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Title: Implementation Fidelity of Malaria Test and Treat Guidelines amongst Healthcare Providers in Kisumu, Kenya, 2019

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DECLARATION

I Maero, Athanasius Lutta declare that this research report is my own, unaided work. It is being submitted in partial fulfilment of the requirements of the Degree of Master of Science in Epidemiology (Field of Implementation Science) at the University of The Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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Candidates Signature: ………… …………………………

Date: …7th September 2020…………………...

DEDICATION

I dedicate this work to the Almighty God for His unending grace, my wife Millicent Lumiti, sons Adriel Wanga and Ariel Lumiti, and grandparents for the special role you have played in my growth. To my late father Joseph Wanga Maero, and mother Jacinta Esther Waka.

ABSTRACT

Background: Malaria is an infection of global importance affecting over 3 billion people annually. Sub-Sahara Africa accounts for over 80% of global infections and nearly 90% of mortalities. In Kenya, malaria contributes 8% of the disease burden in the population nationally and over 50% in the Lake and Coastal regions. The WHO recommended test and treat guidelines for malaria in 2010 thus standardizing the treatment of malaria. Kenya adopted the guideline that year. The purpose of this study was to assess the implementation fidelity of malaria test and treat guidelines amongst healthcare providers working in the outpatient department in health facilities in Kisumu, Kenya.

Methods: This was a quantitative cross-sectional study design that utilized multistage sampling. Available and willing providers working in the outpatient departments of study facilities were enrolled upon being informed about the details of the study and their rights. Signed informed consent was obtained before data collection. Data collection was done by the researcher using a web-based questionnaire built-in REDCap. Data analysis was conducted in Stata 15.1. The scores of the items for implementation fidelity and determinants that were assessed on a Likert or binary scale were checked for internal consistency; and, subsequently summed to generate composite scores for the variables for each participant. Descriptive and inferential analyses were done, and a non-parametric regression model fitted.

Results: The mean implementation fidelity was 69.5% (±4.0%). Implementation content and dose were the better dimensions of fidelity at 72.4% and 69.7% respectively, intervention differentiation and quality of delivery followed at 66.3% and 61.4%. The determinants that positively influenced implementation fidelity were females, 1.5 (95% CI: 0.28 – 2.95; p=0.0460); knowledge, 0.1 (95% CI: -0.01 – 0.14; p=0.0710); nature of intervention, 0.1 (95% CI: 0.01 – 0.12; p=0.0190); and, implementation context, 0.1 (95% CI: -0.01 – 0.28; p=0.0680). Whereas facilitation strategies, - 0.1 (95% CI: -0.09 - -0.02; p=0.0010); and non-clinicians, - 1.5 (95% CI: -3.0 – 0.06; p=0.0570) negatively influence the outcome variable.

Conclusion: The implementation fidelity of 69.5% was moderate considering malaria test and treat guidelines aim at 100%. The sex of the provider and the nature of the intervention were significant facilitators of implementing with fidelity, facilitation strategies were a significant hindrance. Further research on hindering determinants, as well as knowledge of malaria and utilization of non-clinicians which had some evidence of association with implementation fidelity, could generate knowledge on how to better implementation fidelity.

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May God bless you!

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LIST OF ABBREVIATIONS

ACT	Artemisinin-based combination
AL	Artemether-Lumefantrine
ERC	Ethics Review Committee
HREC	Human Research Ethics Committee
ID	Implementation Determinant
IF	Implementation Fidelity
JOOTRH ERC	Jaramogi Oginga Odinga Teaching and Referral Hospital ERC
m-RDT	Rapid Diagnostic Test-kit for malaria
OPD	Outpatient department
SP	Sulfadoxine-pyrimethamine
TDR	The Special Programme for Research and Training in Tropical Diseases
TT	Test and Treat
UNDP	The United Nations Development Programme
UNICEF	The United Nations Children's Fund
WHO	World Health Organization
WITS	University of The Witwatersrand, Johannesburg

OPERATIONAL DEFINITION OF TERMS

1. **Implementation fidelity is** the degree to which an intervention is implemented as planned. In this study, implementation fidelity is qualified by four dimensions: implementation content, dose, quality of delivery, and intervention differentiation.
   a. **Implementation content** also referred to as *implementation adherence*, is the extent to which recommended strategies/interventions are implemented.
   b. **Intervention differentiation** is the ability of the provider to distinguish the recommended strategies/interventions for the disease and/or patients.
   c. **Implementation dose** or simply *dose*, is the frequency, duration, and coverage of implementing the recommended strategies/interventions. Also, *intervention exposures*.
   d. **Quality of delivery** refers to providing appropriate care in a prescribed manner.

2. **Implementation determinants** are the factors that facilitate or hinder implementation fidelity. The implementation determinants assessed in this study were age, sex, type of provider, type of facility a provider works in, the experience of a provider treating malaria, knowledge of malaria, facilitation strategies, and nature of the intervention, participant responsiveness, and implementation context.
   a. **Facilitation strategies** the tools and strategies used to standardize the implementation of recommended interventions/strategies.
   b. **Implementation context** is the nature of the working environment characterised by administrative support, resourcing, feedback and communication (interactions).
   c. **The nature of the intervention** refers to the provider's perception of the qualities of the recommended intervention. This study assessed the clarity, trialability, and adaptability of malaria test and treat guidelines. Other implementation research studies have often used intervention complexity.
      i. *Clarity of the intervention*, whether the guidelines or interventions are clear.
      ii. *Trialability of the intervention*, the extent to which the intervention can be moved from initial to full adoption.
      iii. *Adaptability*, if the intervention fits in the routine, norms or usual practices of a provider.
      iv. *Intervention complexity* is how simple the intervention is to understand.
   d. **Participant responsiveness** is the acceptability of the provider or the patient of the recommended interventions/strategies.

CHAPTER ONE: INTRODUCTION

1.1. Background

Malaria is a parasitic infection that causes fever and illness in the tropics. It is caused by the *Plasmodium* parasite, commonly transmitted during a blood meal by a female *Anopheles* mosquito (1). It manifests with a wide range of nonspecific signs and symptoms; but, commonly fever, chills, headache, and vomiting; a high clinical acumen is required to promptly diagnose and treat (2). The disease accounts for 3.2 billion cases of morbidity annually in more than 95 countries (3). A mere 15 countries from Sub Saharan Africa, account for at least 80.0% of malaria burden, and, 90.0% of the mortality (3–6). Malaria has been ranked as the fourth cause of morbidity and mortality in developing countries where it causes up to 10.7% of deaths (7). The disease causes at least one million deaths among children under five years annually [ibid].

Children below the age of five, pregnant women, and individuals with sickle cell disease are the most at risk of malaria (8–11). The infection is severe among individuals with weak immunity, those with frequent exposure to mosquito bites or those with delayed treatment, and those exposed to drug-resistant strains of *Plasmodium* (12,13). The sequelae for severe malaria infections include high cost of treatment due to hospitalization and/or drug regimes, inability to engage in productive activities, loss of livelihoods, risk of organ damage, and, death (14–17). Severe malaria in children has been associated with convulsions which can lead to brain damage (18–20). Loss of pregnancy has been reported among pregnant women especially with malaria infection of the placenta (21). Sickle cell anaemia is aggravated in the presence of malaria among patients with sickle cell disease (8,22,23). Similarly, frequent malaria infections and/or infection with aggressive strains of malaria such as *Plasmodium falciparum* has been associated with severe anaemia (10,14,24).

According to the Ministry of Health in Kenya, as of 2010, malaria was causing 5.8% deaths, was the sixth leading cause of mortality, and the third main contributor of disability-adjusted life years at 7.2% (25). While about 8% of the country's population is affected annually, malaria is the leading cause of outpatient morbidity in Western and Coastal parts of Kenya (25,26). A disproportionately larger than 50% of malaria-related mortalities in Kenya are from the Lake and Coastal endemic regions, commonly because of delayed diagnosis and treatment of patients (6,26). The twice as high prevalence of malaria in the endemic region varies with climatic seasons and altitude ranging from 20 to 50% (5,14,26,27). In Western Kenya, where this study was conducted, malaria is the leading cause of morbidity (5,25), accounting for over two million new cases each year (28,29), and over 2000 deaths in children under the age of five (30). Greater than 70% of the population in Western Kenya is at risk of malaria (4). It is associated with an increased incidence of anaemia among children and pregnant women, and malnutrition among children in the region (5). Until 2009, treating patients for malaria was not harmonized because of gaps in malaria testing, and case management guidelines (31). The quest for malaria-endemic countries moving away from presumptive malaria treatment to universal testing, and confirming a malaria diagnosis before providing antimalarial was recommended by the WHO as an international standard in 2010 (32).

Microscopic examination of blood samples from patients suspected to have malaria is the gold standard for diagnosing malaria (33). The rapid diagnostic test for malaria (m-RDT) was introduced to address access to malaria testing at the point of care and stem presumptive treatment of the disease (34,35). Prompt universal confirmation of malaria diagnosis among suspected patients facilitate appropriate care, and rational use of malarial drugs (35,36). Evidence of drug resistance to antimalarial due to indiscriminate prescription and non-compliance has been cited with an antimalarial like sulfadoxine-pyrimethamine (SP) (37). The National Malaria Control Program of Kenya adopted artemisinin-based combination therapy (ACT) in 2004 as the first-line treatment for uncomplicated malaria, reserving SP for malaria prophylaxis in pregnancy (4,26) similar changes in malaria case management were witnessed in countries like Ghana, Nigeria, Uganda and Tanzania (13,38,39).

Despite a high public health system readiness for treating malaria through the test and treat guidelines, differential compliance to the protocol has been shown in several malaria-endemic countries including Kenya (40,41). Health provider influences and organizational support in implementing the malaria test and treat guidelines influence the prompt and optimal response of the system to the disease (41,42). Some providers have not optimally adhered to the guidelines and continue to treat patients presenting with fever as malaria presumptively (43), especially, where structural support is weak (44–47). Consequently, poor quality of routine testing continues to deny patients the benefits of prompt diagnosis and treatment (48). Indiscriminate prescriptions continue to undermine the rational use of antimalarial an important goal of the malaria test and treat guidelines (32).

1.2. Problem Statement

Kisumu is one of the counties in Western Kenya which borders Lake Victoria and has vast lowlands prone to flooding and breeding of mosquitoes (49). Over 60% of the county population is Luo, who make up to 50% of those vulnerable to sickle cell anaemia in the country (23,50). As high as 80% mortality and disability has been documented among children with sickle cell disease, if not promptly and appropriately treated (22,23,50). Poor implementation fidelity of malaria test and treat guidelines, lead to an incorrect diagnosis, delayed treatment, irrational antimalarial prescription, and ultimately poor quality of care among patients with malaria (51,52). The sequelae for delayed treatment of malaria among patients include progression to severe malaria, prolonged hospitalization, loss of income, poor growth in children, organ damage, and death (14,16,17). Sub-optimal implementation fidelity compounds the burden of malaria which makes up to 30% of outpatient and 19% of inpatient hospital attendance in Kenya (25). The disease impacts negatively on livelihoods and significantly drains resources for development through absenteeism at work, inability to generate income, and the cost of seeking treatment among others (25,35). This is despite the recommendation that a patient with a history of fever or any other sign and symptom suspected for uncomplicated malaria should be tested to confirm a malaria diagnosis thus ensuring appropriate treatment is provided (53).

1.3. Research Question, Aim, and Objectives

1.3.1 Research Question

What is the implementation fidelity of malaria test and treat guidelines, and its determinants, amongst healthcare providers working in the outpatient department of health facilities in Kisumu County, Kenya?

1.3.2 Study Aim

To assess implementation fidelity (IF) on malaria test and treat guideline, and its determinants, amongst healthcare providers working in the outpatient department (OPD) of health facilities in Kisumu County (KC), Kenya.

1.3.3 Study Objectives

1) To measure IF of malaria test and treat guidelines amongst healthcare providers working in the OPD of health facilities in Kisumu County.

2) To describe the determinants of IF of malaria test and treat guidelines amongst healthcare providers working in the OPD of health facilities in Kisumu County.
3) To determine the relationship between IF of malaria test and treat guidelines and its determinants, amongst healthcare providers working in the OPD of health facilities in Kisumu County.

1.4 Justification

There are two known studies to the researcher that have been done to assess the adherence of health care providers to malaria test and treat guidelines in Kenya. Firstly, the Riley study, a survey, conducted in public and private health facilities in Western Kenya focusing on the knowledge and adherence of health care providers on malaria case management guidelines in pregnancy (51). Secondly, the Juma study, which was a national survey, focused on the adherence to malaria test and treat recommendations amongst healthcare providers; and restricted their analysis to health facilities with the antimalarial, artemether-lumefantrine, in stock (54). This study was conducted in both public and private health facilities, amongst providers working in the outpatient department using an implementation fidelity framework.

Different from the previous studies, this study quantified implementation fidelity of malaria test and treat guidelines amongst healthcare providers; described the determinants of implementation fidelity of malaria test and treat guidelines; and, assessed the relationship between the implementation fidelity scores and its determinants using an implementation fidelity framework. The knowledge generated will inform health managers, the healthcare providers, policymakers, and researchers about the level of implementation fidelity of malaria test and treat guidelines, the dimensions of implementation fidelity; associated determinants that need strengthening, and the facilitative determinants that should be sustained (45,47,51). By increasing the implementation fidelity of the recommended strategies in the malaria test and treat guidelines, healthcare stakeholders will improve the quality of care for malaria patients, and avert malaria-associated sequelae (40,53,55).

1.5. LITERATURE REVIEW

1.5.1 The Rationale for Malaria Test and Treat Guidelines

Universal diagnosis for patients presumed to have malaria was recommended in 2009 by the World Health Organization (WHO) to ensure that patients receive a prompt life-saving diagnosis (37,56,57). Ruling out a malaria infection first instead of treating presumptively supports the decision on whether a patient will receive antimalarial or get additional investigations and alternative treatment (24,44). The test-first strategy prevents the provider from prescribing malaria treatment to patients with uncomplicated disease unless confirmed by a malaria test (58). In 2010, the WHO released the second guideline for the treatment of malaria, incorporating universal testing of patients suspected with uncomplicated malaria as a key strategy before treatment (59). Quality health care requires that patients access and utilize appropriate treatment (60,61). Part of the strategies of the malaria test and treat guidelines are measures ensuring commodity security, and steps fostering appropriate patient care like point-of-care diagnosis (51,62,63).

Presumptive treatment of malaria is associated with indiscriminate prescription of antimalarial, and to variations in diagnostic practices amongst healthcare workers including differential adherence to the test results (52). Poor adherence to malaria test and treat guideline leads to an increase in disease burden associated with, a high cost of treatment, and an increase in caseload, depletion of antimalarial commodities and irrational antibiotic prescriptions (13,63,64). The presumptive treatment of malaria has exposed patients to multiple drug treatments because of misdiagnosis (63). Factors associated with patients using multiple drugs include a high risk of adverse drug events, drug resistance, and treatment failure (13,63). Malaria test and treat guidelines, therefore, are a call for evidence-based practices in the care of patients suspected with malaria, by improving case detection and reporting, increasing identification of those requiring alternative care, and rationalizing drug use (65).

1.5.2 The Context for Malaria Test and Treat Guidelines in Kenya

The roll-out of malaria test and treat guidelines in Kenya was systematic. The artemisinin combination therapy (ACT) policy was implemented in 2006; followed by the launch of national laboratory guidelines in 2007, and the National Malaria Strategy in 2009 which aligned to WHO's call for malaria test and treat (53). In 2009, Kenya revised its malaria case management guidelines to incorporate the test, treat, and track strategies (26,57). Further revisions to case management guidelines were made specifying diagnosis before treatment in 2010, followed by phased national wide training of 5000 in-service health care workers, and, rolling out m-RDTs at points of care in health facilities (54,57,66). The recommendation to confirm a malaria diagnosis before issuing antimalarial lead to a drastic reduction of ACTs dispensed by nearly half between 2010 and 2013 in Kenya (32). Full implementation of these guidelines has not been attained, the latest, 2016 malaria case management guideline recommends that providers can treat malaria presumptively in the event they cannot perform a malaria test (53). Initiating antimalarial in the event of a clinical diagnosis of severe malaria is life-saving (60,67,68). The recommendation that allows a health care provider to adapt to diverse clinical settings might be a strategy of ensuring that the test and treat guidelines are implementable (69,70).

1.5.3 The Intervention Strategies of Malaria Test and Treat Guidelines

Patients suspected of malaria often present with febrile illness and may have a clinical history of having been exposed or travelled to a malaria-endemic place (18,43,71). All patients should undergo a routine assessment of their weight, temperature, and blood pressure (20,60). Physical examination should be conducted by the provider to identify the signs of the disease, besides taking the history and noting the age of the patient (20,66). Patients suspected with malaria should then be tested for malaria; several tests are available for diagnosing the disease, but, microscopic examination of blood smears by an expert trained in malaria microscopy is the gold standard (31,37,40). Patients testing positive for malaria should be issued recommended antimalarial; whereas, those who test negative for malaria are assessed for another disease and provided with the appropriate management they require (44,57). The theory of change behind the malaria test and treat guidelines inform standardized clinical practice of assessing, diagnosing and treating malaria patients, and promoting efficient and effective innovations aimed at improving clinical outcomes and the quality of care (48,51,57).

1.5.4 The Implementation Strategies of Malaria Test and Treat Guidelines

Not all health facilities in developing countries have malaria microscopy services (33). Limited access to expert microscopy is a bottleneck for universal testing for patients suspected with malaria the reason malaria rapid diagnostic testing (m-RDT) was introduced at the point-of-care (48,72). There is a consensus that m-RDTs are a simple and feasible means of confirming a malaria diagnosis (73). But, the accuracy and reliability of malaria rapid diagnostic tests (m-RDTs) have been questioned (71,74) especially where malaria strains other than *P. falciparum* exist (33,72,74). Through quality assurance programs, a percentage of the specimen is collected from testing points and retested using validated diagnostic kits (within or outside the health facility), and the results are compared with those given to patients at the testing points; thus, validating and improving the quality of diagnostic services (36,75).

Different types of antimalarial are prescribed to patients with varying degrees of malaria infection. Malaria case management guidelines in Kenya differentiate the management of uncomplicated and complicated malaria (53). Uncomplicated malaria should be treated with artemisinin combination therapy (ACT) or artemisinin respectively; while, artesunate is indicated for severe malaria (53,66). Patients who fail first-line treatment should be treated with dihydroartemisinin-piperaquine (DHA-PPQ); whereas quinine may be used to treat severe malaria (53). The dose of antimalarial is dependent on the weight and age of the patient (31,57,76). Moreover, providers are expected to administer the first dose of antimalarial through directly observed therapy (DOT) among patients with uncomplicated malaria (9,77–79). A case of uncomplicated malaria is treated as an outpatient; those with complicated malaria should be admitted to receive treatment from the hospital until they stabilize (53).

1.5.5 Implementation Fidelity of Malaria Test and Treat Guidelines

Implementation fidelity was the implementation outcome of this study used to assess the success of implementing malaria test and treat guidelines (80). Implementation fidelity refers to the degree to which an intervention is implemented as planned (81,82). Evidence holds that the degree to which providers implement malaria test and treat guidelines is varied. In a cross-sectional study conducted in Sudan, less than 50.0% of children below the age of five, suspected to have malaria, were tested to confirm the diagnosis (83). During a survey that assessed compliance with the national malaria treatment guideline in Ghana, compliance with the guidelines was between 85.0% and 95.0% (60). Comparable implementation fidelity of malaria test and treat guidelines was reported in a survey conducted in Kenya in 2014 (32).

1.5.6 The Dimensions of Implementation Fidelity of Malaria Test and Treat Guidelines

Implementation fidelity of a provider to malaria test and treat guidelines can be described through several dimensions (81,82,84). *Adherence* to the intervention (*implementation content*) is the degree to which an implemented intervention corresponds to the recommendations in the guideline (82). *Implementation dose* encompasses the <u>frequency</u>, the <u>duration,</u> and <u>coverage</u> of contents of the guideline, and may also be referred to as the *intervention exposure* (81,85). Some implementation researchers, suggests that adherence to the intervention and implementation dose suffice as dimensions of implementation fidelity (45,81). A systematic review of 162 studies conducted in schools that assessed the extent to which inconsistencies in fidelity and dosage threatened internal validity of outcome studies, by Dane and Schneider, found that poor adherence and coverage levels were associated with poor outcomes in programs and among their beneficiaries (86). Providers should adhere to testing all patients suspected to have uncomplicated malaria; those who test positive should receive the right antimalarial drug prescribed in the right dose and duration (53,76). Brownson, on the other hand, observes that *quality of delivery* and *intervention differentiation* are some of the additional dimensions of implementation fidelity (87).

Quality of delivery refers to delivering appropriate services in the prescribed manner (81,82). Interventions that are delivered as they were intended, and appropriately, are associated with achieving their intended purpose (81). DOT has been implemented successfully in the treatment of tuberculosis, this innovation improves adherence among patients and prevents the emergence of drug resistance if implemented correctly (58,88). Additional quality of care strategies includes educating patients on their infection and its management and informing them on when to return to the facility for further management (2,5,76). Intervention differentiation refers to the distinct elements of a program (81). The provider should be able to identify the unique strategies of the intervention to better manage patients presenting with different degrees and types of infection as recommended by the guideline (89). Malaria test and treat guidelines provide that a patient with uncomplicated malaria will receive treatment as an outpatient while those with severe malaria have to be hospitalized; similarly, different types of antimalarial are given based on the severity of malaria (60).

1.5.7 Implementation Determinants of Malaria Test and Treat Guidelines

1.5.7.1 Provider Characteristics and Knowledge of the Intervention Strategies

Provider characteristics may explain observed fidelity to guidelines. The age of the provider, their experience offering treatment and their level of education have been shown to influence the level of implementation fidelity of treatment guidelines (47). Other notable factors of adherence to guidelines include the cadre or profession of the provider and the type of facility in which they work (13,63,90). The level of knowledge of a provider is associated with implementation fidelity (89). In a stratified cluster-randomized control trial, it was established that training clinicians to improve practice and quality of care have the potential of halving overtreatment; although, basic training in itself was insufficient to enhance adherence to treatment guidelines (91). Other sources suggest that besides improving a provider's knowledge on the content of the treatment guideline, providers should be supported in better decision making, and program managers should consider employing context-specific behaviour change strategies required in the transition to the evidence-based treatment protocols (92,93).

1.5.7.2 Facilitation Strategies and the Implementation Context

Facilitation strategies optimize and standardize implementation through tools and strategies such as training, provision of copies of guidelines and manuals, and giving feedback on the implementation of strategies (82,85). A coordinated capacity building like coaching, supportive supervision, and, monitoring and evaluation has been associated with better implementation fidelity (82,89). Emphasis is laid on systematic monitoring and shared decision making; allowing regular communication between the providers and program managers, integrated with feedback on adherence to treatment guidelines (46,94). Stock-outs and supply chain breakdown have contributed to providers treating malaria presumptively (31,36).

Lipsey defines implementation context as the total of the social, organizational, and group systems and structures, their linkages, past and current events (95). Brownson considers these, situational factors or real-world influences, and points out that they include prevailing organization, economic, political, and environmental situations (85). In a comparative case study of 10 studies, Burchett and colleagues established that health care providers performed well when their contexts and priorities overarched (52). A supportive work environment fosters a provider's adherence to guidelines (62). To ensure sustainable change, systematic monitoring, and capacity building initiatives protecting the social and power structures around the provider are encouraged (94). Regular staff meetings, administrative and financial support, and sound leadership have been shown to facilitate implementation fidelity (46,96). Weak health systems and poor facilitation strategies are associated with low implementation coverage, and a poor quality of delivery (40,57,97).

1.5.7.3 Participant Responsiveness

The realm of participant responsiveness encompasses the provider and beneficiaries of an intervention (82). The perceptions and lack of interest of participants on the relevance and the intended outcomes of an intervention are related to how they are engaged with it (81). Negative beliefs and a poor attitude of a participant have been associated with poor levels of implementation fidelity (98,99). A descriptive study conducted in Malawi established that behavioural influences among providers affected the implementation of malaria guidelines despite adequate facilitation (94). Employing strategies that improve treatment-seeking behaviour such as patient education, have been shown to increase the acceptability of interventions; and, translating to increases in workloads in health facilities impacting on the capacity of the provider to adhere to treatment guidelines (62,94). Increased utilization of health services among patients may also be as a result of the quality of delivery, and/or free or subsidized medical care (70). To improve participant responsiveness, program managers should ensure that participants are meaningfully engaged with the interventions and that the services provided are of good quality (20,100,101).

1.5.7.4 The Nature of the Intervention

Detailed but clear interventions are better than those that are complex and vague, which are more difficult to implement resulting in a reduction in fidelity (82). The clarity of treatment guidelines has been associated with better implementation fidelity (54). Providers have also demonstrated a preference for interventions they can adapt to their contexts; adaptable interventions are associated with increased adherence to guidelines (52,102). However, certain interventions may not be acceptable and/or feasible to the provider's contexts leading to poor implementation (100,103). There is a proposal for ensuring good adherence to guidelines by focusing on what providers prefer other than what they know (104). The trade-off between fidelity and adaptability of intervention strategies is, therefore, an important aspect of implementation that may not be overlooked (102). Those opposed to measuring adherence with an adjusted degree of adaptability infer that it is the lack of clarity in the treatment guidelines that lead to partial implementation (89). Proposers of adapting interventions to contexts observe that the emotional stability of a provider influences their compliance with treatment guidelines, suggesting that psychometric assessments would help in appreciating the implementation of guidelines in their contexts (102,103).

1.5.8 Implementation Research Frameworks

Implementation research investigates how evidence-based interventions and their strategies are integrated, implemented, and utilized within a given context (85). This implies that interventions undergo a systematic, yet complex process of being rolled out, implemented, and eventually getting entrenched within the targeted system (105). The eight implementation outcomes that can be used to assess the success of interventions are acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability; these outcomes describe the implementation process involved and may serve as intermediate measures of service delivery and clinical outcomes (80). Consistent findings hold that implementation success is also influenced by factors beyond the dimensions of implementation outcomes considered as implementation determinants (80,81). To better assess the implementation success of an intervention, frameworks informed by theory and/or empirical knowledge have been developed (106,107). Those frameworks that examine implementation barriers and facilitators are called determinant frameworks; those that describe the steps followed in addressing the determinants of an intervention, process models; while, those that highlight the results of implementing an intervention, evaluation frameworks (106–108). The three types of frameworks are categorized according to the aim of evaluation despite having inherent overlaps; implementation research frameworks may also be classified as dissemination or implementation models (106,108).

1.5.9 The Conceptual Framework for Implementation Fidelity

This study used an implementation fidelity framework adapted from two implementation fidelity frameworks (Figure 1.1). The four dimensions of fidelity: adherence to the intervention, implementation dose, quality of delivery, and intervention differentiation were adapted from the implementation fidelity framework proposed by Brownson (85). Facilitation strategies, the nature of the intervention, participant responsiveness, and the nature of implementation context were four dimensions of the determinants of implementation fidelity adapted from Hasson's implementation fidelity framework (82). The fifth dimension of the determinants of implementation fidelity, provider characteristics, was adapted from the implementation fidelity framework by Brownson (85).

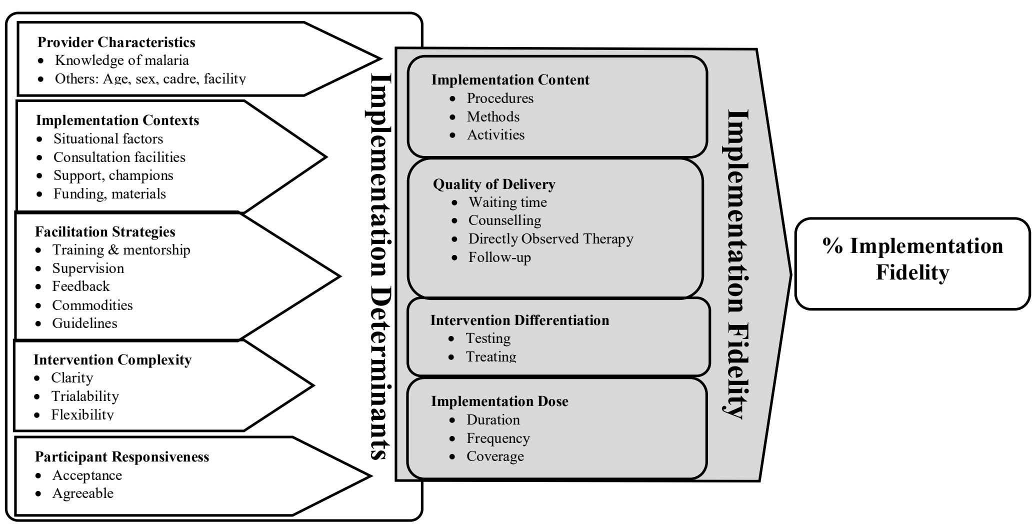


Figure 1.1: Conceptual Framework for Implementation Fidelity of Malaria Test and Treat Guidelines and its Determinants

1.5.10 Gaps in Literature and How this Study Tackles Them

Some of the literature that was reviewed in this study presented an opportunity to advance knowledge and bridge gaps, overt, and potential. Ridde conducted a case study in two districts in Burkina Faso measuring the implementation fidelity of the distribution of mosquito nets and home-based treatment of children with fever by community health workers (109). Similarly, the case study conducted by Compaore in Burkina Faso assessed the implementation fidelity of seasonal malaria chemoprevention strategies (45). While the study by Ridde and that by Compaore used an implementation research approach to investigate implementation fidelity, they focused on the three aspects of fidelity i.e. content, coverage, and schedule which narrows the dimensions of fidelity to two, content and dose according to Carroll's framework for assessing Implementation Fidelity (81). This study assessed implementation fidelity using four dimensions: implementation content, quality of delivery, intervention differentiation, and dose according to the Implementation Fidelity Framework by Brownson (85); hence using a broader approach to systematically evaluate implementation fidelity of malaria test and treat guidelines amongst providers (82).

A cross-sectional study in Uganda assessed the factors affecting adherence to national malaria treatment guidelines among public health workers (47). Variously, a Nigerian study investigated factors influencing adherence to malaria diagnosis and treatment guidelines among health workers in both the public and the private sector (110). The Ugandan and Nigerian studies focused on understanding the influence of implementation determinants on the implementation adherence. Other studies have focused on other types of implementation outcomes or have investigated other implementation outcomes together with implementation fidelity. A pilot study in Nigeria used SMS messages to increase the acceptability of and adherence to malaria rapid diagnostic test-kit results among patients seeking care from the private sector drug retailers (73). Liu surveyed the association of risk preferences with malaria care-seeking behavior and the acceptability of m-RDTs among adult customers purchasing antimalarial medication at selected drug stores in Nigeria, to inform RDT scale-up plans (64). This study focused on one implementation outcome, fidelity, and described implementation determinants associated with implementation fidelity of malaria test and treat guidelines amongst health providers based in the outpatient departments of study facilities. By focusing the scope of this study, it was possible to concentrate on the identification of enablers and barriers of implementation fidelity (107).

To describe implementation fidelity associated with the supply side of services, this study targeted healthcare providers working in both public and private health facilities and assessed them on all forms of malaria. There is evidence about studies that either recruited more groups of participants, or that used secondary data, focused on health facilities that were either well stocked with antimalarial commodity, a particular set of facilities, or patients. While a rich base of context-specific information may be obtained by using a mix of methodologies, errors may arise if this is poorly done and the reliability of the data and/or validity of the study may be questionable (111). During a retrospective audit of malaria records in Mozambique to assess prescription practices of the first-line antimalarial for uncomplicated malaria, the researchers selected study sites based on the availability of laboratory data, testing services, and geographic location (75). By administering the study questionnaire to health providers involved in the implementation of the malaria test and treat guidelines, primary data was used to assess the outcome and explanatory variables in this study, providing useful information about the extent of guideline dissemination and implementation among study participants (85).

CHAPTER TWO: METHODOLOGY

2.0. Introduction

The methods used in this study are presented in this chapter. A description of the study design, study setting, sampling procedure, study sites, study participants, the calculated power of the study, the research instrument, data collection, and the process of data management is provided. The study variables, the analysis plan, ethics clearance, and considerations, as well as the plan for disseminating findings, are detailed.

2.1. Study Design

This was a quantitative cross-sectional study. The cross-sectional study design was appropriate as it allowed collecting data on implementation fidelity of malaria test and treat guidelines amongst healthcare providers, and its determinants at the same time; thereby, examining both the outcome of interest and the explanatory variables simultaneously (112).

2.2. Study Setting

Kisumu is one of the 47 counties in Kenya located in the Western region (Appendix C1). There are seven sub-counties in Kisumu County namely: Kisumu Central, Kisumu East, Kisumu West, Muhoroni, Nyakach, Nyando, and Seme. As of 2015, the County had an estimated population of 1.1 million people out of which 51% were female (113), children less than five-years-old made up 17% of the population. Kisumu has 200 registered health facilities out of which 112 are public and 82 private, the rest are non-governmental or faith-based facilities offering focused or specialized care (113,114). Malaria is the leading cause of morbidity in the county, contributing over 14, 000 hospital admissions annually. A 45% burden of malaria has been recorded in Kisumu before (113). The choice of Kisumu County as the study setting was based on its proximal location and access to the researcher.

2.3. Sampling Procedure

Multistage sampling was used. The seven sub-Counties in Kisumu were listed alphabetically in Excel and a list of random numbers generated in an adjacent column corresponding to the listed sub-counties (Appendix C2). An extended table sorting was done in ascending order based on the list of random numbers selecting the Kisumu Central sub-County which listed first, as the primary selection unit. The secondary selection unit entailed a census of all the non-specialist (general medical care) health facilities in Kisumu Central. All providers working in the outpatient department (OPD) of enlisted health facilities constituted the tertiary selection unit.

2.4. Study Sites

Kisumu Central is located in the Municipality of Kisumu and has 61 health facilities serving approximately 168, 000 people (114). According to the Kenya Master Health Facility List, Kisumu Central has 15 facilities with in-patient services and a total bed capacity of 942 beds and 30 cots [ibid]. The health facilities offering general medical (non-specialist) services, 12 public and 28 privately owned, in the sub-County were targeted. A total of 30 study sites were reached comprising seven public and 23 private health facilities (Appendix C3).

2.5. Study Participants

Eligibility Criteria: All healthcare providers (HCPs) working in the OPD of the study sites were eligible respondents. The HCPs comprised of medical doctors, medical officer interns, nurses, nurse interns, clinical officers, clinical officer interns, pharmacists, and nutritionists. Other providers were community health workers, counsellors, health records information officers, and public health officers. A total of 123 HCPs consented to participate in the study.
Exclusion Criteria: Any HCP working in the OPD of the study site who did not consent or was unavailable at the time of the study was ineligible to participate.

2.6. The Research Instrument

A closed-ended questionnaire was used. Structuring the questionnaire was done to gather uniform responses to the items in the study tool, increasing the ease in handling study responses during analysis (115). The tool had a total of 55 items divided into three sections (Appendix A3). Table 2.1 provides a summarized layout of the questionnaire. The first section had items describing the characteristics of the provider, with two subsections; the first subsection had four items collecting information on the socio-demographics of the provider, and the second subsection on the providers' knowledge of malaria had 10 items. The second section collected information on implementation fidelity and had four subsections: content/adherence, dose, quality of delivery, and intervention differentiation; which had 12, six, four, and two items respectively. The last section was on implementation determinants with four subsections: facilitation strategy, nature of the intervention, participant responsiveness, and implementation context which had six, three, two, and six items respectively.

Table 2. 1: Summary Layout of the Study Questionnaire

Section	Element Assessed	Number of items
Section A	***Provider Characteristics***	
Subsection A1	Socio-demographics	4
Subsection A2	Knowledge of malaria	10
Section B	***Implementation Fidelity***	
Subsection B1	Content/Adherence	12
Subsection B2	Dose	6
Subsection B3	Quality of Delivery	4
Subsection B4	Intervention Differentiation	2
Section C	***Implementation Determinants***	
Subsection C1	Facilitation Strategy	6
Subsection C2	Nature of Intervention	3
Subsection C3	Participant Responsiveness	2
Subsection C4	Implementation Context	6
Total		**55**

The items for knowledge of malaria, quality of delivery, facilitation strategy, and implementation context were adapted from:

- Quality of Care: A process for making strategic choices in health systems, pp. 31-35;
- Case Management Guide for Tutors: Training module on malaria control, pp. 84-86;
- Service Availability and Readiness Assessment (SARA): An annual monitoring system for service delivery reference manual, pp. 182-183; and,
- Measuring the Impact of Health Systems Strengthening: A review of the literature, p. 20 (116–119).

The rest of the items were developed based on the dimensions of the implementation fidelity framework for this study (Figure 1.1). Table 2.2 provides a summary of the keywords used in the study.

Table 2.2 The Key Words / Variables and their Operational Meaning as used in the Questionnaire and the Study

Key Words / Variables	Operationalized meaning
Implementation content – the degree of implementing recommended strategies, also *implementation adherence*.	
Implementation context – the nature of administrative support, resourcing, and interactions at the workplace.	
Implementation dose – the frequency, duration, and coverage of implementing recommended strategies.	
Implementation fidelity – the extent to which an intervention is implemented as planned/recommended.	
Intervention differentiation – ability to distinguish recommended strategies for the disease and/or patients.	
Facilitation strategies – provision of tools and strategies aimed at standardizing recommended implementation.	
Nature of intervention – trialability, adaptability, and clarity of the guideline in the provider's perspective.	
Participant responsiveness – the patient's acceptability of the recommended interventions.	
Quality of delivery – providing appropriate care in a prescribed manner.	

2.7. Reliability and Validity of the Research Instrument

The researcher obtained assistance from the study supervisors and utilized feedback from a protocol review panel at WITS, to refine the instrument. Face validity was improved by pretesting, assessing the adequacy of the items, and rewording of questions. Concurrency of items was addressed by devising measurement scales appropriate to the study variables. A brief on the reliability and validity of the tool are presented in Table 2.3. The internal consistency of the items for respective dimensions of fidelity and determinants was checked. The 24 items for implementation fidelity had a Cronbach alpha value of 0.7204. The Cronbach alpha values for the respective dimensions of implementation fidelity ranged between 0.0720 and 0.5042. The Cronbach alpha values for the determinants of implementation fidelity was between 0.2120 and 0.7238.

Critiques of Cronbach alpha observe that it either overestimates or underestimates internal consistency, and recommend alternative measures such as Raykov's composite reliability (Rho) (120,121). Interpretation of Rho is similar to Cronbach's alpha; variables with values greater than 0.7 have satisfactory internal consistency, but those above 0.5 are acceptable (122–124). The Rho values were good for implementation dose and context and acceptable for quality of delivery. The extent to which the items of a variable differ with those of another variable, conceptually, is said to be discriminant validity; whereas, coherence of items of a variable, convergent validity (125,126). Discriminant and convergent validity are statistical estimates of the construct validity of an instrument (127,128). The average variance extracted (AVE) values were used to assess discriminant and convergent validity. AVE values greater than 0 suggest discriminant validity; to illustrate convergent validity, AVE values ≥ 0.5 are acceptable, but values greater than 0.7 are preferred (126). The questionnaire had good discriminant validity. There was no problem with the convergent validity of implementation dose, intervention differentiation, and participant responsiveness.

Table 2.3: Internal Consistency and the Average Variance Extracted Values for the Study Questionnaire

Variable	No. of items	Cronbach alpha	*Rho values	**AVE values
Implementation Content	12	0.5042	0.1230	0.3020
Implementation Dose	6	0.3577	0.9470	0.8210
Quality of Delivery	4	0.4193	0.5490	0.2840
Intervention Differentiation	2	0.0720	0.2450	0.5010
Implementation Fidelity	**24**	**0.7204**	**0.1210**	
Determinants				
Knowledge of Malaria	10	0.4329	0.1330	0.1310
Facilitation Strategy	6	0.7238	0.0980	0.3680
Nature of Intervention	3	0.4456	0.3820	0.2400
Participant Responsiveness	2	0.2120	0.4710	0.5070
Implementation Context	6	0.5448	0.7030	0.2980

*Rho = Raykov's composite reliability score; **AVE=average variance extracted

2.8. Data Collection and Management

Interview sessions were conducted by the researcher between 20th May and 10th June 2019. Data capture was real-time through a web-based, online version of the study questionnaire built-in REDCap (the Research Electronic Data Capture) software. Validation rules specifying the range of values that could be entered for continuous variables such as age between 18 to 99 years, auto-calculation of duration based on dates, and setting variables requiring one response to single choice selection were used to minimize data entry errors. Making questionnaire items required fields prevented the submission of incomplete data forms. Study variables were coded in REDCap before data collection reducing transcription and coding errors post data collection. Captured data spontaneously created a REDCap database that was stored on an assigned secure server hosted by WITS. Further data validation was done in REDCap through the data validation menu by checking for missing data or instrument completeness.

Table 2.4 provides a summary of the study variables and their codes. The items for implementation content, dose, quality of delivery, nature of the intervention, participant responsiveness, and implementation context were assessed using three-point Likert scales, where code 1 was the least score and 3 the highest. Binary scales were used with the items of intervention differentiation, knowledge of malaria, and facilitation strategies in which code 0 had the least weight, and 1 the highest.

Table 2.4: A Summary of Study Variables, their Codes, and Range of Values

Variable	No. of Items	Scale Coding	Min. & Max. Scores	
			Actual	In %
Implementation Fidelity:				
Implementation Content	12	1=Never, 2=Sometimes, 3=Always	12 – 36	33.3% - 100.0%
Implementation Dose	6	1=Never, 2=Occasionally, 3=Always	6 – 18	33.3% - 100.0%
Quality of Delivery	4	1=Disagree, 2=Neutral, 3=Agree	4 – 12	33.3% - 100.0%
Intervention Differentiation	2	0=True, 1=False	0 – 2	0.0 – 100.0%
Implementation Determinants:				
Knowledge of Malaria	10	0=False, 1=True	0 – 10	0.0 – 100.0%
Facilitation Strategies	6	0=No, 1=Yes	0 – 6	0.0 – 100.0%
Nature of Intervention	3	1=Disagree, 2=Indifferent, 3=Agree	3 - 9	33.3% - 100.0%
Participant Responsiveness	2	1=Never, 2=Sometimes, 3=Each time	2 – 6	33.3% - 100.0%
Implementation Context	6	1=Never, 2=Occasionally, 3=Always	6 - 18	33.3% - 100.0%

Collected data were exported to Microsoft Excel as a spreadsheet file and subsequently as a data file to Stata version 15.1 for analysis. The variable profession was recoded in Stata, from 14 categories to a dichotomous variable, provider, coded as 1=Clinician, and 2=Non-clinician. In this study, a clinician was considered a trained healthcare professional who is active in practice and prescribes treatment based on direct engagement with patients (129). Appendix D3, Table D2 lists the cadres by category of the provider.

2.9. Study Variables

2.9.1 Outcome Variable

The outcome variable was the implementation fidelity of malaria test and treat guidelines, assessed by four dimensions: Implementation content, dose, quality of delivery, and intervention differentiation.

2.9.2 Explanatory Variables

Age in years, sex, provider, the experience of treating malaria in years, type of facility a provider works in, knowledge of malaria, facilitation strategies, nature of the intervention, participant responsiveness, and implementation context were the 10 explanatory variables.

2.9.3 Variable Assessment for Factor Analysis

The items for variables that had Cronbach alpha values lower than 0.5 (Table 2.3) were assessed for sampling adequacy and examined if they were an identity matrix (Table 2.5). None of the variables had a Kaiser-Meyer-Olkin (KMO) value greater than 0.5, and the correlation matrix for the variables had an identity matrix given p-values >0.05. Factor analysis does not apply to these variables because the KMO values are less than 0.5 and have nonsignificant Bartlett's test of sphericity which is unacceptable (130,131).

Table 2.5: Results for Sampling Adequacy and Test of Sphericity for Identity Matrix

Variable	No. of items	*KMO	**BTS p-value
Implementation Fidelity Domain			
Implementation Dose	6	0.3577	0.9470
Quality of Delivery	4	0.4193	0.5490
Intervention Differentiation	2	0.0720	0.2450
Determinants of Implementation Fidelity			
Knowledge of malaria	10	0.4329	0.1330
Nature of Intervention	3	0.4456	0.3820
Participant Responsiveness	2	0.2120	0.4710

*KMO = Kaiser-Meyer-Olkin test; **BTS = Bartlett's Test of Sphericity

2.9.4 Operationalization of Study Variables

The Cronbach alpha value for implementation fidelity, facilitation strategy, and implementation context were greater than 0.5 thresholds; hence, scores for items of these variables were added to generate composite scores for each study participant. Despite, the Cronbach alpha values for knowledge of malaria, nature of the intervention, and participant responsiveness being lower than the 0.5 thresholds, these variables failed to pass for factor analysis. Nonetheless, the scores for the items of the rest of variables were summed up to generate composite scores for every study participant, (in line with the Research Plan, Appendix A6); Consequently, the variables implementation fidelity, knowledge of malaria, facilitation strategy, nature of the intervention, participant responsiveness, and implementation context were used as continuous variables in their analysis. The data type for age and experience of the providers treating malaria was continuous; while, the sex of the providers and type of facility as categorical variables. Table 2.3 provides a summary of how the study variables were operationalized.

Table 2.6: A Summary of the Operationalization of Study Variables

Variable	Variable Type	Minimum and Maximum Scores / Values
Implementation Fidelity	Continuous	57.4% – 77.9%
Knowledge of Malaria	Continuous	10.0% – 60.0%
Facilitation Strategy	Continuous	0.0% – 100.0%
Nature of Intervention	Continuous	33.3% – 100.0%
Participant Responsiveness	Continuous	33.3% – 100.0%
Implementation Context	Continuous	11.1% – 33.3%
Age in years	Continuous	20.0 – 68.0
Sex	Categorical	0=Male, 1=Female
Provider	Categorical	1=Clinician, 2=Non-clinician
Experience treating malaria in years	Continuous	1.0 – 35.0
Facility type	Categorical	1=Public, 2=Private

2.10. Data Analysis

2.10.1 A description of the provider characteristics

Background characteristics of study participants were provided through descriptive analyses. The counts and frequencies of categorical variables: sex, provider, and facility type were determined and presented. The distribution of continuous variables was checked using a histogram. Since the age of the participants and their experience treating malaria in years have a right-skewed distribution; their median and interquartile range was used.

2.10.2 Objective 1: To measure implementation fidelity of malaria test and treat guidelines amongst healthcare providers working in the OPD of health facilities in Kisumu County, Kenya

The distribution of composite scores for implementation fidelity and its dimensions was assessed on a histogram. The scores for implementation fidelity were skewed to the left. Intervention differentiation had a left skew; but, the scores for implementation content, dose, and quality of delivery approximated normality. Therefore, the median and interquartile range of fidelity scores for selected study characteristics were presented. Tables were used to summarize the measures of central tendency and dispersion of implementation fidelity, and its dimensions. A further assessment of implementation fidelity by selected characteristics was done.

2.10.3 Objective 2: To describe the determinants of implementation fidelity of malaria test and treat guidelines amongst healthcare providers working in the OPD of health facilities in Kisumu County, Kenya

The distribution of the determinants of implementation fidelity that were not described under the background of provider characteristics is assessed. The distribution of the composite scores for implementation context, nature of the intervention, knowledge, and participant responsiveness is a left-skew; facilitation strategy has a right-skew. Hence, the median and interquartile range values are presented.

2.10.4 Objective 3: To determine the relationship between implementation fidelity of malaria test and treat guidelines and its determinants amongst healthcare providers working in the OPD of health facilities in Kisumu County in Kenya

First, the linearity and correlation of implementation fidelity and the explanatory variables were assessed (Appendix D1, Figure D1), establishing collinearity between implementation context and participant responsiveness. Participant responsiveness was thus excluded in subsequent regression analyses (on the basis that it comprised of two items unlike implementation context which had six). Secondly, a full multiple regression analysis (Model 1) was estimated and the assumptions of linear regression were assessed (Appendix D1). There was a violation of the assumption of normality and homogeneity of variance. The possibility of transforming the outcome variable was assessed on a Qladder plot but it was deemed unsuitable (Appendix D1, Figure D2). Thirdly, a non-parametric inferential method that adjusts coefficients to precision, and resamples to reduce sampling variance was considered given the violation of the assumptions of linear regression, and the non-probability sampling used in the study (132,133). A bootstrap regression analysis (Model 2) was done, and its estimates compared with Model 1 (Appendix D2). Fourthly, unadjusted regression estimates are obtained and compared with the adjusted model (Model 2). Finally, an interaction between the variables age and experience treating malaria was assessed a priori but was not found. A significance level of 5% was used but regression coefficients are also checked at $\alpha=0.01$ and $\alpha=0.10$ and this is specified in the specific output results.

2.11. The Calculated Power of the Study

With a sample size of 123 respondents, a fidelity score of 69.5%, and an estimated population fidelity of 50.0% the present study achieved a 99.5% power at 5% significance ($\alpha=0.05$). This study attained the critical threshold to adequately respond to its purpose (134,135).

2.12. Ethical Consideration

Approvals and ethics clearances for this study were obtained from WITS Medical Human Research Ethics Committee (HREC) (approval no. M181173) and the Jaramogi Oginga Odinga Teaching and Referral Hospital Ethics Review Committee (JOOTRH ERC) in Kenya (approval no. ERC.IB/VOL.1/569) (Appendix B1 and B2). A research permit was obtained from the National Commission for Science, Technology, and Innovations (NACOSTI) to conduct the study in Kisumu County (approval no.182269). The management of study sites provided permission to access the facilities. All study participants were informed about the study and a copy of the detailed participant information sheet (Appendix A4) was issued.

Written informed consent was obtained from all respondents who were willing to participate in the study (Appendix A5). Participants were informed about the lack of direct benefits or compensation. They were at liberty to opt-out at any point without any recourse. Confidentiality was assured before the interviews were administered, and no identifying information such as names, phone numbers, and national or work identification numbers was collected. Collected responses remained anonymized during data analysis and reporting. The collected data shall be used for no other purpose except that indicated for this study. All data shall be kept safely in a password-protected laptop.

2.13. Dissemination Plan

The compiled research report will be submitted to the University of The Witwatersrand, Johannesburg; the National Commission for Science, Technology, and Innovations, Kenya; JOOTRH ERC; and, the Department of Health in Kisumu for public access. Study findings will be communicated to healthcare providers, health program managers, researchers, and other stakeholders through workshops, and conference presentations. The report will be prepared for journal publication.

CHAPTER THREE: RESULTS

3.0. Introduction

In this chapter, the main study findings on implementation fidelity of malaria test and treat guidelines amongst healthcare providers working in the Kisumu Central sub-County are presented. In the first section of the chapter describes the characteristics of the study participants. This is by a presentation of implementation fidelity scores and the scores of its dimensions: implementation dose, implementation content, quality of delivery, and intervention differentiation. A description of the level of implementation fidelity with selected provider characteristics is then provided. The chapter concludes with a description of the determinants of implementation fidelity, and, a presentation of the results of the associations between implementation fidelity and its determinants.

3.1. Characteristics of Study Participants

Table 3.1 presents the characteristics of the study participants. Data were collected from 123 providers involved in the provision of malaria treatment at the outpatient departments of seven public and 23 private health facilities. Of the 123, 67 were female and the rest male. Respondents' median age was 29.0 years (IQR 24.0 – 34.0). Up to 76.4% of the providers were clinicians, and the rest were non-clinicians. The participants had a median of 4.0 years (IQR 2.0 – 6.0) of experience treating malaria; 59.3% of them were working in public facilities.

Table 3.1: Characteristics of the Study Participants

Variable	Category/Description	Frequency (n)	Percent (%)
Sex	*Male*	56	45.5%
	Female	67	54.5%
Age in years	*Median; *IQR*	29.0	24.0 – 34.0
Provider	*Clinician*	94	76.4%
	Non-clinician	29	23.6%
Experience treating malaria in years	*Median; *IQR*	4.0	2.0 – 6.0
Facility type	*Public*	73	59.3%
	Private	50	40.7%

3.2. Measuring Implementation Fidelity amongst Healthcare Providers

The average implementation fidelity score was 69.5% ±4.0% and had a median of 69.1% (IQR 66.2%-73.5%).

3.2.1 Implementation Fidelity of Malaria Test and Treat Guidelines

The distribution of implementation fidelity scores is presented in Figure 3.1.

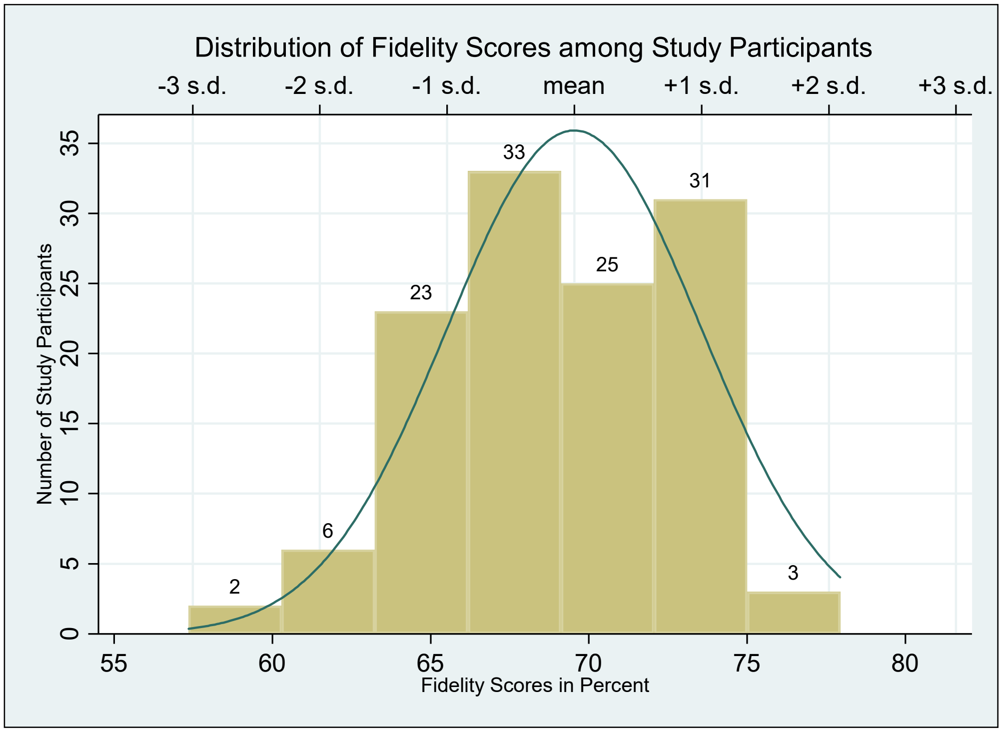


Figure 3.1: Histogram of the Overall Implementation Fidelity Score

Table 3.2 provides a summary description of the mean and its standard deviation, and the median and corresponding interquartile range values for implementation fidelity and its dimensions. The mean implementation fidelity of malaria test and treat guidelines was 69.5% ±4.0%. On average, implementation content was 72.4% ±6.1%; and, the frequency, coverage, and duration of adhering to malaria test and treat guidelines (implementation dose) was 69.7% ±7.9%. The providers could distinguish the strategies for treating malaria and its severity among patients (intervention differentiation) at 66.3% ±28.3% on average. The quality of delivering the recommended interventions had a mean of 61.4% ±11.4%.

Table 3.2: Summary Description of the Implementation Fidelity and its Dimensions

Variable	Mean (standard deviation)	Median (interquartile range)
Implementation Fidelity	69.5% (±4.0%)	69.1% (66.2% - 73.5%)
Implementation Content	72.4% (±6.1%)	72.2% (69.4% - 75.0%)
Implementation Dose	69.7% (±7.9%)	66.7% (66.7% - 77.8%)
Quality of Delivery	61.4% (±11.4%)	58.3% (50.0% - 75.0%)
Intervention Differentiation	66.3% (±28.3%)	50.0% (50.0% - 100.0%)

3.2.2 Implementation Fidelity of Malaria test and treat Guidelines by Selected Characteristics

The scores for implementation fidelity differed by sex and provider. Female providers and clinicians had 1.5% points higher fidelity scores compared to their male counterparts. The median fidelity score for providers working in public facilities was identical with those of providers working in private facilities (Table 3.3).

Table 3.3: Description of Implementation Fidelity Scores by Selected Provider Characteristics

Variable	Category Description	Composite Values in Percent	
		Median	Interquartile Range
Sex	*Male*	69.1%	65.4% - 72.1%
	Female	70.6%	67.7% - 73.5%
Provider	*Clinician*	70.6%	67.7% - 73.5%
	Non-clinician	69.1%	66.2% - 72.1%
Facility type	*Public*	69.1%	67.7% - 73.5%
	Private	69.1%	66.2% - 73.5%

Appendix D4 illustrates fidelity scores by the cadre of the respondents.

3.3. A Description of the Determinants of Implementation Fidelity of Malaria Test and Treat Guidelines

The distribution of the scores for knowledge of malaria, facilitation strategies, nature of the intervention, participant responsiveness, and implementation context, the five determinants that were not part of the provider characteristics described in section 3.1., is presented in Table 3.4. The clarity, trialability, and adaptability of malaria test and treat guidelines (nature of intervention) which had a median of 77.8% (IQR 55.6% - 88.9%) and participant responsiveness with a median of 66.7% (IQR 66.7% – 83.3%) recorded higher scores. Knowledge of malaria and facilitation strategies had lower scores with median values of 40.0% (IQR 30.0% - 50.0%) and 33.0% (IQR 33.3% - 50.0%) respectively. The implementation context was the least described determinant with a median value of 22.2% (IQR 22.2% - 22.8%).

Table 3.4: Summary Description of the Determinants for Implementation Fidelity Domain

Variable	Median	Interquartile Range
Knowledge of malaria	40.0%	30.0% - 50.0%
Facilitation Strategies	33.3%	33.3% - 50.0%
Nature of intervention	77.8%	55.6% – 88.9%
Participant responsiveness	66.7%	66.7% - 83.3%
Implementation context	22.2%	22.2% - 27.8%

3.4. Relationship Between Implementation Fidelity and its Determinants

Sex, knowledge of malaria, nature of the intervention, implementation context, and facilitation strategies were statistically significant independent determinants associated with the implementation fidelity of malaria test, and treat guidelines (Table 3.5). For every additional female provider involved in the treatment of malaria, implementation fidelity increased by 1.5 units (95% CI: 0.28 – 2.95; $p=0.0460$) compared to male providers. A unit increase in the score of knowledge of malaria was associated with an increase of implementation fidelity of 0.11 units (95% CI: 0.04 – 0.18; $p=0.0030$). A unit increase in the clarity, trialability, and adaptability of malaria test and treat guidelines (nature of intervention) was associated with a 0.11 unit increase in implementation fidelity (95% CI: 0.07 – 0.14; $p<0.0001$). A unit increase in a supportive work environment (implementation context) was associated with a 0.13 unit increase in implementation fidelity on average (95% CI: -0.01 – 0.28; $p=0.0680$). Whereas, a significant reduction of implementation fidelity of 0.09 units was observed with a unit increase in the type of facilitation strategies employed among the providers (95% CI: -0.13 - -0.05; $p<0.0001$).

Significant variables associated with implementation fidelity of malaria test and treat guidelines in the adjusted (dependent) model were knowledge of malaria, nature of interventions, provider, and facilitation strategies. Involving a non-clinician in place of a clinician in treating malaria at the outpatient department, holding other variables constant, was associated with a 1.5 units drop in implementation fidelity on average (95% CI: -3.03 - 0.06; $p=0.0570$); while a unit increase in the facilitation strategies for malaria was related with a 0.06 unit decrease in implementation fidelity on average (95% CI: -0.09 - -0.02; $p<0.0010$) taking account of the other variables in the model. A unit increase in knowledge of malaria taking account of the other determinants in the model was associated with an increase of implementation fidelity of 0.07 units (95% CI: -0.01 – 0.14; p=0.0710); similarly, a unit rise in the clarity, trialability, and adaptability of the guidelines (nature of intervention) was associated with a 0.06 unit increase in implementation fidelity (95% CI: 0.01 - 0.12; p=0.0190) all the other variables held constant.

Table 3.5: Relationship between Implementation Fidelity of Malaria Test and Treat Guidelines and its Determinants amongst Healthcare Providers

Variable	**Unadjusted Coefficients**		**Adjusted Coefficients**	
	Coefficient	**95% CI**	**Coefficient**	**95% CI**
Age (years)	0.05	-0.01 - 0.12	0.04	-0.10 – 0.18
Sex				
Male (reference)	0.00	-	0.00	-
Female	1.49**	0.28 – 2.95	0.43	-0.96 – 1.82
Provider				
Clinician (reference)	0.00	-	0.00	-
Non-clinician	-1.48	-3.53 – 0.58	-1.48*	-3.03 – 0.06
Experience treating malaria (years)	0.03	-0.07 – 0.12	-0.04	-0.20 – 0.13
Facility				
Public	0.00	-	0.00	-
Private	-0.66	-2.22 – 0.90	-0.41	-1.77 – 0.95
Knowledge of Malaria	0.11***	0.04 – 0.18	0.07**	-0.01 – 0.14
Facilitation Strategies	-0.09***	-0.13 – -0.05	-0.06***	-0.09 - -0.02
Nature of Intervention	0.11***	0.07 – 0.14	0.06**	0.01 – 0.12
Implementation Context	0.13*	-0.01 – 0.28	0.09	-0.03 – 0.22

*** $p<0.01$, ** $p<0.05$, * $p<0.1$; 95% CI = 95% confidence interval; R-squared (adjusted model) = 32.4%

A complimentary to Table 3.5 is provided in Appendix D5.

CHAPTER FOUR: DISCUSSION AND CONCLUSION

4.0 Introduction

This chapter discusses the study findings with respect to the research questions, and in the context of literature. A highlight of the implications of the study findings to policy and practice is provided. The chapter concludes with a brief on the study limitations and strengths.

4.1 Level of Implementation Fidelity of Malaria Test and Treat Guidelines

Universal testing for malaria and treating confirmed cases of uncomplicated malaria disease is recommended (57). The level of implementation fidelity in this study was 70%, evidence that the providers working in the outpatient department are yet to fully implement malaria test and treat guidelines with fidelity. A comparable finding of implementation fidelity of 75% was recorded in a survey conducted in outpatient health facilities to assess malaria testing and treatment practices following test and treat guidelines in Malawi (68). In a cross-sectional study conducted in Sudan assessing provider adherence to treatment protocol in children under the age of five, fidelity was lower than 50% (83). Lower implementation fidelity levels have been recorded in a cross-sectional study done in Ghana, and a randomized control trial conducted in Uganda of 39% and 20% respectively (136,137). Higher protocol adherence amongst providers has been reported exceeding 80% (13,60); suggesting that healthcare providers can implement malaria guidelines at better implementation fidelity considering the moderate finding of this study.

Among the dimensions of implementation fidelity assessed in this study, the scores for implementation adherence of 72% and implementation dose of 70% were higher compared to those of intervention differentiation (66%) and quality of delivery (61%). The providers were more likely to observe the recommended test and treat strategies of malaria compared to practices that required them to observe clinical standards when providing services or those that needed them to distinguish between malaria patients or disease categories. This finding lends support to Carrol's observation that implementation fidelity is more associated with the implementation content and dose (81). A cross-sectional study conducted in Nigeria to assess the adherence of healthcare workers to malaria diagnosis and treatment guidelines documented an adherence of 60%, but noted lower adherence values among providers that experienced a poor supply of malaria commodities (110). Low adherence to treatment guidelines has been associated with poor facilitation strategies and hostile implementation contexts which program managers need to address (45).

Implementation dose, related to testing patients suspected with malaria is not consistent despite more than 70% of patients receiving the right medication (20,31,54). A comparable value of implementation dose was reported in an earlier survey conducted in Kenya to assess the health systems' readiness in implementing test and treat guidelines and the quality of treating outpatients with fever (66). Good participant responsiveness is associated with better implementation coverage among providers (73). Data-driven implementation has also been associated with an implementation content and a dose of up to 72% amongst providers (96).

About 40% of providers do not observe prescribed clinical standards when managing malaria patients. On the other hand, many studies stop at the descriptions of the quality of delivery leading to a paucity of data on quantifications of this dimension. Proxies of quality based on provider practices, knowledge, health facility resourcing, access and utilization of healthcare, and patient-centeredness have been used (43,57,138). It was noted that well-structured supportive supervision and capacity building providers were associated with a better quality of delivery, in a malaria survey conducted in Kenya assessing the reasons for providers changing their diagnosis and treatment practices, (54). There is evidence that as much as 49% of patients suspected to have malaria, who test negative, are issued antimalarial despite the provider’s knowledge of the right management (139). Evidence suggests a need for health providers implementing test and treat guidelines to be provided with systematic supervision, capacity development, and monitoring by health managers and malaria control programs.

On average, 34% of providers are unable to distinguish between types of malaria and treatment options available to mean that providers involved in the management of malaria patients should be capacity built and provided with the supplies and tools they need. The values of intervention differentiation among providers offering treatment for malaria in literature are similar to those of this study (2,31,68). The literature points out that most providers distinguish the care for certain patients better; such as those with uncomplicated malaria or children older than six months, further pinpointing the need for focused capacity building, and guideline strengthening (140). Consequently, employing inclusive case management approaches may be a solution to improving adherence to guidelines (139,141,142). Improving the accuracy of the provider to differentiate care for patients with different forms of the disease is related to strategies that foster quality of delivery (13,143).

4.2 Determinants of Implementation Fidelity of Malaria Test and Treat Guidelines

The significant determinants of implementation fidelity of malaria test and treat guidelines amongst healthcare providers were sex, type of provider, knowledge of malaria, facilitation strategies, nature of the intervention, and implementation context. Other determinants that were assessed and are discussed are age, the experience of treating malaria, facility type, and participant responsiveness. Literature has documented age, the experience of providers, type of provider, facility type, facilitation strategies, knowledge, nature of the intervention, and implementation context as some of the determinants of implementation fidelity (47,51,98).

4.2.1 The Sex of the Provider

This study found a positive, significant, independent association among female providers and implementation fidelity compared to their male counterparts. Whereas there were more female providers reached (55%) than the males, the difference in numbers may not potentially explain the better independent implementation fidelity. In a retrospective review of general practitioners' practices when treating coeliac disease conducted by Martin et al., established a positive association between female general practitioners and prescription guidelines in the United Kingdom (144). Literature suggests that the "better" adherence to guidelines amongst female providers is linked to their nature of stakeholder engagement, communication, and decision making practices (145,146). Some evidence holds that there is no association between the sex of a provider and prescribed interventions (147). A meaningful variance to the findings of this study is that the sex of providers was insignificantly dependent on implementation fidelity adjusting for other study variables. Such a finding would imply that there are determinants in play that may compensate for the differences that might exist between the sex of providers on implementation fidelity of malaria test and treat guidelines.

4.2.2 Type of Provider

Non-clinical providers were associated with a decrease in implementation fidelity of malaria test and treat guidelines. One would speculate that the absence of a significant independent association between the providers and implementation fidelity suggests that there are no differences between clinicians and non-clinicians when it comes to treating patients for malaria based on the test and treat strategy. However, overarching factors that may be differentiating the practice between the providers might explain the observed difference in this study. Different levels of implementation fidelity have been noted among providers

(136). In a cross-sectional study conducted in Ghana that assessed the implementation of malaria guidelines and its challenges, medical doctors achieved up to 80% implementation fidelity while the rest of the providers recorded no more than 50% fidelity (71). In general, literature holds that clinicians have better adherence to treatment guidelines compared to non-clinicians (34,70). Other studies have discovered that although non-clinicians may adhere poorly to guidelines if trained and facilitated, their implementation fidelity compares to that of clinicians (31,63).

4.2.3 Knowledge

Data in this study revealed a positive significant relationship between the provider's knowledge of malaria and implementation fidelity. Providers with more knowledge of malaria and its management implemented the test and treat guidelines with higher fidelity. Evidence posits that an increase in the provider's knowledge improves implementation fidelity of guidelines (45,91,94). Training a provider increases their self-efficacy thereby improving their fidelity to guidelines (102). A departure from this viewpoint suggests that basic training and provision of additional cues for information such as job aids may not be sufficient to improve the fidelity of a provider to guidelines (52,91). In a study that analysed secondary data for malaria from Cameroon and Nigeria and a cross-sectional study conducted in Kenya, found that no evidence linked the knowledge of a provider with implementation fidelity to guidelines (43,104). Training messages that contradict recommended guidelines decrease implementation fidelity (148). Consequently, health managers should consider training all providers on malaria test and treat guidelines.

4.2.4 Facilitation Strategies

In this study, the facilitation strategies identified by the providers were significantly associated with a decrease in implementation fidelity suggesting poor facilitation. Good facilitation strategies can be defined as the availability of treatment commodities and supplies, appropriate capacity building, supportive supervision, and routine monitoring, a deficiency of any of these could then be regarded as poor facilitation (45,75). Additional elements of good facilitation associated with better implementation fidelity include the availability of copies of treatment guidelines at points of care, and comprehensive training and follow up packages (51,60). A source points out that good facilitation is not adequately associated with implementation fidelity amongst providers, but increasing the providers' awareness of innovative implementation strategies applicable to treatment guidelines and supporting them to apply such innovations could increase fidelity to interventions (110).

4.2.5 The Nature of the Intervention

The nature of the intervention had a positive significant association with implementation fidelity. Malaria test and treat interventions that were clear, trialable, and adaptable by the providers may potentially be perceived as appropriate and thus associated with higher implementation fidelity. Conversely, health providers question the accuracy of malaria rapid diagnostic test kits and point out that they are inappropriate for diagnosing certain cases of malaria (71,92,110). Different interventions including treatment guidelines have characteristics distinct to them (98,149). These distinct characteristics influence the degree to which a provider adheres to guidelines (34). Hence, more directive strategies that match local preferences, and allow adaptability of intervention characteristics in favour of provider priorities have been suggested (52,62). Some authorities are advocating for the inclusion of disruptive interventions, simple complementary innovations such as short text message reminders, to enhance implementation fidelity among providers (73,104). Further research is required to determine the influence of innovations on implementation fidelity.

4.2.6 Implementation Context

The implementation context of the providers in this study was independently associated with a significant increase in implementation fidelity; holding to account other determinants, this association was insignificant. Providers who reported support from management and colleagues, availability of funds for the program, reliable supplies, and quality laboratory services were more likely to implement the malaria guidelines with fidelity. These findings underpin the critical role of the health system in providing a supportive environment linked to better performance (98,150). A poor working environment may be one with high operational costs, inadequate resources, high caseloads, and weak leadership and management hindering the implementation of recommended interventions (13,69,96,148). In a retrospective audit of medical records in Mozambique, external quality assurance of malaria microscopy was recognized as a positive work enabler of clinician’s adherence to malaria guidelines. Further evidence supports the inclusion of quality improvement strategies at points of care which are known to strengthen the implementing recommended interventions (150,151).

4.3 A Summary of the Key Findings

The implementation fidelity of malaria test and treat guidelines was not fully achieved amongst study participants. The sex of a provider, the type of a provider (the cadre of a provider), knowledge of malaria, facilitation strategies, the nature of the intervention, and the implementation context were the key determinants associated with implementation fidelity of malaria test and treat guidelines. Implementation fidelity was higher among female providers, among those with higher knowledge of malaria, and with interventions that were clear and could be tried and/or adapted, or in supportive implementation contexts. Being non-clinician and the kind of facilitation strategies employed among study participants was associated with lower implementation fidelity of malaria test and treat guidelines.

4.4 Implications of the Study Findings to Clinical Practice and Policy

A high cost of treatment, poor growth among children, loss of livelihood, organ damage, and death are some of the repercussions of inappropriate malaria treatment among patients (14–16). On the other hand, irrational use of antimalarial commodities, the emergence of drug-resistant malaria, and irregular clinical practice are some of the health systems constraints linked to low implementation fidelity of malaria guidelines (51,52). Malaria program and site managers, and healthcare providers have a big role in ensuring that malaria guidelines are implemented appropriately. This includes maintaining a high adherence and dose of the recommended interventions, applying evidence-based implementation, and providing high-quality services. Collaborations between program managers, key stakeholders, and researchers are required in upholding facilitative determinants, and addressing those hindering implementation fidelity of malaria test and treat guidelines.

The findings of this study pinpoint opportunities for further research on the implementation fidelity of malaria test and treat guidelines amongst healthcare providers. Possible questions for research include:

1. Which change concepts will improve the implementation fidelity of malaria test and treat guidelines?
2. How do malaria program managers, and healthcare providers adapt malaria test and treat guidelines in their contexts?

4.5 Limitations of the Study

The data collected were from self-reported responses prone to measurement error. Challenges with items requiring respondents to remember information may have limited the accuracy of data. Social desirability bias arising from respondents providing responses that suit them or favour the study could not have been prevented. Despite collecting data real-time on REDCap, errors during data capture may have occurred subtly influencing the results at hand. Responses from providers that declined to participate or those that could not be reached could have influenced the results of the study in either way. Lastly, attributing a causal relationship between the outcome and explanatory variables could not be possible with the cross-sectional study design. Nevertheless, the findings are useful in informing improvements of health interventions in low resource settings.

4.6 Strengths of the Study

This study had noteworthy strengths despite its limitations. The research instrument was developed based on the existing implementation fidelity framework, and the tool was pretested and refined in line with the recommendations of test-takers, study supervisors, and the panel of protocol reviewers to whom it was presented. Using a quantitative cross-sectional study design allowed the collection of data for both the outcome and explanatory variables, thus measuring implementation fidelity and assessing the relationship between the outcome and explanatory variables providing a snapshot of the success of the implementation. Given the sample size, significance level, and the population parameters of the outcome variable, this study was highly powered to provide the results that were obtained; hence, information that may have been missed from non-respondents might not have adversely affected the study. The statistical method of sample resampling and generating precise estimates for study variables compensated for sampling variance, and overcame the limitations of parametric analysis increasing the validity of our findings. Lastly, this study has illustrated the feasibility of operationalizing an implementation research framework and its role in guiding the assessment of an implementation outcome.

4.7 Conclusion

Implementation fidelity of malaria test and treat guidelines in Kisumu Central is yet to be fully accomplished amongst healthcare providers working in the outpatient departments of health facilities in the sub-County. The level of implementation fidelity that was established in this study is moderate compared with the findings of other studies in the literature.

Significant facilitative determinants of implementation fidelity of malaria test and treat guidelines in this context were female providers, and the nature of the intervention which is guidelines that had clarity, and allowed for trialability and flexibility. The facilitative strategies employed were a barrier to implementing the guidelines with fidelity. There was some evidence that knowledge of malaria facilitative, unlike engaging non-clinical providers to implement the malaria test and treat guidelines with fidelity.

4.8 Recommendations

1. Further research should be conducted to identify additional context-specific factors associated with the implementation fidelity of malaria test and treat guidelines. Such an information mix (43) would build a base for policy and decision making aimed at strengthening the adherence of the providers to the guidelines.
2. Upholding the nature of the intervention deemed to be clear, and that allow providers to try and implement with flexibility within their contexts as well as addressing untoward facilitative strategies will foster implementation with fidelity. Through context-specific strategic plans that account for the various characteristics of front-line providers, it is possible to underscore and address critical determinants associated with implementation fidelity.
3. This research developed and used a questionnaire informed by existing implementation research frameworks. The questionnaire should be adopted in measuring implementation fidelity. However, the tool will benefit from additional steps that will strengthen its content and construct validity, as well as reliability (123).
4. Lastly, implementation fidelity was assessed as a proxy indicator for the actual practice of implementing malaria test and treat guidelines. The researcher suggests that further research could be considered on other implementation outcomes such as the acceptability, feasibility, and adoption of malaria test and treat guidelines to further knowledge on the implementation success of these guidelines.

References

1. Desai M, Buff AM, Khagayi S, Byass P, Amek N, Van Eijk A, et al. Age-specific malaria mortality rates in the KEMRI/CDC health and demographic surveillance system in Western Kenya, 2003-2010. PLoS One. 2014;9(9).

2. Deye N, Vincent F, Michel P, Ehrmann S, Da Silva D, Piagnerelli, M. …, et al. Malaria. J R Army Med Corps. 2013;

3. Autino B, Noris A, Russo R, Castelli F. Epidemiology of malaria in endemic areas [Internet]. Vol. 4, Mediterranean Journal of Hematology and Infectious Diseases. Catholic University in Rome; 2012 [cited 2018 Oct 22]. p. e2012060. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23170189

4. User S, (NMCP) NMCP, Kenya National Bureau of Statistics (KNBS), ICF, International., KNMCP, et al. Kenya Malaria Indicator Survey 2015 [Internet]. Kenya National Bureau of Statistics. Nairobi, Kenya, and Rockville, Maryland, USA; 2016 Jul. Available from: https://dhsprogram.com/pubs/pdf/MIS22/MIS22.pdf

5. Sultana M, Sheikh N, Mahumud RA, Jahir T, Islam Z, Sarker AR. Prevalence and associated determinants of malaria parasites among Kenyan children. Trop Med Health. 2017;

6. WHO. World Malaria Report 2017. World Health Organization. 2017.

7. WHO. The world health report 2003: Shaping the future. Geneva Wold Heal Organ [Internet]. 2003 [cited 2018 Sep 28];204. Available from: http://www.who.int/whr/2003/en/whr03_en.pdf

8. Foote EM, Sullivan KM, Ruth LJ, Oremo J, Sadumah I, Williams TN, et al. Determinants of Anemia among Preschool Children in Rural, Western Kenya. Am J Trop Med Hyg. 2013;

9. Baiden F, Owusu-Agyei S, Okyere E, Tivura M, Adjei G, Chandramohan D, et al. Acceptability of Rapid Diagnostic Test-Based Management of Malaria among Caregivers of Under-Five Children in Rural Ghana. PLoS One. 2012;

10. Biemba G, Dolmans D, Thuma PE, Weiss G, Gordeuk VR. Severe anaemia in Zambian children with Plasmodium falciparum malaria. Trop Med Int Heal [Internet]. 2000 Jan 1 [cited 2018 Oct 18];5(1):9–16. Available from: http://doi.wiley.com/10.1046/j.1365-3156.2000.00506.x

11. Moschovis PP, Wiens MO, Arlington L, Antsygina O, Hayden D, Dzik W, et al. Individual, maternal and household risk factors for anaemia among young children in sub-Saharan Africa: a cross-sectional study. BMJ Open [Internet]. 2018 May 14 [cited 2018 Oct 22];8(5):e019654. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29764873

12. Juma DW, Omondi AA, Ingasia L, Opot B, Cheruiyot A, Yeda R, et al. Trends in drug resistance codons in Plasmodium falciparum dihydrofolate reductase and dihydropteroate synthase genes in Kenyan parasites from 2008 to 2012. Malar J. 2014;

13. Ezenduka CC, Okonta MJ, Esimone CO. Adherence to treatment guidelines for uncomplicated malaria at two public health facilities in Nigeria; implications for the 'test and treat' policy of malaria case management. J Pharm Policy Pract. 2014;7(1):1–10.

14. Akhwale WS, Lum JK, Kaneko A, Eto H, Obonyo C, Björkman A, et al. Anemia and malaria at different altitudes in the western highlands of Kenya. Acta Trop [Internet]. 2004 Jul 1 [cited 2018 Oct 18];91(2):167–75. Available from: https://www.sciencedirect.com/science/article/abs/pii/S0001706X04000737

15. Seo M, Baker P, Ngo KN-L. Cost-effectiveness analysis of vaccinating children in Malawi with RTS,S vaccines in comparison with long-lasting insecticide-treated nets. Malar J [Internet]. 2014 Feb 24 [cited 2018 Sep 28];13(1):66. Available from: http://malariajournal.biomedcentral.com/articles/10.1186/1475-2875-13-66

16. Mathanga DP, Campbell CH, Eng J Vanden, Wolkon A, Bronzan RN, Malenga GJ, et al. Comparison of anaemia and parasitaemia as indicators of malaria control in household and EPI-health facility surveys in Malawi. Malar J. 2010;

17. Snow RW, Bastos de Azevedo I, Lowe BS, Kabiru EW, Nevill CG, Mwankusye S, et al. Severe childhood malaria in two areas of markedly different falciparum transmission in East Africa. Acta Trop [Internet]. 1994 Sep 1 [cited 2018 Oct 18];57(4):289–300. Available from: https://www.sciencedirect.com/science/article/abs/pii/0001706X94900744

18. Kassile T. Prevention and management of malaria in under-five children in Tanzania: A review [Internet]. Vol. 14, Tanzania Journal of Health Research. 2012 [cited 2018 Oct 19]. Available from: http://www.bioline.org.br/pdf?th12033

19. Tarimo DS, Lwihula GK, Minjas JN, Bygbjerg IC. Mothers' perceptions and knowledge on childhood malaria in the holendemic Kibaha district, Tanzania: Implications for malaria control and the IMCI strategy. Trop Med Int Heal [Internet]. 2000 Mar 1 [cited 2018 Oct 18];5(3):179–84. Available from: http://doi.wiley.com/10.1046/j.1365-3156.2000.00537.x

20. Fenny AP, Hansen KS, Enemark U, Asante FA. Quality of uncomplicated malaria case management in Ghana among insured and uninsured patients. Int J Equity Health. 2014;13(1).

21. Brabin BJ. An analysis of malaria in pregnancy in Africa. Bull World Health Organ. 1983;

22. Makani J, Williams TN, Marsh K. Sickle cell disease in Africa: burden and research priorities. Ann Trop Med Parasitol [Internet]. 2007;101(1):3–14. Available from: http://www.tandfonline.com/doi/full/10.1179/136485907X154638

23. Grosse SD, Odame I, Atrash HK, Amendah DD, Piel FB, Williams TN. Sickle cell disease in Africa: A neglected cause of early childhood mortality. Am J Prev Med. 2011;41(6 SUPPL.4).

24. Daou M, Kouriba B, Ouédraogo N, Diarra I, Arama C, Keita Y, et al. Protection of Malian children from clinical malaria is associated with recognition of multiple antigens. Malar J [Internet]. 2015 Feb 5 [cited 2018 Oct 22];14(1):56. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25653026

25. Ministry of Health. Health Sector Human Resources Strategy 2014-2018. Strateg Manag Handb [Internet]. 2014;1–22. Available from: http://www.health.go.ke/wp-content/uploads/2016/04/Kenya-HRH-Strategy-2014-2018.pdf

26. GoK MoH, Ministry of Health. The epidemiology and control profile of malaria in Kenya: reviewing the evidence to guide the future vector control. National Malaria Control Programme, Ministry of Health. Technical support provided by the LINK

Project (London School of Hygiene and Tropi [Internet]. 2016. Available from: http://virtual.lshtm.ac.uk/wp-content/uploads/2016/11/Kenya-Epidemiological-Profile.pdf

27. Shanks GD, Hay SI, Omumbo JA, Snow RW. Malaria in Kenya's western highlands. Vol. 11, Emerging Infectious Diseases. 2005. p. 1425–32.

28. Siteti M., Injete S., Wanyonyi W. Malaria parasite species prevalence and transmission dynamics at selected sites in the Western highlands of Kenya. CHRISMED J Heal Res [Internet]. 2016;3(1):45. Available from: http://www.cjhr.org/text.asp?2016/3/1/45/172399

29. Nyaguara, O. Amek, Annemieke VE, Lindblade KA, Hamel M, Bayoh N, Gimnig J, Kayla, F. Laserson Laurence, Slutsker Thomas S, et al. Infant and child mortality in relation to malaria transmission in KEMRI/CDC HDSS, Western Kenya: validation of verbal autopsy. Malar J [Internet]. 2018;17(37). Available from: https://doi.org/10.1186/s12936-018-2184-x

30. Sifuna P, Oyugi M, Ogutu B, Andagalu B, Otieno A, Owira V, et al. Health and demographic surveillance system profile: The Kombewa health and demographic surveillance system (Kombewa HDSS). Int J Epidemiol. 2014;43(4):1097–104.

31. Rowe AK, de León GFP, Mihigo J, Santelli ACFS, Miller NP, Van-Dúnem P. Quality of malaria case management at outpatient health facilities in Angola. Malar J. 2009;

32. Zurovac D, Githinji S, Memusi D, Kigen S, Machini B, Muturi A, et al. Major improvements in the quality of malaria case-management under the "test and treat" policy in Kenya. PLoS One. 2014;

33. Wanja EW, Kuya N, Moranga C, Hickman M, Johnson JD, Moseti C, et al. Field evaluation of diagnostic performance of malaria rapid diagnostic tests in western Kenya. Malar J. 2016;

34. Kachur SP. "Beyond 'test and treat' - malaria diagnosis for improved pediatric fever management in sub-Saharan Africa" by Emily White Johansson. Glob Health Action. 2016;

35. Chuma J, Okungu V, Molyneux C. The economic costs of malaria in four Kenyan districts: do household costs differ by disease endemicity? Malar J. 2010;

36. Millar KR, McCutcheon J, Coakley EH, Brieger W, Ibrahim MA, Mohammed Z, et al. Patterns and predictors of malaria care-seeking, diagnostic testing, and artemisinin-based combination therapy for children under five with fever in Northern Nigeria: A cross-sectional study. Malar J. 2014;

37. Musuva A, Ejersa W, Kiptui R, Memusi D, Abwao E. The malaria testing and treatment landscape in Kenya: results from a nationally representative survey among the public and private sector in 2016. Malar J. 2017;

38. Kassam R, Collins JB, Liow E, Rasool N. Narrative review of current context of malaria and management strategies in Uganda (Part I). Vol. 152, Acta Tropica. 2015. p. 252–68.

39. Zurovac D, Tibenderana JK, Nankabirwa J, Ssekitooleko J, Njogu JN, Rwakimari JB, et al. Malaria case-management under artemether-lumefantrine treatment policy in Uganda. Malar J. 2008;

40. Hussain MA, Dandona L, Schellenberg D. Public health system readiness to treat

malaria in Odisha State of India. Malar J. 2013;

41. Boadu NY, Amuasi J, Ansong D, Einsiedel E, Menon D, Yanow SK. Challenges with implementing malaria rapid diagnostic tests at primary care facilities in a Ghanaian district: A qualitative study. Malar J. 2016;15(1).

42. Arrow KJ, Panosian C, Gelband H. Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance. Institute of Medicine (US) Committee on the Economics of Antimalarial Drugs. 2004.

43. Nyandigisi A, Memusi D, Mbithi A, Ang'wa N, Shieshia M, Muturi A, et al. Malaria Case-Management following change of policy to universal parasitological diagnosis and targeted Artemisinin-Based combination therapy in Kenya. PLoS One. 2011;

44. Singlovic J, Ajayi IO, Nsungwa-Sabiiti J, Siribié M, Sanou AK, Jegede AS, et al. Compliance With Malaria Rapid Diagnostic Testing by Community Health Workers in 3 Malaria-Endemic Countries of Sub-Saharan Africa: An Observational Study. Clin Infect Dis. 2016;63(suppl 5).

45. Compaoré R, Yameogo MWE, Millogo T, Tougri H, Kouanda S. Evaluation of the implementation fidelity of the seasonal malaria chemoprevention intervention in Kaya health district, Burkina Faso. PLoS One. 2017;

46. Connery H, Greenfield S, Livchits V, McGrady L, Patrick N, Lastimoso CS, et al. Training and fidelity monitoring of alcohol treatment interventions integrated into routine tuberculosis care in Tomsk, Russia: The IMPACT effectiveness trial. Subst Use Misuse. 2013 Jun;48(9):806–14.

47. Bawate C, Callender-Carter ST, Nsajju B, Bwayo D. Factors affecting adherence to national malaria treatment guidelines in management of malaria among public healthcare workers in Kamuli District, Uganda. Malar J. 2016;15(1).

48. Zurovac D, Midia B, Ochola SA, English M, Snow RW. Microscopy and outpatient malaria case management among older children and adults in Kenya. Tropical Medicine and International Health. 2006.

49. Odongo DO, Wakhungu WJ, Stanley O. Causes of variability in prevalence rates of communicable diseases among secondary school Students in Kisumu County, Kenya. Zeitschrift Fur Gesundheitswissenschaften [Internet]. 2017 Jul 10;25(2):161–6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350242/

50. Aluoch JR, Aluoch LH. Survey of sickle disease in Kenya. Trop Geogr Med. 1993;45(1):18–21.

51. Riley C, Dellicour S, Ouma P, Kioko U, Ter Kuile FO, Omar A, et al. Knowledge and adherence to the national guidelines for malaria case management in pregnancy among healthcare providers and drug outlet dispensers in rural, western Kenya. PLoS One. 2016;11(1).

52. Burchett HED, Leurent B, Baiden F, Baltzell K, Björkman A, Bruxvoort K, et al. Improving prescribing practices with rapid diagnostic tests (RDTs): Synthesis of 10 studies to explore reasons for variation in malaria RDT uptake and adherence. BMJ Open. 2017;7(3).

53. Ministry of Health MCP. National Guidelines for the diagnosis, treatment and prevention of malaria in Kenya [Internet]. 5th ed. Nairobi, Kenya: Ministry of Health National Malaria Control Program, Kenya; 2016. 62 p. Available from:

http://www.thehealthcompass.org/sites/default/files/project_examples/Kenya_Malaria_Tx_Guideline_2010.pdf

54. Juma E, Zurovac D. Changes in health workers' malaria diagnosis and treatment practices in Kenya. Malar J. 2011;

55. Chuma J, Abuya T, Memusi D, Juma E, Akhwale W, Ntwiga J, et al. Reviewing the literature on access to prompt and effective malaria treatment in Kenya: Implications for meeting the Abuja targets. Malar J. 2009;

56. Ochieng W, Kitawi RC, Nzomo TJ, Mwatelah RS, Kimulwo MJ, Ochieng DJ, et al. Implementation and operational research: Correlates of adherence and treatment failure among Kenyan patients on long-term highly active antiretroviral therapy. J Acquir Immune Defic Syndr [Internet]. 2015 Jun;69(2):e49–56. Available from: https://doi.org/10.1097%2Fqai.0000000000000580

57. Zurovac D, Githinji S, Memusi D, Kigen S, Machini B, Muturi A, et al. Major Improvements in the Quality of Malaria Case-Management under the "Test and Treat" Policy in Kenya. PLoS One. 2014 Mar;9(3):e92782.

58. Searle KM, Hamapumbu H, Lubinda J, Shields TM, Pinchoff J, Kobayashi T, et al. Evaluation of the operational challenges in implementing reactive screen-and-treat and implications of reactive case detection strategies for malaria elimination in a region of low transmission in southern Zambia. Myer L, editor. Malar J [Internet]. 2016 Jul 25 [cited 2018 Jul 3];15(1):1051–5. Available from: https://doi.org/10.1097%2F00002030-199905280-00011

59. WHO. Guidelines for the treatment of malaria. 2nd ed. Geneva: World Health Organization; 2010. 210 p.

60. Zoyah JC, Diedong AL. Health Professionals' Compliance with National Treatment Guidelines for Treatment of Severe Malaria in Children in Bolgatanga Hospital, Upper East, Ghana [Internet]. Vol. 4, International Journal of Humanities and Social Science. 2014 [cited 2018 Oct 12]. Available from: www.ijhssnet.com

61. Isiguzo C, Anyanti J, Ujuju C, Nwokolo E, De La Cruz A, Schatzkin E, et al. Presumptive treatment of Malaria from formal and informal drug vendors in Nigeria. PLoS One. 2014;9(10).

62. Diggle E, Asgary R, Gore-Langton G, Nahashon E, Mungai J, Harrison R, et al. Perceptions of malaria and acceptance of rapid diagnostic tests and related treatment practises among community members and health care providers in Greater Garissa, North Eastern Province, Kenya. Malar J. 2014;13(1).

63. Boyce MR, O'Meara WP. Use of malaria RDTs in various health contexts across sub-Saharan Africa: a systematic review. BMC Public Health. 2017;17(1).

64. Liu J, Modrek S, Anyanti J, Nwokolo E, De La Cruz A, Schatzkin E, et al. How do risk preferences relate to malaria care-seeking behavior and the acceptability of a new health technology in Nigeria? BMC Health Serv Res. 2014;14(1).

65. Graz B, Willcox M, Szeless T, Rougemont A. "Test and treat" or presumptive treatment for malaria in high transmission situations? A reflection on the latest WHO guidelines. Malar J [Internet]. 2011;10(1):136. Available from: https://doi.org/10.1186/1475-2875-10-136

66. Zurovac D, Guintran JO, Donald W, Naket E, Malinga J, Taleo G. Health systems

readiness and management of febrile outpatients under low malaria transmission in Vanuatu. Malar J. 2015;

67. Bejon P, Berkley JA, Mwangi T, Ogada E, Mwangi I, Maitland K, et al. Defining Childhood severe falciparum malaria for intervention studies. PLoS Med. 2007;

68. Namuyinga RJ, Mwandama D, Moyo D, Gumbo A, Troell P, Kobayashi M, et al. Health worker adherence to malaria treatment guidelines at outpatient health facilities in southern Malawi following implementation of universal access to diagnostic testing. Malar J. 2017;16(1).

69. Druetz T, Corneau-Tremblay N, Millogo T, Kouanda S, Ly A, Bicaba A, et al. Impact evaluation of seasonal malaria chemoprevention under routine program implementation: A quasi-experimental study in Burkina Faso. Am J Trop Med Hyg. 2018;

70. Druetz T, Ridde V, Kouanda S, Ly A, Diabaté S, Haddad S. Utilization of community health workers for malaria treatment: Results from a three-year panel study in the districts of Kaya and Zorgho, Burkina Faso. Malar J. 2015;

71. Akanteele Agandaa S, Kweku M, Agboli E, Takase M, Takramah W, Tarkang E, et al. Implementation and challenges of test, treat and track (T3) strategy for malaria case management in children under five years in the Bongo District, Ghana. Clin Res Trials. 2016;

72. Falade CO, Ajayi IO, Nsungwa-Sabiiti J, Siribié M, Diarra A, Sermé L, et al. Malaria Rapid Diagnostic Tests and Malaria Microscopy for Guiding Malaria Treatment of Uncomplicated Fevers in Nigeria and Prereferral Cases in 3 African Countries. Clin Infect Dis. 2016;63(suppl 5).

73. Modrek S, Schatzkin E, De La Cruz A, Isiguzo C, Nwokolo E, Anyanti J, et al. SMS messages increase adherence to rapid diagnostic test results among malaria patients: Results from a pilot study in Nigeria. Malar J. 2014;13(1).

74. Ayogu E, Ukwe C, Nna E. Assessing the reliability of microscopy and rapid diagnostic tests in malaria diagnosis in areas with varying parasite density among older children and adult patients in Nigeria. J Postgrad Med. 2016;62(3).

75. Salomão CA, Sacarlal J, Chilundo B, Gudo ES. Prescription practices for malaria in Mozambique: Poor adherence to the national protocols for malaria treatment in 22 public health facilities. Malar J. 2015;14(1).

76. Yakasai AM, Hamza M, Dalhat MM, Bello M, Gadanya MA, Yaqub ZM, et al. Adherence to Artemisinin-Based Combination Therapy for the Treatment of Uncomplicated Malaria: A Systematic Review and Meta-Analysis. Vol. 2015, Journal of Tropical Medicine. 2015.

77. Varkey P, Reller MK, Resar RK. Basics of quality improvement in health care. Vol. 82, Mayo Clinic Proceedings. 2007. p. 735–9.

78. Ajayi IO, Nsungwa-Sabiiti J, Siribié M, Falade CO, Sermé L, Balyeku A, et al. Feasibility of Malaria Diagnosis and Management in Burkina Faso, Nigeria, and Uganda: A Community-Based Observational Study. Clin Infect Dis [Internet]. 2016;63(suppl 5):S245–55. Available from: https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciw622

79. Cohen J, Fink G, Berg K, Aber F, Jordan M, Maloney K, et al. Feasibility of

Distributing Rapid Diagnostic Tests for Malaria in the Retail Sector: Evidence from an Implementation Study in Uganda. PLoS One. 2012;

80. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Heal Ment Heal Serv Res [Internet]. 2011 Mar 19 [cited 2018 Apr 3];38(2):65–76. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20957426

81. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci [Internet]. 2007 Dec 30 [cited 2018 Apr 3];2(1):40. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-2-40

82. Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. Implement Sci. 2010 Sep;5:67.

83. Bilal JA, Gasim GI, Abdien MT, Elmardi KA, Malik EM, Adam I. Poor adherence to the malaria management protocol among health workers attending under-five year old febrile children at Omdurman Hospital, Sudan. Malar J. 2015;14(1).

84. Mihalic S. The importance of implementation fidelity. Emot Behav Disord Youth. 2004;4(4):83–105.

85. Brownson RC, Colditz GA, Proctor EK. Dissemination and Implementation Research in Health: Translating Science to Practice. Dissemination and Implementation Research in Health: Translating Science to Practice. 2012.

86. Dane A V, Schneider BH. PROGRAM INTEGRITY IN PRIMARY AND EARLY SECONDARY PREVENTION: ARE IMPLEMENTATION EFFECTS OUT OF CONTROL? Clin Psychol Rev [Internet]. 1998 Jan;18(1):23–45. Available from: http://www.sciencedirect.com/science/article/pii/S0272735897000433

87. Proctor KE, Brownson CR. Measurement Issues in Dissemination and Implementation Research. In: Brownson RC, Colditz GA, Proctor EK, editors. Dissemination and Implementation Research in Health: Translating Science to Practice. New York: Oxford University Press; 2012. p. 268.

88. Thakur R, Vk S. A Study of Clinical Profile of Recurrent Tuberculosis in People Living with HIV/AIDS. J AIDS Clin Res [Internet]. 2018 Apr 24;9(4):1–5. Available from: https://www.omicsonline.org/open-access/a-study-of-clinical-profile-of-recurrent-tuberculosis-in-people-living-with-hivaids-2155-6113-1000764-100776.html

89. Breitenstein SM, Gross D, Garvey C, Hill C, Fogg L, Resnick B. Implementation Fidelity in Community-Based Interventions. Res Nurs Health [Internet]. 2010 Jul 17;33(2):164–73. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409469/

90. Kabaghe AN, Visser BJ, Spijker R, Phiri KS, Grobusch MP, Van Vugt M. Health workers' compliance to rapid diagnostic tests (RDTs) to guide malaria treatment: A systematic review and meta-Analysis. Vol. 15, Malaria Journal. 2016.

91. Mbacham WF, Mangham-Jefferies L, Cundill B, Achonduh OA, Chandler CIR, Ambebila JN, et al. Basic or enhanced clinician training to improve adherence to malaria treatment guidelines: A cluster-randomised trial in two areas of Cameroon. Lancet Glob Heal. 2014;2(6).

92. Altaras R, Nuwa A, Agaba B, Streat E, Tibenderana JK, Strachan CE. Why do health workers give anti-malarials to patients with negative rapid test results? A qualitative study at rural health facilities in western Uganda. Malar J. 2016;15(1).

93. Faust C, Zelner J, Brasseur P, Vaillant M, Badiane M, Cisse M, et al. Assessing drivers of full adoption of test and treat policy for malaria in Senegal. Am J Trop Med Hyg. 2015;93(1).

94. Malenga T, Kabaghe AN, Manda-Taylor L, Kadama A, McCann RS, Phiri KS, et al. Malaria control in rural Malawi: implementing peer health education for behaviour change. Global Health. 2017 Dec;13(1):84.

95. Lipsey MW, Cordray DS. Evaluation Methods for Social Intervention. Annu Rev Psychol [Internet]. 2000 Feb 1;51(1):345–75. Available from: https://doi.org/10.1146/annurev.psych.51.1.345

96. Pérez D, Lefèvre P, Castro M, Sánchez L, Toledo ME, Vanlerberghe V, et al. Process-oriented fidelity research assists in evaluation, adjustment and scaling-up of community-based interventions. Health Policy Plan. 2011;26(5):413–22.

97. Ridde V, Druetz T, Poppy S, Kouanda S, Haddad S. Implementation Fidelity of the National Malaria Control Program in Burkina Faso. PLoS One [Internet]. 2013 Jul 17;8(7). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3724672/

98. Asiimwe C, Kyabayinze DJ, Kyalisiima Z, Nabakooza J, Bajabaite M, Counihan H, et al. Early experiences on the feasibility, acceptability, and use of malaria rapid diagnostic tests at peripheral health centres in Uganda-insights into some barriers and facilitators. Implement Sci. 2012;

99. Pulford J, Smith I, Mueller I, Siba PM, Hetzel MW. Health Worker Compliance with a 'Test And Treat' Malaria Case Management Protocol in Papua New Guinea. PLoS One [Internet]. 2016 Jul 23;11(7):e0158780. Available from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0158780

100. Afoakwah C, Deng X, Onur I. Malaria infection among children under-five: the use of large-scale interventions in Ghana. BMC Public Health [Internet]. 2018 Apr 23 [cited 2018 Oct 19];18(1):536. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29685120

101. Ochodo E, Garner P, Sinclair D. Achieving universal testing for malaria. Vol. 352, BMJ (Online). 2016.

102. Owczarzak J, Broaddus M, Pinkerton S. A qualitative analysis of the concepts of fidelity and adaptation in the implementation of an evidence-based HIV prevention intervention. Health Educ Res [Internet]. 2016 Apr;31(2):283–94. Available from: https://academic.oup.com/her/article-lookup/doi/10.1093/her/cyw012

103. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci [Internet]. 2017 Aug 29 [cited 2018 Apr 13];12(1):108. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28851459

104. Mangham-Jefferies L, Hanson K, Mbacham W, Onwujekwe O, Wiseman V. Mind the gap: Knowledge and practice of providers treating uncomplicated malaria at public and mission health facilities, pharmacies and drug stores in Cameroon and Nigeria. Health Policy Plan. 2015;30(9).

105. Durlak JA, DuPre EP. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. Am J Community Psychol [Internet]. 2008 Jun 1 [cited 2018 Apr 2];41(3–4):327–50. Available from: http://doi.wiley.com/10.1007/s10464-008-9165-0

106. Helfrich CD, Weiner BJ, McKinney MM, Minasian L. Determinants of implementation effectiveness: Adapting a framework for complex innovations. Med Care Res Rev. 2007;64(3):279–303.

107. Nilsen P. Making sense of implementation theories, models and frameworks. 2015 [cited 2018 Apr 4]; Available from: https://implementationscience.biomedcentral.com/track/pdf/10.1186/s13012-015-0242-0

108. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: Models for dissemination and implementation research. Am J Prev Med. 2012;43(3):337–50.

109. Ridde V, Druetz T, Poppy S, Kouanda S, Haddad S. Implementation fidelity of the national malaria control program in Burkina Faso. PLoS One. 2013;

110. Bamiselu OF, Ajayi I, Fawole O, Dairo D, Ajumobi O, Oladimeji A, et al. Adherence to malaria diagnosis and treatment guidelines among healthcare workers in Ogun State, Nigeria. BMC Public Health. 2016;16(1).

111. Skelly A, Dettori J, Brodt E. Assessing bias: the importance of considering confounding. Evid Based Spine Care J. 2012;

112. Bruce N, Pope D, Stanistreet D. Quantitative Methods for Health Research: A Practical Interactive Guide to Epidemiology and Statistics. Quantitative Methods for Health Research: A Practical Interactive Guide to Epidemiology and Statistics. 2008.

113. Ngugi E, Kipruto S, Samoei P, Kamula GM, Sivi-Njonjo K, Lakin J, et al. Exploring Kenya's Inequality: Kisumu County [Internet]. Nairobi; 2017. Available from: http://pai.org/wp-content/uploads/2014/07/PAI_Kisumu.pdf

114. Kenya National Bureau of Statistics. County statistical abstract Kisumu county 2015 [Internet]. 2015. Available from: https://www.knbs.or.ke/download/kisumu/

115. Çakır H, Cengiz Ö. The Use of Open Ended versus Closed Ended Questions in Turkish Classrooms. Open J Mod Linguist [Internet]. 2016 [cited 2019 Aug 19];6:60–70. Available from: http://www.scirp.org/journal/ojmlhttp://dx.doi.org/10.4236/ojml.2016.62006http://dx.doi.org/10.4236/ojml.2016.62006http://creativecommons.org/licenses/by/4.0/

116. Alva Eckhard Kleinau Amanda Pomeroy Kathy Rowan S. Measuring the Impact of Health Systems Strengthening A Review of the Literature Measuring the Impact of Health Systems Strengthening A Review of the Literature Written by (in alphabetical order) [Internet]. 2009 [cited 2018 Sep 30]. Available from: https://www.k4health.org/sites/default/files/measuring reform hss.pdf

117. World Health Organization. Quality of care: A process for making strategic choices in health systems. J Am Med Assoc [Internet]. 2006;267:1–50. Available from: http://www.who.int/management/quality/assurance/QualityCare_B.Def.pdf

118. World Health Organization. Case Management Guide for Tutors: TRAINING MODULE ON MALARIA CONTROL. 2012 [cited 2018 Sep 29]; Available from:

www.who.int

119. World Health Organization. Service Availability and Readiness Assessment (SARA) An annual monitoring system for service delivery Reference Manual [Internet]. 2013 [cited 2018 Sep 30]. Available from: www.who.int

120. Raykov T. Estimation of Composite Reliability for Congeneric Measures. Appl Psychol Meas [Internet]. 1997 Jun 27 [cited 2019 Aug 19];21(2):173–84. Available from: http://journals.sagepub.com/doi/10.1177/01466216970212006

121. Raykov T, Shrout PE. Reliability of Scales With General Structure: Point and Interval Estimation Using a Structural Equation Modeling Approach. Struct Equ Model A Multidiscip J [Internet]. 2002 Apr [cited 2019 Aug 19];9(2):195–212. Available from: http://www.tandfonline.com/doi/abs/10.1207/S15328007SEM0902_3

122. Yang Y, Green SB. Coefficient alpha: A reliability coefficient for the 21st century? J Psychoeduc Assess [Internet]. 2011 [cited 2019 Aug 12];29(4):377–92. Available from: http://jpa.sagepub.com

123. Boateng GO, Neilands TB, Frongillo EA, Melgar-Quiñonez HR, Young SL. Best Practices for Developing and Validating Scales for Health, Social, and Behavioral Research: A Primer. Front Public Heal [Internet]. 2018 [cited 2019 Aug 12];6:149. Available from: www.frontiersin.org

124. Tavakol M, Dennick R. Making sense of Cronbach's alpha. Int J Med Educ [Internet]. 2011 Jun 27 [cited 2019 Aug 19];2:53–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28029643

125. Zaid M, Yahya M;, Zainal B;, Sayadi A, Rasid A, Razzaq A, et al. Validation Measurement Model of Emotional Intelligence among Technical Teachers in Vocational Colleges Ministry of Education Malaysia [Internet]. 2017 [cited 2019 Aug 19]. Available from: https://pdfs.semanticscholar.org/f37e/2fa2b8826aedfc8b86d4eff5f6a090f5ef82.pdf

126. Fornell C, Larcker DF. Evaluating Structural Equation Models with Unobservable Variables and Measurement Error. J Mark Res [Internet]. 1981 Feb [cited 2019 Aug 19];18(1):39. Available from: https://www.jstor.org/stable/3151312?origin=crossref

127. Drost AE. Validity and Reliability in Social Science Research. Int Perspect High Educ Res [Internet]. 2011 [cited 2019 Aug 19];38(1):105–24. Available from: https://www.researchgate.net/publication/261473819_Validity_and_Reliability_in_Social_Science_Research

128. Furr RM, Bacharach VR. Psychometrics : An Introduction [Internet]. 2nd ed. SAGE Publications, Inc; 2013 [cited 2019 Aug 19]. 351–352 p. Available from: http://93.174.95.29/_ads/B89D0DE552D1F9BC7422AC6F0C2CF3A3

129. Mosby. Mosby's Medical Dictionary. 10th ed. 2016. 2000 p.

130. Hutcheson GD, Sofronious N. The multivariate social scientist : introductory statistics using generalized linear models [Internet]. Sage Publications; 1999 [cited 2019 Sep 8]. 276 p. Available from: http://93.174.95.29/_ads/83676C58067D77CAEAAE249CC6C2068D

131. Field A. Discovering statistics using IBM SPSS statistics [Internet]. 2018 [cited 2019 Sep 8]. 1070 p. Available from: http://93.174.95.29/_ads/75CCC20CC5CACEC5FB3B02FCE0DE6038

132. Campbell DT, Fiske DW. Psychological Bulletin CONVERGENT AND DISCRIMINANT VALIDATION BY THE MULTITRAIT-MULTIMETHOD MATRIX 1 [Internet]. 1959 [cited 2019 Aug 19]. Available from: https://www2.psych.ubc.ca/~schaller/528Readings/CampbellFiske1959.pdf

133. Bland JM, Altman DG. Cronbach's alpha. BMJ [Internet]. 1997 Feb 22 [cited 2019 Aug 19];314(7080):572. Available from: http://www.ncbi.nlm.nih.gov/pubmed/9055718

134. Case LD, Ambrosius WT. Power and sample size. Methods in molecular biology (Clifton, N.J.). 2007.

135. Suresh K, Chandrashekara S. Sample size estimation and power analysis for clinical research studies. Journal of Human Reproductive Sciences. 2012.

136. Kwarteng A, Asante KP, Abokyi L, Gyaase S, Febir LG, Mahama E, et al. Provider compliance to artemisinin-based combination therapy at primary health care facilities in the middle belt of Ghana. Malar J. 2015;14(1).

137. Lal S, Ndyomugenyi R, Paintain L, Alexander ND, Hansen KS, Magnussen P, et al. Community health workers adherence to referral guidelines: evidence from studies introducing RDTs in two malaria transmission settings in Uganda. Malar J. 2016;15(1):1–13.

138. Chaisson LH, Katamba A, Haguma P, Ochom E, Ayakaka I, Mugabe F, et al. Theory-informed interventions to improve the quality of tuberculosis evaluation at Ugandan health centers: A quasi-experimental study. PLoS One. 2015;

139. Bruxvoort KJ, Leurent B, Chandler CIR, Ansah EK, Baiden F, Björkman A, et al. The Impact of Introducing Malaria Rapid Diagnostic Tests on Fever Case Management: A Synthesis of Ten Studies from the ACT Consortium. Am J Trop Med Hyg [Internet]. 2017 Oct [cited 2019 Aug 27];97(4):1170–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28820705

140. D'Alessandro U, Ubben D, Hamed K, Ceesay SJ, Okebe J, Taal M, et al. Malaria in infants aged less than six months - is it an area of unmet medical need? Malar J [Internet]. 2012 Dec 2 [cited 2018 Oct 22];11(1):400. Available from: http://malariajournal.biomedcentral.com/articles/10.1186/1475-2875-11-400

141. Chandler CIR, Meta J, Ponzo C, Nasuwa F, Kessy J, Mbakilwa H, et al. The development of effective behaviour change interventions to support the use of malaria rapid diagnostic tests by Tanzanian clinicians. Implement Sci [Internet]. 2014 Dec 26 [cited 2019 Aug 27];9(1):83. Available from: http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-9-83

142. Rambaud-Althaus C, Shao AF, Kahama-Maro J, Genton B, d'Acremont V. Managing the Sick Child in the Era of Declining Malaria Transmission: Development of ALMANACH, an Electronic Algorithm for Appropriate Use of Antimicrobials. Borrmann S, editor. PLoS One [Internet]. 2015 Jul 10 [cited 2019 Aug 27];10(7):e0127674. Available from: https://dx.plos.org/10.1371/journal.pone.0127674

143. Abdelgader TM, Ibrahim AM, Elmardi KA, Githinji S, Zurovac D, Snow RW, et al. Progress towards implementation of ACT malaria case-management in public health facilities in the Republic of Sudan: A cluster-sample survey. BMC Public Health. 2012.

144. Martin U, Mercer SW. A comparison of general practitioners prescribing of gluten-free foods for the treatment of coeliac disease with national prescribing guidelines. J Hum Nutr Diet [Internet]. 2014;27(1):96–104. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/jhn.12116

145. Hansen WB. Pilot test results comparing the All Stars program with seventh grade DARE: Program integrity and mediating variable analysis. Subst Use Misuse. 1996;31(10):1359–77.

146. Gouni-Berthold I, Berthold HK. Role of Physician Gender in Drug Therapy BT - Sex and Gender Differences in Pharmacology. In: Regitz-Zagrosek V, editor. Berlin, Heidelberg, Heidelberg: Springer Berlin Heidelberg; 2012. p. 183–208. Available from: https://doi.org/10.1007/978-3-642-30726-3_10

147. Ward R, Stevens C, Brentnall P, Briddon J. The attitudes of health care staff to information technology: a comprehensive review of the research literature. Heal Inf Libr J [Internet]. 2008 Jun 1;25(2):81–97. Available from: https://doi.org/10.1111/j.1471-1842.2008.00777.x

148. Wasunna B, Zurovac D, Goodman CA, Snow RW. Why don't health workers prescribe ACT? A qualitative study of factors affecting the prescription of artemether-lumefantrine. Malar J. 2008;

149. Shah MP, Briggs-Hagen M, Chinkhumba J, Bauleni A, Chalira A, Moyo D, et al. Adherence to national guidelines for the diagnosis and management of severe malaria: A nationwide, cross-sectional survey in Malawi, 2012. Vol. 15, Malaria Journal. 2016.

150. Soumya A, Eckhard K, Amanda P, Kathy R. Measuring the Impact of Health Systems Strengthening: A Review of the Literature [Internet]. 2009 [cited 2019 Aug 19]. Available from: https://www.k4health.org/sites/default/files/measuring reform hss.pdf

151. Leatherman S, Ferris TG, Berwick D, Omaswa F, Crisp N, Cris P. The role of quality improvement in strengthening health systems in developing countries. Int J Qual Heal Care. 2010;22(4):237–43.

Appendix A1 : Signed Plagiarism Declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I _Maero Athanasius Lutta______________ (Student number: __1905380 ___) am a student registered for the degree of _MSc. Epidemiology in the field of Implementation Science _ in the academic year _2020__.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: ______ ___________________ Date: __27th March 2020________________

Appendix A2: Turnitin Report – Score Page

1905380:Maero_IF_for_malaria_test_and_treat_guideline_Repor.

ORIGINALITY REPORT

4%	2%	3%	%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	worldwidescience.org Internet Source	1%
2	www.researchsquare.com Internet Source	<1%
3	Adela Budimu, Basiliana Emidi, Sixbert Mkumbaye, Debora C. Kajeguka. "Adherence, Awareness, Access, and Use of Standard Diagnosis and Treatment Guideline for Malaria Case Management among Healthcare Workers in Meatu, Tanzania", Journal of Tropical Medicine, 2020 Publication	<1%

Appendix A3: Questionnaire

Questionnaire ID ……………. **Date of Interview:** dd / mm / yyyy
Facility Name: ………………………………… **Facility Type**: Public ☐ Private ☐

Section A1: Provider Characteristics ~ Health Provider Socio-demographics

1. Age of Provider (in years): ……………………..
2. Sex: Male ☐ Female ☐
3. Profession / Cadre:

Medical Doctor ☐ Nurse ☐ Clinical Officer ☐ Medical Officer Intern ☐
Clinical Officer Intern ☐ Other (specify): ………………………………………

4. How long have you provided treatment on malaria (in years)?

Section A2: Provider Characteristics ~ Provider's Knowledge of Malaria

5. Microscopic examination of a blood smear **cannot** be used to diagnose malaria. True ☐ False ☐
6. Malaria Rapid Diagnostic Test (mRDT) can be used to confirm a diagnosis of suspected malaria. True ☐ False ☐
7. Patients suspected to have uncomplicated malaria do **not** have to be tested for malaria to confirm if they have malaria True ☐ False ☐
8. Coartem/AL is the first-line drug used for treating uncomplicated malaria? True ☐ False ☐
9. Artesunate does **not** treat severe malaria? True ☐ False ☐
10. Convulsions or loss of consciousness are signs of **uncomplicated** malaria. True ☐ False ☐
11. Piperaquine is recommended for treating **uncomplicated** malaria? True ☐ False ☐
12. Piperaquine is **only** indicated if a patient with **uncomplicated** malaria fails to respond on AL after 3 days of treatment True ☐ False ☐
13. Malaria RDTs **can be used** reliably to **detect treatment failure** within 21 days of the previous infection True ☐ False ☐
14. Primaquine is **not** recommended for uncomplicated vivax malaria infection True ☐ False ☐

Section B: Implementation Fidelity of Malaria Test and Treat Guideline

B1: Content / Adherence

Procedure	Never	Sometimes	Always
15. I ensure patients seeking treatment are weighed before the consultation	○	○	◉
16. I take the history for all patients seeking treatment for malaria	○	○	○
17. I treat patients with malaria without examining them	○	○	○
18. I use mRDTs without checking the expiry date	○	○	○
19. I use gloves when collecting samples for a malaria test	○	○	○
20. I **do not** wipe the pricking site with a wet swab	○	○	○
21. I **use syringe needles** to prick the finger	○	○	○
22. I wipe off the first drop of blood after a prick	○	○	○
23. It is **not necessary** to use a capillary tube to collect blood for a malaria test	○	○	○

24. I read mRDT **results before 15** minutes	◌	◌	◌
25. I dispose of used **capillary tube in the sharps** box	◌	◌	◌
26. I ensure patients have taken their first dose of antimalarial from the hospital	◌	◌	◌

B2: Dose

27. I request a malaria test for patients when I suspect malaria Never ☐ Occasionally ☐ Always ☐
28. I **prescribe** an antimalarial **when I suspect** uncomplicated malaria
Never ☐ Occasionally ☐ Always ☐
29. I **prescribe** an antimalarial when **malaria test is negative** Never ☐ Occasionally ☐ Always ☐
30. I issue an antimalarial when malaria test is positive Never ☐ Occasionally ☐ Always ☐
31. I prescribe AL for less than three days in patients with uncomplicated malaria
Never ☐ Sometimes ☐ Always ☐
32. I prescribe antimalarial treatment for seven days in patients with severe malaria
Never ☐ Sometimes ☐ Always ☐

B3: Quality of Delivery

Parameter	Agree	Neutral	Disagree
33. Patients wait less than 30 minutes before I treat them	☐	☐	☐
34. I **do not** advise all my patients on the importance of testing for malaria first when I suspect malaria	☐	☐	☐
35. I request patients to **return** for a malaria test on the following day when I get **invalid results** with mRDT	☐	☐	☐
36. I advise patients on when to return to hospital should they not improve on antimalarial	☐	☐	☐

B4: Intervention Differentiation

37. Patients with uncomplicated malaria **do not** need to be admitted for treatment True ☐ False ☐
38. Malaria treatment **can be initiated** before confirming a malaria diagnosis in patients with suspected severe malaria True ☐ False ☐

Section C: Implementation Fidelity Determinants

C1: Facilitation Strategies

39. I have **not** been trained in malaria case management in the past three years? Yes ☐ No ☐
40. I received facility-based mentorship on malaria in the past three months? Yes ☐ No ☐
41. I **do not** have a copy of the malaria case management guideline? Yes ☐ No ☐
42. I have received supportive supervision aimed at improving malaria services in the past six months?
Yes ☐ No ☐
43. mRDTs are always available in the consultation room for testing malaria when serving patients?
Yes ☐ No ☐
44. Antimalarials are **not always** available in the hospital for patients with malaria Yes ☐ No ☐

C2: Nature of the Intervention

45. I have **never tried** using mRDTs for diagnosing malaria before

Disagree ☐ Indifferent ☐ Agree ☐

46. Sometimes I request microscopic diagnosis for malaria **instead of** testing with mRDT in the clinic

Disagree ☐ Indifferent ☐ Agree ☐

47. The malaria guideline is **not clear** on the clinician's role in treating malaria

Disagree ☐ Indifferent ☐ Agree ☐

C3: Participant Responsiveness

48. Patients suspected of malaria **do not accept** to be tested first before being issued antimalarial.

Each time ☐ Sometimes ☐ Never ☐

49. Patients that test negative for malaria agree to be treated for other medical conditions and not malaria.

Each time ☐ Sometimes ☐ Never ☐

C4: Implementation Context

Questions: 50 to 55: *which statement is most applicable to malaria services in this facility?*

Statement	Never	Occasionally	Always
50. Medical colleagues **request** antimalarial treatment **without undergoing** a malaria test	☐	☐	☐
51. I have the required non-pharmaceutical supplies to allow testing for malaria	☐	☐	☐
52. The administration **does not** ensure that the workload at the OPD is manageable by assigning staff duties well	☐	☐	☐
53. Malaria or laboratory coordinator cross-checks microscopy results at least once each quarter	☐	☐	☐
54. The funds allocated to malaria treatment are **not adequate**	☐	☐	☐
55. We have a multi-disciplinary team for the OPD that reviews records and malaria treatment	☐	☐	☐

End

************ **Thank You** ************

Appendix A4: Information Sheet

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

STUDY INFORMATION SHEET

Introduction

Good day, I am *Maero Lutta* a Master Science Epidemiology (field of Implementation Science) student at The University of The Witwatersrand in South Africa. I invite you to participate in a research study, "**Implementation Fidelity of Malaria Test and Treat Guidelines amongst Healthcare Providers in Kisumu, Kenya, 2019.**" This study is sponsored by WHO / TDR and Maero Athanasius Lutta is the Principal Investigator.

Purpose of the Study

The study aims to assess implementation fidelity for malaria test and treat guidelines, and its determinants, amongst health workers in the outpatient department (OPD) at Kisumu County, in 2019.

Procedures: What will happen if you participate?

It will take between 15 & 30 minutes of your time to answer about 50 questions. The questions will be read to you, and most of them are closed-ended.

Some of the things you should know about this research study are:

1) You are free to volunteer to participate in the study, and that you are free to withdraw from the study at any point. This document is to assist you to decide if you will participate.
2) Before accepting to participate in this study, it is important that you fully understand the study purpose, procedures, benefits and risks that may be involved.
3) You are free to speak your mind, and that the responses you give during participation will be treated anonymously.
4) You are free to ask questions and seek clarifications regarding the study.
5) You are free not to respond to any study questions.
6) Only a study number will be assigned to your participation, and therefore all your responses will be kept anonymous.
7) Your responses will be captured on a password-protected research laptop which is only accessible to the researcher.
8) There is no direct benefit for participating in this study. But, since this is academic research your participation will help answer the research question.
9) Should you have any questions about this study, please contact me at any time via cell phone +254 729 842 614 and/or email maerolutta@gmail.com.

10) The research report will be available online through the university's library. Should you wish to receive a summary of the report, we will be delighted to send it to you on request.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee") and Jaramogi Oginga Odinga Teaching and Referral Hospital Ethics and Review Committee (JOOTRH ERC). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za; and the Secretariat of JOOTRH ERC on telephone number 057-20 20 801 or -20 20 803 or -20 20 321 or cell phone number 0723 431 452, or email ercjootrh@gmail.com. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Date: MM / YYYY

Yours Sincerely,

Maero Athanasius Lutta

Email: maerolutta@gmail.com or 1905380@students.wits.ac.za

Cell phone: +254 729 842614

Internal Study Supervisor

Professor Latifat Ibisomi

Email: Latifat.Ibisomi@wits.ac.za

Cell phone: +27 11 717 2607

Local Study Supervisor

Dr Martin Atela

Email: m.atelah@googlemail.com

Cell phone: +254 733 280 413

20180329

Iain0007/InfoSheet

Appendix A5: Informed Consent Form

Participant Interview Informed Consent Form

Study Title: Implementation Fidelity of Malaria Test and Treat Guidelines amongst Healthcare Providers in Kisumu, Kenya, 2019

Study Purpose: To assess implementation fidelity for malaria test and treat guidelines, and its determinants, amongst health care providers in the outpatient department (OPD) in health facilities in Kisumu County, Kenya.

The institution (s): The University of the Witwatersrand, Johannesburg, South Africa

I the undersigned, confirm that I have been given information about the study.

Therefore,

- I agree to voluntarily participate in this research project.
- I have read this consent form and the information it contains and has had the opportunity to ask questions about the study.
- I agree with my responses being used for education and research on the condition that my privacy is respected, subject to the following:
  - ➢ I understand that my personal details will not be included in the research; otherwise, will be used in aggregate form only, so that I will not be personally identifiable;
  - ➢ I understand that I am under no obligation to take part in this project.
  - ➢ I understand that I have the right to withdraw from this study at any stage.

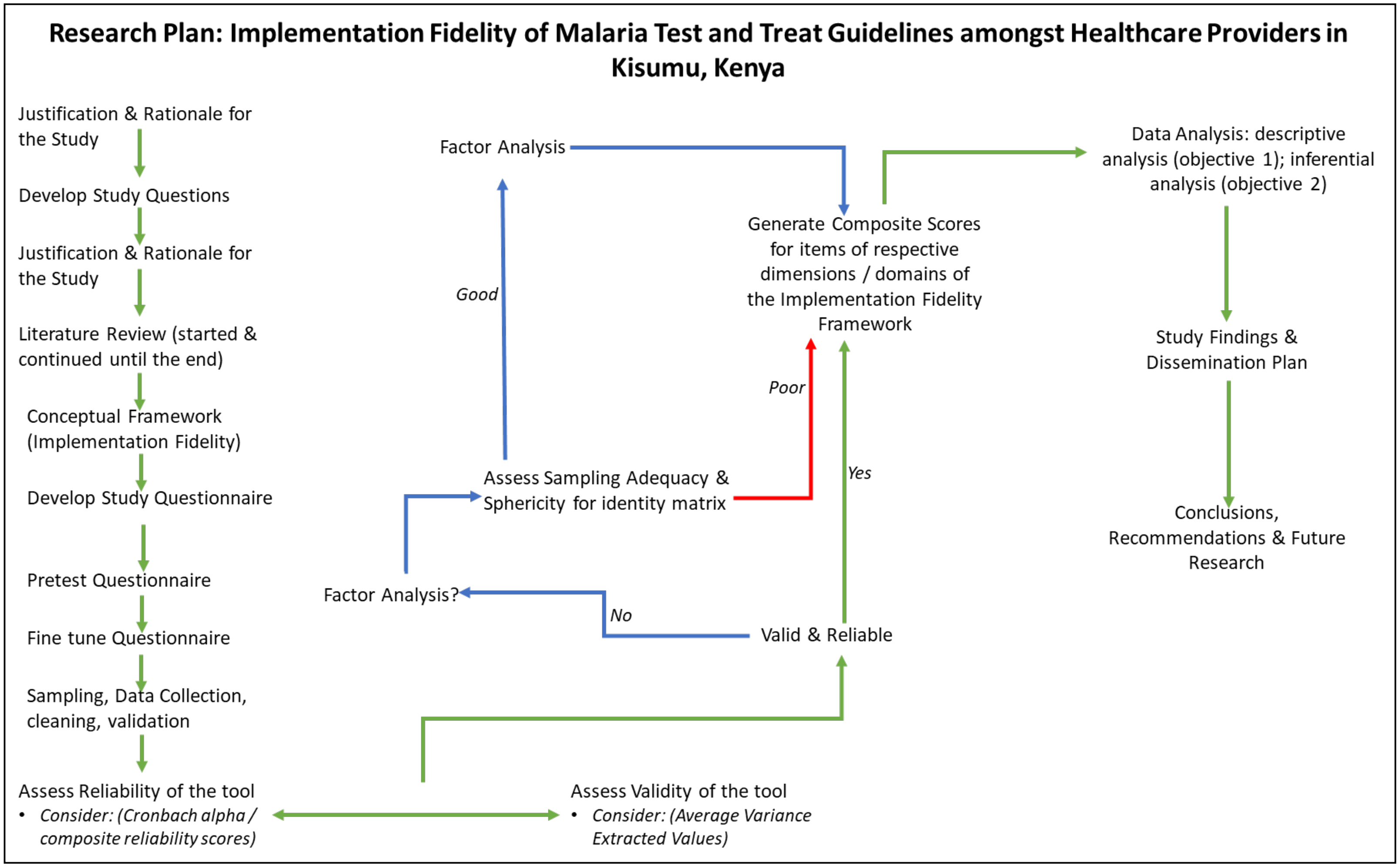
(Make a tick/cross in the box below)

☐ I hereby consent to participate in this research study.

Interviewee's Signature: ………………………………. Date: dd / mm / yyyy

Interviewer's Signature: ………………………………. Date: dd / mm / yyyy

Appendix A6: The Executed Research Plan



Appendix B1: HREC (Medical) Ethics

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Mr AL Maero
School of Public HealthSchool of Public Health
Medical School
University

E-mail: maerolutta@gmail.com

CC: Supervisor: Professor L Ibisomi <Latifat.Ibisomi@wits.ac.za>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 10/05/2019

REF: *R14/49*

PROTOCOL NO: M181173 *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: *Implementation fidelity of Malaria Test and Treat Guidelines amongst healthcare providers in Kisumu, Kenya, 2019*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

Appendix B2: JOOTRH ERC Clearance

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

Ref: ERC.IB/VOL.1/569

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

Date 14th March, 2019

Maero Athanasius Lutta

Dear Maero,

RE: FORMAL APPROVAL OF THE PROTOCOL STUDY ENTITILED: IMPLEMENTATION FIDELITY OF MALARIA TEST AND TREAT GUIDELINES AMONGST HEALTHCARE PROVIDERS IN KISUMU, KENYA, 2019

The JOOTRH ERC reviewed your protocol and found it ethically satisfactory. You are therefore permitted to commence your study immediately. Note that this approval is granted for a period of one year (w.e.f. 14th March, 2019 to 14th March, 2020). If it is necessary to proceed with this research beyond approved period, you will be required to apply for further extension to the committee.

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

In case the study site is JOOTRH, kindly report to the Chief Executive Officer before commencement of data collection.

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

The JOOTRH – IERC takes this opportunity to thank you for choosing the Institution and wishes you the best in your future endeavours.

Yours sincerely,

INSTITUTIONAL ETHICS & REVIEW COMMITTEE
14 MAR 2019
JOOTRH

for: WILBRODA N. MAKUNDA
SECRETARY- IERC
JOOTRH - KISUMU

Appendix C1: Map of Study Area

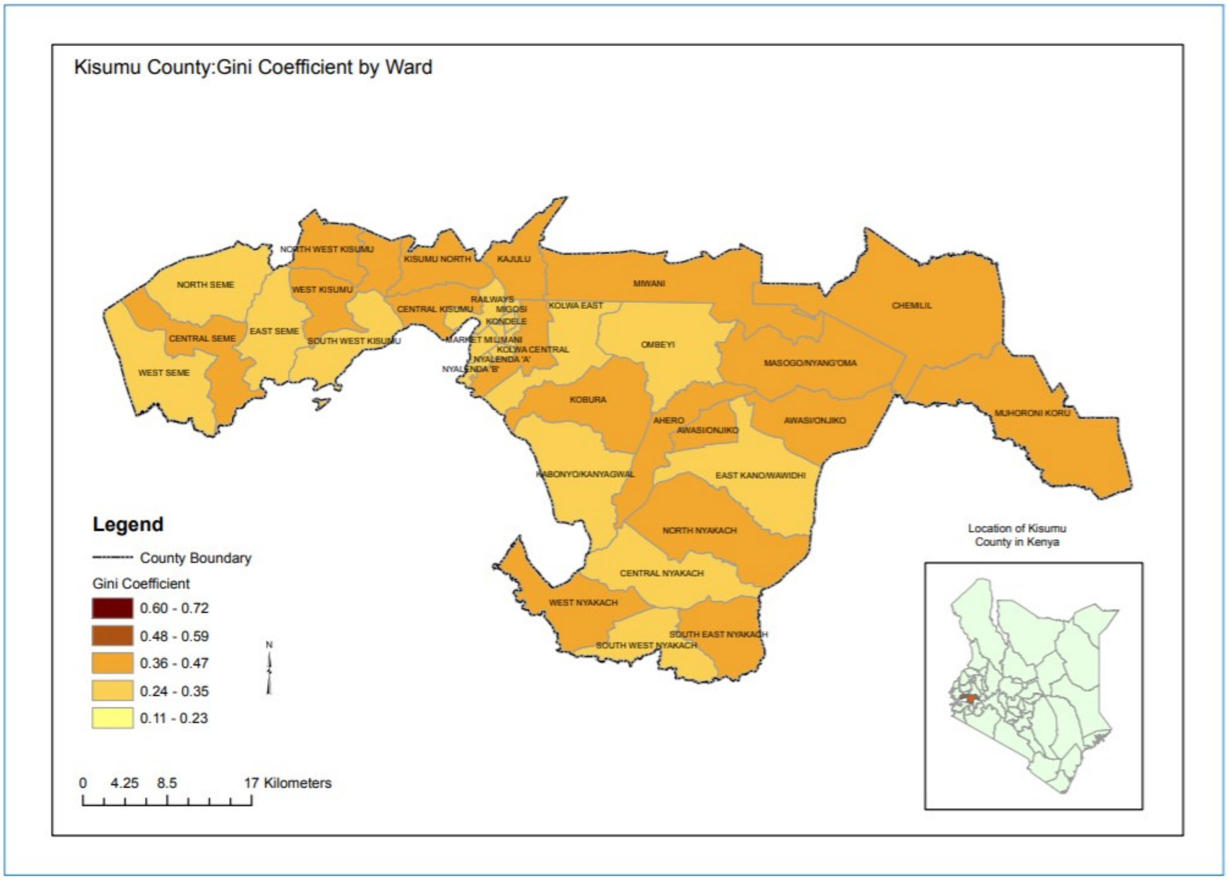


Figure C1: Map for the Study Area

Source: Exploring Kenya's Inequality: Kisumu County(113)

Appendix C2: Random Cluster Selection

Table C1: Random Number Table Used for Random Cluster Selection

Sub County	Excel Generated Random Numbers
Kisumu Central	0.134170936
Kisumu East	0.136827858
Kisumu West	0.348293641
Nyakach	0.388527435
Muhoroni	0.409521512
Seme	0.47923723
Nyando	0.516338727

Appendix C3: List of Study Facilities and the Distribution of Participants

Table C2: Table Showing the List of Study Facilities and the Distribution of Participants

No.	Facility Name	Facility Type	Participants	Percent
1.	AAR Health Care-Kisumu	Private	1	0.81
2.	Avenue Hospital Kisumu	Private	4	3.25
3.	Bliss GVS Health Care -Mega Plaza	Private	2	1.63
4.	Gods Will Clinic	Private	2	1.63
5.	Interfelk Medical Centre	Private	2	1.63
6.	Inuka Medical Center	Private	2	1.63
7.	Jalaram Nursing Home	Private	3	2.44
8.	Jaramogi Oginga Odinga Teaching Referral	Public	15	12.20
9.	Joy Paediatric Medical Center	Private	3	2.44
10.	Kisumu County Hospital	Public	18	14.63
11.	Kisumu Police Lines Dispensary	Public	4	3.25
12.	Lumumba Sub County Hospital	Public	18	14.63
13.	Medicross Clinic	Private	1	0.81
14.	Meridian Medical Centre-Kisumu	Private	1	0.81
15.	Migosi Sub County	Public	7	5.69
16.	Milimani Hospital	Private	11	8.94
17.	Nyalenda Health Centre	Public	6	4.88
18.	Railways Dispensary (Kisumu)	Public	5	4.07
19.	St Judes Clinic	Private	1	0.81
20.	St Vincent Clinic (Kisumu East)	Private	1	0.81
21.	St. Lydia Okore Dispensary	Private	1	0.81
22.	Star Maternity & Nursing Home	Private	3	2.44
23.	Tayib Aisha	Private	1	0.81
24.	Marie Stopes	Private	3	2.44
25.	St Jones & Ring Road Health Clinic	Private	1	0.81
26.	Family Health Options Kenya	Private	2	1.63
27.	Ahava Medical Clinic	Private	1	0.81
28.	Helsamy Clinic	Private	1	0.81
29.	Prime Care Medical	Private	1	0.81
30.	Global International	Private	2	1.63
	Total		123	100%

Appendix D1: Exploratory Data Assessment and Post Estimation Tests

The correlation of implementation fidelity and its determinants was assessed by plotting a matrix graph (Figure D1). The graph matrix suggested collinearity between the variables, implementation context (context_percent) and participant responsiveness (PR_percent). Therefore, participant responsiveness was excluded from the regression analyses.

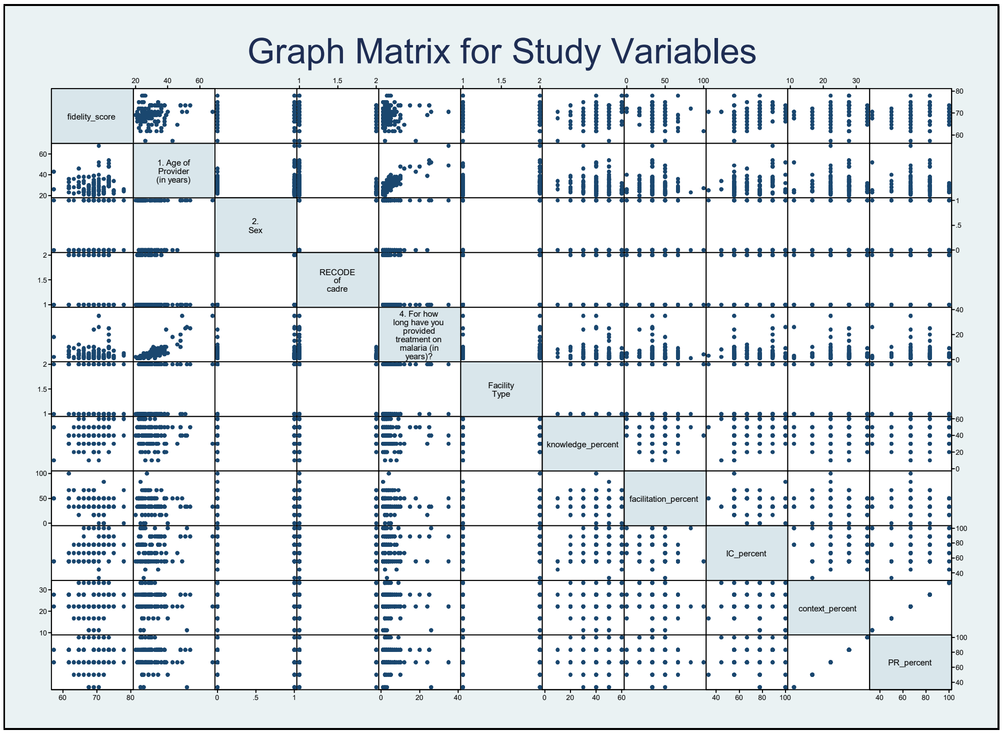


Figure D1: Graph Matrix for Study Variables

The full multiple regression model (Model 1, Appendix D2) was run and its residuals predicted. Post-estimation results:

- The p-value for normality based on Smirnov-Kolmogorov was 0.0382.
- The p-value for the Breusch-Pagan / Cook-Weisberg test for constant variance was 0.0057.
- The variance inflation factor (VIF) scores were below 10.0 with an overall score of 1.93, suggesting a lack of multicollinearity among the variables in the model.
- Durbin-Watson d-statistic of 1.9534 refuted the presence of autocorrelation in the model.

Given the p-values for the normality test and test for constant variance, the residuals do not approximate normality and are heteroskedastic violating the indication of linear regression (Model 1, Appendix D2). We examined the effect of transforming the outcome variable through a Qladder plot (Figure D2) but observed that transformation would not improve the data for analysis. Hence, a non-parametric regression model (bootstrap regression) was selected (Model 2, Appendix D2).

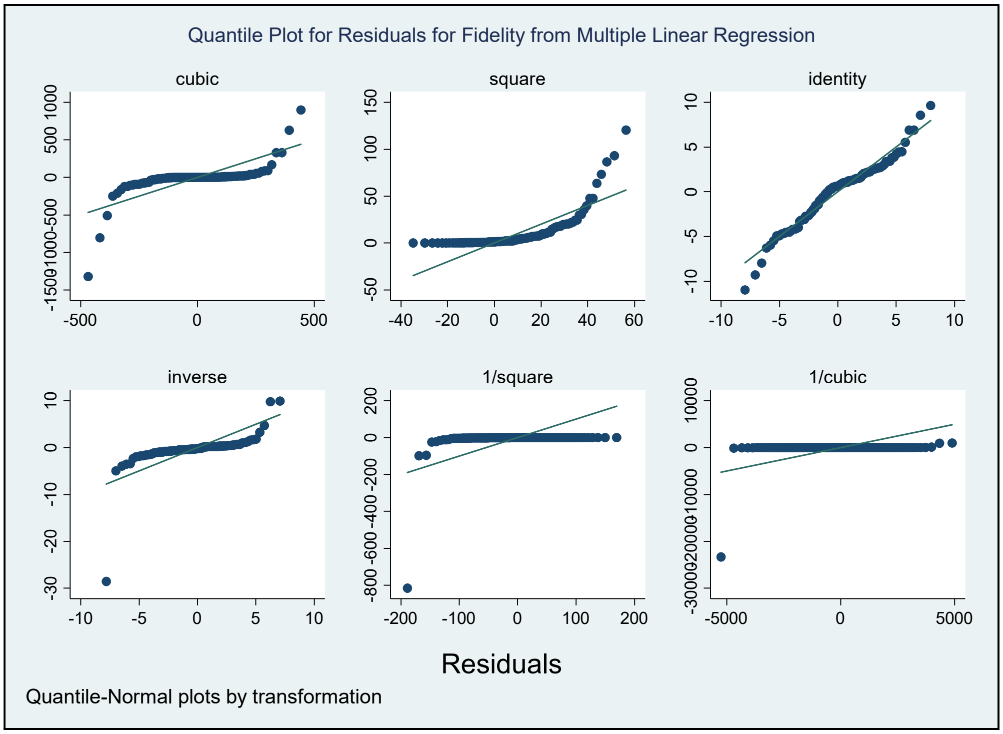


Figure D2: Qladder Plot for the Residuals of Implementation Fidelity

No outlier influence was demonstrated.

Appendix D2: Table Comparing Regression Analysis Models for Implementation Fidelity

Table D1: Comparing Regression Analysis Models for Implementation Fidelity and its Determinants

Variable	Model 1 Coefficients		Model 2 Bootstrap Coefficients	
	Coefficient (95% CI)	p-value	Coefficient	p-value
Age (years)	0.04 (-0.12 - 0.21)	0.6510	0.04 (-0.10 – 0.18)	0.6380
Sex				
Male (reference)	0.00	0	0	0
Female	0.43 (-0.86 – 1.72)	0.5120	0.43 (-0.96 – 1.82)	0.5340
Provider				
Clinician (reference)	0.00	0	0	0
Non-clinician	-1.48 (-3.01 – 0.05)	0.0570*	-1.48 (-3.03 – 0.06)	0.0570*
Experience treating malaria in years	0.04 (-0.24 – 0.17)	0.7300	-0.04 (-0.20 – 0.13)	0.7040
Facility				
Public	0.00	0	0	0
Private	-0.41 (-0.17 – 0.90)	0.5380	-0.41 (-1.77 – 0.95)	0.5670
Knowledge of Malaria	0.07 (0.02 – 0.11)	0.0120**	0.07 (-0.01 – 0.14)	0.0710*
Facilitation Strategies	-0.06 (-0.10 - -0.02)	0.0030***	-0.06 (-0.09 - -0.02)	0.0010***
Nature of Intervention	0.06 (0.02 – 0.11)	0.0100**	0.06 (0.01 – 0.12)	0.0190***
Implementation Context	0.09 (-0.04 – 0.23)	0.1780	0.09 (-0.03 – 0.22)	0.1480
_cons	61.56***	<0.0001	61.56***	<0.0001
N	123		123	
R – Squared	0.324		0.324	
Adjusted R – Squared	0.270		0.270	
Root Mean Squared Error	3.433		3.433	

*** p<0.01, ** p<0.05, * p<0.1; 95% CI = 95% confidence interval; R-squared (adjusted model) = 32.4%

The two models have similar estimates of the population parameters.

Appendix D3: Table Showing the Distribution of the Study Participants by Designation and Facility Type

Table D2: Distribution of the Study Participants by Designation and Facility Type

Provider	Cadre/Designation	Public Facility (n)	Private Facility (n)	Total
Clinician	Clinical Officer	10	13	23
	Clinical Officer Intern	6	2	8
	Doctor	3	3	6
	Doctor Intern	2	1	3
	Nurse	28	15	43
	Nurse Intern	1	0	1
	Nurse Student	1	0	1
	Nutritionist	1	0	1
	Pharmacist	3	5	8
	Sub-total	55	39	94
Non-clinician	Community Health Worker	3	0	3
	Counsellor	0	1	1
	Laboratory Technologist	13	9	22
	Public Health Officer	1	1	2
	Research Officer	1	0	1
	Sub-total	18	11	29
Total		**73**	**50**	**123**

Appendix D4: Bar Chart Illustrating Fidelity Scores by the Cadres of the Study Participants

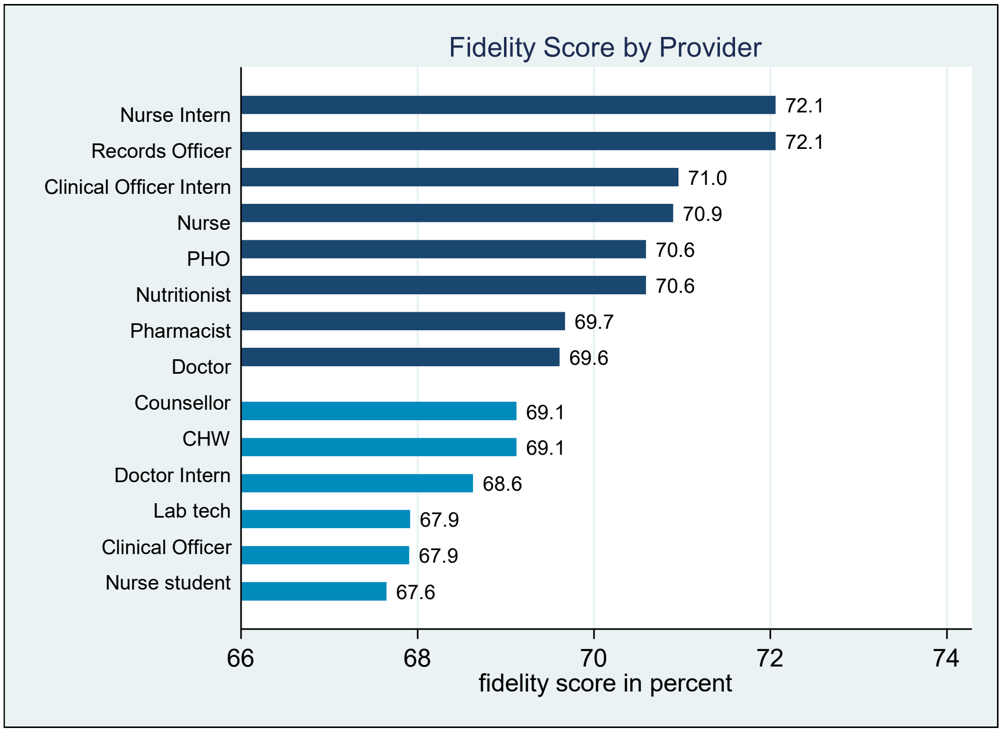


Figure D3: Bar Chart Illustrating Fidelity Scores by the Cadres of Study Participants

Appendix D5: Relationship between Implementation Fidelity of Malaria test and treat Guidelines and its Determinants amongst HCPs

Table D3: Relationship between Implementation Fidelity of Malaria Test and Treat Guidelines and its Determinants amongst Healthcare Providers

Variable	Unadjusted Model		Adjusted Model	
	Coefficient (95% CI)	**P-value**	**Coefficient (95% CI)**	**P-value**
Age (years)	0.05 (-0.01 - 0.12)	0.1010	0.04 (-0.10 – 0.18)	0.6380
Sex				
Male (reference)	0.00	0	0	0
Female	1.49 (0.28 – 2.95)	0.0460**	0.43 (-0.96 – 1.82)	0.5340
Provider				
Clinician (reference)	0.00	0	0	0
Non-clinician	-1.48 (-3.53 – 0.58)	0.1590	-1.48 (-3.03 – 0.06)	0.0570*
Experience treating malaria in years	0.03 (-0.07 – 0.12)	0.5980	-0.04 (-0.20 – 0.13)	0.7040
Facility				
Public	0.00	0	0	0
Private	-0.66 (-2.22 – 0.90)	0.4100	-0.41 (-1.77 – 0.95)	0.5670
Knowledge of Malaria	0.11 (0.04 – 0.18)	0.0030***	0.07 (-0.01 – 0.14)	0.0710*
Facilitation Strategies	-0.09 (-0.13 – -0.05)	<0.0001***	-0.06 (-0.09 - -0.02)	0.0010***
Nature of Intervention	0.11 (0.07 – 0.14)	<0.0001***	0.06 (0.01 – 0.12)	0.0190**
Implementation Context	0.13 (-0.01 – 0.28)	0.0680*	0.09 (-0.03 – 0.22)	0.1480
_cons	61.56***	<0.0001	61.56***	<0.0001

*** p<0.01, ** p<0.05, * p<0.1; 95% CI = 95% confidence interval; R-squared (adjusted model) = 32.4%