty and disease (Snyman et al., 2025).

In western Uganda, where malaria is endemic, understanding the prevalence of malaria among febrile patients is crucial for effective management and treatment strategies (Nakisuyi et al., 2023; Acan et al., 2025). Recent studies indicate that the prevalence of malaria can vary significantly depending on the diagnostic methods employed, including microscopy, rapid diagnostic tests (RDTs), and molecular techniques (Kandathil et al., 2024; Wilairatana et al., 2021) For instance, a study by Akindele et al. reported a big prevalence difference of malaria ranging from 36% to 80% when comparing Rapid Diagnostic tests (RDTs) to microscopy (Akindele et al., 2021). This discrepancy highlights the importance of selecting appropriate diagnostic tools, as reliance on RDTs alone may lead to underdiagnosis of malaria, particularly in cases of low parasitemia (Adokiya et al., 2023). Microscopy has traditionally been regarded as the gold standard for malaria diagnosis due to its ability to provide detailed information about the species and density of the malaria parasites. However, it is labor-intensive and requires skilled personnel, which can be a limitation in resource-constrained settings (Niyibizi & Gatera, 2020). In contrast, RDTs offer a rapid and user-friendly alternative, allowing for quicker diagnosis and treatment initiation (WHO, 2023; Boyce et al., 2021). Studies have shown that RDTs can achieve sensitivities and specificities comparable to microscopy, although their performance can vary based on the specific test used and the prevalence of malaria in the population (Shah et al., 2022; Zeleke et al., 2023). For example, Prah et al. found that HRP2-based RDTs demonstrated a sensitivity of 95% and specificity of 95.2% (Prah et al., 2021). However, the accuracy of RDTs can be compromised in cases where individual patients have low parasitemia (low parasite density), which may be undetectable by these tests (Adokiya et al., 2023).

The concordance between RDTs and microscopy is critical for validating the reliability of malaria diagnoses. In a comparative study, Yusuf et al. found that microscopy detected significantly more positive cases than RDTs, indicating a potential for false negatives with rapid tests (Yusuf et al., 2022). This is particularly concerning in clinical settings where misdiagnosis can lead to inappropriate treatment and increased mortality and morbidity. Furthermore, the challenges associated with microscopy, such

as staff shortages and inconsistent power supply, can hinder its effectiveness as a diagnostic tool in rural healthcare settings (Region & Kiprop, 2022). Therefore, while RDTs provide a valuable alternative, their limitations necessitate a complementary approach that includes microscopy, particularly in cases where the clinical suspicion of malaria is high.

Although children under five years old are often the primary focus in malaria surveillance due to their high vulnerability, recent trends and operational constraints have warranted increased attention toward older populations (Namuganga et al., 2021). This study is nested within a broader investigation on the role of leptospirosis and rickettsiosis in acute undifferentiated fever patients in Uganda, where children would require a substantially larger sample size to detect these infections, as their fevers are more commonly caused by viral illnesses. Therefore, adolescents and adults aged 12 years and above were selected as the study population to ensure feasible detection of target pathogens, including malaria, within the scope of the parent study.

Recent studies show that adolescents and adults can exhibit high malaria prevalence, particularly in rural areas where access to preventive measures is less reliable (Maniga et al., 2022). For instance, a retrospective study in Kisii County, Kenya, found that individuals aged 14 years and older constituted 44.5% of malaria cases, emphasizing the need to address malaria in older populations alongside children (Maniga et al., 2022).

1.2 Problem statement

In Uganda, the National Malaria Indicator Survey (NMCD) results have shown parasite prevalence among persons aged 15–49 in certain regions ranging of up to 20% in high-transmission areas (NMCD, 2020). For instance, studies have reported malaria prevalence rates of up to 51.1% among pregnant women in high-burden areas of Uganda (Mangusho et al., 2023). In children under five years old, the prevalence of malaria is particularly concerning due to their heightened vulnerability. Studies have shown that this age group often has higher infection rates than older populations, although recent findings suggest a shift, with increasing prevalence in children aged 5 to 9 years old (Thomas et al., 2020; Touré et al., 2016).

The reliance on traditional diagnostic methods, such as microscopy, has been complicated by issues of accessibility, skill availability, and the potential for misdiagnosis due to overlapping symptoms with other diseases, such as leptospirosis, rickettsiosis, influenza and typhoid fever (Mensah et al., 2024; Wilairatana et al., 2022). For instance, febrile patients often present with symptoms that are indistinguishable from those of other infections, leading to delays in appropriate treatment and increased morbidity (Wilairatana et al., 2022).

The prevalence of malaria among febrile patients in Kigorobya is not well-documented, which poses a challenge for healthcare providers in making informed decisions regarding treatment protocols. This variability underscores the need for localized data to guide effective malaria control strategies. Additionally, the concordance between RDTs and microscopy in diagnosing malaria remains inadequately explored in this context, which is essential for validating the use of RDTs as a reliable diagnostic tool (Omoya & Ajayi, 2020; Shah et al., 2022).

The dual challenge of accurately diagnosing malaria and determining its prevalence among febrile patients at Kigorobya Community Hospital necessitates a comprehensive investigation. While children are known to be at higher risk for malaria, there is a relative scarcity of data on malaria burden and diagnostic accuracy among adolescents and adults in rural Ugandan settings. This study aims to address this gap by evaluating the performance of RDTs against the gold standard of microscopy and providing critical insights into the prevalence and distribution of malaria in this underrepresented population group.

1.3 Study objectives

1.3.1 General objective

To determine the prevalence of malaria and assess the diagnostic performance of malaria Abbott rapid diagnostic test compared to microscopic blood smear test among adolescent and adult febrile patients at Kigorobya Community Hospital.

1.3.2 Specific objectives

i. To determine the prevalence of malaria among patients with acute undifferentiated fever aged 12 years old and above attending Kigorobya Community Hospital from April 2024 to December 2024.
ii. To assess the concordance between malaria Abbott rapid diagnostic tests (RDTs) and microscopy (blood smear) test results in diagnosing malaria among patients with acute undifferentiated fever.

1.4 Scope of the study

1.4.1 Geographical scope

This study was conducted at Kigorobya Community Hospital in Hoima District, located 202 Km in western Uganda. Malaria is endemic in 95% of the country, and transmission occurs throughout the year, with two peak transmission seasons in June—July and November—December (Bosco, et al. 2020).

1.4.2 Content scope

This study focused on two key aspects: malaria prevalence and diagnostic accuracy of malaria testing methods among febrile patients aged 12 years and above attending Kigorobya Community Hospital from April 2024 to December 2024. It determined the proportion of febrile patients who test positive for malaria using microscopy and assess the concordance, sensitivity, and specificity of malaria rapid diagnostic test compared to microscopy, the gold standard for malaria diagnosis.

1.4.3 Time scope

This study covers the period from April 2024 to December 2024. Data collection was conducted in 2024 among febrile patients aged 12 years and above attending Kigorobya Community Hospital.

1.5 Justification of the study

Malaria remains a critical public health issue in Uganda, particularly in rural areas where the disease burden is disproportionately high. Accurate and timely diagnosis is essential for effective treatment and control of malaria, as misdiagnosis can lead to inappropriate treatment, increased morbidity, and mortality. While Rapid Diagnostic

Tests have gained popularity due to their convenience and speed, there is a pressing need to evaluate their diagnostic performance against microscopy, which is still regarded as the gold standard for malaria diagnosis (Shah et al., 2022).

Kigorobya Community Hospital, serving a rural population, provides a unique opportunity to assess the prevalence of malaria and the reliability of RDTs in a real-world healthcare setting. The hospital's context is particularly relevant given the challenges faced in rural healthcare, such as limited access to skilled personnel and diagnostic facilities (Kumar et al., 2020).

This study is crucial as it will provide insights into the true extent of malaria among acute undifferentiated fever patients in this region, which is vital for informing public health strategies and resource allocation. Previous studies have demonstrated that submicroscopic infections can significantly contribute to the overall malaria burden, particularly in high transmission areas like Uganda (Habyarimana & Ramroop, 2020). Therefore, understanding the prevalence of malaria in febrile patients is essential for addressing these hidden infections and implementing effective control measures.

Moreover, by comparing the performance of RDTs with microscopy, this study will provide insights into the accuracy and potential limitations of Abbott RDTs, which could directly impact malaria diagnosis and treatment decisions. Research has shown that while RDTs are designed to be rapid and cost-effective, their sensitivity can vary significantly, particularly in cases of low parasitemia (Hoque et al., 2023). This variability underscores the importance of validating RDTs in local contexts to ensure that they are reliable diagnostic tools for healthcare providers.

1.6 Significance of the study

By assessing malaria prevalence and diagnostic concordance, the findings will provide evidence-based recommendations for improving malaria case management in the following ways:

The study will offer updated malaria prevalence data, hence, presenting health authorities with information that can be used to design targeted interventions for high-risk populations.his study aligns with global health initiatives aimed at improving

diagnostic tools and treatment outcomes for malaria, thereby supporting the broader goal of malaria elimination (Orech et al., 2024). This study is not only timely but also essential for advancing our understanding of malaria diagnostics in rural Uganda, with the potential to inform policy and practice in malaria management.

This study will generate valuable insights to inform public health practices and policies, benefiting the community. Finally, the study will contribute to academia by advancing knowledge and understanding in the field of malaria infection.

1.7 Conceptual framework

The study assessed the prevalence of malaria among acute undifferentiated fever patients at Kigorobya Community Hospital and compared the performance of malaria rapid diagnostic tests (RDTs) with microscopy. Independent variables include patient characteristics (age, gender, marital status, place of residence, education), the diagnostic tool used (RDT vs. microscopy blood smear test). The dependent variables are malaria prevalence and diagnostic performance, evaluated through sensitivity, specificity, PPV, NPV, and concordance between RDT and microscopy blood smear test.

Confounders such as seasonality and co-infections may affect diagnostic outcomes.

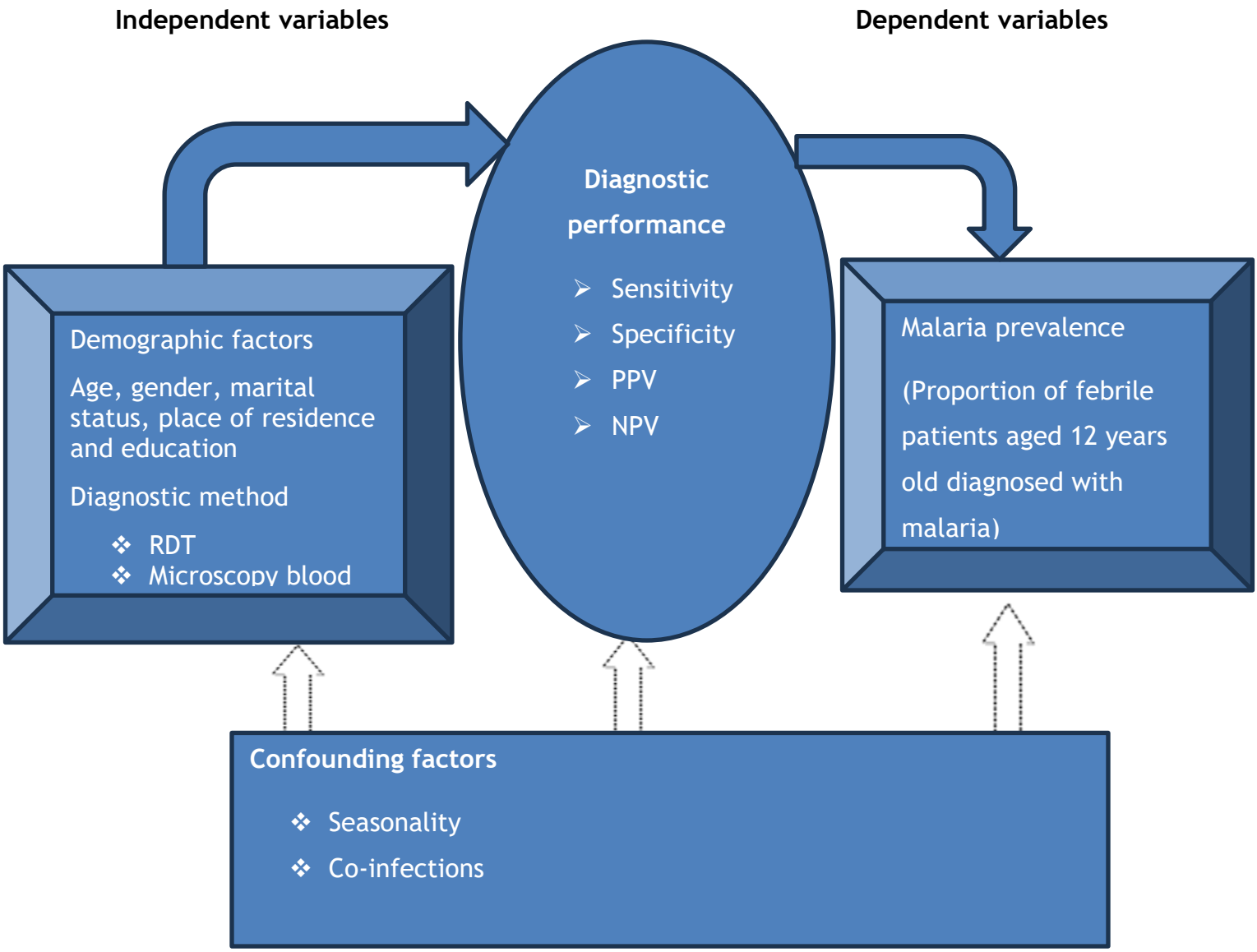

Figure 1 Conceptual framework

Source: Construct by the author.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Malaria is a life-threatening parasitic disease caused by Plasmodium species, with Plasmodium falciparum being the most prevalent in sub-Saharan Africa. Globally, in 2023, the number of malaria cases was estimated at 263 million, with an incidence of 60.4 cases per 1000 population at risk (World Malaria report 2024). This is an increase of 11 million cases from the previous year and a rise in incidence from 58.6 cases per 1000 population at risk in 2022. The World Malaria report 2024 points out that, in 2023, there were 246 million cases and subsequent 569 000 deaths in the WHO African Region. Worse more, over the past 5 years, there was marked increase in the number of cases in Uganda totaling to 1.3 million (World Malaria report 2024). According to HMIS monthly report of September 2024, Bunyoro region had test positivity rate of 37.5 % from all the tests conducted (MOH, 2024). As a major public health concern, malaria's endemic nature in numerous regions necessitates effective diagnostic tools to manage and control further spread.

Malaria diagnosis traditionally relies on microscopy, which is considered the gold standard due to its capacity to confirm the presence of parasites in stained blood smears. However, the advent of rapid diagnostic tests has transformed malaria diagnostics by offering quicker results and requiring less specialized training to administer. The RDTs typically detect malaria antigens such as histidine-rich protein 2 (HRP2) and plasma lactate dehydrogenase (pLDH), providing an alternative in settings where microscopy is either unavailable or impractical
(Hawash et al., 2022; Zeleke et al., 2023).

Evaluating the diagnostic accuracy of RDTs against microscopy is particularly important among febrile patients, as acute undifferentiated fever is a common clinical presentation of malaria but may also result from a wide range of other infections, making accurate diagnosis essential for appropriate case management (Irshad et al., 2024). Accurate diagnostic tools not only enhance patient management but also provide essential epidemiological data critical for malaria control efforts. This literature review

aims to synthesize findings on malaria prevalence and the performance of RDTs relative to microscopy among febrile patients. The subsequent literature review is presented along the specific research objectives.

2.2 Malaria prevalence

Over the past two decades, the global landscape of malaria has undergone significant changes due to intensified efforts in its prevention and control. The World Health Organization (WHO) reports highlight a decline in global malaria cases, from 237 million in 2010 to an estimated 229 million in 2019, alongside a reduction in mortality rates, which reflects effective interventions implemented over the years (Chu et al., 2023). However, despite these improvements, malaria remains a critical public health challenge, particularly in sub-Saharan Africa, where over 90% of the global cases and deaths occur (Mtonga & Nawa, 2024). Recent data indicate that while the total number of cases appears to have diminished, many countries are experiencing stagnation or even increases in incidence rates. These trends are attributed to various factors, including inadequate access to healthcare, climatic fluctuations, and the growing resistance to antimalarial drugs (Mandefro et al., 2024; Tampubolon et al., 2023).

In sub-Saharan Africa, malaria continues to be endemic, imposing a substantial burden on health systems with significant morbidity and mortality among vulnerable populations, particularly children and pregnant women (Chu et al., 2023; Tian et al., 2024). In 2019, it was estimated that sub-Saharan Africa accounted for 94% of all malaria cases and fatalities globally, exemplifying the region's ongoing struggle against this disease (Chu et al., 2023). Specifically, Uganda remains heavily impacted by malaria, with a prevalence of 19.5% among its general population, which further underscores the urgent need for targeted interventions (Tian et al., 2024). Addressing these challenges requires a multifaceted approach that includes improving healthcare access, enhancing vector control strategies, and fostering community engagement in malaria prevention initiatives.

Recent evidence also suggests that the landscape of malaria control is evolving, necessitating continuous surveillance and adaptive strategies (Mtonga & Nawa, 2024).

As global efforts progress, the dynamics of malaria transmission must be closely monitored to ensure effective responses to changing epidemiological patterns (Mtonga & Nawa, 2024).

Epidemiological studies indicate that malaria incidence is observed across various age groups, although patterns can differ significantly between children and adults. Recent studies show that adolescents and adults can exhibit high malaria prevalence, particularly in rural areas where access to preventive measures is less reliable (Maniga et al., 2022c). For instance, a retrospective study in Kisii County, Kenya, found that individuals aged 14 years and older constituted 44.5% of malaria cases, emphasizing the need to address malaria in older populations alongside children (Maniga et al., 2022c).

Further, the prevalence of malaria infections in adolescents and adults often correlates with socioeconomic conditions and exposure levels. Factors such as lack of insecticide-treated bed nets and limited access to antimalarial treatment contribute to the disease burden in these populations (Mesfun & Ayalneh, 2022). Research in Ghana revealed that malaria prevalence among adults ranged from 11.2% to 40.0%, indicating that this demographic group should not be neglected in malaria prevention strategies (Tetteh et al., 2023).

Malaria transmission in Uganda is influenced by several interconnected factors. Climate is a primary driver, with seasonal rainfall affecting mosquito breeding and survival rates (Tefera et al., 2022). Studies indicate that malaria transmission peaks during the rainy season, aligning with higher mosquito populations (Bouraima et al., 2023).

The vector behavior also plays a crucial role, as the primary vectors (Anopheles species) exhibit variations in feeding habits and breeding sites that can alter transmission dynamics (Msugupakulya et al., 2023). The emergence of new vector species that include **Anopheles stephensi,** could complicate the malaria landscape by introducing urban malaria transmission in previously low-burden areas (Msugupakulya et al., 2023)

Healthcare access significantly influences malaria transmission. Inadequate healthcare infrastructure, especially in rural areas, leads to delays in diagnosis and treatment, which allows for continued transmission. Mobile health interventions and community

health worker programs, alongside improving awareness regarding preventive measures, are vital strategies to enhance healthcare access and reduce malaria incidence in high-risk populations (Coleman et al., 2023).

2.3 Clinical presentation of malaria in febrile patients

Acute undifferentiated fever (AUF) presents a significant clinical challenge, as it can be caused by a wide range of infectious and non-infectious etiologies. Malaria is often a primary consideration; however, effectively differentiating it from other febrile illnesses such as typhoid fever, leptospirosis, and non-typhoidal Salmonella infections is crucial for appropriate management (Aziz et al., 2022). The spectrum of differential diagnoses can include serious conditions like systemic lupus erythematosus and rickettsial diseases (Kularathna et al., 2024).

A study published on the diagnostic challenges during the COVID-19 pandemic highlighted instances where malaria was mistakenly not considered, with symptoms confusing and mirroring those of COVID-19 and other endemic febrile illnesses (Nelwan et al., 2023). This underscores the critical need for healthcare providers to adopt a methodical approach to evaluate AUF. Timely travel history and exposure assessment are essential to narrow down differential diagnoses effectively (Gao et al., 2023; Arisanti et al., 2024).

The reliance on accurate diagnostic tools becomes paramount in the context of febrile illness management. Malaria diagnosis hinges on both clinical suspicion and laboratory confirmation. Traditional methods, such as microscopy blood smear test, while established as the gold standard, face challenges concerning sensitivity and specificity, particularly in low-parasitemia cases common among adults in endemic regions (Martiáñez-Vendrell et al., 2022). The RDTs have emerged as invaluable tools as a result of their ease to operate and quicker results; however, they also possess limitations, particularly in detecting Plasmodium vivax and in situations with antigen persistence following treatment (Bansal & Mangat, 2022).

In contexts where malaria is endemic, the ability to accurately distinguish malaria from other febrile illnesses can significantly influence treatment trajectories and public

health outcomes. Recent literature stresses the importance of implementing multimodal diagnostic strategies that encompass clinical, epidemiological, and laboratory assessments (Ajakaye & Ibukunoluwa, 2020). Enhanced surveillance systems and access to advanced molecular diagnostics have been reported to facilitate more precise diagnoses and inform effective management plans, especially in high-burden areas where febrile illness frequently leads to morbidity and mortality (Moutombi et al., 2022; Kawanishi et al., 2024).

2.4 Malaria diagnosis – Rapid diagnostic tests against microscopy blood smear test

Microscopy is widely accepted as the gold standard for malaria diagnosis due to its high specificity and sensitivity for parasite detection. However, it relies heavily on the expertise of laboratory personnel to prepare and analyze blood smears, which can be time-consuming, especially in high-burden settings. Reports indicate that the sensitivity of microscopy can vary significantly; for example, some studies have reported sensitivities as high as 99% under optimal conditions (Saeung et al., 2025), while others report lower levels in less controlled environments, particularly regarding low-level parasitemia (Karani et al., 2023). Moreover, the necessity for well-trained staff raises concerns about the potential for false-negative results, as the accuracy of microscopy is contingent upon the skill and experience of the laboratory personnel (Kolekang et al., 2022)

Despite its established reliability, microscopy has limitations, particularly in rural or resource-limited settings where there may be insufficient human resources. Studies indicate that inadequate adherence to diagnostic guidelines exacerbates these challenges and hinders effective malaria case management (Kolekang et al., 2022). The growing complexity of malaria presentations has also been linked to missed diagnoses in cases of submicroscopic infections, which are often undetectable by standard microscopy (Msugupakulya et al., 2023; Osun et al., 2024).

The RDTs have become increasingly popular for diagnosing malaria, largely due to their rapid turnaround times and ease of use. These tests utilize antigen detection methods, targeting malaria-specific proteins such as histidine-rich protein 2 (HRP2) and lactate dehydrogenase (pLDH), allowing quicker diagnoses compared to microscopy (Vidyasagar

& Venkatesha, 2022). Recent studies indicate that RDTs can provide results with high specificity (ranging from 86% to 100%) and reasonable sensitivity, often outperforming microscopy in low-parasitemia cases (Onken et al., 2022). For example, findings in Tanzania and Ethiopia have shown that RDTs can yield diagnostic accuracy comparable to microscopy, with some settings favoring RDTs for their simpler execution and faster results (Onken et al., 2022).

Additional studies indicate that RDTs may have lower sensitivity compared to microscopy, particularly in cases of low parasitemia, which can lead to false negatives (Alanazi et al., 2022; Shah et al., 2022). For example, a study found that RDTs exhibited a sensitivity of only 62.3%, raising concerns about their reliability in clinical settings where malaria is suspected (Shah et al., 2022). Furthermore, the potential for cross-reactivity with other infections can result in false positives, complicating the diagnostic landscape further (Alanazi et al., 2022).

The Abbott Malaria Rapid Diagnostic Test (RDT) has been validated across various clinical settings, yet its diagnostic accuracy exhibits variability, particularly in high-transmission regions. In one study, Yigezu et al. reported a sensitivity of 77.4% and a specificity of 96% for the Abbott RDT, highlighting concerns about its reliability in areas like Uganda where accurate diagnosis is critical (Yigezu et al., 2023). Recent evaluations of Abbott's malaria RDTs have demonstrated high sensitivity and specificity in detecting Plasmodia infections. For instance, a 2024 comparative study reported an 88.8% sensitivity for the Abbot RDT in samples with parasite densities above 20 parasites/µL, surpassing traditional microscopy methods (Kayode et al., 2024). Additionally, a 2023 study in Madagascar found the Abbot Malaria RDT test to have a sensitivity of 96.5% in symptomatic patients (Rakotoarisoa et al., 2025). These findings highlight the variability of the diagnostic performance (efficacy) of Abbott RDTs in diverse epidemiological settings.

Nonetheless, RDTs also have limitations. Their sensitivity can be compromised at lower parasite densities, which are typically found in areas with declining transmission rates. Some reports have shown that RDTs exhibit sensitivities as low as 62% compared to microscopy, underscoring concerns about their performance under various transmission

conditions (Igbawua et al., 2024). Additionally, RDTs may yield false-positive results, particularly in populations with high immunologic exposure, complicating their interpretation further (Fuente, 2024; Prah et al., 2022).

Comparative studies evaluating the diagnostic performance of RDTs against microscopy have shed light on the strengths and weaknesses of both methods. A systematic review has indicated that while microscopy traditionally holds higher sensitivity for identifying malaria infections, RDTs can show improved sensitivity under certain circumstances, especially in areas of low transmission (Acquah et al., 2022; Belachew et al., 2022). Reports from Nigeria have also shown RDTs with lower sensitivity (approximately 26%) compared to microscopy, reaffirming that microscopy often remains the preferred diagnostic modality for accurate malaria detection (Igbawua et al., 2024; Akindele et al., 2022).

Moreover, the performance of RDTs varies significantly depending on local epidemiology and the density of malaria parasitemia. In high-transmission environments, RDTs frequently demonstrate better performance, detecting a higher prevalence due to elevated circulating antigen levels, while their sensitivity may fall below acceptable thresholds in lower transmission settings (Acquah et al., 2022; Madkhali et al., 2022). This distinction is crucial for planning malaria interventions in diverse epidemiological contexts.

Ultimately, the choice between RDTs and microscopy should consider local factors, including disease prevalence, available resources, and the demographics of the populations being served. Continuous efforts are necessary to assess the efficacy of diagnostic tools across different settings to improve malaria case management strategies (Dahal et al., 2023; Manjurano et al., 2023).

2.5 Concordance between Rapid Diagnostic Tests and Microscopy

Concordance in diagnostic studies refers to the degree to which two diagnostic tests produce comparable results when evaluating the same condition. High concordance between two diagnostic methods, such as RDTs and microscopy for malaria, is crucial because it can impact clinical decisions, treatment efficacy, and overall disease

management. In malaria diagnosis, achieving high concordance is particularly important in ensuring that both false positives and negatives are minimized, thereby safeguarding patient health and supporting appropriate resource allocation in endemic regions (Pembet et al., 2022). Evaluating the level of agreement, often quantified using the kappa coefficient, allows researchers to understand how well these tests align. Thus, the importance of concordance is evident, as it can influence the choice of diagnostic methodology in varied clinical settings, particularly in areas with limited access to laboratories or trained personnel (Mooney et al., 2022).

A growing body of literature has addressed the concordance between RDTs and microscopy in diagnosing malaria across diverse geographical contexts. In a study conducted in Dolisie, Republic of the Congo, RDT showed a kappa coefficient of 0.86 with microscopy, indicating “almost perfect agreement” between the two testing methods (Pembet et al., 2022). Conversely, research in southwestern Nigeria found only moderate agreement (kappa of 0.60) between blood smear microscopy and RDTs, highlighting that while RDTs are beneficial, discrepancies persist (Oyeniyi et al., 2022).This inconsistency raises concerns regarding RDT efficacy in clinical settings where microscopy is the gold standard, emphasizing the need for ongoing evaluation of RDT performance across different demographics and malaria transmission intensities.

Another investigation by Berzosa et al. in Equatorial Guinea highlighted that RDTs outperformed microscopy in diagnosing low-density and mixed infections, indicating a potential advantage of RDTs over traditional microscopy in specific contexts (Berzosa et al., 2018). These findings point out the critical role of contextual factors in interpreting diagnostics. A similar conclusion was noted by Yusuf et al., where microscopy revealed more positive cases than RDTs, raising questions about RDT sensitivity in the presence of lower parasitic densities (Yusuf et al., 2022). These findings underline the importance of context when interpreting diagnostic results and the necessity for reliable assessments to determine the appropriate diagnostic strategies in various healthcare settings.

Moreover, the quality of the tests themselves can affect concordance. Variations in RDT production quality, which may lead to inconsistencies in sensitivity and specificity, can

result in varying outcomes across studies (Pembet et al., 2022). The emergence of Plasmodium falciparum variants lacking the histidine-rich protein 2 (HRP2) can also yield false-negative results for HRP2-based RDTs, further complicating the diagnostic landscape (Huang et al., 2022). Consequently, understanding these factors is essential for improving diagnostic accuracy and ensuring reliable malaria management.

2.6 Summary of key literature findings

The reviewed literature emphasizes malaria as a persistent global public health burden, particularly in sub-Saharan Africa. Effective control and management of the disease heavily rely on prompt and accurate diagnosis. Rapid Diagnostic Tests (RDTs) and microscopy remain the cornerstone diagnostic tools in many settings. However, challenges related to the sensitivity, specificity, and overall diagnostic accuracy of these tools are frequently reported, especially among older populations and in regions with variable malaria transmission intensity. Moreover, existing evidence points to the need for more context-specific evaluations of malaria diagnostic methods, tailored to different demographic and epidemiological conditions, to enhance their reliability and effectiveness in real-world settings.

2.7 Gaps in literature

Despite the wealth of research on malaria diagnosis and management, significant gaps persist, particularly regarding malaria diagnosis among adolescents and adults in low-resource settings (Alsabri et al., 2025; Yalley et al., 2024). Most existing studies have primarily focused on pediatric populations and pregnant women, leaving a paucity of data on adolescent and adult populations, especially in rural and peri-urban settings (Odio et al., 2020; Adebusuyi et al., 2024). Additionally, while rapid diagnostic tests (RDTs) and microscopy remain the cornerstone of malaria diagnosis, there is insufficient evidence comparing the effectiveness of these methods among older age groups, who may present with atypical or subtle symptoms.

Moreover, there is a notable gap in local evidence from Kigorobya Community Hospital, which serves a high-burden area but lacks context-specific data on diagnostic accuracy and case management among adolescents and adults. This gap impedes the formulation

of tailored malaria control strategies and hinders the development of context-appropriate diagnostic algorithms. Therefore, generating local evidence from Kigorobya Community Hospital will bridge this gap, inform local healthcare practices, and guide policymakers in optimizing malaria diagnosis and management for adolescents and adults.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This section outlines the research design, study setting, population, sample size, sampling techniques, data collection methods, and data analysis strategies employed to assess the prevalence of malaria and evaluate the diagnostic performance of rapid diagnostic tests compared to microscopy among acute undifferentiated fever patients aged 12 years old and above at Kigorobya Community Hospital.

3.2 Study design

This is a descriptive cross-sectional study nested within a larger research project entitled "The Role of Leptospirosis and Rickettsiosis in acute undifferentiated fever patients in Uganda (SPIRIT study)," jointly conducted by the University of Zurich, Switzerland, and the Infectious Diseases Institute (IDI), Makerere University, in Uganda. This sub-study assessed the prevalence of malaria among patients with acute undifferentiated fever and compare the diagnostic performance of rapid diagnostic tests versus microscopy at Kigorobya Community Hospital.

3.3 Area of study

The study was conducted at Kigorobya Community Hospital (Health Centre IV), in Kigorobya sub-County, Hoima district located 202 Km west of Uganda. The hospital was selected because it serves a high number of febrile patients from malaria-endemic communities. As a rural facility, it primarily relies on malaria RDTs for malaria diagnosis, making it an important site to assess malaria prevalence and evaluate the diagnostic accuracy of RDTs in the absence of routine microscopy. Also, the hospital serves as a key healthcare facility for the catchment population within the Bunyoro sub-region and the Democratic Republic of Congo estimated to be 100,000 people including both rural and urban residents.

3.4 Sources of information

- Patient medical records: Data on febrile patients, including age, gender, marital status, place of residence, and education level.
- Malaria diagnostic results: Results from rapid diagnostic tests and microscopy blood smears test from the laboratory.
- Published literature: Existing research and studies on malaria prevalence, RDT accuracy, and diagnostic challenges.

3.5 Population and sampling techniques

3.5.1 Study population

The study population consisted of patients aged 12 years old and above presenting with acute undifferentiated fever at Kigorobya Community Hospital from April 2024 to December 2024. This study is nested within a broader investigation on the role of leptospirosis and rickettsiosis in acute undifferentiated fever patients in Uganda. These diseases are more commonly detected in older age groups, and including children would have required a significantly larger sample size due to the predominance of viral infections in that population. Therefore, the study was designed to focus on adolescents and adults for both feasibility and diagnostic yield.

3.5.1.1 Inclusion criteria

The following inclusion criteria was considered for participants to be enrolled into the study:

i. A signed and dated informed consent form showing that the respondent or their authorized representative was informed of all relevant details of the study
ii. Aged 12 years or older
iii. One or more measured temperatures ≥ 38.0°C or a reported fever within the last two weeks
iv. Onset of symptoms is less than 2 weeks prior to assessment for enrollment.

3.5.1.2 Exclusion criteria

The respondents who had any of the following characteristics were excluded from the study:

i. Obvious symptoms or signs of a focal infection (e.g. significant bacterial skin infection, upper respiratory tract infection (RTI) without evidence of systemic illness
ii. Previous participation in this study
iii. Inability to give consent.

3.5.2 Sampling techniques

A convenience sampling method, specifically consecutive sampling, was used to recruit participants. All eligible febrile patients aged 12 years and above presenting to the outpatient department of Kigorobya Community Hospital during the study period (2024) were approached for inclusion. Patients who met the inclusion criteria and provided informed consent were enrolled consecutively until the required sample size was achieved.

Patients who declined participation or did not meet the inclusion criteria were excluded, and recruitment continued with subsequent eligible patients.

3.5.3 Sample size determination

The sample size was calculated using Cochran's formula for sample size estimation:

$$n = \frac{Z^2 P(1- P)}{d^2}$$

Where:

n = sample size

Z= Z-score for the desired confidence level (1.96 for 95% confidence)

P= Estimated prevalence of malaria among febrile patients in western Uganda from a similar study was assumed to be 24.8%)(Okello et al., 2015)

d = margin of error (5%)

n = $\frac{1.96^2 \text{ X } 0.248 \text{ X } (1\text{-}0.248)}{(0.05)^2}$ = 287 participants.

3.6 Variables of the study

Independent variables

- Age: recorded in completed years
- Gender: male or female
- Place of residence
- Level of education: highest level of formal education attained (e.g., no formal education, primary, secondary, tertiary)
- Marital status: individuals relationship status was categorized as single, married, widowed, separated and divorced.

Dependent variables

- Malaria prevalence: proportion of febrile patients testing positive for malaria using microscopy.
- Diagnostic performance: sensitivity, specificity, positive predictive value, and negative predictive value of RDT compared to microscopy blood smear test.

3.7 Data collection procedure

This study is nested within a bigger project titled "The role of Leptospirosis and Rickettsiosis in acute undifferentiated fever patients in Uganda", led by Prof. Anou Dreyfus of the University of Zurich and Dr. Jonathan Mayito of the Infectious Diseases Institute (IDI), Makerere University. The study is funded by the Swiss National Science Foundation (SNSF) under the "SPIRIT" scheme (Grant number: IZSTZ0_190156).

As the study Medical Officer, I was actively involved in patient screening, clinical assessment, and collection of data. The malaria diagnosis for participants was done using both RDT and microscopy. For RDT, the Abbott malaria HRP2-based RDT kit was used on venous blood samples, following the manufacturer's instructions. A drop of blood was added to the test cassette, buffer applied, and results read after the recommended time. Microscopy was performed on thick blood smears stained with

Giemsa, and slides were examined under a light microscope by qualified laboratory technologists. For quality assurance, a subset of slides was re-read by a second technologist. All testing was done blindly, hence the technician at the microscope did not know the RDT test result.

For this sub-study, secondary data were extracted from the SPIRIT study REDCap database using a structured data extraction tool developed by the researcher (Appendix 3). The tool was used to collect demographic, clinical, and laboratory variables including age, gender, marital status, education level, place of residence, fever characteristics, and malaria test results.

3.8 Data collection instruments and equipment

The data for this study was collected between April and December 2024 as part of the broader research project titled "The role of leptospirosis and rickettsiosis in acute undifferentiated fever patients in Uganda".

A structured data extraction tool was used to obtain relevant demographic, clinical, and laboratory information from the SPIRIT study database. The data extraction tool consisted of predefined variables aligned with the objectives of the study and was designed to ensure uniform and consistent collection of data from participant records. The data extraction tool is attached in Appendix 3.

All extracted data were entered and managed using Research Electronic Data Capture (REDCap), a secure web-based application designed for reliable data collection, storage, and management.

3.9 Data analysis

Data was checked for completeness, accuracy, and consistency using Microsoft Excel. Inconsistent and missing data were addressed through cross-referencing with source documents. Data was exported to SPSS statistical software version 26 for analysis. Descriptive statistics (mean, median, frequencies, and proportions) were calculated for demographic and clinical characteristics.

Malaria prevalence was estimated as a proportion with a 95% confidence interval. Concordance between RDTs and microscopy was assessed using kappa statistics and sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Tables and graphs were used to present findings clearly and concisely.

3.10 Confidentiality measures

All patient data entered into REDcap was securely stored and managed in compliance with ethical guidelines for data protection. The study team ensured that all data were anonymized during the entry and extraction processes to maintain patient confidentiality.

3.11 Quality/error control

To ensure the accuracy, consistency, and reliability of the data collected for this study, the following quality and error control measures were implemented:

i. All personnel were trained on the study protocols, ethical guidelines, and data entry procedures, ensuring consistency and compliance during data collection.
ii. REDcap's built-in validation checks flagged out-of-range values and missing data, enabling prompt correction to maintain data accuracy.
iii. The study was monitored through IDI's internal monitoring systems to ensure ongoing compliance with study protocols and ethical standards.

3.12 Ethical considerations

This study is a sub-study nested within the broader research project titled "The role of leptospirosis and rickettsiosis in acute undifferentiated fever patients in Uganda".

The parent study received ethical approval from both the Institutional Review Board (IRB) at the Infectious Diseases Institute (IDI) – Makerere University (IDIREC reference number: IDIREC FEF 2023-43) and the Swiss Ethics Commission (reference number: AO-2023-00023) (Appendix 1).

The parent protocol was designed as a larger cohort study allowing for nested and secondary analyses, within which the current sub-study was conducted.

All participating patients, parents, or legal guardians provided written informed consent before sample collection. The informed consent process adhered to principles set out in the Declaration of Helsinki, the current International Council for Harmonization and Good Clinical Practice guidelines, and applicable regulatory requirements (GCPN, 2026).

Prior to data extraction, necessary permissions and access rights to the red cap system was confirmed by the Infectious Diseases Institute, Makerere University. The data was backed up to ensure there is no risk of loss during the extraction process.

Confidentiality and anonymity of participant information were maintained throughout the data analysis process. Unique study identification numbers were assigned to participants in place of personal identifiers. The dataset used for this analysis was fully anonymized. There was blinding and consistency (always same reader) of the RDT and microscopy. Only one laboratory technician conducted all malaria testing for the study, including both the RDTs and malaria microscopy. Measures were taken to minimize bias. Microscopy slides were labeled using unique study codes without patient identifiers. During slide reading, RDT results were not referenced, and results were recorded separately. The linkage between RDT and microscopy results was done later by the researcher during the review of site laboratory results to guide appropriate patient management and prescription.

Access to data was restricted to authorized personnel only and stored in password-protected electronic systems. A formal letter of authorization to use the project data was obtained from the Principal Investigators: Dr. Anou Dreyfus (University of Zurich) and Dr. Jonathan Mayito (IDI).

In addition, ethical clearance for the sub-study was obtained from the Research and Ethics Committee of Uganda Christian University (UCU-REC), which reviewed and approved the secondary use of anonymized data within the study.

3.13 Dissemination of study results

The findings of this study will be disseminated to relevant stakeholders at community, district, national, and international levels. At the local level, results will be shared with health facility staff and district health teams through presentations and summary reports to support improvement in malaria prevention and case management practices.

At the national level, the findings will be shared with the Ministry of Health Uganda, particularly the National Malaria Control Division, and other implementing partners to inform policy formulation, planning, and program implementation.

The results will also be disseminated through presentations at scientific conferences and submission to peer-reviewed journals for publication, contributing to the broader scientific community.

CHAPTER 4: DATA ANALYSIS, PRESENTATION AND INTERPRETATION OF RESULTS

4.0 Introduction

This chapter presents the study results that include the demographics of study participants, prevalence of malaria, temperature and parasitemia levels, and concordance between malaria RDTs and microscopy.

4.1 Demographics of study participants

A total of 213 respondents residing in Hoima, Buliisa and Amuria districts were included in this study. This reflects the total number of eligible participants recruited at Kigorobya Community Hospital within the SPIRIT study during the study period (April–December 2024), and all available records from this site were included in the analysis. The demographic characteristics of the participants are summarized in Table 4.

Table 4 Distribution of respondents' demographic factors

Variables (n = 213)	Frequency	Percent (%)
Gender		
Female	156	73.2
Male	57	26.8
Education level		
Primary	126	59.2
Secondary	63	29.6
Tertiary	3	1.4
None	21	9.9
Marital status		
Single	59	27.7
Married	135	63.4
Widowed	2	0.9
Separated	10	4.7
Divorced	7	3.3
Place of residence		
Hoima	211	99
Buliisa	1	0.5
Amuria	1	0.5

Source: Research findings by the author

The majority 156 (73.2%) were females, while males comprised 57 (26.8%). In terms of educational attainment, most 126 (59.2%) respondents had completed primary education, followed by secondary education 63 (29.6%). Regarding marital status, the majority 135 (63.4%) of respondents were married, while 59 (27.7%) were single. In regard to geographical distribution, a majority 211 (99%) of participants resided in Hoima district, with only one respondent each from Buliisa and Amuria districts (0.5% respectively).

4.1.1 Age of study participants

The sample consisted of 213 participants whose ages ranged from 12 to 65 years. The majority of the participants were aged between 19 and 34 years with more than half of the participants aged 19 years older (n=122,57.3%), 35 years and above (n=77,36.2%) and the least were 12 to 18 years (n=14, 6.6%).

Table 5 Age distribution of the respondents

Respondents Age (N =213)		
Mean		31.8
95% Confidence Interval	Lower	30.2
	Upper	33.5
Median		29.00
Range		53.0
Minimum		12.0
Maximum		65.0
Percentiles	25	21.00
	50	29.00
	75	40.00

Source: Research findings by the author

Mean age of respondents was 31.82 years (95% CI: 30.16–33.48) with a median of 29 years. The 25th percentile was 21 years and the 75th percentile was 40 years. The

distribution of ages shows that the study population was predominantly composed of young and middle-aged adults. The relatively narrow confidence interval suggests that the mean age estimate is precise and representative of the target population.

4.2 Prevalence of Malaria

The prevalence of malaria among adolescent and adult febrile patients at Kigorobya Community Hospital was assessed using two diagnostic methods: the Malaria Abbott Rapid Diagnostic Test (RDT) and microscopy (blood smear). A malaria case was defined as any participant with a positive result on either the RDT or microscopy.

4.2.1 Overall prevalence

The overall prevalence of malaria among adolescent and adult febrile patients at Kigorobya Community Hospital, considering positive results from either the Abbott RDT or microscopy, was 34.7% (95% CI 0.283–0.411), confirming that approximately one in three patients had malaria. This overall estimate provides a summary measure of malaria burden in the study population before examining results by specific diagnostic methods.

4.2.2 Prevalence of malaria using RDT

The overall prevalence of malaria among adolescent and adult febrile patients at Kigorobya Community Hospital assessed using the Rapid Diagnostic Tests (RDT) diagnostic methods confirmed that 73 out of 213 patients tested positive, yielding a malaria prevalence of 34.3% (95% CI 0.279–0.407) (Figure 2).

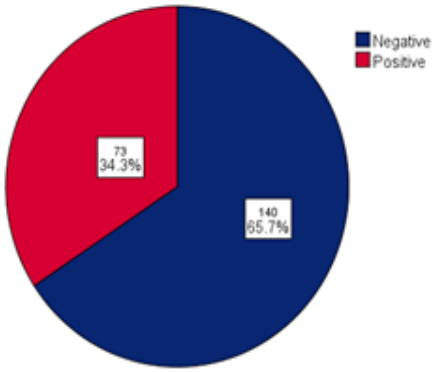

Figure 2 (a): Prevalence of Malaria using RDT

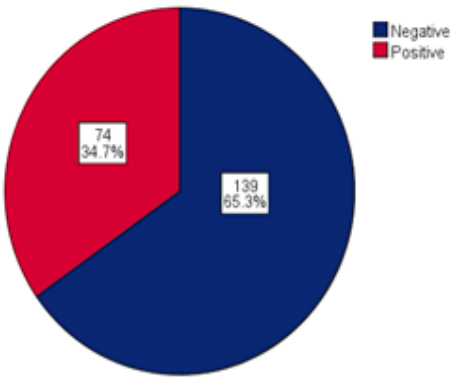

Figure 2 (b): Prevalence of malaria using Microscopy

Figure 2 Prevalence of malaria using RDT and microscopy

Source: Research findings by the author.

4.2.3 Prevalence of malaria using Microscopy

The overall prevalence of malaria among adolescent and adult febrile patients at Kigorobya Community Hospital assessed using the microscopy diagnostic method confirmed 74 positive cases, resulting in a slightly higher prevalence of 34.7% (95% CI 0.283–0.411) (Figure 2).

4.2.4 Age and malaria prevalence

Table 6 and 7 presents age characteristics and malaria diagnosis by microscopy and RDT among patients with acute undifferentiated fever respectively. The findings indicate that the age group 19 to 34 had highest malaria prevalence of 65.8% (95% CI 0.31-0.48, p-value of 0.030). The malaria diagnosis by RDT (34.3%) compared to malaria diagnosis by microscopy (34.7%).

Table 6 Age and malaria prevalence by RDT

Variable (n=213)	Malaria RDT results		95% Confidence Intervals	
	Negative	Positive	Lower	Upper
Age group				
12 to 18	7 (5.0%)	7 (9.6%)	0.24	0.76
19 to 34	74 (52.9%)	48 (65.8%)	0.31	0.48
35 and above	59 (42.1%)	18 (24.7%)	0.14	0.33

Source: Research findings by the author.

Table 7 Age and malaria prevalence by microscopy

Variable (n=213)	Malaria Microscopy results		95% Confidence Intervals	
	Negative	Positive	Lower	Upper
Age group				
12 to 18	7 (5.0%)	7 (9.5%)	0.24	0.76
19 to 34	74 (53.2%)	48 (64.9%)	0.31	0.48
35 and above	58 (41.7%)	19 (25.7%)	0.15	0.35

Source: Research findings by the author.

4.2.5 Association between demographic factors and malaria prevalence

The association between demographic factors and malaria diagnosis by the Malaria Abbot Rapid Diagnostic Tests (RDT) and microscopy methods (blood smear) among patients with acute undifferentiated fever was assessed using the Pearson Chi-square test.

4.2.5.1 Demographic factors and Malaria Prevalence by RDT

The findings in table 8 indicate that age group was significantly associated with malaria prevalence (x^2 = 6.989, p = 0.030, Cramér's V = 0.181), suggesting that younger individuals, particularly those aged 19–34 years, were more likely to test positive compared to other age categories. Malaria prevalence had no significant difference by

gender (x^2 = 2.120, p = 0.145), although a higher proportion of males (32.9%) tested positive compared to females (23.6%). Similarly, education level (x^2 = 2.876, p = 0.411), marital status (x^2 = 3.493, p = 0.479), and place of residence (x^2 = 1.053, p = 0.591) did not show a significant effect on malaria prevalence.

Table 8 Demographic factors and malaria prevalence by RDT

Variable (n=213)	**Malaria RDT results *n (%)***		**Pearson Chi-square (X^2)**	**P-Value**	**Phi & Cramér's V**
	Negative	Positive			
Age group					
12 to 18	7 (5.0%)	7 (9.6%)	6.989	0.030*	0.181
19 to 34	74 (52.9%)	48 (65.8%)			
35 and above	59 (42.1%)	18 (24.7%)			
Gender					
Female	107 (76.4%)	49 (67.1%)	2.120	0.145	0 .100
Male	33 (23.6%)	24 (32.9%)			
Education level					
Primary	86 (61.4%)	40 (54.8%)			
Secondary	38 (27.1%)	25 (34.2%)	2.876	0.411	0 .116
Tertiary	3 (2.1%)	0 (0.0%)			
None	13 (9.3%)	8 (11.0%)			
Marital status					
Single	35 (25.0%)	24 (32.9%)			
Married	90 (64.3%)	45 (61.6%)	3.493	0.479	0 .128
Widowed	1 (0.7%)	1 (1.4%)			
Separated	8 (5.7%)	2 (2.7%)			
Divorced	6 (4.3%)	1 (1.4%)			
Place (District) of residence			1.053	0.591	0.070
Hoima	138 (98.6%)	73 (100.0%)			
Buliisa	1 (0.7%)	0 (0.0%)			

Amuria	1 (0.7%)	0 (0.0%)			
					***Significant at p < 0.05**

Source: Research findings by the author.

4.2.5.2 Demographic factors and malaria prevalence by microscopy

The findings suggest that malaria positivity in this study population was independent of gender, education level, marital status, and place of residence as indicated in Table 9. No statistically significant association was found between gender and malaria positivity, (x^2 = 1.861, p = 0.172, Phi = 0.093). Similarly, education level was not significantly associated with malaria positivity, (x^2 = 2.649, p = 0.449, Cramér's V = 0.112). Marital status also showed no significant association with malaria diagnosis, (x^2 = 2.317, p = 0.678, Cramér's V = 0.104). Additionally, place of residence did not significantly influence malaria diagnosis, (x^2 = 1.075, p = 0.584, Cramér's = 0.071).

Table 9 Demographic factors and malaria prevalence by microscopic

Variable (n=213)	**Malaria Microscopy results n (%)**		**Pearson Chi-square (X^2)**	**P-Value**	**Phi & Cramér's V**
	Negative	Positive			
Age group					
12 to 18	7 (5.0%)	7 (9.5%)	6.019	0.049*	0.168
19 to 34	74 (53.2%)	48 (64.9%)			
35 and above	58 (41.7%)	19 (25.7%)			
Gender					
Female	106 (76.3%)	50 (67.6%)	1.861	0.172	0.093
Male	33 (23.7%)	24 (32.4%)			
Education level					
Primary	85 (61.2%)	41 (55.4%)	2.649	0.449	0.112
Secondary	38 (27.3%)	25 (33.8%)			
Tertiary	3 (2.2%)	0 (0.0%)			
None	13 (9.4%)	8 (10.8%)			

Marital status					
Single	35 (25.2%)	24 (32.4%)			
Married	90 (64.7%)	45 (60.8%)	2.317	0.678	0.104
Widowed	1 (0.7%)	1 (1.4%)			
Separated	8 (5.8%)	2 (2.7%)			
Divorced	5 (3.6%)	2 (2.7%)			
Place (District) of residence					
	137 (98.6%)	74			
Hoima	1 (0.7%)	(100.0%)	1.075	0.584	0.071
Buliisa	1 (0.7%)	0 (0.0%)			
Amuria		0 (0.0%)			
***Significant at p < 0.05**					

Source: Research findings by the author.

4.3 Temperature and parasitemia levels

The mean body temperature of the study participants (N = 213) was 36.8°C (SD = 0.83), ranging from 34.6°C to 39.8°C. The Plasmodia was identified in all study participants. Among the 74 participants who tested positive for malaria parasites, the mean temperature was 36.8° C (SD = 0.87), ranging from 35.0°C to 39.3°C, and also their parasitemia levels ranged from 37 parasites/µl to 72,000 parasites/µl, with a mean of 1,417.18 parasites/µl (SD = 8,323.19), shown in table 10.

Table 10 Temperature and parasitemia levels

Variables	**Temperature all participants (*°C*)**	**Temperature of malaria cases (*°C*)**	**Parasitemia(parasites/ml)**
N	213	74	74
Mean	36.8	36.8	1417.18
Median	36.7	36.7	318.00
Std. Deviation	0.83	0.9	8323.19
Range	5.20	4.30	71963

Minimum	34.60	35.00	37
Maximum	39.80	39.30	72000

Source: Research findings by the author.

4.4 Concordance between malaria RDTs and Microscopy

The study assessed the concordance between malaria diagnosis using Abbott Rapid Diagnostic Tests (RDTs) and microscopy among patients presenting with acute undifferentiated fever at Kigorobya Community Hospital.

4.4.1 Association between malaria RDT and microscopy tests

The analysis of concordance between malaria RDT and microscopy was based on the assumption that microscopy was the gold standard; – microscopy (thick and thin blood smears) was assumed to be the definitive method for malaria diagnosis, against which the RDT results were compared. The Pearson Chi-square test was used to determine the statistically significant association between the two tests.

Out of 213 patients, 139 tested negative on both RDT and microscopy, while 73 tested positive on RDT and 74 on microscopy, demonstrating a high level of consistency between the two diagnostic approaches. Only one patient tested positive by microscopy but negative by RDT, and no cases were found to be RDT-positive but microscopy-negative. The Pearson Chi-square test revealed a statistically significant association between the two tests ($X^2 = 208.621$, $p < 0.05$), and the Cohen's Kappa coefficient was 0.990, indicating a nearly perfect agreement. These findings confirm that the Abbott RDT is highly consistent with microscopy results and is appropriate for malaria diagnosis among febrile patients, especially in settings with limited laboratory capacity (Table 11).

Table 11 Association between malaria RDT and microscopy tests

Variable (n=213)	Malaria Microscopy results		Pearson Chi-square (X^2)	P-Value	Kappa
	Negative	Positive			
Malaria RDT results					
Negative	139 (100.0%)	1 (1.4%)	208.621	<0.001	0.990
Positive	0 (0.0%)	73 (98.6%)			
					***Significant at p < 0.05**

Source: Research findings by the author.

4.4.2 Diagnostic performance of malaria RDT compared to microscopy

Considering microscopy as a reference diagnostic method for malaria, performance of the Abbott malaria RDT was compared to microscopy among fever patients at Kigorobya community hospital.

Therefore, from table 9; the True Positives (TP) = 73, True Negatives (TN) = 139, False Positives (FP) = 0, False Negatives (FN) = 1

Table 12 Diagnostic performance of malaria RDT compared to microscopy tests

Parameter	Formula	Value (%)	95% CI
Sensitivity (SE)	TP / (TP + FN)	98.65	92.5-99.9
Specificity (SP)	TN / (TN + FP)	100.00	97.4-100.0
Positive Predictive Value (PPV)	TP / (TP + FP)	100.00	95.1-100.0
Negative Predictive Value (NPV)	TN / (TN + FN)	99.29	95.8-99.9

Source: Research findings by the author.

The Abbott malaria RDT showed excellent diagnostic performance compared to microscopy, with a sensitivity of 98.65% and a specificity of 100%. The Positive Predictive Value (PPV) was 100%, indicating that all RDT positive results corresponded

to true malaria cases. The NPV was 99.29%, indicating that almost all RDT-negative results could have correctly indicated the absence of malaria.

4.4.3 Summary of the key findings from this study

The RDT detected malaria in 34.3% of participants, compared with 34.7% detected by microscopy. The findings confirm that the Abbott RDT is highly consistent with microscopy results and can be dependably used for malaria diagnosis in febrile patients, especially in settings.

The findings indicate that the 19–34 age group had the highest malaria prevalence; malaria was diagnosed by RDT in 65.8% of participants and by microscopy in 64.9%.

The younger individuals, particularly those aged 19–34 years, were more likely to test positive compared to other age categories. Gender was not significantly associated with malaria prevalence ($x^2 = 2.120$, $p = 0.145$), although a higher proportion of males (32.9%) tested positive compared to females (23.6%). Similarly, education level ($x^2 = 2.876$, $p = 0.411$), marital status ($x^2 = 3.493$, $p = 0.479$), and place of residence ($x^2 = 1.053$, $p = 0.591$) were not significantly linked with malaria prevalence.

Marital status also showed no significant association with malaria diagnosis, ($x^2 = 2.317$, $p = 0.678$, Cramér's V = 0.104). Additionally, place of residence did not significantly influence malaria diagnosis ($x^2 = 1.075$, $p = 0.584$, Cramér's = 0.071).

The Positive Predictive Value (PPV) was 100%, indicating that all RDT positive results corresponded to true malaria cases. The NPV was 99.29%, indicating that almost all RDT-negative results could have correctly indicated the absence of malaria.

CHAPTER 5: DISCUSSION

5.0 Introduction

This chapter presents a discussion of results and is presented along the specific objectives, which guided the study.

5.1 Prevalence of malaria among patients

In this facility based cross -sectional study at Kigorobya Community Hospital, malaria positivity among adolescent and adult febrile patients was 34.3% by RDT and 34.7% by microscopy. The highest prevalence of 65.8% was found in the 19-34 age group, indicating a high level of malaria in this population.

The observed facility prevalence of 34.7% is close to the national averages of 36%, (MOH,2025). The national figure covers all ages, but prevalence is generally higher among children than adults, and local transmission can vary by region. As such the prevalence in this study aligns with national trends. Although national efforts such as distribution of insecticide -treated nets (ITNs), indoor residual spraying (IRS), wider access to diagnostics, and community health initiatives have advanced malaria control, persistent infection still remain.

The observed prevalence of 34.7% does not align with findings from other parts of Uganda. For example, the test positivity reported in several western Ugandan facilities was lower than 40-55% (MoH, 2025) while Ssewante et al. (2025) found 61.8% positivity among febrile patients in Busoga and Lango northern district in Uganda. However, the current study's prevalence was higher than the prevalence of 17% in Kampala (Rek et al.,2025). Seasonal patterns, local ecological conditions and uneven intervention coverage likely contribute to this prevalence. This variability highlights the importance of data synthesis to quantify the national burden and develop targeted interventions.

Across East Africa, facility test positivity among febrile patients also varies. In Tanzania the facility positivity prevalence reported much lower rates of 14% based on studies published between 2014 and 2024 (Sebukoto et al., 2026). Similarly, in Ethiopia, the

prevalence of malaria was lower at 27.3% (Legesse & Berhane, 2025). The differences could be attributed to the differences in health-seeking behavior, transmission ecology and climate, interventional coverage, diagnostic capacity, and reporting completeness affect measured prevalence.

Malaria prevalence in this community could be reduced through a multisectoral, evidence-based approach that includes practical interventions such as strengthening community case management; improving diagnosis and treatment using RDTs and ACT therapies; reinforcing health system capacity and supply chains; and enhancing vector control, surveillance, and targeted responses at facility and sub-county levels through regular monthly monitoring.

5.2 Timing of patient's presentation and fever history

Interestingly, the mean temperature among malaria-positive patients was 36.8°C, with a median of 36.7°C, suggesting that many patients presented to the health facility when fever was no longer present (Ongondo et al., 2024). This implies that febrile illness may have been transient or resolved by the time of consultation, highlighting potential delays in health-seeking behavior or prior self-medication before presentation. It also underscores the importance of parasitological diagnosis, as reliance on clinical fever alone may underestimate malaria cases in such settings.

5.3 Parasite density

The mRDT and microscopy showed there was a wider range of parasite densities. The results for parasite densities are consistent with previous studies done in Uganda of high-transmission settings (Bosco et al.,2020; Nankabirwa et al., 2015). In previous high transmission areas, several immune mechanisms likely influenced varying levels of parasite densities (Doolan et al., 2009). This is contrary in low-transmission areas such as Myammar, where there have been rapid decreases in malaria prevalence, just two or three bites can form exposure-related immunity and suppress parasite loads (Ghinai et al., 2017). Many of the asymptomatic infections identified in these studies are likely due to previous exposure with parasite densities suppressed to submicroscopic levels.

5.4 Demographic factors of study participants

Similar to other studies, this study also revealed that age was found to be associated with increased malaria infection. This is consistent with previous studies in Ethiopia (Beyene et al., 2025). This study suggests that if the retirement age is set at 60 years a significant proportion of the workforce (65% of those aged 19–34 and 25% of those aged 35-60) suffers from malaria infection. This is likely because these age groups are most active during peak mosquito biting hours, increasing their exposure to malaria. This may lead to reduced efficiency and productivity among these individuals. Therefore, innovative and effective interventions to control malaria could be identified and implemented in this community. In the present study, gender, education level, marital status and place of residence were not significantly associated with malaria prevalence. This suggests that factors other than gender—such as age, occupation, or exposure to mosquito breeding sites—may have a greater influence on malaria risk.

5.5 Concordance between RDTs and microscopy

5.5.1 Overview of concordance between RDT and microscopy

The concordance between microscopy and Abbott RDTs is vital for validating the reliability of malaria diagnoses. In this study, 73 patients were RDT positive and 74 were microscopy positive, indicating strong concordance between the two diagnostic methods. The Cohen's Kappa coefficient was 0.990, indicating a nearly perfect agreement. Similarly, in western Ugandan study of Kiryandongo the concordance between mRDT and microscopy was very good, where the RDT measured 12.8% and microscopy 12.2% malaria prevalence with a kappa statistic (κ) at 0.75 (Acan et al., 2025). These findings confirm that RDT can be considered a reliable diagnostic tool for malaria diagnosis in febrile patients, especially in settings with limited laboratory capacity. Finally, the differences in kappa statistics are small; the variation may be due to health-facility factors—such as temporary staff involved in data entry and aggregation—rather than the malaria burden affecting the quality of RDT data.

5.5.2 Sensitivity

In the present study, generally, Abbott malaria RDT compared to microscopy showed excellent diagnostic accuracy with a sensitivity of 98.65%. The high sensitivity recorded in this study is far above the WHO recommendations of about 95%. This could be attributed to good transport and storage conditions of the RDTs as well as parasitic factors, such as the high parasite density in the study area compared to and the rest of sub-Saharan Africa with exception of a low one in Eritrea and Ethiopia. (Okanda et al., 2023).

Comparative findings had been reported by some researchers around the country 91% in 32 districts between 2021-2023 (Kabbale et al., 2025). Others have reported high sensitivity with moderate specificity of 65.00% in Kenya (Wasena et al., 2025; Perkins et al., 2025) and 62.2% in Ethiopia (Tamir et al.,2025), in acute febrile illness, signifying regular false-positive results. Moreso a Nigerian study indicated extremely lower sensitivity of RDT 29% (Ogunfowokan et al.,2020). The high sensitivity observed in this study is likely due to elevated parasite densities in the study population, exceeding the minimum threshold for mRDT detection (< 100 asexual parasites/μL or < 0.002% of red blood cells infected) (WHO,2006; Gillet et al., 2011; Baldini,2024). The implication of the high sensitivity in this study is that in areas with high malaria parasitaemia, there is no need to cross – check a negative result with a microscopy and clinical acumen of the physician to rule out possibilities of false negative results with the mRDT. Additionally, mRDTs shortens the time between the patients becoming infectious and receiving treatment. Thus, the duration of infectiousness is shortened, leading to decreased malaria transmission (Thein et al., 2025).

5.5.3 Specificity

The study found a specificity of 100% for RDT, comparable with findings from other past studies (Oyeyemi et al., 2015; Anagu et al.,2015; Musa & Yahaya ,2016; Otojareri et al., 2023; Tilahun et al., 2024). In contrast the findings of Wasena et al. in Kenya reported decreased PfHRP2-based RDT specificity of 65% compared to microscopy for diagnosis of malaria (in acute febrile illness, indicating frequent false-positives may occur, underscoring the importance of cautious interpretation of results in clinical contexts.

The implication of a high specificity of 100% in this study implied that mRDT may be used in primary healthcare centres to exclude the absence of malaria where microscopes are hardly seen or where the required human expertise is lacking. Consequently, mRDTs could be more economical and the preferred options for parasitological diagnosis of malaria than microscopy (Lin et al., 2022).

Variations in RDT performance between different studies may be ascribed to low parasite density, mixed infections, or functional factors such as storage conditions and user proficiency (Legesse & Berhane, 2025) as well as quality control issues during manufacturing (Wongsrichanali et al.,2007). Additionally, differences in the test methodology, types of RDTs used and the microscopist's level of expertise could contribute to possible variations.

5.5.4 Positive Predictive Value and Negative Predictive Value

In the present study, the PPV was 100%, correctly indicated truly infected cases and the NPV was 99.29%, indicating the absence of malaria. The PPV found in this study is comparable to what had been reported by Umegbolu et al. in Southeast Nigeria, which demonstrated a PPV of 100% and a low NPV of 60% (Umegbolu et al., 2018). Similarly, a comparable PPV of 100% and lower NPV of 61.5% were reported in Cameroon (Ngalame et al., 2024). However, much lower NPVs have been reported from other studies (Oyeyemi et al., 2015; Anagu et al., 2015; Musa & Yahaya, 2016). In Kenyan study, Wasena et al. showed low positive predictive value of 35.1%, requiring confirmatory testing, while the negative predictive value was high (98.89%), underpinning the reliability of mRDTs in ruling out malaria (Wasena et al., 2025). Additionally, the high NPV and sensitivity of RDTs imply that true malaria cases would rarely be missed, making it a suitable test for primary diagnosis of malaria (Mbabazi et al., 2015).

This implies that the RDT results presented here demonstrate that both positive and negative RDT results correctly indicate true malaria cases and absence of malaria, respectively. This contrasts with the false negative RDT results commonly reported in community malaria surveys and low transmission areas in sub-Saharan Africa (Watson et al., 2019; Ongonda et al., 2024). Finally, the findings of this study confirm that

mRDTs, particularly Abbott mRDT, can be continued for use in the diagnosis of malaria in resource-limited and field settings including low-transmission areas. Further, the mRDTs could aid in differentiating causes of fever (Mortazav et al., 2025). Given, the Abbot RDT brand performance the diagnostic tools can be deployed as front-line RDTs to complement surveillance of malaria and field effectiveness studies.

5.6 Parasite density

The mRDT and microscopy indicated a wider range of parasite densities. These findings are consistent with previous studies conducted in high transmission settings in Uganda (Bosco et al.,2020; Nankabirwa et al., 2015). In previous high transmission areas, several immune mechanisms likely influenced varying levels of parasite densities (Doolan et al., 2009). This contrasts with low-transmission areas such as Myammar, where rapid decreases in malaria prevalence mean even just 2 or 3 infectious bites can induce exposure-related immunity and suppress parasite loads (Ghinai et al., 2017). Many of the asymptomatic infections identified in these studies are likely due to previous exposure with parasite densities suppressed to submicroscopic levels.

5.7 Practice and Policy

Accurate diagnosis is crucial for effective malaria control, as gene mutations and rising drug resistance increasingly undermine current treatment strategies (WHO,2023). The present study highlights opportunities for optimizing malaria diagnosis by revealing differences in performance between Abbott mRDTs and microscopy blood smear tests. The mRDTs demonstrated exceptionally high specificity and PPV, positioning mRDTs as a powerful tool to reduce overtreatment, decrease the risk of drug resistance, and enhance antimicrobial stewardship. These findings support a strategic approach to the integration of mRDTs as a reliable and valid diagnostic algorithm, complemented by strengthened quality assurance and targeted vector control measures to maximize impact in high prevalence areas. Thus, they advance progress towards malaria elimination goals. Furthermore, the Abbott Malaria Antigen P.f./pan RDT demonstrated high sensitivity, making it suitable for use in low-resource settings with limited trained personnel and laboratory infrastructure.

5.8 Limitations and strengths of this study

The strength of this study is that all samples were collected and tested on-site, minimizing potential sample degradation and allowing accurate comparison between RDT and microscopy results. Additionally, adherence to recommended standard practice protocols (including proper blood film preparation, use of high quality reagents, and adequate training) enhanced the quality of the results. Although the primary use of mRDTs is for diagnosing symptomatic malaria, they can also be used for several research or surveillance purposes.

However, regarding limitations, the samples were collected from febrile patients aged 12 years and above, which limits generalizability to asymptomatic or non-health-seeking populations and to other age groups. To strengthen the findings, the study was conducted during the two peak malaria transmission seasons, ensuring that the results reflect periods of high malaria activity and may be relevant to other areas with similar transmission patterns. As such, the findings may be applicable to settings with comparable transmission patterns. The study sought information on the respondents whether they had received antimalarial treatment prior to presenting to the hospital. An insignificant number had received prior treatment and as such this was not further explored.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.0 Introduction

This chapter presents the conclusions drawn from the study findings and outlines the recommendations and areas that require further research. The conclusions are presented consistent with study objectives.

6.1 Conclusions

There was a moderate prevalence of malaria among febrile patients in this study, with 73 out of 213 participants (34.3%) testing positive, indicating a considerable malaria burden in this setting. This highlights the need for sustained malaria control measures and careful clinical evaluation of febrile illnesses.

The Abbott RDT is superior to microscopy in terms of diagnostic effectiveness and efficiency for malaria, given its ease of use and minimal training requirement. The study also demonstrates strong concordance between mRDTs and microscopy results, validating mRDTs as a reliable tool for diagnosing malaria in settings with limited resources or expertise. The results of the study will be useful to scientists, health practitioners working in this field, and policy makers involved in malaria control in Uganda and other similar settings. Finally, the study findings may further inform clinical decision-making, improve treatment efficacy, and enhance overall disease management.

6.2 Recommendations

6.2.1 At National level

The Ministry of health and the entire health sector could consider deploying Abbot RDTs at all levels for the diagnosis of febrile illnesses, with prompt treatment guided by national guidelines. There is a need for training laboratory scientists to become certified WHO malaria microscopist.

6.2.2 At district level

There is need for District Health Officers to strengthen continuous professional development to enhance the health workforce's capacity in malaria treatment. This could be done through regular mentorships coupled with good clinical practice. Finally, ensuring equitable distribution of mRDTs at all levels of care could advance Uganda's last-mile efforts towards achieving its national and SDG targets.

6.2.3 At community level

The District Health Teams could strengthen malaria control community interventions through local organizations and networks facilitating peer mentoring and training. Additionally, education on early health seeking behavior could help foster connections and reduce malaria infections.

6.3 Areas for further research

Future research should focus on comparative performance studies of rapid diagnostic tests, microscopy, and real-time PCR for detection of malaria parasites among various high risk sub-populations. Such studies could provide valuable insights into the performance of diagnostic tools in malaria control and surveillance, informing healthcare practices and policy decisions. Also, regional comparative studies may be important to examine malaria prevalence and associated factors across various areas of Uganda. This research could highlight specific local challenges and offer strategies tailored to the unique needs of different sub group populations. Finally, the health sector could also consider such periodic studies so as to elucidate emerging trends with use of mRDTs and microscopy blood smear tests.

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APPENDICES

Appendix 1: REC Approval letters

IDI REC approval letter

Infectious Diseases Institute
Research Ethics Committee
(IDI-REC)

22nd April 2025

Dr. Jonathan Mayito
Principal Investigator

Category of Review
[ ] Initial Review
[X] Continuing Review
[ ] Amendment
[ ] Study closure
[ ] SAE review
[ ] Deviations/ violations
[ ] Termination of study

Dear Jonathan,

Re: Renewal of the study titled # IDIREC REF 2023-43 "The role of leptospirosis and rickettsiosis in acute undifferentiated fever patients in Uganda-SPIRIT study."

Thank you for submitting the above progress report to IDIREC.

This is to inform you that after review of your progress report dated 15th April 2025, IDIREC approval has been granted to you to continue with your study for another one year up to **07th June 2026.** At that time, IDIREC would expect you to submit a progress report and request for renewal, prior to the expiry date to allow timely review.

Kindly share the progress report with the Uganda National Council of Science and Technology (UNCST).

Yours sincerely,

Dr. David Patrick Kateete
Chairperson

INFECTIOUS DISEASES INSTITUTE
RESEARCH ETHICS COMMITTEE (IDIREC)
RENEWAL
VALID UNTIL
07 Jun 2026

SWISS REC approval

Kanton Zürich
Kantonale Ethikkommission

Prof. em. Dr. med. David Nadal
Präsident Abteilung A

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12.Mai 2023 / cwe

Statement of the Kantonale Ethikkommission Zürich according to Human Research Act (HRA) Art.51

Statement ID	AO_2023-00023
Statement re.	☐ a data registry ☐ a biobank ☒ a research project outside of the scope of the HRA ☐ an ethical question
Project title	The role of leptospirosis and rickettsiosis in acute undifferentiated fever patients
Responsible person at main site	Dr. med. vet. Anou Dreyfus
Lead Ethics Committee	Kantonale Ethikkommission Zürich
Main site / Institution	University of Zurich

Statement

- ☒ positive statement with additional remarks
- ☐ statement with list of deficiencies
- ☐ a statement can't be given

The ethic commission has reviewed the submitted documents (see Attachment) and can confirm that this research project fulfills the general ethical and scientific standards for research involving human beings (see HRA Art.51 para. 2).

Additional remarks:

(Additional remarks are not charges or conditions. Changes to the documents can be performed by the sponsor and will no be reviewed by the ethics committee.)

Protokoll

- Beachten Sie, dass alle Pflichten gegenüber der Kantonalen Ethikkommission Zürich entfallen, da das Forschungsprojekt nicht unter das HFG fällt. Z.B. müssen Amendments nicht von der KEK ZH geprüft und bewilligt werden, schwerwiegende Ereignisse der KEK ZH nicht gemeldet werden, usw.
- 3.4: Bitte unterscheiden Sie beim Widerruf der Einwilligung zwischen der Einwilligung in die Studie und der Einwilligung in die Aufbewahrung und Weiterverwendung der Daten und Proben. Im ersten Fall dürfen die bereits erhobenen Daten und Proben für die Studienanalysen verwendet werden und werden anschliessend in verschlüsselter Form aufbewahrt. Im zweiten Fall sollen die Daten und Proben nicht mehr für Forschung verwendet werden (die Daten werden vollständig anonymisiert und die Proben vernichtet).
- 7.3: Geben Sie an, wo die Schlüsselliste aufbewahrt wird und wer darauf Zugriff hat.

Teilnehmer-Information (Erwachsene, Kinder, Eltern)

- Allgemeine Bemerkung: Die verschiedenen Informationen unterscheiden sich inhaltlich leicht voneinander. Es wäre sinnvoll, sie aneinander anzugleichen.
- Ergänzen Sie, dass auch eine Urinprobe entnommen werden soll.
- Beschreiben Sie, wie die Vertraulichkeit gewährleistet wird. Die Daten und Proben werden für die Analysen verschlüsselt, d.h. alle identifizierenden Angaben (Name, Adresse, Geburtsdatum usw.) werden gelöscht und durch einen Code ersetzt.
- Stellen Sie klar, dass die Daten und Proben in Uganda und in der Schweiz analysiert werden sollen.
- Geben Sie klar an, dass eine Ablehnung der Einwilligung und ein Widerruf der Einwilligung ohne Begründung möglich sind.
- Beschreiben Sie den Umgang mit Proben und Daten bei einem Widerruf der Einwilligung.
- Beschreiben Sie den Umgang mit den Daten und Proben nach Abschluss der Analysen. (Gemäss Protokoll 7.4 werden die Daten und Proben 10 Jahre aufbewahrt.)
- Geben Sie an, wer für Schäden haftet, welche auf das Forschungsprojekt zurückzuführen sind.
- Information für die Eltern: Bitte korrigieren Sie das Volumen entnommenes Blut (4 plus 2 Teelöffel). Stellen Sie klar, dass die betroffenen Kinder mit der Teilnahme an der Studie einverstanden sein bzw. keine Anzeichen von Widerstand gegen die Teilnahme zeigen sollen.

Teilnehmer-Information Aufbewahrung der Proben (Erwachsene, Eltern)

- Kap. 1: Bitte stellen Sie vom Anfang an klar, dass zusätzlich zu den übrig gebliebenen Proben auch die Studiendaten für weitere Forschungsprojekte aufbewahrt und verwendet werden sollen.
- Kap. 4: Wo werden die Daten und Proben aufbewahrt (Uganda oder Schweiz)?
- Geben Sie an, wer für Schäden haftet, welche auf das Forschungsprojekt zurückzuführen sind.
- Information für die Eltern: Bitte ergänzen Sie, dass die Daten und Proben ins Ausland (in die Schweiz) für Forschungsprojekte übermittelt werden können.
- Es fehlt die Information und Einwilligungserklärung für die Kinder.

CRF

- Wir weisen darauf hin, dass sehr hohe Anforderungen an die Verschlüsselung der Daten und Proben der Studienteilnehmenden zu stellen sind.
- Insb. sollen das vollständige Geburtsdatum und die genaue Adresse (Dorf) aus Vertraulichkeitsgründen nicht mit den Studiendaten erfasst werden.

Übriges

- Bitte reichen Sie uns den Beschluss der lokal zuständigen Ethikkommission bzw. Behörde nach.

Fees

Amount: CHF 1200.- Tariff code: 2.1

In accordance with the applicable swissethics fee schedule.

Please note:

This statement doesn't constitute an approval according to the Human Research Act.

Annette Magnin
Geschäftsführerin

Dr. sc. nat. Tobias Rosenberger
Leiter wiss. Sekretariat

Attachment: - Submitted documents

Attachment

List of submitted documents

Dokument	Dok.Datum	Version
1. Cover Letter		
230302-coverletter-spirit-ricklep-signad-ml-1.pdf	02/03/2023	
9. Participant information sheet and informed consent (ICF)		
070223-spirit-english-icf.docx	07/02/2023	1
enrolment-crf-english.docx	07/02/2023	1
070223-spirit-storage-consent-english.docx	07/02/2023	1
070223-spirit-pediatric-storage-icf.docx	07/02/2023	1
070223-spirit-pediatric-english-icf.docx	07/02/2023	1
070223-spirit-pediatric-english-assent.docx	07/02/2023	1
10. Study plan (protocol)		
230316-swissethicsspirit-ricklep-v1-fin-signad-ml.pdf	07/02/2023	1
11. Investigator's CV		
20230317-cv-short-dreyfus-v1.pdf	17/03/2023	1
bio-sketch-m-lamorde2022-rf.pdf	17/03/2023	1
12. Agreement between sponsor/commissioned institution/grant provider		
230125-spirit-collaborative-research-agreement-v2-sj-kk-ad-js-docx-1.pdf	13/03/2023	1

UCU REC exemption letter

UGANDA CHRISTIAN UNIVERSITY
A Centre of Excellence in the Heart of Africa

Office of the Vice Chancellor
Research Ethics Committee UG-026

18th August, 2024

Ogwang Joel
Uganda Christian University
Email: egerujoelo@gmail.com

UG-REC-026 EXEMPTION NOTICE

To: Ogwang Joel, Principal Investigator

Re: UCUREC Application titled ***Malaria Prevalence and Diagnostic performance of a Rapid Diagnostic Test Versus Microscopy among Adolescent and Adult Febrile Patients at Kigorobya Community Hospital.***

Application Number: **IDIREC-2023-743**

Version: 1.0

UGANDA CHRISTIAN UNIVERSITY
EXEMPTED
18 AUG 2025
RESEARCH ETHICS COMMITTEE

Type: [ ] Initial Review
[ ] Protocol Amendment
[ ] Letter of Amendment (LOA)
[ ] Continuing Review
[ ] Material Transfer Agreement
[*] Other, Specify: EXEMPTION REQUEST

I am pleased to inform you that the UG-REC-026; UCUREC exempted the above referenced application.

Exemption of the research is for the period from 18th August, 2025, to 18th August, 2026.

This research is considered minimal risk category since there is no humans involved in research.

As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and additions to the protocol must be submitted to the REC for re-review and approval prior to the activation of the changes. The REC exemption number assigned to the research should be cited in any correspondence.

Research and Ethics
P.O. Box 4, Mukono, Uganda, Plot 67-173, Bishop Tucker Road, Mukono Hill
Tel: +256 (0) 312 350 885 Fax: +256 (0) 4142 90 800 Email: rec@ucu.ac.ug Web: www.ucu.ac.ug
UCUREC is accredited by Uganda National Council for Science & Technology, FDA, and National Institutes for Health of the United States of America

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Office of the Vice Chancellor
Research Ethics Committee UG-026

3. Reports of unanticipated problems during study or other must be submitted to the UCUREC for notification. New information that becomes available which could change the status of the study; i.e. involving members of the research team, guardians, or any unexpected occurrence must be communicated to UCUREC.

4. Regulations require review of an exempted study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the REC eight weeks prior to the above expiration date of 18th August, 2026 in order to continue the study beyond the exempted period.** Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study, at which point any change in approach to data collection must be communicated.

Signed and Stamped

.....

Prof. Peter Waiswa
UCUREC Chairperson,
pwaiswa@musph.ac.ug

UGANDA CHRISTIAN UNIVERSITY
EXEMPTED
18 AUG 2025
RESEARCH ETHICS COMMITTEE

Research and Ethics
P.O. Box 4, Mukono, Uganda, Plot 67-173, Bishop Tucker Road, Mukono Hill
Tel: +256 (0) 312 350 885 Fax: +256 (0) 4142 90 800 Email: rec@ucu.ac.ug Web: www.ucu.ac.ug
UCUREC is accredited by Uganda National Council for Science & Technology, FDA, and National Institutes for Health of the United States of America

APPENDIX 2: Data sharing agreement

Dr. OGWANG JOEL AND INFECTIOUS DISEASES INSTITUTE- MAKERERE DATA USE AGREEMENT

FOR SECONDARY USE OF DATA FROM THE SPIRIT STUDY

Section 1: Parent Study Information:

Title of Parent Study: The Role of Leptospirosis and Rickettsiosis in Acute Undifferentiated Fever Patients in Uganda.

Institution:

Infectious Diseases Institute (IDI), Makerere University and the University of Zurich.

Principal Investigators:

Prof. Anou Dreyfus (University of Zurich)

Dr Mayito Jonathan (Infectious Diseases Institute- Makerere)

Section 2: Requesting Researcher Information

Full Name:

Dr. Ogwang Joel

Affiliation: Uganda Christian University, Master of Public Health (MPH) Student,

Title of Sub-study:

Malaria Prevalence and Diagnostic Performance of Rapid Diagnostic Tests Versus Microscopy Among Adolescent and Adult Febrile Patients at Kigorobya Community Hospital

Section 3: Description of Data Requested

A. Demographic Data:

☑ Age

☑ Sex

☑ Occupation

☑ Education level

☑ Marital status

☑ Address or location.

B. Clinical Signs and Symptoms:

☑ Presence of fever (Yes/No)

☑ Duration of fever (in days)

☑ Temperature measured (in °C)

C. Laboratory Data:

☑ Study ID

☑ Date of hospital visit

☑ Malaria blood smear and Rapid diagnostic test results.

Section 4: Purpose of Data Use

☑ Data analysis

☑ Academic research

☑ Reporting for MPH thesis

☑ Publication in academic journal(s)

Section 5: Data Protection and Use Terms

Data will be stored securely (password-protected digital storage or encrypted drive).

Data access will be restricted to the following individuals:

Dr. Ogwang Joel (MPH Student)

Prof. Basaaza Robert (Co-Supervisor)

Prof. Anou Dreyfus (Supervisor/PI)

Data will be stored for a maximum duration of two (2) years.

Data will not be shared with any third parties.

Data will be used only for the purposes outlined in this agreement.

Any publications or presentations resulting from the use of this data will acknowledge the parent study and the PI appropriately.

Section 6: Signatures

I, the undersigned, as Principal Investigator of the SPIRIT study, hereby grant permission for the use of the above-listed data by the requesting researcher under the stated terms.

(1) Name of PI: Prof Anou Dreyfus.

Signature:

Date: Bern, 27.05.2025

(2) Name of PI: Dr. Mayito Jonathan.

Signature:

Date: 13/06/2025

Section 7: For Requesting Researcher Use Only

☑ I agree to abide by the terms of this Data Use Agreement

☑ I will ensure the confidentiality and security of all data received

Name of Researcher: Dr. Ogwang Joel

Signature: _____

Date: _____21st/May/2025_____

Appendix 3: Data extraction tool

Title: Structured Data Extraction Tool for the Study: Malaria Prevalence and Diagnostic Performance of Rapid Diagnostic Tests Versus Microscopy Among Adolescent and Adult Febrile Patients at Kigorobya Community Hospital in Hoima district of western Uganda

Variable category.	**Variable**	**Response format**
Patient identification		
	Study ID	----------
	Date of hospital visit	---/---/----
Demographic characteristics		
	Age (years)	-------
	Gender	Male / Female
	Occupation	----------
	Educational level	None / Primary / Secondary / Tertiary
	Marital status	Single / Married / Widowed / Separated / Divorced
	District of residence	------
Clinical characteristics		
	Presence of fever	Yes/ No
	Duration of fever (in days)	--------
	Temperature (ºC)	--------
Laboratory findings		
	Malaria Rapid diagnostic test results	Negative /Positive
	Malaria microscopy results	Negative/ Positive

APPENDIX 3: Work plan

Activity	2024	2025					2026
Time	Apr-Dec	May	May	June	Jul- Sept	Oct - Dec	Jan - Mar
Data collection							
Proposal writing							
Submission of proposal							
Getting permission letter from the university							
Data Extraction from red cap system							
Data analysis							
Report writing							
Submission of research report							

APPENDIX 4: Budget for the research project.

This project was a sub-study of a parent study funded by the Swiss National Science Foundation (SNSF) with a total grant of 500,000 Swiss Francs. No additional funding was available beyond the parent study's allocation.

Item	Cost (UGX)
Photocopying (research proposal, and dissertation)	300,000
Printing	300,000
Binding	100,000
Data for internet access	1,000,000
It expert and typesetting	300,000
Transport	1,000,000
Stationary	300,000
Laptop purchase	2,000,000
Airtime	1,000,000
Miscellaneous	1,000,000
Total amount	7,300,000