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UNIVERSITY OF THE WITWATERSRAND



FACULTY OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirement for the degree of Masters of Science in Epidemiology (Implementation Science)

October 2021

DECLARATION

I, Mina WHYTE declare that this research report is my own work. It is being submitted for the award of a Master of Science degree in Epidemiology in the field of Implementation Science to the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination of degree at this or any other University.



12th October 2021

DEDICATION

To God Almighty, my refuge, strength, and ever-present help.

ABSTRACT

Background: Malaria is still a disease of global public health importance and children under-five years of age are the most vulnerable to the disease. Nigeria has the greatest malaria burden worldwide contributing the highest percentage of all malaria cases and deaths. The "test and treat" strategy in the national malaria guidelines is one of the ways the country aims to control malaria transmission. However, the ineffective translation of the national malaria guidelines into clinical practice is a major barrier to achieving success. The aim of this study was to assess the fidelity of implementation of the national guidelines on malaria diagnosis for children under-five years and examine its associated moderating factors in health care facilities in Rivers State, Nigeria.

Methods: This was an analytical cross-sectional study. The study population comprised public, formal private and informal private health care facilities in Port Harcourt metropolis, Rivers State. Data were collected from 147 facilities using a questionnaire developed based on Carroll's Conceptual Framework for Implementation Fidelity. Frequency, mean and median scores for implementation fidelity and its associated factors were calculated. Univariable and multivariable analyses were used to test for associations between implementation fidelity and the measured predictors.

Results: Mean (SD) implementation fidelity score was 61% (23) and median (IQR) score was 65% (43, 85). Informal private facilities (PPMVs) had the lowest fidelity scores (47%) compared to the public (79%) and formal private facilities (69%). Only 13% of sampled health care facilities had the guidelines available but they had a much higher mean fidelity score (79%) than those who did not (59%). Intervention complexity (adjusted coefficient: -1.88 (-3.42, -0.34)), participant responsiveness (adjusted coefficient: 8.57 (4.83, 12.32)), and type of malaria diagnostic test offered at the facility ($p < 0.001$) were significantly associated with implementation fidelity of health care facilities to the malaria test and treat guidelines.

Conclusion: Fidelity of implementation to the malaria "test and treat" strategy was below the national target of 100% among sampled health care facilities in Rivers State, Nigeria. This shows that there are core elements of the guidelines that are still not fully implemented by health care facilities. There is a need for strategies to increase fidelity, especially in the informal private sector, for malaria control programme outcomes to be achieved.

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LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
HIV	Human immunodeficiency virus
LGA	Local government area
PPMV	Proprietary patent medicine vendor
RDT	Rapid diagnostic test
UNITAID	Global health initiative with an emphasis on tuberculosis, malaria, and HIV/AIDS
WHO	World Health Organisation

NOMENCLATURE

Adherence	This is a measure of fidelity, and describes how well the health care facilities followed the guidelines as intended by those who developed it.
Content	The essential or core components of an intervention.
Coverage	This refers to if all the intended recipients of an intervention actually received it.
Facilitation strategies	Supportive measures provided by the programme implementers and/or stakeholders to ensure optimal and standardised fidelity of implementation. These include training, provision of guidelines, supportive supervision etc.
Frequency	How often the intervention was conducted or received by the intended recipients.
Implementation fidelity	The degree to which an intervention is implemented according to its original design or plan.
Intervention complexity	This describes how simple or complex an intervention is perceived to be by the implementers.
Malaria "test and treat" strategy	Diagnosis of all suspected malaria cases with a confirmatory test, either with a rapid diagnostic test (RDT) or microscopy, and prompt and correct treatment.
Presumptive treatment for malaria	Diagnosis and treatment of malaria based on symptoms only, without any confirmatory tests
Participant responsiveness	The level of response, engagement or ownership of an intervention by the implementers or recipients.
Proprietary patent medicine vendor	A person without formal training in pharmacy who sells orthodox pharmaceutical products on a retail basis for profit.

1 CHAPTER ONE: INTRODUCTION

This chapter gives an overview of malaria, its public health burden, and the importance of parasitological diagnosis before treatment with antimalarials or the "test-and-treat" strategy. It summarises some studies that have assessed adherence to the malaria case management guidelines and factors associated with adherence, across different settings. In addition, it introduces the concept of fidelity of implementation and the conceptual framework used as a guide to measure fidelity in this study. Lastly, it describes the evidence gap that exists and will be filled by the study, as well as the study aim and objectives.

1.1 Background

1.1.1 Global burden of malaria

Malaria is an infectious disease caused by Plasmodium parasites which are transmitted to humans through the bite of a female Anopheles mosquito.(1) It is a major public health problem globally, with about 228 million cases and 405 000 deaths annually.(2) Malaria also contributes to the poverty cycle through the reduction of productive labour time for adults, increase in missed school days for children, and greater health expenses for families and countries.(3–6) The huge, ongoing health and socioeconomic impact of malaria made it a specific target of the Sustainable Development Goal 3 which aims to end the malaria epidemic, among other communicable diseases, by 2030.(7) To achieve this, the focus of interventions must be in the Africa and South-East Asia regions as about 96% of the global malaria burden is concentrated in Africa and India.(2) Africa has the highest burden of the disease with 213 million cases (93%) occurring in this region.(2) Six countries account for half of malaria cases globally namely, Nigeria, Democratic Republic of Congo, Uganda, Niger, Mozambique, and Cote D'Ivoire.(2,8) Nigeria has the greatest malaria burden worldwide contributing a quarter (25%) of all malaria cases, and also the highest percentage (24%) of all malaria deaths.(2,9) Children under-five years of age are the most vulnerable to the disease. United Nations Children's Fund claims that "every two minutes a child under five dies of malaria"(10 p1); indeed, 67% of malaria deaths (272 000 deaths) occurred in this age group in 2018.(2) In Africa, malaria causes one out of every five deaths in children

under-five years, and 14% of all deaths in this age group in Nigeria.(10) The significant morbidity and mortality caused by the disease has necessitated the mobilisation of global funding for the control and elimination of malaria.

Substantial investments have been made in malaria control and elimination programmes by the governments of affected countries and their international partners. In 2018, WHO estimated that US$2.7 billion was spent on malaria intervention programmes on high-impact interventions like insecticide treated nets, malaria rapid diagnostic tests (RDTs), and artemisinin-based combination therapy for treatment of uncomplicated malaria.(2,11,12) This contributed to a global downward trend in malaria morbidity and mortality from 239 million cases in 2010 to 217 million cases by 2015.(1,13) However, these gains seem to have stalled between 2016 – 2018 as malaria cases increased in the 10 highest-burden African countries, with Nigeria among three countries that reported an increase of more than 500 000 cases in 2017.(2,13) Some reasons for the resurgence of malaria include weakening of control programmes,(14) higher treatment costs,(3,15) and the emergence of drug-resistant parasites.(13,16,17) In order to halt the rise in cases, a coordinated global response was initiated by the World Health Organisation to develop policy recommendations on malaria.

1.1.2 The "test-and-treat" strategy

The World Health Assembly in 2015 adopted the *Global Technical Strategy for Malaria 2016 –2030* as part of plans to ensure the health-related Millennium Development Goals are supported for completion in the post-2015 era.(1) This global strategy aims to reduce malaria cases and deaths by at least 40% by 2020, 75% by 2025, and 90% by 2030.(1) The strategic framework consists of three pillars, the first of which is ensuring "universal access to malaria prevention, diagnosis and treatment" available to all populations at risk.(18) This has been abbreviated as the "test and treat" strategy.(19,20) Nigeria also rolled out the *National Malaria Strategic Plan 2014 – 2020* in line with WHO's Global Technical Strategy. One of the seven key objectives is *to test all suspected cases of malaria before treatment by 2020*.(21) It discourages all forms of presumptive treatment, i.e. treatment not based on a positive malaria test result. The *Nigeria National Guidelines for Diagnosis and Treatment of Malaria* (2015) were developed to provide clear and comprehensive steps to assist health care providers in achieving this objective.(22)

Based on the national guidelines, malaria diagnosis is done either by use of light microscopy (gold standard) or malaria rapid diagnostic test (RDT) kits.(22) The type of test offered at a facility depends on factors such as the level of the health care facility (primary, secondary or tertiary), skill of the provider and patient caseload.(22) The guidelines recommend microscopy tests for secondary and tertiary level health care facilities, while RDTs can be used at facilities at all levels, and in communities.(22) At least one type of testing method should be available in public and private health care facilities that manage malaria cases.

1.1.3 The health care sector

The health care sector in Nigeria comprises of the public (government-owned facilities) and private health care sectors. The public health care sector is divided into three tiers which correspond with the administration level of government responsible for each tier i.e. federal, state, or local government, according to the provisions of the Nigerian Constitution.(23) While the Federal Government operates facilities that provide tertiary health care services, local governments operate only primary health care facilities, and the state governments run health facilities offering primary, secondary and tertiary care.(24,25)

The private health care sector in Nigeria caters to a higher proportion of health care needs of the populace than the public health care sector, as seen in many low- and middle-income countries.(26,27) The private health care sector is further divided into two; the formal sector (e.g. private hospitals, clinics, pharmacies) and the informal sector (e.g. proprietary patent medicine vendors, traditional medicine providers, etcetera).(28) In both the public and private health care sectors, proprietary patent medicine vendors (PPMVs) experience the highest patronage as a survey in Nigeria reported that most children with febrile illness were taken by their caregivers to a PPMV for treatment (51.1% of all children with febrile illness).(28) Proprietary patent medicine vendors are “persons without formal training in pharmacy who sell orthodox pharmaceutical products on a retail basis for profit”(29 p2) and are licensed by the Pharmaceutical Council of Nigeria to sell only over the counter drugs in their original manufacturer packaging.(30) They make up about 40% of the private health care sector,(30) and are the main point of care in many communities, especially among poor and under-served populations due to quick service delivery, close proximity to clients, flexible operational hours and affordable payment schemes.(31,32) However, poor

compliance with regulations and guidelines regarding health care practices has been noted among PPMVs.(30,33,34) These drug retailers are approved to use RDT kits to test patients before treating for malaria.(35)

1.1.4 Implementation science and fidelity of implementation

Implementation science is "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care".(36 p2) It aims to bridge the "science to service gap", which exists from the problem of many evidence-based interventions being available, but not enough of them having been integrated into routine practice to improve the health care system.(37) According to Durlak and Dupre,(38) developing an intervention, in this instance the national malaria guidelines, is just the first step. Translating it into real world practice, and maintaining it, there is the real challenge.(38)

Therefore, implementation science focuses on "how" an intervention or programme is implemented, as this affects the success or failure of the intervention. Eight implementation outcomes have been identified, which are quite different from intervention or programme outcomes, namely – acceptability, adoption, appropriateness, cost, feasibility, fidelity, reach and sustainability (see Figure 1.1 below).(39) They serve as indicators of the success of implementation, and key intermediate outcomes to clinical or service outcomes.(38,39)

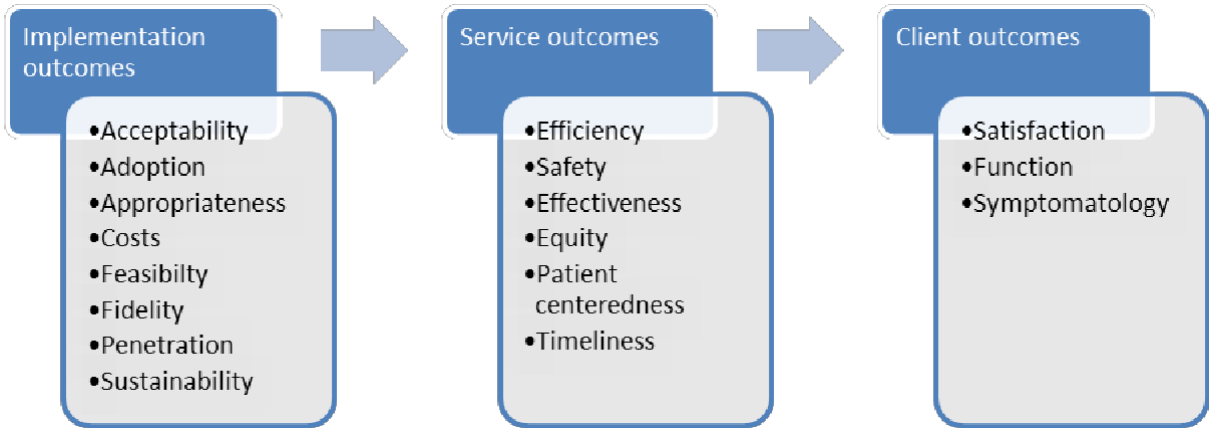


Figure 1.1 Implementation outcomes and their link to service and client outcomes (39)

Fidelity, as an implementation outcome, is an important factor for intervention or programme success. Fidelity of implementation is the degree to which a programme or protocol is implemented as intended by those who originally developed or designed it.(40,41) It is recommended that fidelity needs to be measured for all primary interventions and it is analysed at the level of the individual providers, or the organisation or institution providing the health care service.(39,40) It assists in determining if an intervention failed because it was poorly implemented or due to characteristics of the intervention itself.(42,43) Higher levels of fidelity are usually associated with better programme outcomes.(44) Fidelity of implementation is usually measured in terms of adherence to the protocol or guidelines, the amount of the intervention/programme delivered, or the quality of delivery of the intervention/programme.(39,43) This study chose to measure adherence as our dimension of fidelity, because the intervention of interest is a guideline with outlined steps for health care providers and facilities to follow.

1.2 Literature review

Several studies have been conducted to assess adherence to guidelines in health care settings, even though the definitions of adherence vary. Most studies measured adherence as a categorical outcome based on how well, or if at all, providers performed selected activities listed in the malaria guidelines. The literature looked at adherence to malaria testing before treatment and factors related to compliance by health care providers and health care facilities. It also looked at health care providers characteristics and facility characteristics which are associated with adherence. It also introduces the chosen framework for assessing fidelity of implementation, as well as the key moderators of fidelity.

1.2.1 Adherence to malaria guidelines on testing before treatment

Global studies that have been conducted to assess compliance to malaria case management guidelines show that adherence can differ across various settings. A study carried out across primary health care facilities in Papua New Guinea assessed compliance to the malaria “test and treat” protocol using a checklist.(45) The checklist had sections on specific practices encompassing diagnosis, prescription, and treatment. Overall compliance was reported as 63%, with compliance highest for testing and lowest for correct prescriptions.(45) An

investigation into the adherence to national malaria guidelines at a children's hospital in Khartoum, Sudan showed that 44% of febrile children below five years of age were tested, using either microscopy or RDT, before treatment with antimalarials.(46) Another study conducted among public health care workers in Uganda, assessed compliance with the national malaria guidelines as "adherence" or "non-adherence", depending on whether testing was done before treatment, and only test-positive cases were treated.(47) Overall adherence was reported as 51%.(47) In 2020, Budimu, Emidi, Mkumbaye and Kajeguka carried out a study among health care workers in Tanzania to determine adherence to the standard malaria treatment and diagnosis guidelines.(48) They reported strict adherence as 55%, partial adherence as 5%, and non-adherence as 40%.(48) These studies show that adherence to the "test and treat" protocol among health care providers does not reach the global target of 100% for malaria testing before treatment in some developing countries, where malaria is endemic. The situation in Nigeria is similar to what has been reported above.

In Nigeria, compliance with testing before treatment of malaria cases is also poor as studies have reported adherence levels below 50%. Two studies conducted in Southern Nigeria to assess malaria case management reported high incidences of presumptive case management, with only about one third of patients tested before treatment with antimalarials.(49,50) Another study conducted in South-West Nigeria among health care workers in public and private facilities, using the same definitions as Budimu et al.(48) discussed in the preceding paragraph, reported strict adherence as 44%.(51) Even where the health care providers have demonstrated knowledge of the test and treat strategy, there still seems to be low adherence to the case management protocol. For instance, studies conducted in public health care facilities in the Northern and Southern regions of Nigeria showed adherence to testing before treatment to be below 50%.(52,53) The same studies reported that more than two-thirds of the health care workers knew that all patients should be tested before treatment according to the malaria guidelines.(52,53) This reported poor adherence to malaria guidelines in Nigeria is a major barrier to the achievement of the national strategy to control malaria transmission through effective diagnosis and treatment. Some factors have been identified through global and local research to contribute to poor compliance levels to malaria guidelines.

1.2.2 Factors associated with adherence to malaria guidelines

There is still much to be learnt about the factors that moderate health care workers' adherence to guidelines, as this would further explain the reason for the differences in adherence levels reported in the studies reviewed. Although, a number of studies have assessed the associations between various facilitation strategies and implementation fidelity to malaria guidelines, no literature could be found which reported on the other moderating factors in our framework and malaria guidelines specifically. None of these studies also include the informal private health care sector.

1.2.2.1 Health care provider characteristics

Professional cadre of health care providers has been significantly associated with higher levels of awareness and adherence to malaria case management guidelines across various settings. The Ugandan study by Bawate et al.(47) reported that, among nursing staff, higher staff cadres were more likely to adhere to the malaria guidelines compared to the nursing aides which were the lowest cadre. Staff cadre was also significantly associated with correct diagnosis and treatment of clients in a Kenyan facility survey assessing management of malaria in pregnancy.(54) In a setting similar to our study site in Southern Nigeria, doctors and laboratory scientists/technicians were seen to be more aware of the malaria guidelines, and were also significantly more likely to perform a microscopy or RDT test than other cadre of health care workers.(49)

The ability of the health care worker to conduct a malaria diagnostic test, either using RDT or microscopy, has been shown to be associated with adherence. A systematic review of health care worker adherence specifically to RDT use for malaria diagnosis found that lower cadres of health care workers had higher compliance than their more senior colleagues.(55) This was probably because they had been trained only in the use of RDTs for malaria diagnosis, and so they had more trust in its results. A Northern Nigerian study assessing the use of malaria RDT kits in 54 public health care facilities reported that health care workers who had the skills to use RDT kits were three times more likely to conduct a test before treatment than their colleagues, who were not trained to use RDT kits.(56)

The number of years of qualified practice as a health care worker has also been found to be significantly associated with adherence. A study assessing adherence among workers in primary health care centres in Botswana to drug prescription and treatment guidelines of common ailments showed that years of practice was significantly associated with full adherence to protocols (57). Age of health care worker was also identified as a significant factor associated with adherence to the national malaria guidelines in a study in Malawi.(58) An increase in age was seen to be associated with increased odds of correct treatment and testing practices.(58)

1.2.2.2 Facility characteristics

The type of health care facility has been cited as a factor influencing adherence to guidelines. A study assessing adherence to case management for malaria in pregnancy in Kenya, reported that correct malaria case management practice was significantly higher in public or private clinics (31%), as compared to drug stores (3%).(54) Some studies in Nigeria have also reported this association. One study showed presumptive diagnosis was significantly more likely to be used for febrile patients in private facilities (95%) than public facilities (23%).(51) Another study in South Eastern Nigeria found RDTs were more available in public than in private facilities (39% vs 26%).(49) Also, health care workers in public facilities were almost twice as likely to test for malaria with RDTs than private facilities (62% public as against 37% private), although this association was not significant.(49)

Availability of a malaria diagnostic test in the health care facility is another factor associated with adherence to the "test and treat" policy. A study in Uganda showed that presence of a functional laboratory significantly improved adherence in public health care facilities.(47) Another pre- and post-intervention study in Kenya reported that facilities providing both microscopy and RDT tests showed significantly higher adherence to malaria case management guidelines than those offering one type of test or none at all.(59) However, as has been mentioned in the preceding section, availability of the tests at the health care facility is not enough to ensure adherence. The facility must have trained health care workers with the requisite skills to perform these tests before there can be compliance with testing before treatment.

Availability of guidelines in the health care facility has been reported as a significant predictor of adherence to the guidelines in a health care facility survey monitoring implementation of the "test and treat" policy in Kenya.(59) A review of RDT kit use for malaria diagnosis before treatment in Niger State, Nigeria showed limited access to malaria case management guidelines, due to unavailability at the facility or being locked away, contributed to poor adherence to the guidelines.(60)

1.2.3 Conceptual Framework for Implementation Fidelity

The *Conceptual Framework for Implementation Fidelity* (see Figure 1.2 below) by Carroll, Patterson, Wood, Booth, Rick and Balain(40) was used in this study, as it makes adherence the baseline measurement for fidelity. The choice of adherence as our measure of fidelity is based on the fact that the intervention of interest is a guideline. Therefore, the extent to which implementers adhere to the instructions or recommendations in the national malaria guideline will best determine their fidelity of implementation of the guideline. Carrol et al.'s (40) framework has been used, in its original or modified form, in previous studies measuring adherence to guidelines.(61–63)

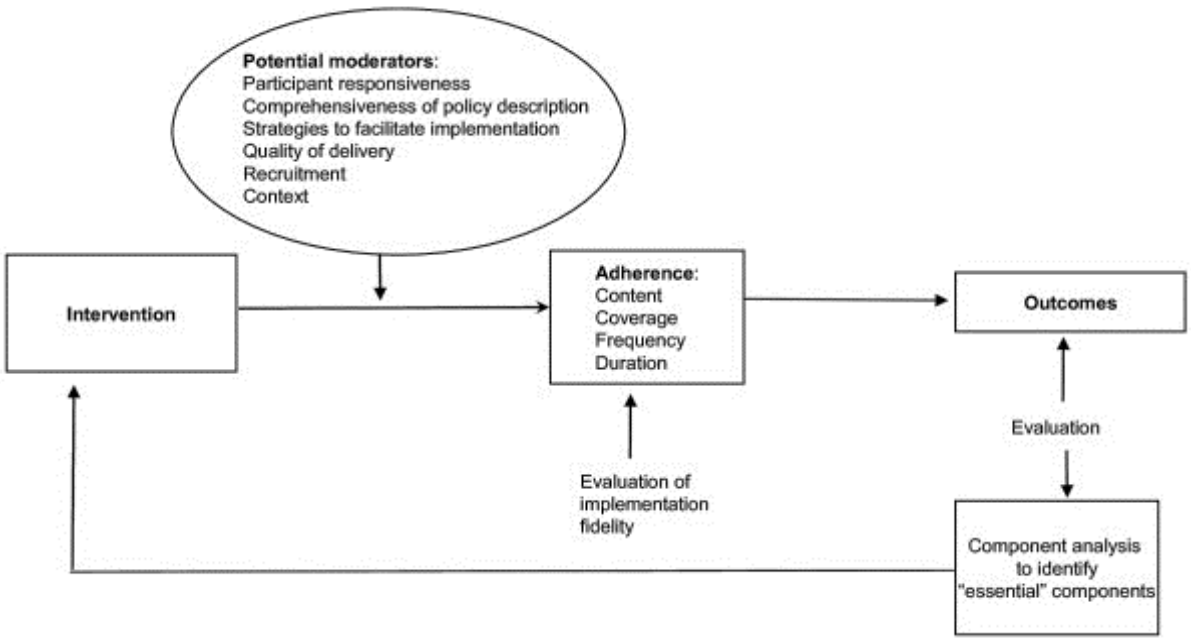


Figure 1.2 Carroll et. al.'s Conceptual Framework for Implementation Fidelity (40)

The framework describes four components of adherence; content, coverage, frequency and duration, as well as potential moderating factors and their relationship.(40) Content refers to the "active ingredients" of the guidelines. They are the essential or core components of the guidelines which should be followed as stipulated for adherence to be high.(40) In the case of the malaria 'test and treat' strategy, testing all suspected cases before treatment using microscopy or RDT, and treating only test-positive cases with antimalarials, were taken as the core components of the guidelines. Coverage and frequency are the "dose" of the intervention i.e. how often the intervention is delivered, and to how many of the target population. Duration refers to if the intervention is being implemented over as much time as prescribed e.g. if clients were to be educated on a health-related subject over a prescribed number of hours.(40) Since the malaria "test and treat" strategy is not delivered as a time-bound intervention, duration was not measured in this study.

1.2.3.1 Moderating factors of implementation fidelity

There are five key moderators of implementation fidelity (adherence) based on the framework used for this study: participant responsiveness, comprehensiveness of policy description, strategies to facilitate implementation (facilitation strategies), quality of delivery, recruitment and context. They are proven factors that moderate or influence the extent to which there is fidelity of implementation of an intervention.(40) This study will consider three moderating factors – intervention complexity, participant responsiveness and facilitation strategies.

Intervention complexity refers to whether the intervention is perceived by the key players or implementers as simple or complex to use.(64) It not only refers to the real nature of the intervention but also, how it is described or presented to the users.(65) Simple and detailed interventions are more likely to have high fidelity as compared to complex or vague ones.(40,66) A study assessing the attributes that can influence the use of clinical guidelines, observed that when the guideline recommendations were clear, the users were almost twice as likely to adhere to them compared to when the recommendations were vague and non-

specific (67% vs 36%).(67) Likewise in a qualitative study on TB directly observed therapy, researchers found that health care workers viewed patient management as a burden, and the complexity of having multiple protocols led to poor adherence.(63)

Participant responsiveness can refer both to the providers and the recipients of the intervention.(65) From the view of the providers, it can be the level of enthusiasm they have about an intervention(40) or if the providers feel the intervention has a clear advantage over the status quo, and it is in line with their values or perceived needs.(68) Higher levels of implementation fidelity are associated with increased participant responsiveness.(65) A study on HIV prevention intervention curriculum among school children in The Bahamas showed that teachers with a higher perception of the importance of the programme also had higher fidelity of implementation to the intervention curriculum.(69)

Facilitation strategies are supportive measures provided by the programme implementers and/or stakeholders to ensure optimal and standardised fidelity of implementation.(40) These can be through the provision of training, guidelines, job aids, monitoring and supervision.(40,62) A survey conducted among public health care facilities in Kenya, after the introduction of the "test and treat" policy, reported overall adherence increased from 16% to 50% following the deployment of job aids, malaria case-management training and commodity supply.(59) Other studies have also found training on malaria case-management,(54,56) and the presence of job aids in the consulting room,(47) as significant factors associated with adherence to malaria guidelines. Supportive supervision is also an important facilitation strategy to improve adherence. Health care workers who received supervision were three times more likely to perform a rapid diagnostic test for malaria than those who received no supervision in a study assessing malaria RDT use in Zamfara State, Nigeria.(56)

1.3 Problem Statement

Prior to the implementation of the "test and treat" strategy, malaria diagnosis was based mainly on clinical diagnosis.(22,27) However, changes in the transmission pattern of malaria in sub-Saharan Africa,(70) the increase in malaria cases in the last half-decade,(1) and the spread of drug-resistant *Plasmodium* parasites(13,16,17) underscores the importance of

proper parasitological diagnosis before treatment. As was stated in the background, the national target for parasitological diagnosis in Nigeria, is all cases (i.e. 100%) by 2020.(21) However, adherence to testing before treatment is still poor.

The 2018 Nigeria Demographic and Health Survey (NDHS) reported diagnosis before treatment to be at 11.8% nationally.(71) A study conducted in a South Western State in Nigeria showed that 83% of children under-five years, who had been presumptively diagnosed and prescribed antimalarials, were actually negative for malaria parasites after microscopy tests were performed.(72) Rivers State, our study site, has seen a decline in malaria diagnosis and testing in children under the age of five years (from 19.3% in 2013 to 8.7% in 2018), with an increase in treatment of febrile illnesses with antimalarials over the same period (from 19.7% in 2013 to 32% in 2018).(71,73) This decline in testing and increase in treatment with antimalarials suggests increasing presumptive diagnosis and overtreatment with antimalarials.

Available studies on adherence to malaria guidelines in Nigeria mostly sampled health care facilities either in the public or private sector separately. The few studies which included the private sector were limited to the formal health care facilities i.e. clinics and hospitals. There is paucity of information on adherence to the 'test and treat" strategy in the informal private sector, in particular the PPMVs which experience the highest patronage of febrile patients. In addition, while most studies assessed health care provider characteristics, there is still insufficient information on facility level characteristics associated with compliance to malaria guidelines. Assessing moderating factors at facility level could improve sustainability of implementing the "test and treat" strategy, especially in the private health care sector where there is usually a high staff turnover. While there is some information on how facilitation strategies can affect fidelity to guidelines, there is limited evidence on how moderating factors, such as participant responsiveness and intervention complexity affect adherence to the guidelines on universal malaria testing before treatment.

1.4 Justification

Overtreatment with antimalarials results in unnecessary patient expenses, increased risk of developing drug resistance and delayed effective treatment of the true underlying disease in

young children.(2,12,51) However, even with the decline in testing before treatment of malaria, no study has been carried out in Rivers State to assess adherence to the national malaria guidelines.

The *National Guidelines for Diagnosis and Treatment of Malaria* (2015) was developed to guide health care providers in performing parasitological diagnosis before treatment. Therefore, the level of adherence to the guidelines is an important indicator for the success or failure of the "test and treat" strategy on the roadmap to malaria elimination by 2030.

Assessment of the factors associated with adherence will provide useful information for stakeholders in Rivers State to implement facility-focused strategies to improve malaria case management in children under-five years.

1.5 Research Questions

1. What is the level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities in Rivers State, Nigeria?

2. What are the associated moderating factors that affect fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities in Rivers State, Nigeria?

1.6 Aim

To assess the fidelity of implementation of the national guidelines on malaria diagnosis for children under-five years and examine its associated moderating factors in health care facilities in Rivers State, Nigeria.

1.7 Objectives

1. To measure the level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities in Rivers State, Nigeria.

2. To describe factors that affect fidelity of implementation of national guidelines for malaria diagnosis in health care facilities in Rivers State, Nigeria.

3. To examine the associations between the moderating factors and level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities in Rivers State, Nigeria.

2 CHAPTER TWO: METHODS

This chapter gives details of the processes and methods used in carrying out this research study. These include the study design, study site, study population, sampling strategy, sample size calculation, data collection, data management, selected variables, and methods used for statistical analysis of the data.

2.1 Study design

This was a descriptive, cross-sectional study with analytical components.

2.2 Study site

The study was conducted in two local government areas, Port Harcourt and Obio/Akpor, in Rivers State. Rivers State is a commercial hub located in the South-South region of Nigeria with an estimated population of 7 300 000.(74) The majority of Rivers State households (47%) sampled in the Demographic and Health Survey belonged to the highest wealth quintile, with high literacy rate for both women (84%) and men (95.2%).(71)

The annual average rainfall is 200.45mm and average ambient temperatures are between 22°C – 31°C, with humidity ranging between 69% – 122%.(75) The climate is conducive for breeding of mosquitoes and it is a mesoendemic transmission area for malaria. The most recent Malaria Indicator Survey reported the prevalence of malaria in children under five-years as 19.5%.(28) It has a robust health care system consisting of public and private health care facilities at primary, secondary and tertiary level, coordinated by the State Ministry of Health. The capital of Rivers State is Port Harcourt metropolis, which is made up of Port Harcourt and Obio/Akpor local government areas.(76)

Obio/Akpor local government area (LGA) is an urban LGA with an area of 260km^2 (77) and a projected population of 742 000 for 2020 (based on the last national census).(74) There are 24 public health care facilities in this LGA (78) and various private health care facilities. Port Harcourt LGA is also urban and covers an area of 109km^2.(77) Its projected population for 2020 is 864 000.(74) There are 19 public health care facilities in this LGA (78) and many private health care facilities. In Nigeria, LGAs are divided into smaller sub-divisions known

as political wards. Wards are local authority areas used for electoral purposes.(79) Obio/Akpor LGA has 17 wards, while Port Harcourt LGA has 20 wards.(74)

2.3 Study population

The study population comprised public and private health care facilities in Port Harcourt and Obio/Akpor LGAs of Rivers State that provided malaria treatment services to children under five years of age. Public health care facilities were considered as those managed and operated by government at any level, while private health care facilities were defined as facilities operated by any entity besides the government - whether individuals, organisations, religious bodies etc. Private health care facilities were further classified as "formal", i.e. hospitals or clinics and drug retail outlets operated by trained pharmacists, or "informal", i.e. private drug retail outlets operated by any person without formal training in pharmacy.

2.4 Sampling

2.4.1 Sampling design

A multi-stage sampling design was used for this study. For the public health care facilities, a sampling frame consisting of all public health care facilities in Obio/Akpor and Port Harcourt LGAs was made available by the Rivers State Ministry of Health, and the Primary Health Care Management Board. There were 43 public health care facilities in total in the sampling frame, and 30 public health care facilities were selected through simple random sampling using a random number table.

Cluster and systematic sampling were used to select private facilities, as there was no comprehensive list of these facilities available. The already existing ward structure in the State was used to select clusters. Ten wards were randomly selected from each LGA from a comprehensive list of all political wards published by the National Population Commission,(74) and each ward was taken as a cluster. Subsequently, six private facilities (three formal and three informal) were selected from each ward through systematic sampling to get a total of 120 private facilities. To achieve this, data collectors randomly selected the first facility and subsequently skipped two facilities from each eligible facility where a questionnaire was administered.

Inclusion criteria: Health care facilities that provided malaria treatment services to children under-five years of age and had been operating for at least six months at the time of data collection.

Exclusion criteria: Health care facilities that met the inclusion criteria but were not open for services at the time of data collection.

2.4.2 Sample size

The required sample size for this study was calculated using Stata version 15 (Stata Corporation, College Station, TX, USA).(80) The mean and standard deviation of the adherence scale to be developed were not yet known at the time of sample size calculation, as there were no previous studies that have measured implementation fidelity of facilities to national malaria guidelines using a quantitative scale. Therefore, sample size and power considerations were given for a binary variable (good fidelity vs poor fidelity). Assuming that approximately 50% of facilities had good fidelity, a sample size of 150 would allow the actual proportion to be estimated with a precision of $\pm$ 8%. The sample size calculation did not take into account the effect of clustering of health care facilities within wards as only a small number, i.e. six facilities, were selected from each ward.

Further, a moderating factor, intervention complexity, was considered to be binary (complex vs non-complex), and it was assumed that 60% of respondents viewed the guidelines as "complex" and 40% viewed the guidelines as "not complex", so the study had over 80% power to detect an absolute difference of 25% in the proportion with good fidelity between those who viewed the guidelines as "complex" and those who viewed the guidelines as "not complex".

2.5 Data collection

2.5.1 Data collection measures

A structured questionnaire was used for data collection. The questionnaire was developed using Carroll's Conceptual Framework for Implementation Fidelity.(40) It was divided into four sections that collected information on:

(i) **characteristics of the facility** – the type of facility, how long it had been in operation and the type of malaria diagnostic test offered, if any;

(ii) **characteristics of the respondent** – the age, sex and professional cadre of the head of facility or any other designated respondent;

(iii) **the constructs for implementation fidelity** – content, coverage and frequency in the implementation of the national malaria guidelines; and

(iv) **moderating factors** – intervention complexity, participant responsiveness and facilitation strategies.

The questionnaire draft was checked for fluency and adequacy by the principal investigator and her supervisors until a final draft was agreed upon. The tool was pre-tested for clarity and comprehension from a lay perspective at health care facilities outside of the study area and revised based on feedback from this exercise. The final version was printed out as hard copies for deployment. A detailed participant information sheet providing adequate information on the study, as well as an informed consent sheet, were provided with each questionnaire (Appendix B).

2.5.2 Training of data collectors

Data collectors received one-day training before data collection, including discussions on the national malaria "test and treat" guidelines, the study aims and objectives, research ethics, consent forms, participant information sheets, and administration of the questionnaire. All data collectors had at least an undergraduate university degree and previous experience of participating in at least one quantitative survey.

2.5.3 Field work

Data were collected by the principal investigator and trained data collectors using pre-tested interviewer-administered questionnaires. The principal investigator accompanied each data collector on their first day of data collection for supervision and on-the-field training. At each health care facility, the questionnaire was administered to the head of facility, or any staff

member designated by the head of facility after they had given informed consent. Data collection was carried out over a period of 16 days (9th to 25th March 2020).

2.6 Data management

Completed questionnaires were reviewed, checked for missing variables and coded by the principal investigator. Data were entered by the principal investigator and saved on a secure, password-protected laptop. The dataset was exported to Stata version 15 (Stata Corporation, College Station, TX, USA),(80) where it was cleaned and recoded before analysis. Hard copies of the questionnaires and consent forms are stored in a secure location up till a period of five years after the end of the research study.

2.6.1 Study variables

The outcome variable was implementation fidelity, while there were ten explanatory variables grouped as moderating factors, facility characteristics, or respondent characteristics.

2.6.1.1 Outcome variable

Implementation fidelity was measured as a continuous, quantitative variable, which gave us more power to detect significant differences in the analysis. Implementation fidelity is a latent variable, i.e. it cannot be directly observed, but is derived from other observable variables.(81) From the framework presented in Figure 1.2, this study measured three out of the four components that make up fidelity: content, coverage and frequency, due to the nature of the intervention of interest. These components/constructs were our observable variables for which data were obtained from the questionnaires. They were all treated as quantitative variables and the responses under each were assigned scores.

Content: Under this construct, the core elements of the malaria "test and treat" strategy in the guidelines were measured. The core elements of the strategy were identified as:

i. Parasitological diagnosis (testing) should be carried out for all suspected cases of malaria

ii. Light microscopy and malaria rapid diagnostic tests are the two recommended methods for parasitological diagnosis.

iii. Antimalarial treatment should only be initiated for patients whose diagnostic tests are positive.

Based on this, facilities were asked if they performed/recommended malaria tests for all children under-five years, using RDT or microscopy, before administering treatment to only test positive cases, as recommended in the national guidelines. The four items under content were scored "1" for Yes and "0" for No, resulting in a minimum content score of 0 and maximum score of 4.

Coverage: For this construct, we assessed how many out of the last ten children aged five years and below, who had been treated for malaria at the facility, had a positive malaria test result. The minimum score was 0 and the maximum score was 10.

Frequency: This was assessed by how often the facility performed/requested malaria diagnostic tests before treatment of children younger than five years. It was measured on a five-point Likert scale with a minimum score of 1 for "Never" and the maximum score of 5 for "Always".

The scale reliability coefficient (Cronbach's alpha) was used to assess if the eight items on the questionnaire provided a reliable measure of implementation fidelity. Cronbach's alpha coefficient was 0.79 which is acceptable.(82) Each construct was scored and assigned equal weights for scores between 0 – 33.3 (details provided under Data Analysis). The weighted scores were summed up to create a percentage fidelity score with a range of 0 – 100%. Converting to a percentage score for fidelity was chosen for easy interpretation and comparison with prior studies, which treated fidelity (adherence) as a categorical variable and presented their results as percentages.

2.6.1.2 Explanatory variables

The explanatory variables were potential factors associated with implementation fidelity. They were grouped broadly as moderating factors of implementation fidelity, facility characteristics, and respondent characteristics.

Moderating factors: These included intervention complexity, participant responsiveness and facilitation strategies based on our chosen conceptual framework (see Figure 1.2). The use of quantitative scores to measure moderating factors of implementation fidelity has been reported in previous studies assessing implementation fidelity to health care interventions.(69,83) However, there is no validated scale for the measurement of these factors; therefore, the scale used in this study was developed based on the adopted fidelity framework in the context of the national malaria guidelines.

i. Intervention complexity was defined as the simplicity or complexity of the national guidelines to providers.(40,65,84) It was a continuous variable with two items on the questionnaire measured on a five-point Likert scale from "1" for strongly disagree to "5" for strongly agree. The higher the intervention complexity score, the more complex the participants viewed the guidelines.

ii. Participant responsiveness referred to the acceptance of the national malaria guidelines by providers as the best practice and its relative advantage over presumptive treatment.(40,65,84) It was also a continuous variable with two items on the questionnaire with a minimum score of 0 and a maximum score of 6. The higher the participant responsiveness score, the more responsive the participants were to the guidelines.

iii. Facilitation strategies captured if any support had been made available to facilities by government and/or its partners to enhance the implementation of the guideline.(40,65) The variable was a categorical, binary variable labelled as "1" for a positive response, and "0" for a negative response. Support strategies were compiled from relevant literature and reports (21,27,35,51,60) and listed as multiple-choice options in the questionnaire.

Facility characteristics: These comprised of the location of the facility, the type of facility (public, private formal or private informal), type of malaria test offered (no test, RDT and/or microscopy as the two recommended methods in the guidelines), duration of operation (captured as a continuous variable in months), and availability of the national malaria guidelines in the facility (yes or no). These were based on literature as potential factors associated with implementation fidelity.(47,49,51,60)

Respondent characteristics: These were age, sex and professional cadre. Age was categorised in ascending order, from 18 years and above, as an ordinal variable. Sex was categorised as a binary variable – either male or female; and professional cadre was categorised as a nominal variable, viz. doctor, nurse, pharmacist, community health care worker, technician and non-health care worker. These characteristics were also based on literature as potential determinants of fidelity to guidelines.(47,54,58,85) Details of each category of explanatory variables and their data values are shown in Table 2.1 below.

The constructs of fidelity and the outcome variable, fidelity, were created by summing the items that represent the construct on the questionnaire. The same method was used to create the moderating factor variables – intervention complexity and participant responsiveness, by also adding the scores under each item for the factors. Cronbach's alpha scores were not obtained for the moderating factors as they were only two-item scales, and their true reliability may be underestimated.(86) Other variables were analysed as measured in the questionnaire.

Table 2.1 Explanatory variables

Variables	**Type of variable**	**Label (Value)**
Moderating factors for implementation fidelity		
Intervention complexity	Categorical	
Guidelines are easy to understand	Categorical, nominal	Strongly disagree = 1 Disagree = 2 Neutral = 3 Agree = 4 Strongly Agree = 5
Testing before treatment is costly to implement	Categorical, nominal	Strongly disagree = 1 Disagree = 2 Neutral = 3 Agree = 4 Strongly Agree = 5
Participant responsiveness	Continuous	
Accepts guidelines as best practice	Categorical, binary	No = 0 Yes = 1
Testing before treatment is better than presumptive treatment	Categorical, nominal	Strongly disagree = 1 Disagree = 2 Neutral = 3 Agree = 4 Strongly Agree = 5
Facilitation strategies		
Staff training on guidelines	Categorical, binary	No = 0 Yes = 1
Facility support	Categorical, binary	No = 0 Yes = 1
Type of facility support: Provision of guidelines Supportive supervision On-the-job mentoring Provision of diagnostic test supplies Provision of treatment chart	Categorical, binary	No = 0 Yes = 1 (for each category)

Variables	Type of variable	Label (Value)
Facility characteristics		
Local Government Area	Categorical, binary	Obio/Akpor = 1 Port Harcourt = 2
Facility type	Categorical, nominal	Public = 1 Formal private = 2 Informal private = 3
Malaria test offered at facility	Categorical, nominal	None = 0 Light Microscopy =1 mRDT = 2 Both = 3
Duration of operation (months)	Numerical, continuous	-
Availability of guidelines	Categorical, binary	No = 0 Yes = 1
Respondent characteristics		
Sex	Categorical, binary	Male = 1 Female = 2
Professional cadre	Categorical, nominal	Doctor = 1 Nurse = 2 Pharmacist =3 CHEW = 4 Technician = 5 Non-health care worker = 6
Age (years)	Categorical, ordinal	18 – 24 = 1 25 – 34 = 2 35 – 44 = 3 44 – 54 = 4 >54 = 5

2.8 Data Analysis

Statistical analyses were carried out using Stata version 15 (Stata Corporation, College Station, TX, USA).(80) The constructs of fidelity were described using frequency (proportion), mean (standard deviation) and median (interquartile range). The numerical moderating factors associated with fidelity – intervention complexity and facilitation strategies – were also summarised as frequency (proportion), mean (standard deviation) and median (interquartile range). Facility and respondent characteristics were summarised using frequency (proportion), except duration of operation, which was a continuous variable and was summarised as mean (standard deviation (SD)) and median (interquartile range (IQR)).

Inferential statistics were performed using univariable and multivariable analyses. Univariable analysis was conducted to assess the relationship between the facility and respondent characteristics, and fidelity score with Mann Whitney U and Kruskal Wallis tests as the outcome variable, fidelity score, was not normally distributed. Further univariable analyses were performed by fitting simple linear regression models to determine the relationship between the explanatory variables and the outcome, and the results were compared with those found using the non-parametric tests. Lastly, multivariable analyses were carried out using multiple linear regression modelling to provide adjusted coefficients for the relationships between fidelity score and the moderating factors. The outcome variable was fitted in one model with the three moderating factors only, and also in another model with all the measured factors, i.e., moderating factors, facility and respondent characteristics.

2.8.1 Objective One: To measure the level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities

Implementation fidelity was measured from three constructs – content, coverage and frequency as stated above. Cronbach's alpha coefficient was 0.79 for the unweighted items which shows high internal consistency. Descriptive analyses were carried out to produce a frequency table for the construct scores, including mean (SD) and median (IQR). From our chosen conceptual framework, the constructs which make up fidelity are of equal importance. Thus, to standardise the scoring for each construct, they were given equal weights. The

weights were created to produce a total possible score of 100, so that when summed up, fidelity score will be a percentage score. This was created with the formula,

$$\frac{X}{Y} \text{ X } \frac{100}{3}$$

Where X is the observed construct score, Y is the maximum construct score, and 100/3 is the constant weight.

The weighted construct scores were calculated using the above formula, and new variables were created for these scores.

Composite scores for implementation fidelity were derived for each respondent by summing up the weighted scores for all three constructs (minimum score = 0, maximum score = 100). The mean (SD) and median (IQR) were calculated for fidelity and illustrated using a box plot.

2.8.2 Objective Two: To describe factors that affect fidelity of implementation of national guidelines for malaria diagnosis in health care facilities

The moderating factors of implementation fidelity from our conceptual framework were intervention complexity, participant responsiveness and facilitation strategies. Mean (SD) statistics were used to describe intervention complexity score and participant responsiveness score. Facilitation strategies were described using frequency, and the types of support received by the facilities were presented using a bar chart.

Facility characteristics (type of facility, type of malaria test offered, and availability of the national malaria guidelines in the facility) were described using frequency and percentage, while duration of operation was summarised as mean (SD) and median (IQR). All respondent characteristics (age, sex and professional cadre) were summarised in a table using frequencies and percentages.

2.8.3 Objective 3: To examine the associations between the moderating factors and level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years in health care facilities

Exploratory data analysis was carried out to check if implementation fidelity score was normally distributed to guide the analysis. A normal line graph and histogram with a normal curve were plotted and the results gave a negatively skewed curve showing that fidelity score was not normally distributed. The outputs of the exploratory analyses are shown in Appendix E.

Unadjusted analyses were conducted to assess the relationship between respondent and facility characteristics and implementation fidelity score using non-parametric tests as the outcome variable was not normally distributed. The association between the outcome and binomial categorical variables, e.g. sex, were assessed using Mann Whitney U test, while Kruskal-Wallis test was computed for multinomial categorical variables e.g. type of malaria test available, and Spearman rank correlation coefficient used to test for the association between duration of facility operation and implementation fidelity score.

Regression analysis was further performed which has the advantage over other analysis methods mentioned above to test the association between fidelity score and multiple explanatory variables in one model, predict the increase or decrease in fidelity score for each factor, and quantify the relationship between fidelity and the moderating factors while adjusting for all other characteristics. Linear regression was chosen the most appropriate method of regression as the outcome variable is continuous.

Simple linear regression modelling using robust estimation of errors was carried out for univariable analysis to investigate the relationship between each factor and fidelity score. Robust estimation of standard errors was used because of the non-normality of the underlying distribution of fidelity. In this instance, only one explanatory variable was fitted into the model with fidelity. Unadjusted coefficients (with 95% Confidence Intervals) and statistical significance values (p-values) are tabulated.

The equation used for the simple linear regression model was:

$$y = \beta_0 + \beta_1 x_i + \varepsilon_i$$

where, y is the dependent variable, β_0 and β_1 were model parameters (intercept and coefficient respectively) and ε_i was the error term.

Level of significance was set at $p<0.05$.

Multiple linear regression modelling using robust estimation of errors was used for multivariable analysis to determine the relationship between the moderating factors and fidelity score, while adjusting for potential confounders. Robust estimation of standard errors was used again to deal with the non-normality of the fidelity score. In these models, more than one explanatory variable was fitted into the model with the outcome variable. The relationships are described by this linear equation:

$$yi = \beta_0 + \beta_1 x_{i1} + \beta_2 x_{i2} + ... + \beta_n x_{in} + \varepsilon_i$$

where, y_i = dependent variable, β_0 is the intercept, x_i are the explanatory variables and β are the coefficients of the variables from 1 to n, and ε_i is the error term.

Statistical significance level was set at $p < 0.05$.

In the first model, the three moderating factors – facilitation strategies, participant responsiveness score and intervention complexity score, were fitted into one model to predict implementation fidelity score.

In the second model, the three moderating factors as well as all facility and respondent characteristics were fitted in the model to predict fidelity. Adjusted coefficients (with 95% Confidence Intervals) and statistical significance values (p-values) are reported in separate tables for both models.

2.9 Regression diagnostics

Regression diagnostics are statistics which test the assumptions of a linear regression model and detect problems in the model or data set.(87) Linear regression models are based on assumptions some of which are:

- There is no multicollinearity in the model (i.e., no high correlation among independent variables)
- The true value of the outcome variable y is linearly related to the explanatory variable x
- The residuals $\varepsilon_{i,}$ are normally distributed
- The residuals have constant variance σ^2 (homoscedasticity)

These assumptions were checked by carrying out regression diagnostics of the residuals of the fitted models.

Multicollinearity of the explanatory variables in the multiple linear regression model were assessed using the variance inflation factor. It can be calculated for each explanatory variable through a regression in which the values of one factor are fitted against values of the other factors.(88) Generally, a variance inflation factor value less than 10 is acceptable.(88)

A linear relationship between the explanatory and outcome variables was assessed by plotting the fitted regression line in a scatter plot of the outcome variable and a moderating factor.(89)

Kernel density and normal probability histogram plots were used to check for normal distribution of the residuals. Kernel density estimates the probability density function of the variable and the graph plots the distribution of the residuals against a normal distribution curve.(90) Visual inspection of both graphs can be used to check if the residuals are normally distributed, depending on how appear to be aligned with or deviated away from the normal curve.

Homoscedasticity (homogeneity of variance) is when the variance of the residuals of the outcome variable is the same across all values of the explanatory variables. Commonly used

methods to test for homoscedasticity are Cook-Weisberg test and graphical plots of the residuals against the predicted values.(91)

Given the skewness of the data and deviations from the assumptions, robust standard errors were used in the regression analysis. The robust estimator is robust to non-normality and heteroscedasticity so long as the observations were measured independent of each other.

2.10 Ethical considerations

Ethical approval was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (clearance certificate number: M1911134). Facility approvals were granted by the Rivers State Health Research Ethics Committee (reference number RSHMB/RSHREC/11.20/VOL.8/049). Permission to conduct the study in selected health care facilities was obtained from the Rivers State Ministry of Health and Rivers State Primary Health Care Management Board. Participant information sheets were read and explained clearly to respondents and those willing to participate in the study gave informed consent by signing a consent form. Participant anonymity and confidentiality was ensured as no personal or facility identifiers were collected from study participants. Participants did not include their facility names on the consent form. The data sheets are stored on a password-protected computer and can only be accessed by the principal investigator and her supervisors for a period of five years after the end of the study, after which they will be deleted.

3 CHAPTER THREE: RESULTS

This chapter presents study findings using the methods of analyses outlined in Chapter 2, according to the study research objectives. Descriptive statistics of the outcome and explanatory variables are presented using tables and graphs. Inferential statistics for univariable and multivariable analyses to determine associations between implementation fidelity score and its factors are presented in tables.

Out of 152 questionnaires administered, five were excluded from the analyses because the facility did not meet the inclusion criteria, i.e. the facilities had been in operation for less than six months (3 facilities) or all responses on the constructs of implementation fidelity were not recorded, as the respondents could not remember treating any child under five years of age for malaria in the last six months (2 facilities) (i.e. no response at all to items under the three constructs, and not a response of "no" or "zero").

3.1 Measurement of the level of fidelity of implementation of national guidelines on malaria diagnosis for children under-five years

The three constructs of implementation fidelity – content, coverage and frequency, were measured on quantitative scales based on eight items. Content score ranged from 0 – 4 and facilities averaged a mean and median score of 2. Coverage score ranged from 0 – 10 with a mean and median of approximately 6, while frequency score ranged from 1 – 5 with a mean and median of approximately 2. Equal mean and median scores suggest the construct scores were not skewed. A detailed description of the (unweighted) construct scores are presented in Table 3.1 below.

Table 3.1 Frequency distribution of scores for three constructs of implementation fidelity

Construct (Scores)	**Frequency (Percentage)**	**Mean (SD)**	**Median (IQR)**
Content	147 (100)	2 (1)	2 (1, 3)
0	11(7.5)		
1	31 (21.1)		
2	32 (21.8)		
3	38 (25.8)		
4	35 (23.8)		
Coverage	146 (99.3)	6 (3)	6 (4, 10)
0	9 (6.2)		
1	2 (1.4)		
2	8 (5.5)		
3	11 (7.5)		
4	12 (8.2)		
5	19 (13.0)		
6	14 (9.6)		
7	13 (9.0)		
8	10 (6.8)		
9	10 (6.8)		
10	38 (26.0)		
Frequency	146 (99.3)	3 (1)	3 (3, 4)
1	3 (2.0)		
2	8 (5.6)		
3	18 (12.3)		
4	57 (39.0)		
5	60 (41.1)		

Composite fidelity score: Total construct scores for each facility were weighted equally and a composite score for fidelity was derived by summing the weighted construct scores to produce a percentage score. The minimum fidelity score of respondents was 0 and the maximum was 93.3%. The mean (SD) fidelity score for all participants was 61.3% (23.4), while the median (IQR) score was 65% (43.3, 85). The box plot in Figure 3.1 shows the distribution of scores.



Figure 3.1 Box plot of implementation fidelity score

3.2 Factors that affect fidelity of implementation of national guidelines for malaria diagnosis

3.2.1 Description of moderating factors: Intervention complexity, participant responsiveness and facilitation strategies

The scores for the three moderating factors (which are the key factors from our framework) were derived by summing item scores on the questionnaire. The mean (SD) intervention complexity score was 3 (2) out of a possible maximum score of 10. The mean (SD) participant responsiveness score was 5 (1) out of a possible maximum score of 6. Moderating factor scores are described in Table 3.2.

Table 3.2 Descriptive statistics of moderating factors of implementation fidelity

Moderating factor	Frequency	Range	Mean (SD)
Intervention complexity	147	1 – 10	3 (2)
Participant responsiveness	147	0 – 6	5 (1)
Facilitation strategies	142		

Of the 147 health care facilities that participated in the study, only 32 (22.5%) had received some kind of support strategy towards the implementation of the national malaria guidelines. This was mainly through the provision of diagnostic test supplies (45.5%) and supportive supervision (42.4%). Figure 3.2 outlines the types of facilitation strategies provided to facilities.

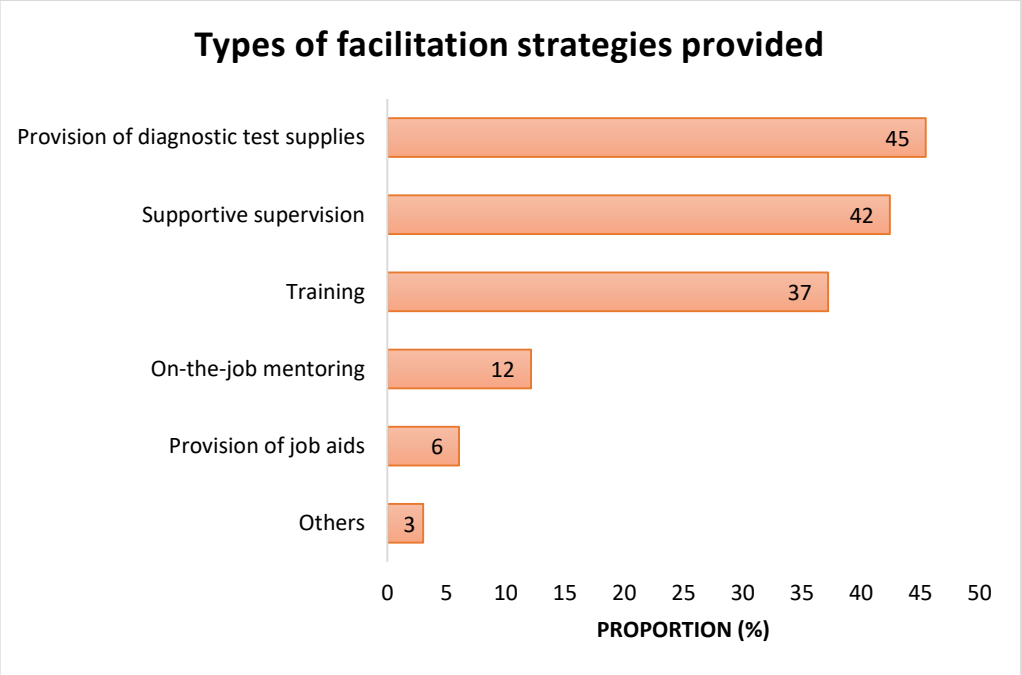


Figure 3.2 Types of support received by facilities towards implementation of the national malaria guidelines.

3.2.2 Description of facility and respondent characteristics

Most of the sampled health care facilities offered one of the two recommended malaria diagnostic tests, with about 25% offering RDT. Only 13% had a copy of the national malaria guidelines available in the facility, while on average, facilities had been in operation for about 120 months (i.e. 10 years). About 65% of respondents were female and most were nurses (41%). The majority of respondents fell within the 35 – 44 years (42%) and 25 – 34 years (29%) age groups. Details are shown in Table 3.3 below.

Table 3.3 Descriptive statistics of other factors of implementation fidelity

Variable	Frequency (Percentage)
FACILITY CHARACTERISTICS	
Facility type	**147 (100)**
Public	30 (20.4)
Formal private	57 (38.8)
Informal private	60 (40.8)
Type of malaria test conducted at facility	**145 (98.6)**
None	57 (39.3)
Light microscopy	21 (14.5)
RDT	36 (24.8)
Both microscopy and RDT	31 (21.4)
Availability of malaria guidelines	**145 (98.6)**
Yes	19 (13.1)
No	126 (86.9)
RESPONDENT CHARACTERISTICS	
Age of respondent	**147 (100)**
18 – 24	11 (7.5)
25 – 34	43 (29.2)
35 – 44	63 (42.9)
45 – 54	25 (17.0)
>54	5 (3.4)

Variable	Frequency (Percentage)
Sex	**146 (99.3)**
Male	51 (34.9)
Female	95 (65.1)
Cadre of respondent	**146 (99.3)**
Doctor	43 (29.5)
Nurse	60 (41.1)
Pharmacist	18 (12.3)
Pharm./Lab. technician	4 (2.7)
CHEW	11 (7.8)
Non-health care worker	10 (6.8)

For the continuous variable, duration of facility operation, the mean (SD) was 119.5(88.4), and the median (IQR) was 108 (48, 156).

3.3 Factors associated with fidelity of implementation of national guidelines for malaria diagnosis

Univariable analyses with non-parametric tests showed that all facility and respondent characteristics, except age, were significantly associated with implementation fidelity score ($p < 0.05$) as shown in Table 3.4.

Simple linear regression analysis showed all factors, including age, to be significantly associated with implementation fidelity score at the 5% significance level. The unadjusted coefficients showed a positive increase in intervention complexity and participant responsiveness for every 1% increase in fidelity score (Table 3.5).

Facilities with a positive response to facilitation strategies had a higher fidelity score by 21% (15, 28) than those who responded in the negative (Table 3.5). Private facilities had negative associations with fidelity score compared to public facilities and females also had lower fidelity scores by 11% (3, 19) compared to males. Age had a positive association with fidelity scores. Ascending from one age group to another resulted in an increase in fidelity score by almost 6% (2, 9). Table 3.5 presents the results of the simple regression analysis.

Table 3.4 Associations between facility and respondent characteristics, and implementation fidelity score using non-parametric tests

Variable	**Fidelity score**		**p-value**
	Mean (SD)	**Median (IQR)**	
Facility type			<0.001*
Public	79.1 (11.6)	83.3 (71.7, 85)	
Formal private	67.2 (21.5)	75 (51.7, 85)	
Informal private	46.7 (21.0)	45 (35, 60)	
Type of malaria test conducted at facility			<0.001*
None	42.8 (18.2)	45 (33.3, 53.3)	
Light microscopy	70 (18.6)	68.3 (53.3, 93.3)	
RDT	72.1 (18.5)	80 (64.2, 85)	
Both microscopy and RDT	78.3 (15.3)	83.33 (71.7, 90)	
Availability of national malaria guidelines			<0.001*
Yes	78.5 (12.6)	83.3 (71.7, 85)	
No	58.5 (23.7)	59.2 (40, 80)	
Duration of facility operation			<0.001*ǂ
Age of respondent			0.125
18 – 24	49.1 (18.9)	51.7 (28.3, 63.3)	
25 – 34	56.2 (26.4)	58.3 (35, 83.3)	
35 – 44	63.8 (22.7)	68.3 (46.7, 85)	
45 – 54	67.5 (20.7)	66.7 (46.7, 85)	
>54	68.7 (13.4)	73.3 (71.7, 76.7)	

Variable	Fidelity score		p-value
	Mean (SD)	Median (IQR)	
Sex			0.005*
Male	68.3 (21.1)	71.7 (48.3, 85)	
Female	57.3 (23.9)	60 (38.3, 80)	
Cadre of respondent			<0.001*
Doctor	79.9 (11.1)	85 (71.7, 85)	
Nurse	49.9 (22.7)	46.67 (35.8, 65)	
Pharmacist	63.4 (20.6)	60.83 (50, 80)	
Pharm./Lab. technician	60.8 (37.9)	64.17 (28.3, 93.3)	
CHEW	50.8 (18.6)	48.33 (40, 63.3)	
Non-health care worker	60.8 (22.25)	55 (45, 85)	

*significant at $p < 0.05$

ǂSpearman rank correlation coefficient test

Table 3.5 Associations between facility and respondent characteristics, and implementation fidelity score using univariable linear regression analysis

Variable	**Coefficient (95% C.I.)**	**P-value**
Moderating factor		
Intervention complexity	1.85 (0.52, 3.19)	0.007*
Participant responsiveness	11.07 (5.54, 16.60)	<0.001*
Facilitation strategies No Yes	 ref 21.39 (15.07, 27.72)	 ref <0.001*
Facility type		<0.001*
Public	ref	
Formal private	-11.95 (-18.97, -4.93)	
Informal private	-32.39 (-39.20, -25.59)	
Type of malaria test conducted at facility		<0.001*
None	ref	
Light microscopy	27.22 (17.93)	
RDT	29.35 (21.60, 37.10)	
Both microscopy and RDT	35.56 (28.32, 42.80)	
Availability of national malaria guidelines		<0.001*
No	ref	
Yes	20 (54.32, 62.68)	
Duration of facility operation	0.07 (0.04, 0.11)	<0.001*
Age of respondent	5.68 (2.12, 9.23)	0.002*

Variable	Coefficient (95% C.I.)	P-value
Sex		0.005*
Male	ref	
Female	-10.98 (-18.56, -3.41)	
Cadre of respondent		<0.001*
Doctor	ref	
Nurse	-30.00 (-36.76, -23.23)	
Pharmacist	-16.46 (-26.57, -6.35)	
CHEW	-29.13 (-40.44, -17.81)	
Pharm./Lab. Technician	-19.05 (-52.37, 14.27)	
Non-health care worker	-19.05 (-32.95, -5.15)	

Multiple regression analysis was performed by fitting two linear regression models. In the first model (model 1), the three moderating factors (key determinants) of implementation fidelity were fitted in the model with fidelity score. Participant responsiveness and facilitation strategies were significant ($p<0.001$) in this model as seen in Table 3.6 below. Intervention complexity was seen to have a negative relationship with fidelity score, although this was not significant at the 5% level.

In model 2 (Table 3.6), adjusting for all other factors, participant responsiveness remained significant in the adjusted model ($p<0.001$). Facilitation strategies was significant in model 1 ($p<0.001$) but was only marginally significant in model 2 ($p = 0.063$). Intervention complexity was not significant in model 1 ($p = 0.752$) but was statistically significant in model 2 ($p = 0.017$). For every unit increase in intervention complexity score, fidelity score decreased by almost 2%; while for every unit increase in participant responsiveness score, fidelity score increased by about 9%, holding all other factors in the model constant. The only respondent or facility characteristic that was significant at the 5% level was type of malaria test conducted at the facility.

Considering the proportion of variability in fidelity score explained by the fitted models according to the R^2 values, model 1 with only the three key moderating factors accounted for about 31% of the variability of fidelity, while model 2 with all the determinants accounted for about 66% of the variability in the outcome. Therefore, it can be said that model 2 is a better predictor of fidelity score in the context of this study.

Table 3.6 Multiple linear regression with robust estimation of standard errors showing association between key moderating factors only, and all determinants and implementation fidelity score

Factor	**Model 1**		**Model 2**	
	Coefficient (95% CI)	**P-value**	**Coefficient (95% CI)**	**P-value**
Moderating factors				
Intervention complexity	-0.24 (-1.73, 1.25)	0.752	-1.88 (-3.42, -0.34)	0.017*
Participant responsiveness	10.56 (5.08, 16.03)	<0.001*	8.57 (4.83, 12.32)	<0.001*
Facilitation strategies No Yes	 ref 19.27 (12.71, 25.83)	 <0.001*	 ref 5.73 (-0.31, 11.76)	0.063
Facility type				0.171
Public			ref	
Formal private			-6.10 (-12.79, 0.58)	
Informal private			-7.40 (-17.57, 2.76)	
Type of malaria test conducted at facility				<0.001*
None			ref	
Light microscopy			21.88 (13.60, 30.16)	
RDT			16.90 (6.78, 27.03)	
Both microscopy and RDT			26.63 (16.88, 36.38)	

Factor	Model 1		Model 2	
	Coefficient (95% CI)	**P-value**	**Coefficient (95% CI)**	**P-value**
Availability of national malaria guidelines				0.176
No			ref	
Yes			6.14 (-2.80, 15.09)	
Duration of facility operation			0.01 (-0.02, 0.04)	0.631
Age of respondent			3.19 (-0.42, 6.80)	0.082
Sex				0.722
Male			ref	
Female			1.09 (-4.96, 7.14)	
Cadre of respondent				0.075
Doctor			ref	
Nurse			-7.50 (-16.38, 1.38)	
Pharmacist			-6.26 (-15.98, 3.45)	
Pharm./Lab. technician			-5.94 -15.51, 3.63)	
CHEW			8.74 (-10.55, 28.02)	
Non-health care worker			5.72 (-7.45, 18.90)	
R^2	31%		65.7%	

*significant at $p<0.05$

R^2 – the proportion of variance of fidelity score explained by the factors in the model

3.4 Regression diagnostics of residuals

Regression diagnostics was performed on the residuals of the linear regression models. The variable inflation factor (VIF) for the multivariable model was 2.1, so there was no high correlation among the explanatory variables.

Scatter plots of the fitted line of the residuals against the observed points showed linear relationships between the outcome variable and key moderating factors, on visual inspection (Appendix F). However, the assumptions that the residuals were normally distributed or had constant variance were not met. The kernel density plot showed the distribution curve of the residuals was well deviated from the normal distribution curve (Appendix F). Although the scatter plot showed only a few values outside the plotted lines, a significant Cook-Weisberg test ($p<0.05$) confirmed that there was heteroscedasticity. These findings formed the basis of the decision to use robust standard errors in the regression analysis, as stated earlier.

4 CHAPTER FOUR: DISCUSSION

In this section, the findings of the study are discussed as well as how they relate to previous studies.

The study assessed the fidelity of implementation of the national guidelines on malaria diagnosis for children under-five years and examined its associated moderating factors in health care facilities in Rivers State, Nigeria. Overall fidelity percentage scores for the sampled population are compared with results of adherence to national malaria management guidelines in other settings. The description of factors associated with implementation fidelity to malaria guidelines, the strengths of these associations and their significance are discussed in comparison with existing literature. Finally, the limitations of the study and its strengths are presented.

This study found fidelity scores to range from 0 – 93% among sampled health care facilities. Public health care facilities, those offering both microscopy and RDT tests, and facilities that had the national malaria guidelines available had the highest mean fidelity scores. Statistically significant predictors of implementation fidelity identified in this study were intervention complexity, participant responsiveness and the type of malaria test conducted at the facility.

4.1 Fidelity of implementation to national malaria guidelines

The mean fidelity score for facilities that participated in the study was 61%. Using 50% as the minimum acceptable standard on a percentage scale, a mean score of 61% can be interpreted as a moderate score. This score is similar to that reported in a health care facility survey in Papua New Guinea where overall adherence to the malaria test and treat protocol was 63%.(45) It is higher than adherence scores from other studies conducted in Nigeria, which sampled both public and private facilities, which reported adherence scores below 50%.(49–51) A close review of the scores for the constructs of fidelity individually show they were all around the halfway mark. An average score of 2 out of 4 for Content (a fidelity construct) suggests that there are some core elements of the guidelines that are not implemented as intended at health care facilities.

The findings showed that most facilities were still administering antimalarials to children below five years of age with negative test results or no malaria test result at all, even though the guidelines require antimalarials to be limited to test-positive cases.(22) This is in keeping with the increase in presumptive diagnosis and treatment of malaria in children seen between 2013 and 2018 from malaria surveys (71,73) and other studies within and outside Nigeria that show health care providers still choosing to clinically diagnose malaria, despite negative test results.(45–47,52,53) Further, this study found mean and median scores for Frequency (another fidelity construct) to be 3 out of a possible 5. This was also unsatisfactory as it interprets in the Likert scale as "not often" when respondents were asked how often malaria tests were performed or requested before treatment at the health care facility. Respondents in this study indicated that some caregivers were unwilling to spend extra on the cost for a test. In actual fact, presumptive diagnosis wastes money and time, as it results in unnecessary drug purchases and delays treatment of the true cause of febrile illness.(12,51)

4.2 Factors associated with implementation fidelity

A total of ten factors associated with implementation fidelity were explored in this study namely, intervention complexity, participant responsiveness, facilitation strategies, age, sex, professional cadre, type of facility, availability of guidelines, type of test offered at the facility and duration of facility operation. These were broadly classified as moderating factors based on the chosen conceptual framework, and other factors, which were the facility and respondent characteristics. The ten factors explored in this study were found to significantly predict about two-thirds of the proportion of variability of implementation fidelity score. In univariable analysis, all respondent characteristics were significantly associated with fidelity score, but in multivariable analysis, they were not significant when adjusted for all factors.

4.2.1 Moderating factors of implementation fidelity

The low mean intervention complexity score from our study findings meant that most respondents did not view the malaria guidelines as complex. They felt it was easy to understand and not costly to implement. There was evidence to show from this study that intervention complexity was significantly associated with implementation fidelity. This finding is similar to other studies which have established intervention complexity as a

significant determinant of fidelity.(64,65) There was an inverse relationship between intervention complexity and implementation fidelity in model 2, which was similar to reports from other studies which reported that the more complex the users think the guidelines are, the lower the fidelity score, and vice versa. A study on adherence among doctors in the Netherlands supports this association as it reported higher adherence to clinical practice guidelines when the users perceived them as clear and simple.(67) Similarly, in another study in Burkina Faso, health care service providers stated that the complexity of administration of seasonal malarial chemoprophylaxis was a major factor to its slow implementation and poor adherence across implementing districts.(62)

In this study, participant responsiveness was targeted at the users and not the recipients of the intervention. Participant responsiveness was high, which suggests most respondents were enthusiastic about the guidelines and felt that testing for malaria before treatment had relative advantage over presumptive diagnosis. A Nigerian study on use of RDTs for "test and treat" among health care workers in public and private facilities, gave similar findings as majority of respondents rated RDTs as "good" or "very good" and felt it was "better than other methods".(49 p6) This study also found that higher participant responsiveness score was significantly associated with higher fidelity score. This is in line with a study in The Bahamas that assessed fidelity of implementation to a HIV training curriculum where teachers in the higher implementation fidelity group perceived the intervention to be very important and had higher programme ownership than those in the moderate and lower fidelity groups.(69)

Only a fifth of the sampled facilities had received support towards the implementation of the national malaria guidelines, and this was mostly in the form of provision of diagnostic test kits. This is largely due to the activities of funding partners like the Global Fund for AIDS, Tuberculosis and Malaria and UNITAID which have supported the Ministry of Health in providing rapid diagnostic test kits to select public and private health care facilities.(21,60,92) However, their efforts need to be complemented by the government to achieve wider coverage of facility support. While there was some evidence to show that facilitation strategies were associated with implementation fidelity, this was not significant. This is quite different from other studies on malaria guidelines that reported strategies like training and provision of job aids were associated with higher levels of adherence to

protocols.(47,59,62) However, it has been said that facilitation strategies do not necessarily translate into better implementation fidelity.(65) It is usually dependent on other characteristics of the intervention, for example, a complex and vague intervention may still have low fidelity even when support strategies are provided.

4.2.2 Facility characteristics

Although this study found that only a few facilities had the national malaria guidelines available at the time of the study, they had much higher fidelity scores than those who did not. This is similar to a study in Kenya where availability of guidelines at the health care facility was reported to be associated with adherence.(59) The high fidelity scores shown in this study for facilities that had guidelines makes a strong case that guidelines should not only be available in the facility but placed where it is easily accessible by staff.(60)

In this study, public health care facilities had higher mean fidelity scores than formal and informal private facilities. Similar results have been reported in studies conducted in public and private facilities in Nigeria, with public facilities having higher percentage of adherence to malaria testing before treatment than private ones.(49,51) It was also found that informal private health care facilities (PPMVs) had particularly low implementation fidelity scores, which is supported by reports from other studies which showed poor compliance of PPMVs to regulations and guidelines.(30,33)

From our findings, health care facilities that offered both RDT and light microscopy tests had the highest mean fidelity scores. This agrees with a survey in Kenya monitoring implementation of the “test and treat” policy, which showed higher adherence to malaria guidelines in facilities that offered both types of diagnostic tests.(59) While offering both types of a test at a facility will improve fidelity, offering any of the diagnostic tests (microscopy of RDT) is much better than none at all, as our results also showed facilities offering none of these tests had mean fidelity scores, which were below average. Although univariable analyses showed all the facility characteristics to be significantly associated with implementation fidelity, when adjusted for all factors, only the type of malaria diagnostic test offered at the facility was significantly associated with fidelity. Therefore, it is important for

facilities offering malaria treatment to children to offer at least one of the diagnostic tests, as RDTs require little skill and are recommended for use in almost all settings.

4.2.3 Respondent characteristics

Most of the respondents in this study fell within the age group of 25 – 44 years, which is very similar to a study in North Western region of Nigeria.(56) Mean fidelity scores were seen to increase with each ascending level of age group, with those 18 – 24 years having the lowest scores and those above 54 years having the highest scores. This is similar to a study conducted across health care facilities in southern Malawi where health care workers' age was a factor of adherence to the national malaria guidelines.(58) It may also be related to the fact that older health care workers may have more years of work experience, as years of practice has also been demonstrated as a significant predictor of implementation fidelity.(57)

Although there were more female respondents in the study, they had lower fidelity scores than their male counterparts, but this was not significant in the final model. Male health care providers in a similar study in Zamfara State, Nigeria had three times the odds of adhering to RDT use before treatment, but this was also not significant when adjusted for other factors.(56) Hence, it can be said that sex of the health care provider is not an important factor to consider in implementing an intervention. Doctors were the second highest cadre of sampled respondents and had the highest mean fidelity score, but this was not significant after adjusting for other factors. Various studies have reported different cadre of health care workers as having the highest adherence scores from nurses (54,56) to laboratory technicians.(49) This might argue the fact that good adherence to malaria case management guidelines can be achieved irrespective of the staff cadre providing the services.

4.3 Strengths and limitations of the study

4.3.1 Strengths of the study

To the best of the author's knowledge, no other study in Rivers State has assessed fidelity of implementation to the test and treat strategy in public, formal private and informal private facilities in Rivers State, Nigeria in the same study. The information will contribute to the knowledge base for academic purposes and policy making in this area of interest. The study

findings can also inform stakeholders on the factors that affect fidelity of implementation to the national malaria guidelines in our locality, especially as another National Malaria Strategic Plan for Nigeria is to be developed in 2021.

The development of a quantitative percentage scale based on a proven conceptual framework for implementation fidelity provides a template for the development of similar tools, particularly for evaluating adherence to the national malaria guidelines. However, this tool should not be used without pretesting and validation in the relevant context.

4.3.2 Limitations of the study

The findings from this study will not be generalizable to other contexts as it is a cross-sectional study and will only be applicable to health care facilities in Port Harcourt metropolis, Rivers State. There may also have been some recall bias from respondents when answering questions under the coverage construct. However, this was largely mitigated by asking respondents questions based on the last ten children under the age of five who had been treated for malaria, as well as checking through health care facility records, where they existed.

Social desirability bias was a possibility as the study participants could have given responses to appear favourable or knowledgeable, which is common with most self-reported evaluations. However, the questionnaire was pretested, and questions structured in the most suitable way to capture the true responses. It is possible that other potential confounders of fidelity may exist outside those assessed which the study was not able to control for as it is a cross-sectional study.

Paucity of information on the use of the Conceptual Framework for Implementation Fidelity to assess adherence to malaria management guidelines limited the depth to which the study findings were discussed. The absence of a standardised tool for measuring implementation fidelity to malaria intervention programmes also affected the development of the data collection tool, which had to be created without reference to any existing parameters.

5 CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

In conclusion, this study was able to measure the fidelity of implementation of health care facilities in Rivers State to the "test and treat" strategy of the national malaria guidelines, when managing children aged under the age of five. It has lent further credence to the fact that fidelity is an important implementation consideration towards achieving intervention outcomes. The fact that facilities are not implementing the guidelines at high fidelity is a major barrier to the achievement of the goals of the National Malaria Strategic Plan, one of which is to ensure that all clients are tested for malaria before treatment by 2020.

From this study, there was high participant responsiveness and low intervention complexity as regards the guidelines which are positive signs that can drive better adoption of the intervention. The significant association between parasitological diagnostic tests and implementation fidelity should encourage policy makers and implementing partners to continue supporting health care facilities with diagnostic test supplies to increase adherence to the guidelines. Poor availability of the guidelines in health care facilities, which reflected in a low mean fidelity score, is another factor that should be addressed. Lastly, low fidelity of implementation of the guidelines among PPMVs, who enjoy the most patronage from caregivers of children under five years of age, suggests a knowledge gap that requires urgent attention.

For effective implementation of the national malaria guidelines in health care facilities, the following recommendations are suggested based on our study findings:

i. Health care providers should be further educated on the importance of adhering to the "test and treat" strategy to improve programme ownership and enhance their adherence to the guidelines.

ii. Emphasis should be placed on training service providers in the private health care sector, with an emphasis on PPMVs, on the national malaria guidelines as well as the use of RDTs to improve their fidelity to testing before treatment.

iii. The national malaria guidelines should be made available to all health care facilities that manage cases of malaria, and where available, it should be easily accessible to all service providers in the facility.

iv. Older and more experience health care workers in a facility can be used to provide on-the-job mentoring to their younger colleagues on adherence to recommendations of the guidelines.

v. Further empirical research on how implementation fidelity can be measured in the Nigerian context, using conceptual frameworks, should be explored.

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APPENDICES

Appendix A 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 Mina Whyte (Student number: 2170903) am a student registered for the degree of MSc Epidemiology (Implementation Science) in the academic year 2019-2020.

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.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature:  Date: 03/04/2021

Appendix B Questionnaire

FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA

HEALTH CARE FACILITY QUESTIONNAIRE

Good day. My name is _____ and I am collecting data for an academic research study to measure the level of adherence of health care facilities, pharmacies and drug stores in Rivers State to the national malaria guidelines.

This facility has been selected to be a part of this study because it provides malaria treatment services to children below 5 years. Participation is strictly confidential and voluntary, and you can decide not to answer these questions at any point in this survey. However, your participation in this survey will be highly appreciated to assist in increasing knowledge for our research study.

Kindly read through the participant information sheet and consent form and if you agree to participate, indicate so on the consent form.

SECTION A: Facility characteristics

1.	LGA	Obio/Akpor ☐ Port Harcourt ☐			
2.	Type of facility	Public	Formal Private (Hospital/Clinic/Pharmacy)		Informal Private (PPMV)
3.	Type of malaria diagnostic test offered at facility	Light microscopy	mRDT	Both	None
4.	The facility has a copy of the current national	Yes ☐ No ☐			

	malaria guidelines.	

SECTION B: Respondent characteristics

1.	Age of respondent (in years)	18 – 24 ☐ 35 – 44 ☐ 25 – 34 ☐ 44 – 54 ☐ >54 ☐
2.	Sex	Male ☐ Female ☐
3.	Professional cadre	Doctor ☐ Nurse ☐ Pharmacist ☐ Community Health Worker ☐ Technician (Laboratory/Pharmacist) ☐ Non-health care worker ☐
4.	Duration of facility operation (*in months*)	

SECTION C: **Implementation fidelity**

(i) **Content**

1. Are you aware that there is a Nigeria National Guidelines for Diagnosis and Treatment of Malaria (2015)?

   Yes ☐ No ☐

2. In this facility, parasitological diagnosis (testing) is recommended/performed in all suspected cases of malaria in children aged under five years?

   Yes ☐ No ☐

3. Light microscopy or malaria rapid diagnostic tests (RDT) are the diagnostic methods are recommended to test for malaria?

   Yes ☐ No ☐

4. Antimalarial treatment is offered to only children aged under five years who test positive for malaria.

   Yes ☐ No ☐

C(ii): **Coverage**

5. For the last child aged under-five years treated with antimalarials at this facility, was a parasitological diagnostic test performed/requested? Yes ☐ No ☐
6. For the last but one child aged under-five years treated with antimalarials at this facility, was a parasitological diagnostic test performed/requested? Yes ☐ No ☐
7. For the last ten children aged under-five years treated with antimalarials at this facility, how many had parasitological diagnostic test performed/requested? _____ (*Fill in a number*)

(*Respondent may check through facility records if available)*

C(iii): **Frequency**

8. How often is parasitological diagnosis performed/requested for at this facility for children under-five years before treatment with antimalarials?

   Always ☐ Usually ☐ Not often ☐ Rarely ☐ Never ☐

SECTION D: Moderating factors

(i) Facilitation strategies

1. Has this facility received any support towards implementing the national guidelines?

   Yes ☐ No ☐

   If yes,

2. What support has been provided from government/stakeholders to the facility as regards implementation of the guidelines *(tick all applicable)*;

   - None ☐

- Training (*whether formal or informal)* ☐
- Provision of guidelines to facility ☐
- Supportive supervision ☐
- On-the-job mentoring ☐
- Provision of diagnostic test supplies (e.g. equipment, kits, reagents etc.) ☐

(ii) Intervention complexity

3. The national guidelines are easy to understand and comply with.

   Strongly agree ☐ Agree ☐ Neutral/Undecided ☐ Disagree ☐ Strongly disagree ☐

4. It is costly to test all patients with fever before treating for malaria.

   Strongly agree ☐ Agree ☐ Neutral/Undecided ☐ Disagree ☐ Strongly disagree ☐

(iii) Participant responsiveness

5. This facility accepts the "test and treat" strategy of the national malaria guidelines as best practice when managing children under-five years with fever.

   Yes ☐ No ☐

6. This facility accepts that testing children under-five years for malaria before treatment is better than presumptive diagnosis and treatment.

   Strongly agree ☐ Agree ☐ Neutral/Undecided ☐ Disagree ☐ Strongly disagree ☐

Thank you for participating in this research study.

Appendix C Study information document

Study title: FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA

Greetings Sir/Ma,

Introduction:

My name is Mina Whyte and I am a student with the University of the Witwatersrand conducting a research study. Research is a process used in seeking new knowledge. In this study we want to learn what is the level of adherence of health care facilities in Rivers State to the national malaria guidelines and what factors are associated with adherence to the guidelines. This is not a routine exercise, neither are we involved in monitoring or supervision activities. Rather, national surveys have reported a decline in adherence to the malaria guidelines in Rivers State as regards diagnosis before treatment and we would like to investigate this further from the health care facilities perspective to provide more information on how well or poorly adherence levels are, and why it is so. This information will help relevant stakeholders, e.g. government and its partners, to develop provider-focused strategies to improve malaria case management in children under-five years.

Invitation to Participate:

We are inviting you to take part in this research study because this facility provides malaria case management to children under-five years.

What is involved in the study?

This is a cross-sectional, descriptive study with analytical components conducted between January and December 2020.

It will involve public and private health care facilities, pharmacies and patent medicine vendors in Rivers State that provide malaria treatment services to children under-five years.

Data will be collected using pre-tested interviewer-administered questionnaires on android devices. The questionnaire will be administered at the facility to the head of facility or whomever he/she delegates.

Questions will be on the facility's practices regarding management of malaria in children under five years, and adherence to the national malaria guidelines.
You only have to answer questions you are willing to, and you can stop the interview at any time.
Each questionnaire will take approximately 15 minutes to complete.

Risks of being involved in the study:
There are no risks to you or the facility from participating in this study.

Benefits of being in the study:
There is no direct benefit to the facility from participating in this study. However, the information provided will be useful to stakeholders for planning intervention strategies focused on health care facilities in both the public and private sector to improve malaria case management in children under-five years who are most vulnerable to the disease, and ultimately take Rivers State closer to malaria elimination.

You will be given pertinent information on the study during the project and after the results are available, if requested.

Participation is voluntary.
Refusal to participate will involve no penalty or loss of benefits to which the you or the facility is otherwise entitled.
Kindly note that you may discontinue participation at any time without penalty, or loss of benefits to which you or the facility is otherwise entitled. There is no requirement to provide a reason for withdrawing and any data collected from this facility will in default be destroyed, unless you specifically consent to its retention.

Reimbursements:
There is to be no payment or cost associated with participation. Questionnaires will be administered at the facility during normal work hours.

Confidentiality:
All personal information will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and her Supervisors.
The only exceptions - and all of them are rare - would normally be:

1. personal information may be disclosed if required by law.
2. the Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint, or for a compliance audit.

If results are published, this may, exceptionally, lead to cohort, or more rarely, individual identification. All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly.

Anonymity of all participants will be ensured as no personal identifiers will be collected in the questionnaires.

Contact details of researcher/s: If you need further information, or want to report adverse events, kindly contact;
Mina Whyte, Principal Investigator, by telephone no. +2348183416697 or by e-mail at minaw2001@yahoo.com, Or
Prof. Jonathan Levin, Supervisor, by e-mail at Jonathan.Levin@wits.ac.za

Outputs

The expected output at the end of this study will be a research report and a journal publication. We will be happy to share the report with you, if requested. Kindly indicate so to us by any of the contact details provided above.

Contact details of HREC administrator and chair – for reporting of complaints / problems.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee") and the Rivers State Health Research Ethics Committee. 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. 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.

Appendix D Participant consent sheet

PROJECT TITLE: FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study, I am free to speak to any of these contacts.

Contact details:

Mina Whyte, Principal Investigator, telephone no. +2348183416697 or by e-mail at minaw2001@yahoo.com

Prof. Jonathan Levin, Supervisor, e-mail at Jonathan.Levin@wits.ac.za

Dr. Wiedaad Slemming, Co-supervisor, email at Wiedaad.Slemming@wits.ac.za

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____

Signature: _____

Date: _____

Witnessed by:

Name of Witness: _____

Signature: _____

Date: _____

Appendix E Exploratory data analysis for implementation fidelity score

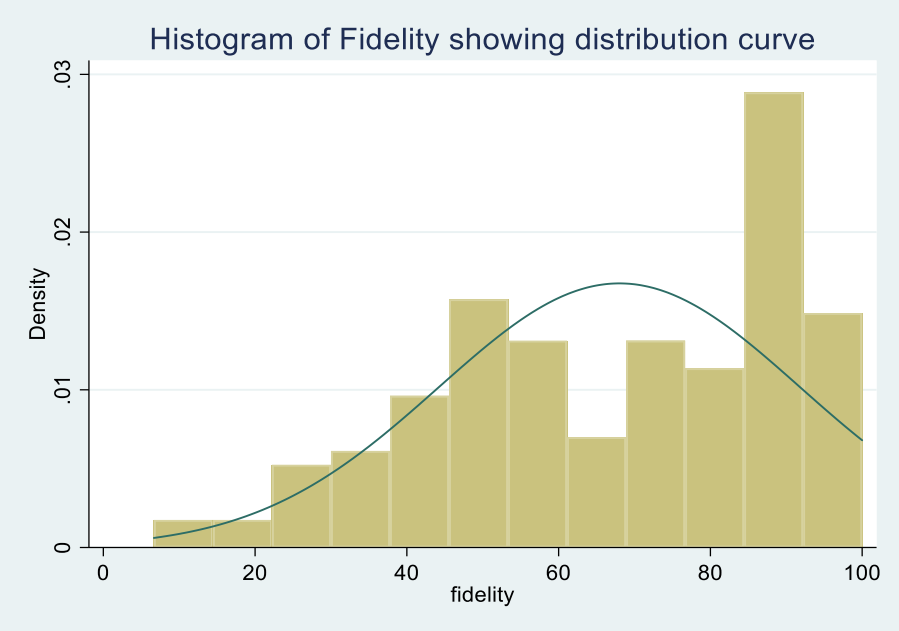


Fig E.1 Histogram of Fidelity showing its distribution curve

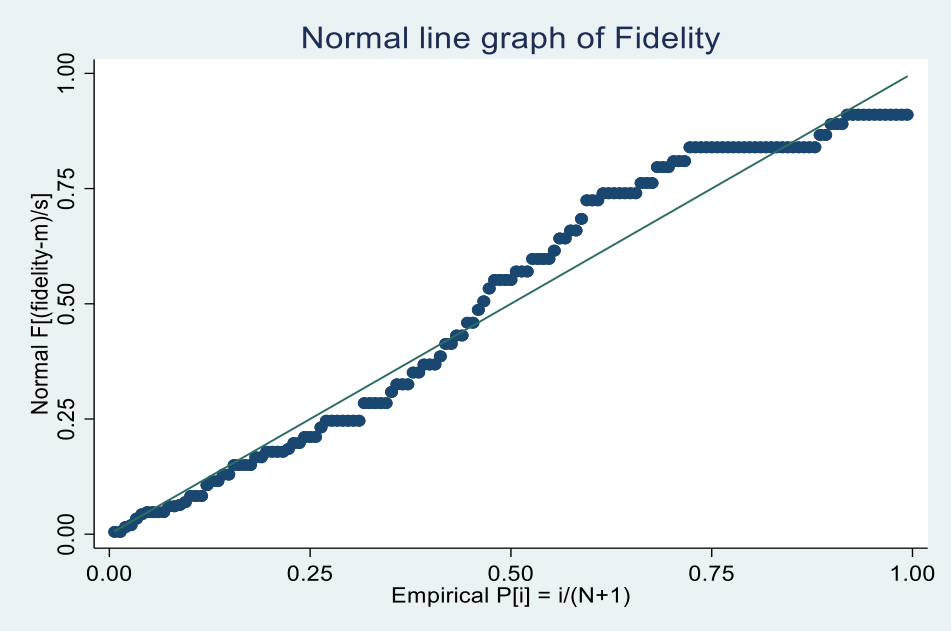


Fig. E.2 Normal probability plot of Fidelity

Appendix F Regression diagnostics of linear regression model

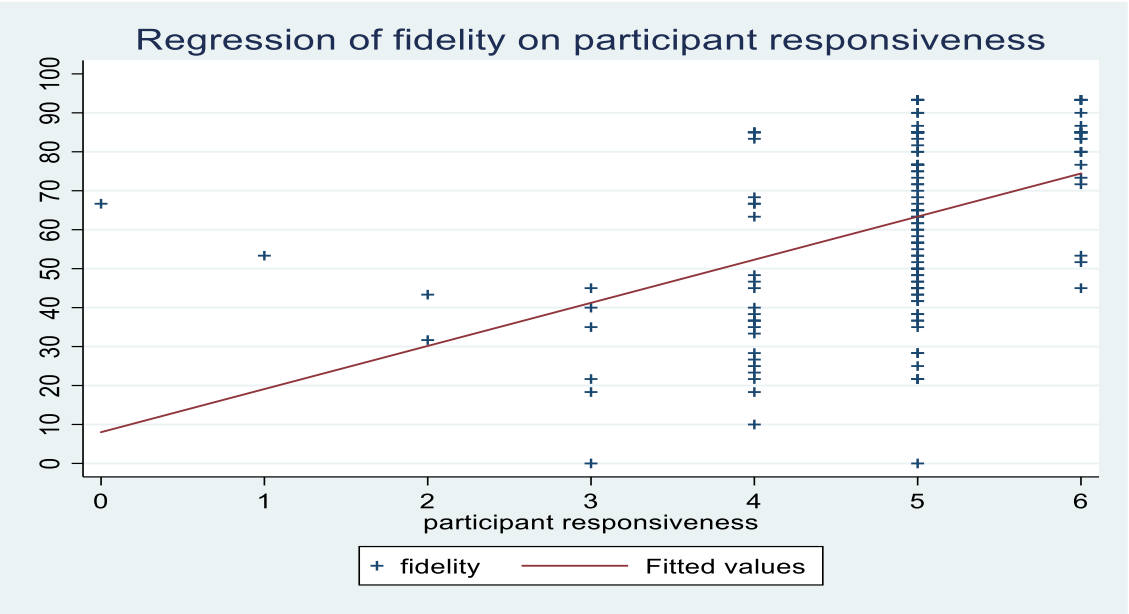


Figure F.1 Plot of regression lines of model fitted with fidelity and participant responsiveness to show linear relationship

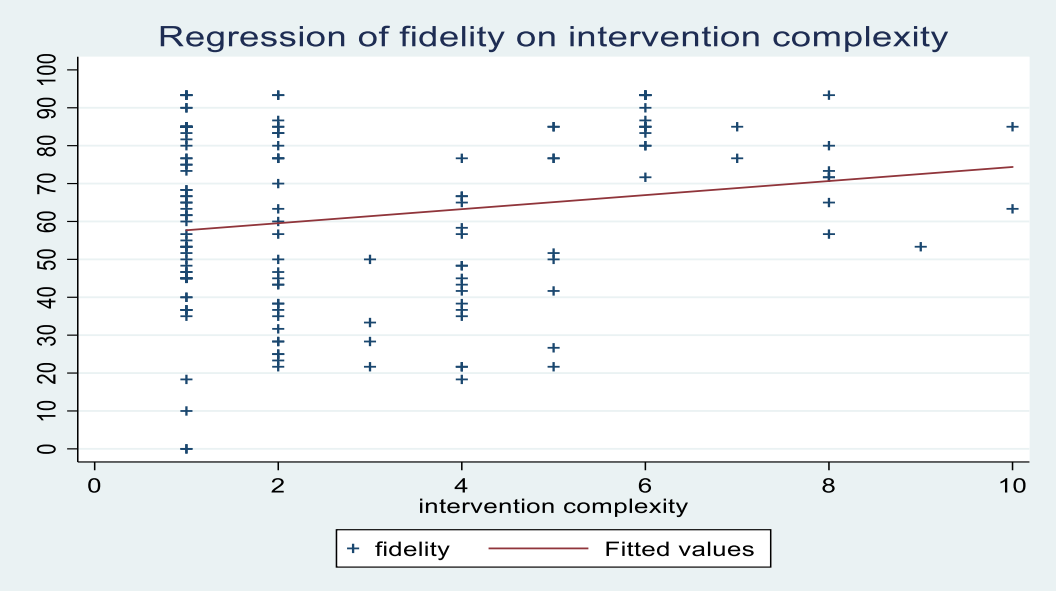


Figure F.2 Plot of regression lines of model fitted with fidelity and intervention complexity to show linear relationship

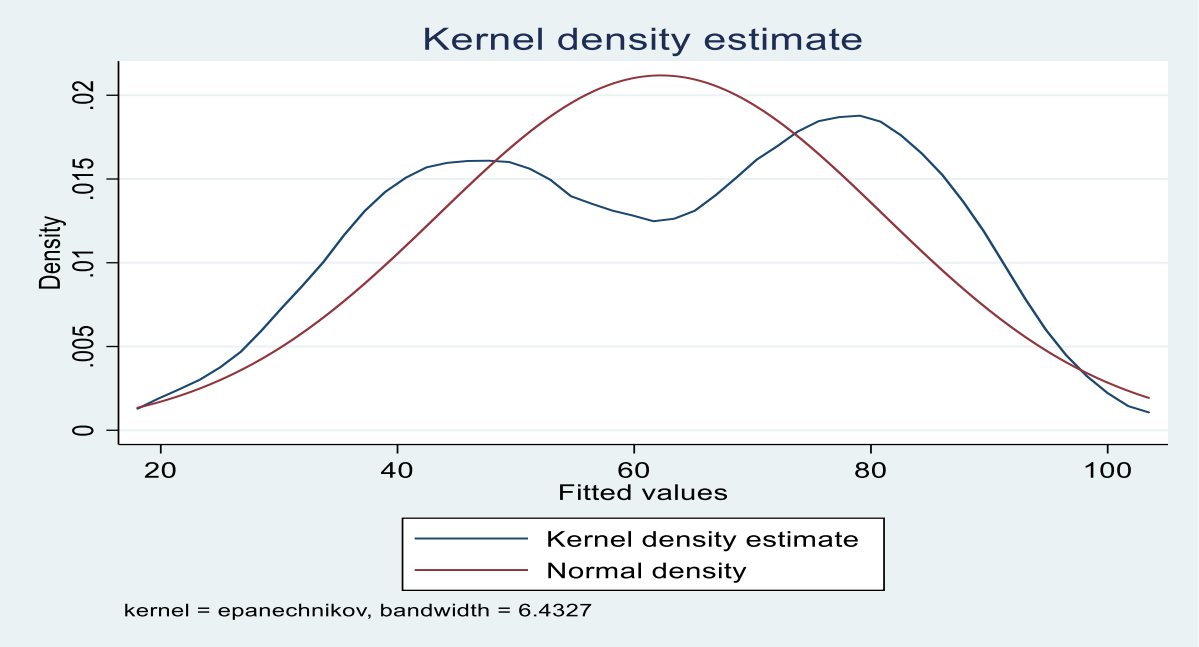


Figure F.3 Kernel density plot showing distribution curve for model residuals

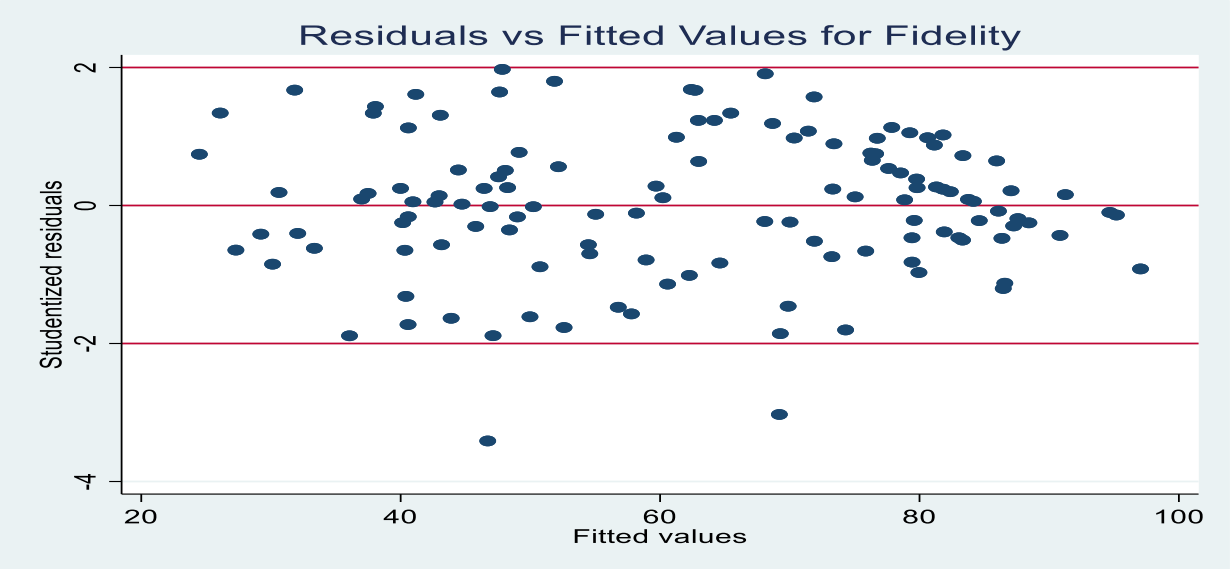


Figure F.4 Plot of studentized residuals against fitted values of fidelity to test for constant variance

Breusch-Pagan / Cook-Weisberg test for heteroskedasticity

```
Ho: Constant variance
Variables: fitted values of fidelity
chi2(1)      =     4.53
Prob > chi2  =   0.0334
```

Appendix G Ethics approval letter from Rivers State Health Research Ethics Committee

GOVERNMENT OF RIVERS STATE OF NIGERIA

RIVERS STATE HEALTH RESEARCH ETHICS COMMITTEE

RSHMB/RSHREC/11.20/VOL.8/049 4th February, 2020

MINA WHYTE MBBS. MSC
2170903

ETHICAL APPROVAL
RE: FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA."

We refer to your letter dated 19th November, 2019 requesting for Ethical Approval of your research project RE: FIDELITY OF IMPLEMENTATION OF NATIONAL GUIDELINES ON MALARIA DIAGNOSIS FOR CHILDREN UNDER-FIVE YEARS IN RIVERS STATE, NIGERIA." After a critical appraisal of your proposal by the Rivers State health Research Ethics Committee approval is hereby given to you to commence your study.

Note the committee reserves the right to withdraw this approval if at any time during the conduct of the study you infringe on the ethical regulations as enshrined in the ethical code of the right of your study subject.

Dr. West, Boma
Chairman, Health Research Ethics Committee

RIVERS STATE HOSPITALS MANAGEMENT BOARD
26 Okoroma Street, P.M.B. 6083, Port Harcourt, Nigeria
Tel: 084-230828, Email: rshmbph@yahoo.com

BOARD MEMBERS
CHIEF DR. SILAS ENEYO (CHAIRMAN); DR. KENNETH EGHUAN OKAGUA (CMD);
DR. NONYENIM SOLOMON ENYINDAH; DR. (MRS.) NGOZI ODU;
CHIEF TONTE HORSFALL;DR. DAVID OGBONNA;
MRS. DAGOGO, JOY, A. (Secretary)

Appendix H Wits Human Research Ethics Committee clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Mina Whyte

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M1911134

NAME: (Principal Investigator)	Dr Mina Whyte
DEPARTMENT:	Epidemiology and Biostatistics
PROJECT TITLE:	Fidelity of implementation of National Guidelines on Malaria Diagnosis for Children under-five years in Rivers State, Nigeria
DATE CONSIDERED:	29/11/2019
DECISION:	Approved
CONDITIONS:	Provide written permissions from the selected health facilities in Rivers State
SUPERVISOR:	Prof Jonathan Levin
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	07/02/2020

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized
to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date