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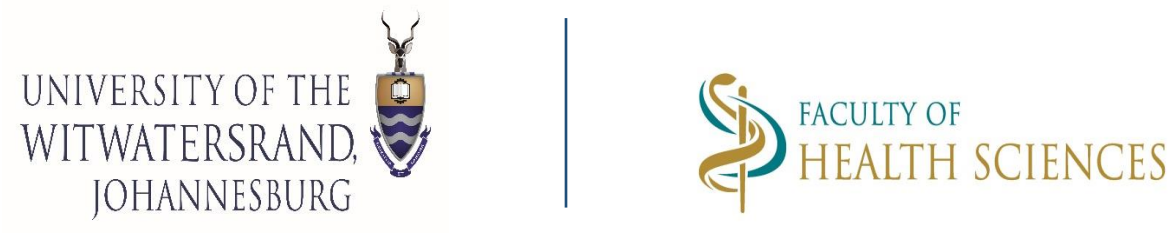
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UNIVERSITY OF THE WITWATERSRAND

FACULTY OF THE HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH



A RESEARCH REPORT SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN EPIDEMIOLOGY-IMPLEMENTATION SCIENCE

TITLE: IMPLEMENTATION FIDELITY OF COMMUNITY DRUG DISTRIBUTORS DURING PREVENTIVE CHEMOTHERAPY (PCT) OF NEGLECTED TROPICAL DISESASE PROGRAM IN PWANI REGION, TANZANIA.

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NOVEMBER 2020

DECLARATION

I, Muhidin Kassim Mahende declare that this research report is my own, unaided research work. It is being submitted for the Degree of MSc Epidemiology-Implementation Science at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Full Name: Muhidin Kassim Mahende

Candidate's Signature: 

Date: 10th November 2020, Johannesburg

DEDICATION

To God Almighty for His amazing grace and blessings, my parents Mr Kassim Shabani and Ashura Josephat for their tireless support, encouragement, and prayers day and night. Not to forget my lovely family, My wife Miss Asmaa Pazi and our children Sumaiyya, Swafiyya and Kassim for their humility and endurance during the whole time of training in South Africa and field research work in Tanzania.

ABSTRACT

Background:

Neglected Tropical Diseases (NTDs) are available in more than 140 countries globally impacting lives, economies, resources, political and daily life interactions. The World Health Organization (WHO) in conjunction with Ministries of Health is promoting the implementation of the mass drug administration program in endemic countries as a ready tool for the prevention, control and towards the elimination of a group of neglected tropical diseases. These target diseases in the Mass Drug Administration (MDA) programs are lymphatic filariasis (elephantiasis), Oncocerciasis (river blindness), schistosomiasis (snail fever), three soil-transmitted helminthiases (caused by *Ascaris*, *Trichuris*, and hookworm), and Trachoma.

The study aimed to assess the implementation fidelity of the PCT program in Tanzania from the providers' perspectives, and together with this, the enabling and inhibiting factors of the program were evaluated.

Methods:

This was a cross-sectional quantitative study that was conducted to evaluate implementation fidelity of the PCT program and fidelity determinants among community drug distributors in Pwani region. This study utilized a researcher administered questionnaire with the district's preventive chemotherapy team which is responsible for the delivery of the program. The team includes healthcare providers in primary healthcare facilities, teachers from selected government primary schools and volunteering community members within the selected region. The study was conducted between January and June 2019. The study employed a one-stage cluster sampling method. Participants were then selected from two clusters of the chosen districts namely Rufiji and Kibaha within the Pwani region. This study composed of two clusters each comprising of 80 participants making a total sample size to be 160. Multivariable linear regression analysis was performed to assess the relationship between the hypothesized predictors and the implementation fidelity score.

Findings:

One hundred and sixty Community drug distributors were recruited in this study of which 75 (46.9%) were males and 85 (53.1%) were females. The mean implementation fidelity score among CDDs was 63.3 (SD 5.8) with a minimum value of 44 and a maximum score of 76.

A multivariable linear regression model was performed in two stages, a model with social-demographic features and predictors singly and later on with all determinants in one model. The final model showed the following predictors; Interventional complexity/Easiness of an intervention (Coeff 0.11, p=0.015 95% CI 0.025-0.20), facilitation strategies (Coeff 0.12, p=0.029 95% CI 0.013-0.23), quality of delivery (Coeff 0.15, p=0.01 95% CI 0.025-0.20) and knowledge (Coeff 0.16, p=0.008 95% CI 0.045-0.28) being significant predictors of Implementation fidelity of PCT program in Pwani region.

Implementation fidelity among CDDs in Pwani region falls under moderate level classification and 4 predictors emerged as significant factors in determining the level of fidelity. These were facilitation strategies, knowledge of an intervention, interventional complexity/Easiness of intervention and quality of delivery.

Conclusion:

The community drug distributors in Pwani demonstrated moderate implementation fidelity on the PCT program delivery. The community drug distributors provided an evaluation of how the PCT program is delivered using their perspectives and perceptions to the program itself. We recommend the use of Implementation Science practices as an additional tool in exploring best practices in healthcare. Implementation Science brings together experiences from scientists and evidence makers with the providers of intervention at ground level. This may offer an easy way for transfer of evidence based intervention to other contexts while having a guide which ensures that implementation outcomes are not varying greatly between the where the intervention originates and where it is adopted.

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ABBREVIATIONS

ALB	Albendazole
ANOVA	Analysis of variance
CDDs	Community drug distributors
CIOMS	Council for International organizations of medical sciences
DOTs	Direct observed treatments
FIMP	Fidelity of Implementation rating system
HREC	Human research ethics committee
HIV	Human Immunodeficiency Virus
IRB-	Institutional review board
IVM	Ivermectin
MDA	Mass drug administration
NIMR	National institute of medical research
NTD	Neglected tropical disease
PCT	Preventive chemotherapy
PZQ	Praziquantel
STH	Soil-transmitted helminths
T-MDA	Target mass drug administration
WHO	World Health Organization
FOYC	Focus of Youth In Caribbean

DEFINITION OF TERMS

Implementation Science: This is the study which helps to provide a linkage between evidence practices/research and routine care settings, it describes the connection existing between research and real-life practices (1).

Implementation fidelity: Is the extent to which a new intervention or an evidence-based practice that has been adapted is carried out as intended by developers aiming to achieve a given outcome (2). It might be a guideline on how a certain drug must be used or even how a surgical procedure must be carried out.

Community drug distributors: Any individual from the given context participating in the preventive chemotherapy program to provide drugs to the community members aiming at prevention and control of neglected tropical diseases (3).

Implementation/facilitation strategies: These are maneuvers of dealing with the contingencies faced on the existing service systems and practice context of concrete implementation activities (4).

Interventional complexity: These are programs or interventions which comprise many essential elements that require special skills and that demands coordination by many people or groups (5).

Participant responsiveness: Participant responsiveness refers to how well participants respond to or are engaged in the delivery of an intervention (6).

Quality of delivery: This is “the extent to which a provider approaches a theoretical ideal in terms of delivering intervention ingredients” (7).

CHAPTER ONE

1.0. INTRODUCTION

This chapter provides a background on the global burden of NTDs and Tanzania in particular. It highlights the significance of implementation fidelity as an implementation outcome measurement for the evaluation of health interventions like Preventive Chemotherapy (PCT). It provides a snapshot on general overview and key features of the PCT program and identifies a gap in the existing literature on implementation fidelity of the PCT program for prevention and control of NTDs. The conceptual framework used as a basis for the evaluation is also covered in this chapter.

1.1. BACKGROUND

NTDs are said to exist as endemic in more than 140 countries globally impacting various populations, economies, resources, political and legal arrangements, health regulations, traditions, cultures, climates, infrastructure and geographical areas (8).

The World Health Organization (WHO) in conjunction with Ministries of Health is promoting the implementation of the mass drug administration program in endemic countries as a ready tool for the prevention, control and towards the elimination of a group of neglected tropical diseases (9). These target diseases in the MDA programs are lymphatic filariasis (elephantiasis), Oncocerciasis (river blindness), schistosomiasis (snail fever), three soil-transmitted helminthiases (caused by *Ascaris*, *Trichuris*, and hookworm), and Trachoma (10). The majority of the affected areas are mainly dealing with five of these diseases, Schistosomiasis, Soil-transmitted helminths (STH), leishmaniasis, lymphatic filariasis, trachoma and Oncocerciasis (11).

Tanzania is among the sub-Saharan African countries with a high burden of neglected tropical diseases (NTDs), being endemic to half (lymphatic filariasis, schistosomiasis, soil-transmitted helminthiases, Oncocerciasis, trachoma, rabies, trypanosomiasis) of all the NTDs (12). Taking an example, the country is placed third with high numbers of lymphatic filariasis and Trachoma cases in the sub-Saharan region whilst its coastal region bordering the Indian Ocean are among places with the highest prevalence of NTDs in the country (13).

Preventive chemotherapy program tackling infectious diseases has been a low-cost tool in many areas globally with appealing results and tremendous success in fighting several diseases like Malaria, NTDs, and others as suggested by WHO (14,15).

Tanzania being among other NTD endemic countries adopted the preventive chemotherapy program in 2006 and integrated the program with other existing health care delivery systems

(16). Through this program which is done annually countrywide targeting five mostly endemic diseases, mass drug administration is carried out using several platforms including established fixed points within communities, health provision centres including hospitals and government primary schools (17).

This study aimed to assess the implementation of the PCT program in Tanzania from the provider's perspectives, and together with this, the enabling and inhibiting factors to the PCT program were evaluated. Specifically, this evaluation assessed several aspects of the PCT implementation fidelity, whereby a fidelity domain called adherence was used to determine at which level are the ingredients of the PCT program being observed (18). This entailed measuring fidelity level using its adherence construct which comprises of Contents and schedule of the program implemented, duration of the implementation, coverage of program components, targeted endemic settings and vulnerable groups in communities, and lastly the frequency of the program implementation (2). On the other hand, moderating factors that affect the implementation fidelity which may result in unintended outcome of the preventive chemotherapy interventions were assessed (6,18).

1.2. PROBLEM STATEMENT

The burden of NTDs in Tanzania and other tropical and sub-tropical countries is still big and in great need of continued support through prevention and control programs while moving towards the WHO goal of elimination of these diseases in major endemic countries by the year 2030 (17). The preventive chemotherapy program was adopted from WHO and has proven to be a success in NTD endemic countries but the success rate in Tanzania is not evenly observed, while other diseases within the same program are reported to show marked decline others are still showing disappointing prevalence rates (16). This may be explained by the fact that the way the preventive chemotherapy was adapted and implemented varies within implementing groups hence observance of different trends of outcomes and coverage disparities (19).

Despite these interventions' success in showing there is marked reduction in transmission of NTDs across risky populations globally since inception, there is a need for implementation monitoring of the program to determine gaps explaining disparities in program delivery (20). WHO and other stakeholders have long been monitoring the execution of the NTD program using monitoring and impact evaluation practices and not implementation science/research techniques (21). Another modality employed by the WHO and other stakeholders in overseeing PCT delivery is monitoring on the drug coverage achieved by the implementing countries

whereby a guideline was released to help implementers monitor the coverage in 2010 (15). Both these measures of evaluation deal with aggregated nationally collected data and not stratified regional or districts statistics.

As of now, there is less evidence available from using implementation science techniques in studying and exploring the successes and bottlenecks in implementing preventive chemotherapy program globally and Tanzania in particular.

Since its inception in Tanzania, the preventive chemotherapy program has not been evaluated at the district and regional level in terms of providers' perspective using implementation research tools and tactics. The assessments have been based on aggregated nationwide level data, which may mask disparities in performances across districts and regions (22). Currently, there is no data on how implementers from the national level to region level adhere to the preventive chemotherapy intervention guideline as stipulated by the Ministry of Health guideline. Information on determinants affecting the PCT adherence at these disaggregated levels of implementation is also unavailable.

Thus, this research work was crucial and necessary in Tanzania looking at one of the implementation outcomes called Implementation Fidelity. Its essence was to look at the level of adherence of the community drug distributors to the WHO guideline on preventive chemotherapy program administering in the selected districts.

1.3 RESEARCH QUESTION, STUDY AIM AND SPECIFIC OBJECTIVES

1.3.1 Research question

What is the implementation fidelity level of preventive chemotherapy (PCT) program for the prevention and control of neglected tropical diseases and factors which determine its delivery among PCT community drug distributors in Pwani region in 2018?

AIM AND SPECIFIC OBJECTIVES OF THE STUDY

1.3.2 Aim

To evaluate the implementation fidelity of preventive chemotherapy (PCT) program for the prevention and control of neglected tropical diseases and factors that determine its delivery among PCT community drug distributors in Pwani region in 2018.

1.3.3 Specific objectives

1. To assess the implementation fidelity of preventive chemotherapy (PCT) program for the prevention and control of neglected tropical diseases and its implementation among PCT community drug distributors in Pwani region in 2018

2. To describe the determinants of implementation fidelity of the preventive chemotherapy (PCT) guideline of neglected tropical diseases among PCT community drug distributors in Pwani region in 2018
3. To investigate the relationship between determinants and implementation fidelity of preventive chemotherapy (PCT) of neglected tropical diseases among community drug distributors in Pwani region in 2018.

1.4 JUSTIFICATION

The literature review was conducted to give light to an emerging body of knowledge in academia on the use of implementation research tools and theories in evaluating complex programs. Cromwell suggests that observed varying coverage rates and failure in reaching WHO coverage goals of 75% by 2020 and eradicating NTDs by 2030 might be explained by the dynamics of the intervention structure itself and perhaps the people implementing the intervention (23). The evaluation of MDA/PCT program regarding implementation outcomes taking an example of fidelity and its determinants is still uncertain. Moreover, there is a lag on the use of implementation research theories and frameworks among policymakers, stakeholders and practitioners in most developing countries specifically in sub-Saharan Africa (24). Another gap in the literature is the lack of clear modality to measure fidelity and standardized reference points for classifying the degree or the level of fidelity as an outcome of implementation for any intervention delivered (25,26). There is limited work that has been done on Implementation Science looking at programs aimed at prevention and control of NTDs especially in developing countries of which implementation of the PCT program is one of the big programs on delivery. Specifically, there is a gap in understanding the implementation of the PCT program among CDDs in Tanzania and this study seeks to add new insights to that gap. This evaluation explores the extent and effectiveness of preventive chemotherapy implementation at the district level.

To my knowledge, there is no similar study that has been conducted aimed at evaluating the implementation of the preventive chemotherapy intervention at the regional level in Tanzania. Research findings from this study are expected to provide a provider's perspective and insight to PCT implementing teams, project managers, Ministry of Health and other stakeholders in NTDs control and prevention on how to fine-tune the strategies for better implementation and prospects for a policy review.

1.5 LITERATURE REVIEW

1.5.0 INTRODUCTION

This section provides a detailed review of the literature about Implementation Science, Implementation fidelity, Determinants of implementation fidelity and the conceptual framework employed in conducting this study. The conceptual framework used is that suggested by Carol et al in 2007 known as Conceptual framework of Implementation fidelity and with some modification adopted from the framework developed by Hasson et al in 2012 (6,18). This framework is a theoretical tool developed to assist in understanding the enabling and inhibiting factors that may alter the implementation processes of intervention.

1.5.1 IMPLEMENTATION SCIENCE/RESEARCH

Scholars such as Proctor (2009) and Fairweather (1974) have explained that implementation science is a "scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice'' or simply a "science to service gap" (4,27,28).

It serves by promoting the strict linkage of what is known from the literature and evidence-based sciences to what and how the practices are in the real world settings like health care, aiming at improving the delivery of a given service or performing a certain procedural task (29).

Failure in complying to the intervention requirements or an evidence-based practice has been linked to observing unintended output like inappropriate care of service delivery or persistence of a clinical condition to patients on certain treatment (30). Implementation science takes a further step in comparison to conventional epidemiological research which usually examines problems from the patients' or recipients perspective only, implementation science provides some room for examining problems from the service providers and recipients concurrently, institutions and different subcategories in healthcare provision levels perspectives (31).

Implementation science addresses interdependent setbacks simultaneously, in contrast to former modalities whereby an innovation was developed and the resolution was made later on how to adopt it and put in real practice settings (32).

Implementation of a program is measurable using its possible outcomes profile; various scholars have explained and defined the eight implementation outcomes but this study will look into implementation fidelity only (33,34). It is through these outcomes whereby various conclusions might be drawn about an interventional implementation process (35).

1.5.2 IMPLEMENTATION OUTCOMES

Several authors have suggested the so-called implementation outcomes as standard measures for describing the results of an intervention delivered (1,33). These are significant because they stand as critical factors in implementation research to define what we are looking upon and what we are aiming to improve or change in the normal existing practices (36).

Implementation outcomes serve many purposes, these include as being indicators for success, proximal indicators of the implementation process and may stand as intermediate outcomes for a service delivered or a quality of care provided in the health system (25,37). The application of reliable, valid, and pragmatic evaluations of implementation outcomes is necessary for monitoring and evaluating implementation efforts and may allow drawing comparisons of the strategies used to deliver an intervention (34). Additionally, many others have also suggested that a majority of scholars agree that effective delivery of the intervention will lead to the intended outcome of an intervention (35,38,39).

Proctor et al in 2009 put forward the theory of outcomes by putting up together the following parameters as standard outcome measures: acceptability, feasibility, uptake, penetration, cost, fidelity, and sustainability (4). These were further modified in 2011 by adding another parameter called appropriateness and the uptake outcome was changed to be renamed as adoption (25,34). Implementation outcomes are inferred or presented as behavioral attitudes and perceptions, intentions and willingness, or just reported observations (25). Implementation outcomes are crucial in evaluating stakeholders' (providers and recipients) perceptions of treatment or a public health program, they also provide a means for evaluating perceptions of strategies used in delivering a program of which some strategies are complex (40,41).

The process of analyzing implementation outcomes not only that it helps to pick those components that are vital to the intervention but also tells the essential content that may determine the modest requirements for improved implementation fidelity (39). It is said also that the main priority for implementation research is to inform why an evidenced-based intervention is successfully delivered in one context but a failure in another similar context (42).

This study will focus on the implementation fidelity outcome as a measure for evaluating the PCT program delivery in Tanzania as adopted from the WHO and is implemented in several other endemic countries globally.

1.5.3 IMPLEMENTATION FIDELITY

Implementation fidelity evaluation and measurements give room for direct assessment of the degree of intervention delivery shift and trend (2). Fidelity has been measured extensively in various fields, in Haiti, a monitoring and evaluation program for NTDs leveraged fidelity concepts using process indicators to measure the success and failure of the NTD program delivered using community drug distributors (43).

It has been noted that once implementers of an adopted intervention like preventive chemotherapy can get higher fidelity measures on the implementation there should be high effectiveness of the intervention in that particular context (1). Fidelity measures have been proven to significantly assist in evaluating new complex programs which are administered in contexts with fewer supervisions and less monitoring processes (44). Implementation fidelity is the most commonly measured outcomes and has been used to compare genuine evidence-based practice and the implemented intervention looking for adherence and exposure dimensions, it has been a big concern of implementation researchers who attempt to compare treatment performance from their laboratory benches to the real-world settings (33).

This study also leveraged implementation fidelity principles and theories using adherence construct to uncover the discrepancy of the PCT program from providers characteristics and their perspectives in Tanzania. Adherence is measured through coverage of an intervention, contents, duration, and frequency of delivering. These are further explored below.

Contents

The content of an intervention is explained as the active components of it like the drug tested, new treatment regimen/procedure, special skills or knowledge that the intervention attempt to convey to the designated beneficiaries and recipients (18).

Berman et al in 1976 measured implementation fidelity and realized that there was a similar observation on this implementation outcome despite employing different strategies, this was explained by the fact that the common guideline/policy used to these programs provided a limited influence on the implementation process (45). Hasson et al have placed an argument in their study on continuum care that intervention implementation may allow some flexibility as long as the active components of an intervention adhered maximumly (6). While Kilbourne et al in 2007 in the Replicating Effective Programs (REP) framework insisted that the active components of an intervention must be standard, only the modality of how they are delivered might be allowed to have some flexibility (46).

Forgatch et al in 2005 on researching parenting management training looking for adherence on the contents of Fidelity of the Implementation rating system (FIMP), high FIMP ratings predicted improvements in parenting practices for both mothers and stepfathers and they concluded that high fidelity was a significant predictor of intended outcomes (47).

Coverage and Dose of an Intervention

Coverage of an intervention is part of the adherence domain which makes sure that whether all the individuals or beneficiaries who must be part and parcel of the intervention are reached by the intervention (18).

The dose of an intervention is defined as the volume of program ingredients received by recipients though other researchers looked at it as that amount of program covered from the original package (7).

The application of consistent implementation procedures and delivering materials enhances the level of implementation fidelity for the program intervention and hence the intended outcome (48). Bo wang et al in 2015 also suggested that teachers who attended the Focus Of Youth In Caribbean (FOYC) training program happened to fall in high implementation group category compared to those who attended fewer sessions of the training program, these teachers were able to deliver more than 80% of the contents to students consistently and they had an adherence of more than 86% (35). A study in Iowa in 1999 found that reduction rates in alcohol consumption in children were higher for those children who received a higher number of required training sessions compared to the rest in the entire sample but the effect diminished during follow up two years later (49).

Mihalic in his 2002 article highlighted the dosage or exposure of an intervention to be a serious challenge to implementation fidelity as there are some inconsistent observations, he added that interventions are less effective when recipients are unable to receive the required dosage or enough exposure (50).

Duration and frequency

Carrol et al in 2007 suggested that if the providers for an implemented program adhere fully and consistently to duration and frequency as suggested by original developers, the level of implementation fidelity may be improved (18).

Duration of an intervention may be described as the continuum of service delivery without interruptions while the frequency of an intervention is explained as the number of rounds or cycles required to deliver the intervention (51).

Implementation standards are developed while highlighting the modest criteria for improved implementation outcomes like the type of providers required, provider to recipient ratios, frequency, and duration enough to deliver the particular intervention (7).

Nurjono et al (2019) found that the frequency of actualization of transition care intervention was observed varying according to the needs of users, providers presence, and their confidence in implementing the program (52).

Hasson et al in 2012 while looking at the interaction between fidelity and moderating factors in complex interventions reported that there was no variation in frequency and duration of the original components but the newly added components showed variation in the dose of an intervention (6).

In Tanzania the PCT program frequency is driven with the burden of the Schistosomiasis: PCT program is implemented once a year in high burden localities, once every 2 years in moderate-high localities, and twice a year for primary school children (11).

1.5.4 IMPLEMENTATION DETERMINANTS

Facilitation strategy

Facilitation is described as an approach employed by facilitators to give necessary support to aid interventional implementers to ascertain the requirements needed which may be absorbed into the implementation to enhance intended outcomes (41,53).

Such approaches usually aim at optimizing and standardizing the implementation fidelity which in turn favour outcomes, these may include the availability of procedural manuals and booklets, guidelines, standard operating procedures, refresher pieces of training, monitoring and provision of timely positive feedbacks to implementers (18,54).

In a study looking at a program dealing with women having history of hip fractures, an observational platform allowed the trainers to be given feedback timely by original program developers on the patients' progress, and they were incorporating the changes received through feedback given promptly, this limited deviations on implementation and led to improved intervention fidelity as well as patients clinical outcome (55). A study (2017) evaluating fidelity on MDA for malaria highlighted that supervision and feedback heightened the quality

of implementation of the program, the performance of community distributors in delivering the program was further influenced by intensive training, availability of guidelines and strong supervision and monitoring strategies (56). Another randomized clinical trial in Australia (2010) used computer-based program to create reminders for scheduling Chlamydia screening sessions to alert providers on age required for screening which was 16-24 years, providers who were trained well on how to set the computer prompt up showed improvement on chlamydia screening during the first consultation though this was not directly linked to an impact of lowering the burden of chlamydia (57). Cucciare et al (2016) suggested on the significance of external facilitation as an important component on integrating new intervention in large healthcare settings where it is assumed that there are numerous hindrances on service delivery, especially when dealing with complex health interventions (58).

This study looked at the effect of availability of manuals/guidelines, refresher training significance, supervisions and linkage systems between providers and coordinators.

Interventional complexity

These are programs or interventions which comprises of many essential elements that require special skills and that demands coordination by many people or groups (5). Carrol et al (2007) hypothesized that interventions designed with simple parameters and procedures require less training and supportive measures to produce desired outcomes compared to complex ones, a modest level of training and guidance is enough to enhance fidelity and outcome (18).

Nurjono et al (2019) have suggested that improved levels of program implementation fidelity are highly influenced by the type of an intervention, the means used to deliver and the interdependence of multiple factors related to that intervention including the interaction between those factors (52,59). This is similar to what suggested by Yeaton and Lee (1981) who described that treatment/intervention integrity and effectiveness of a complex intervention using highly skilled professionals improves the fidelity as compared to using para-professionals, this means with less complex intervention good fidelity levels may be achieved with lesser skilled providers (5).

Another study by Castro et al (2009) in Cuba looking at dengue prevention intervention, authors found that an observed variation on implementation fidelity was largely influenced by the interventional complexity itself which was a result of lack of knowledge among program providers though they concluded that the variation did not affect the outcome of the intervention intended (60).

This study looked at how the CDDs perceived the easiness on delivering the PCT program in terms of program components as well as the context and environmental factors at which the program is administered.

Participants responsiveness

Participant responsiveness refers to how well participants respond to or are engaged in the delivery of an intervention (6,50). It is evident that if participants and recipients perceive an intervention as irrelevant and not helpful their response to embrace the intervention will be challenged making also the coverage and dose of an intervention being disappointing, this will impair the fidelity and perhaps the intended outcome of an intervention (18,52).

A study by Hasson et al. added that participants' responsiveness is a vital factor for enhancing implementation fidelity and intended outcomes, they realized that in the continuum care study work-related frustrations which were due to poor facilitation strategies was defeated by the good perception of participants on the intervention (6).

Gerstner and Finney (2013) on student affairs program concluded that it doesn't matter how the implementers delivers the intervention qualitatively, with all active ingredients and the required dose but if the students' response towards the intervention is poor the impact expected to those students won't be achieved with high success and the fidelity will be challenged (2).

On contrary Muntinga et al (2015) reported to have observed variability in nurses' responses towards the chronic model for frail elders program but the adherence measured showed that the assessment and care plan delivery for the elders was very high (61).

A study evaluating the seasonal malaria chemoprevention in Burkina Faso (2017) supported that the parents' responsiveness to the chemoprevention program by perceiving it useful and effective favoured its successful delivery (56).

This study explored participants responsiveness from providers perspectives but indirectly enquired the CDDs on beneficiary's response towards the program.

Quality of delivery

This is a determinant which is responsible with the manner at which the intervention is delivered so that it produce intended outcomes, inappropriate delivery jeopardizes the degree of implementation fidelity and hence produces unintended outcomes (18). Another study further explained the quality of delivery as those ratings of provider capabilities which evaluates the degree to which a provider can deliver the contents of an intervention consistently in the most ideal way possible (7).

A scoping review (2015) showed that inconsistency and deficit in the quality of delivery close the room for possible identification of essential ingredients for the successful delivery of the intervention which may favour yielding intended outcomes and this may hinder its adoption (62).

Wang et al in 2015 when looking on behaviour of students reveals that quality of implementation was highly related to high knowledge, skills and perceptions on HIV, those who were mentored by teachers belonging to a high and/or moderate implementation clusters demonstrated good knowledge, skills, and perceptions compared to those who belonged to teachers in a low fidelity cluster (35).

Several factors might be jeopardizing the optimal quality of delivery of an intervention, a qualitative study in Tanzania (2015) highlighted three challenges facing midwives practitioners in doing their tasks as; unfavourable-working environment, lack of recognizable status by other cadres and some reported shortage of knowledge and skills (63).

A study on life-skills for drug prevention (2008) reported that teachers and coordinators observed to have high ratings in the quality of delivery of the program were statistically related to an improved level of implementation fidelity (64).

This study looked on team composition structure, easiness of manuals and other related booklets, working tools like weighing scales and height poles and the size of the team concerning area covered.

Incentives

Carrol et al (2007) and others while explaining on the potential relationship among implementation determinants pointed out the possible effect of incentives as it may catalyze the interactive effect of determinants towards fidelity, an incentive may distort the response of both providers as well as participants toward a new intervention (18,52).

A report in Tanzania (2014) highlighted the significance of training and incentives payments as keys in empowering the CDDs with knowledge and boosting their motivation in delivering the program, this was ultimately related to impacts on coverage and reduction of wastage rates of program tools and drugs (65).

In this study, we interviewed the providers on the effect of incentives concerning their participation in the program and its effect on adherence to the manuals and guidelines of the program.

1.5.5 PREVENTIVE CHEMOTHERAPY PROGRAM IN TANZANIA

Despite several ongoing interventions globally, NTDs are still among the leading causes of morbidity and mortality in endemic countries (10). Of the global burden of NTDS 40% of the cases are happening in Africa while only two African countries Morocco (Trachoma) and Togo (lymphatic filariasis) have so far declared the elimination of these NTDs by 2016 (66,67).

WHO has set a 75% coverage target index by 2020 for STH infections and eradication of others in between 2020 and 2025 in all African endemic countries but the implementation strategy is depending also on the burden of a particular disease in a given country (12,68). Unfortunately, despite the program implementation requiring stipulated optimal coverage index, we observe a big disparity in coverage index within countries, taking an example of Tanzania in 2016 where it was reported to have a coverage index of 90% for schistosomiasis while recording only 7% for Trachoma (12,67). Several reports showed that in 2015 close to 1.5 billion people requiring treatment only 988 million people received mass drug treatment of different NTDs across the globe (9,69,70) with no clear description on this discrepancy from the providers' viewpoint.

In Tanzania, the program is implemented annually by two methods as adopted from the WHO preventive chemotherapy guideline: 1. Booth distribution – where drugs have to be distributed in fixed stations and community members come and swallow drugs at these fixed points within their communities as directly observed treatment, 2. Special population group administration - This modality is achieved by administering drugs to specific institutions in the community like schools, marketplaces, health care points, and others as directly observed treatment (11). For this study, we will look at drug administration in primary schools targeting children and in the general community (3). From the WHO manual on the directive of how to implement PCT program across localities with different burdens of NTDs, Pwani region is characterized as a zone with high filariasis burden, moderate schistosomiasis burden, no Oncocerciasis, and high soil-transmitted helminths infections (11). Hence the region is supposed to conduct yearly general mass drug administration (MDA) on Lymphatic filariasis and Oncocerciasis together with yearly targeted mass drug administration on schistosomiasis and soil-transmitted helminthiases for children (71). With general MDA the program is distributing Albendazole and Ivermectin whilst for the targeted mass drug administration the program is distributing Praziquantel and Albendazole tablets (71). Healthcare providers in local communities are responsible for conducting the programs at sub-region and sub-district levels (3). For community distributions, health care providers in Dispensaries and Health centres promote and

mobilize the community to attend and receive drugs at a fixed time in September/October every year with the help of volunteering community drug distributors (71). In primary schools, local health care centres organize in conjunction with local primary schools' authorities and teachers to administer drugs to children in the same round of the year (3).

1.5.6 CONCEPTUAL FRAMEWORK OF IMPLEMENTATION FIDELITY

Implementation researchers suggest that implementation research conducted without employing a theoretical framework is void of foundations of scientific fundamentals and may lack the authority of external validity in other outside contexts (42). This study borrowed the conceptual frameworks developed by Carrol et a (2007) and Hasson et al (2012) (6,18).

Implementation fidelity as defined by Carrol et al (2007) is "the degree to which programs are implemented as intended by the program developers", it moderates the relationship between how implementers of an intervention complied to the interventional needs and the outcome observed (18).

The conceptual Framework of Implementation Fidelity depicts a complex relationship between fidelity and its determinants; these determinants or sometimes termed as moderators have either synergistic or inhibitory effect on the fidelity of a given intervention (64). It has also been reported that the determinants interact with one another affecting the fidelity of the program in one way and also interact or compensate for one another in affecting the program fidelity (19,72).

For high fidelity achievement, researchers recommend that there must be good compliance with intervention ingredients as intended by the developers (1). Carrol et al (2007) and others have highlighted that implementation fidelity is built upon four constructs namely content, coverage, duration, and frequency, on the other hand, there are determinants or moderating factors of fidelity and these include interventional complexity, facilitating strategies, quality of delivery, and participant responsiveness (18). Later on Hasson et al, (2012) modified the framework by adding two more domains namely recruitment and context (6)

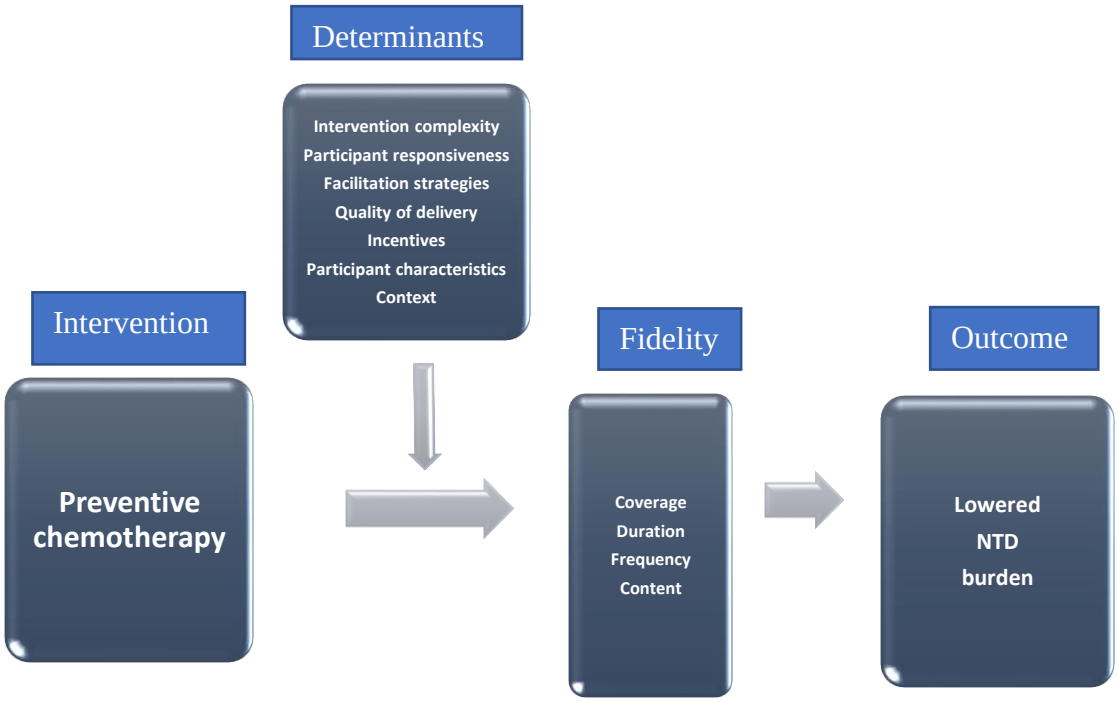


Figure 1: "Conceptual framework of Implementation fidelity" as described by Carrol et al (2007)

SUMMARY

The literature review above showed evidence on the gap that still exists on the knowledge and practice of implementation science. Implementation science is a new subject especially in developing countries and has not widely being utilized in evaluating evidence-based practices. This review provided significant justification for the use of implementation practices in evaluating evidence-based interventions like the preventive chemotherapy program aiming at lowering the transmission of neglected diseases in endemic countries. There is little covered in the scientific literature on evaluating PCT using implementation techniques globally and Tanzania as well.

CHAPTER 2

2.0 RESEARCH METHODOLOGY

2.1 INTRODUCTION

This chapter highlights the methodology which was used to conduct this study. This covers the research study design, study site and location, study population and eligibility criteria, sampling technique employed, sample size, data collection procedure, Data management systems, Data analysis, and Ethical Issues.

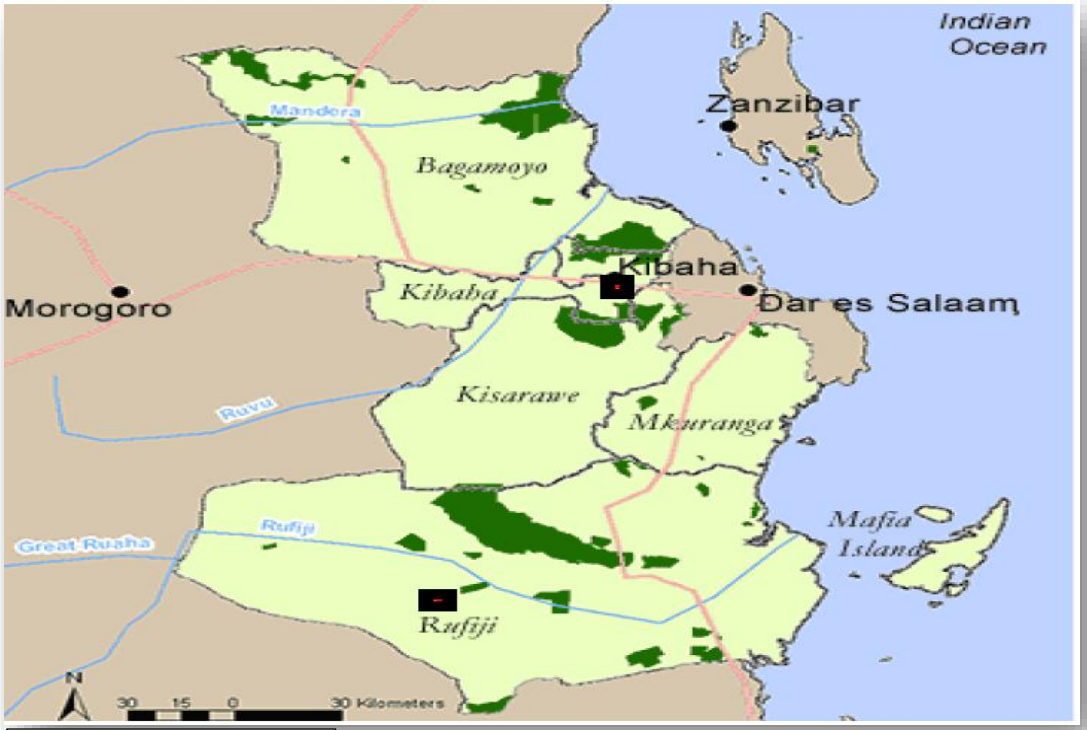
2.2 RESEARCH STUDY DESIGN

This was a cross-sectional quantitative study that was conducted to evaluate implementation fidelity of the PCT program and fidelity determinants among community drug distributors in Pwani region.

2.3 STUDY SITE

Pwani Region is in the middle Eastern part of Tanzania Mainland, between latitudes 6º and 8º south of equator and longitudes 37º30’ and 40º east of Greenwich (see Figure 1), bordering Dar es Salaam city a commercial hub of Tanzania and Indian ocean in the East, Tanga region in the North, Lindi in South and Morogoro region in the West.

Pwani region which houses the two districts of Kibaha and Rufiji had a population of 1,098,668 by Tanzania population and housing census of 2012 (73), Kibaha town has a population of 128,488 while Rufiji district has a population of 217,274. These figures account to the population distribution being 12% and 20% for Kibaha and Rufiji respectively within the Pwani region.



Courtesy: Pwani PORALG

Figure 2: A sketch map of the Pwani region showing the location of study sites of Rufiji and Kibaha.

Among four districts in Pwani, three of them borders the Indian ocean while one district is an island within the Indian ocean. Two of the great rivers Rufiji and Ruvu are flowing throughout most parts of the region characterized by several distributaries and tributaries draining to the Indian ocean favouring many of the inhabitants to be sedentary peasants and small scale fishermen.

Majority of the inhabitants in Rufiji are small scale farmers of paddy (rice), sesame, maize, and cashew nuts while few communities are dwelling along the river Rufiji for fishing activities.

Kibaha which is the capital town of the region located about 40km west of Dar Es Salaam city the commercial hub of the country. The district comprises of small scale traders and vendors in urban and peri-urban areas, but most parts of the rural population are farmers along the basin of the Ruvu river and others are small scale fishermen. Two districts considered in this study are distanced at 202 km apart.

2.4 STUDY POPULATION

This study involved two districts' preventive chemotherapy teams which are responsible for the delivery of the program. The team includes healthcare providers in primary healthcare facilities, teachers from selected government primary schools and volunteering community members within the Pwani region. The study was conducted between January and June 2019.

The Ministry of Health and social welfare when introducing the program faced a challenge of scarce health care professionals to run the program annually and reach most of the population. The program is implemented in two modalities: 1. Annual deworming program in government primary schools nationwide 2. Community mass drug administration in communities showing to have higher burdens of worm infections.

Community volunteers were trained to participate and provide support in communities during mass drug administration campaigns nationally while government primary school teachers were also recruited and trained so that they could conduct the program for pupils in their schools during PCT implementation calendars.

2.5 SAMPLING TECHNIQUE AND SELECTION

The study employed a one-stage cluster convenient sampling method using a district as a cluster. Participants were then selected from each cluster of the chosen districts namely Rufiji and Kibaha within the Pwani region. To enhance analysis stratification by profession was done and participants were selected conveniently amongst primary healthcare providers in selected facilities which are coordinating PCT program in their localities, government primary school teachers in selected government primary schools where the program is implemented and selected community volunteers in villages where the PCT program is implemented. Dispensaries and Health centres coordinating the program were used as a reference for selection of a primary school that was located within 5 km radius from the nearby coordinating health facility.

2.6 SAMPLE SIZE

This study composed of two clusters each comprising of 80 participants. A total sample size of 160 individuals was obtained with a power of 80%, the design effect was 2.0 and a margin of error of 0.05 was considered.

2.7 ELIGIBILITY CRITERIA

This study included members of the PCT implementation team in Pwani region.

1. Those who were 18 years of age and above by interview date

2. Willingness to participate in the study and agreed to sign the written informed consent form.
3. Those who were physically available during the data collection period.
4. Those who have been involved in the PCT program at least 1 round within the past 2 years of implementation.

2.8 DATA MANAGEMENT AND ANALYSIS

2.8.1 Data collection

Data were collected in two ways:

1. An electronic interviewer-based questionnaire by a "REDCAP 7.6.7 - 2018© Vanderbilt University" software which is hosted at the University of Witwatersrand in Johannesburg. The questionnaire was developed in REDCap and then transferred to portable electronic devices (tablets) through a REDCAP mobile application version 3.2.9 of 2019©. Data was captured offline during interviews and then synced later to REDCAP servers after completion of each interview depending on availability of internet connectivity

2. Some few interviews were conducted using paper-based questionnaires and the data was then entered manually to the database of REDCAP due to power outage problems.

2.8.2 Data analysis software

From the REDCAP database, data were transferred to STATA 15.0 software "(Stata Corp 4905 Lakeway Drive College Station, Texas 77845 USA)" for cleaning and analysis process.

2.9 STUDY VARIABLES

2.9.1 Explanatory variables

In this study socio-demographic features of individuals and the fidelity determinants characteristics of implementation as explained in the conceptual framework of fidelity were used as proxies for explaining the fidelity among community drug distributors in the study area.

2.9.2 Socio-demographic features

1. Age
2. sex
3. Education level
4. Duration in the program
5. Knowledge on PCT program

2.9.3 Fidelity determinants

1. Facilitation strategies

2. Interventional complexity
3. Participant responsiveness
4. Quality of delivery

2.10 DATA ANALYSIS PLAN

2.10.1 Response variable

The response variable for this study was implementation fidelity assessed using its domain called adherence. The adherence domain in this intervention was measured using its subdomains namely content, dose or coverage, duration, and frequency.

Content of the PCT intervention was measured by how much the community drug distributors together with PCT managers adhere to the PCT guidelines as designed by WHO and adopted by the ministry of health.

A series of questions were administered to community drug distributors on some general and crucial procedures for implementing the program. The questions were in Likert scale format and a composite score was generated using the responses provided corresponding to contents of an intervention.

The dose of an intervention is a function of two components: 1. frequency 2. Coverage (18). Both components were assessed through a series of questions administered to community drug distributors on their experiences and perception in executing the intervention. The questions' responses were in a Likert scale format which was averaged to form a composite average score as a continuous variable. The two average scores for content and dose were used to generate a single fidelity score which was presented as a percentage. The fidelity score values for CDDs were assessed for normality and did not violate the normality assumptions. Descriptive analysis was done by calculating mean score fidelity with its corresponding standard deviations across various categories of community drug distributors.

2.10.2 Demographic characteristics

Descriptive analysis was done and reported as mean, median, standard deviations and interquartile ranges for continuous variables while frequencies and percentages were used for categorical variables. Chi-squared test was used for assessing the relationship of categorical variables while student t-test was used to asses mean differences between groups for continuous variables whereby the assumptions of normality were not violated. For more than two-group

comparisons, analysis of variance (ANOVA) was used for normally distributed scores while the Kruskal Wallis test was adopted for non-normally distributed scores.

2.10.3 Implementation determinants

Median and mean scores were computed for each fidelity determinant. Mean scores of all key determinants were computed from the item scales. The computed score was further presented as a percentage value.

2.10.4 Relationship between Implementation fidelity and its determinants

Only multivariable analysis was used to assess the relationship between the response variable and the explanatory variables in this study. For this analysis fidelity determinants were assessed singly in the model while adjusting for significant social and demographic characteristics. Furthermore, a multivariable analysis was fitted by including all significant predictors of fidelity and adjusting for significant socio-demographic characteristics. The variables for the final model were included after literature consideration and the backward selection technique which set a liberal probability of inclusion at 0.2. All tests were two-sided at a 5% significance level.

Table 1. Data analysis plan for explanatory and response variables

Variable	**Outcome or explanatory**	**Scale of measurement**
Fidelity score	Outcome	Continuous, composite score / Percentage
Participant responsiveness	Explanatory	-Continuous, -Composite score/Percentage
Interventional complexity	Explanatory	-Continuous, -Composite score/Percentage
Quality of delivery	Explanatory	-Continuous, -Composite score/Percentage
Facilitation strategies	Explanatory	-Continuous, -Composite score/Percentage
Age	Explanatory	Continuous

Profession/Cadre	Explanatory	Categorical 1. Clinician 2. Nurse 3. Teacher 4. Community volunteer 5. Health attendant
Level of knowledge on PCT	Explanatory	-Continuous, -Composite score
Duration	Explanatory	-Continuous
Sex	Explanatory	Categorical 1. Male 2. Female
Education	Explanatory	Categorical: 1. Primary 2. Secondary 3. Certificate 4. Diploma 5. Bachelor

2.11 ETHICAL CONSIDERATIONS

The research proposal for this study was first submitted to the University of Witwatersrand Human research ethics committee (HREC-Medical) for ethical approval and clearance before data was collected. The study was approved unconditionally with HREC-Medical having a reference number M181149 of 12th March 2019. Furthermore, the same protocol was also submitted to the ethical approval body in Tanzania through the National Institute for medical research (NIMR). Clearance was given on 16th January 2019 with reference number NIMR/HQ/R.8a/Vol. IX/3010.

Written permissions were also sought from district administrative and medical authorities of both sites Rufiji and Kibaha and was granted before the commencement of data collection.

2.12 INFORMED CONSENT

Eligible selected participants in this study were provided with a written consent before their participation by reading and asking clarification where needed before putting signatures on consent forms. An English based consent was translated to the Swahili language which was used for this exercise for all participants. Two copies of signed informed consent forms were produced, one was kept with study investigator and the other was given to study participant for further reading.

2.13 BENEFICENCE

There were no direct benefits to study participants during the execution of this study. A small token to cover for costs of transport incurred by respondents was given to all participants who travelled to points of interviews. Participants were assured that this research work will indirectly help them as the findings might inform on the status of the PCT program of which they are important stakeholders.

2.14 CONFIDENTIALITY

Participants were assured that the data collected is solely for research purposes and their responses shall not be made publicly available during and after the completion of the study. Only the study team had access to the data/responses.

The only exceptions available - and all of them are rarely expected to happen for this kind of study to occur were made open to participants, these are:

1. Personal information may be disclosed if required by law/court.
2. The Human Research Ethics Committees (Medical) of the University may exceptionally require personal data to respond to a formal complaint reported or for a compliance auditing.

2.15 ANONYMITY

To maintain the anonymity of the participants, study identification numbers were assigned to each individual and only research team members had access to the database. The study was conducted in compliance with scientific guidelines on research with human individuals like the Declaration of Helsinki and CIOMS (74).

2.16 QUESTIONNAIRE PRETESTING

The questionnaire for this study was piloted and pre-tested before actual data collection commenced. This allowed for face and content validation of the instrument.

2.17 DISSEMINATION PLAN

The study findings of this work will be shared to participants, local authorities in Rufiji and Kibaha districts, Ministry of Health (Directorate of preventive medicine) and the final research

report shared to the University of Witwatersrand. Findings will be shared in local and international platforms through publications and conferences.

2.20 FUNDING

This study was made possible through a research grant from WHO-TDR Geneva through the School of Public Health, Department of Epidemiology and Biostatistics of the University of Witwatersrand, Johannesburg.

2.21 RESEARCH PROCESS TIMELINES

This research study started with a research proposal development from July 2018. It passed through various milestone including assessment and approval by the Wits School of Public Health in the Faculty of health sciences. Data collection was done between February 2019 and May 2019 in both districts.

CHAPTER 3

3.0 INTRODUCTION

This chapter provides the main results on the level of implementation fidelity of PCT program, description of determinants which affects the fidelity of PCT program and the association between the fidelity determinants and the level of fidelity of PCT program amongst CDDs in Pwani region, Tanzania. Descriptive analysis of the study participants is presented including significant socio-demographics, duration in the PCT program and the level of implementation fidelity for this study.

Determinants for implementation fidelity will be described, explained and assessed with regards to how they affect the level of fidelity for the PCT program. Lastly, a relationship between implementation fidelity and its determinants will be described.

3.1 DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

Data were collected from community drug distributors who provided consent to participation from two districts of Kibaha and Rufiji in Pwani region. These CDDs are the ones responsible for administering the program annually during scheduled and any required unscheduled rounds.

The characteristics of the respondents and facilities are shown in Table 2. A total of 160 community drug distributors consented to take part during interviews in both districts, 81 from Rufiji and 79 from Kibaha. Seven government health facilities and 25 government primary schools were visited and used as center points for interviews.

There were 75 (46.88%) males and 85 (53.13%) females in total. The mean age of participants was 38.1 years with a standard deviation of 9.46. In terms of occupation among participants, it was observed that the majority were community volunteers 47 (29.38%), followed by primary school teachers 45 (33.13%), others were 25 (15.63%), nurses were 19 (11.88%) and clinicians were 16 (10%). The participants under the “other occupation” category comprised of community/environmental health officers and social workers which are also part and parcel of the PCT program delivery in Tanzania.

The median duration for a provider to get involved in administering the program since the first recruitment was 4 years with a minimum duration of 1 and a maximum duration of 10 years. Education levels observed among the CDDs were; 32 (20%) had completed primary school education, 14 (8.75%) had attained secondary school education, 106 (66.25%) had attained a college training in health or education and 8 (5%) had attained at least a university degree.

For a formal intensive training on PCT program delivery, 156 (97.5%) agreed to have been trained while 4 (2.5%) disagreed on ever receiving the training. Of those who reported having received formal training, the median number of days of training was 1 day with a minimum of 1 and a maximum of 6 days.

Table 2. Descriptive statistics of study participants across two districts in Pwani.

Variable	Category	**Kibaha N=79**	**Rufiji N=81**	**Total N=160**
Sex	Male, n (%)	38 (50.67%)	37 (49.33%)	75 (46.88%)
	Female, n (%)	41 (48.24%)	44 (51.76%)	85 (53.13%)
Age	Mean (SD)	39.4 (9.1)	36.8 (9.8)	
Duration	Mean (SD)	5.3 (2.6)	3.7 (2.1)	
Occupation	Community volunteers, n (%)	36 (45.57%)	11(13.58%)	47 (29.38%)
	Teachers, n (%)	25 (5.06%)	28 (18.52%)	53 (33.13%)
	Clinicians	5 (6.33%)	11 (13,58%)	16 (10.00%)
	Nurses	4 (31.65%)	15 (34.57%)	19 (11.88)
	Other	9 (11.39%)	16 (19.75%)	25 (15.63%)
Education level	Primary n,(%)	26 (32.91%)	6 (7.41%)	32 (20.00%)
	Secondary n,(%)	11 (13.92%)	3 (3.7%)	14 (8.75%)
	College n, (%)	38 (48.10%)	68 (83.95%)	106 (66.25%)
	University n, (%)	4 (5.06%)	4 (4.94%)	8 (5.00%)
Trained on PCT	Yes n,(%)	77 (97.47%)	79 (97.53%)	156 (97.50%)
	No n, (%)	2 (2.53%)	2 (2.47%)	4 (2.50%)

3.2 MEASURING THE IMPLEMENTATION FIDELITY LEVEL FOR PCT PROGRAM ON NTDS

3.2.1 Reliability assessment

A Cronbach alpha assessment for internal consistency and reliability of items that were used to generate an implementation fidelity composite score was performed. For this analysis, the overall Cronbach alpha for fidelity items was 0.65 at which the values for alpha in the sub-domains were ranging from 0.17 to 0.53. A composite score was generated from all items in the four subdomains of adherence for measuring implementation fidelity. The questions were formulated from the conceptual framework of implementation fidelity, a standardized theoretical framework for the evaluation of implementation fidelity.

3.2.2 Implementation Fidelity Score

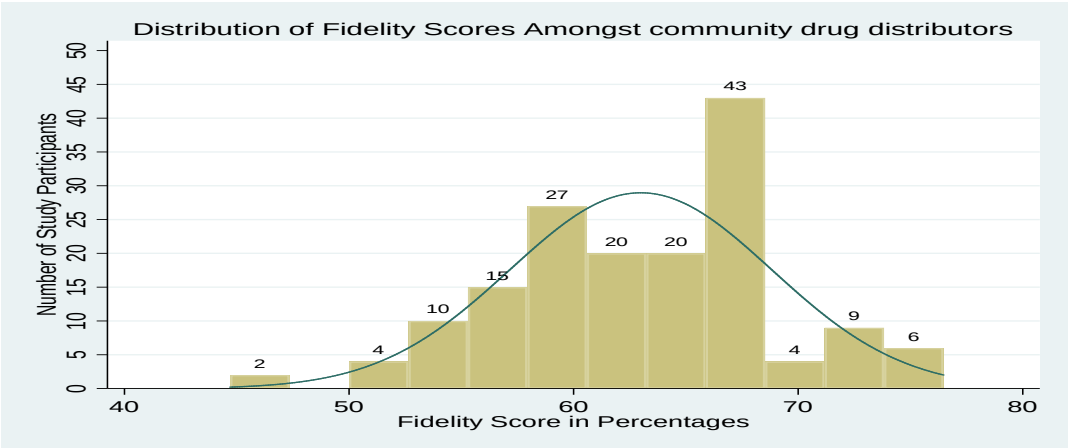
The implementation fidelity score for PCT was generated using four sub-domains of fidelity adherence domain namely frequency, content, duration and coverage of intervention. The Frequency of PCT intervention was determined by the cycles of implementation rounds over years while duration accounted the number of years at which the program is delivered. Seventeen items corresponding to these 4 sub-domains were summed up to create a composite score which was later on converted to a percentage value (Table 3.2).

The computed score for fidelity was checked for the assumption of normality and it did not violate the assumption. A skewness/kurtosis test failed to reject the null hypothesis with p=0,384 and a histogram plot suggested assumptions of normality were not violated (Figure 3.1). The fidelity score mean was used for interpretation of the level of implementation fidelity in this study.

Table 3. Summary Description of the Implementation Fidelity Domain

Latent Variable	Number of items	Likert/Scale Used	Likert/Scale Coding	Range of Composite scores in %	Mean Score in %	Cronbach α value
Content	12	Strongly agree, Agree, neutral, disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	41% – 78%	61.9%	0.5296
Coverage	3	Strongly agree, Agree, neutral, disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	33% – 100%	70.8%	0.33
Frequency and Duration	2	Strongly agree, Agree, neutral, disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	20%-100%	57.3%	0.17
Fidelity (Adherence)	17			44%-76%	63.3%	0.65

Figure 3. Implementation fidelity among community drug distributors in Pwani region.



The mean implementation fidelity score among CDDs was found to be 63.3 (SD 5.8) with a minimum value of 44 and a maximum score of 76. This was classified as moderate fidelity as the recommended by other authors that fidelity to be classified as high is a value not less than 80% (75,76), to date, there isn't a clear reference classification of fidelity in categories of low, middle and high.

3.2.3 Relationship between fidelity and Selected Demographic characteristics

Table 4. Implementation Fidelity scores amongst Community drug distributors using selected demographic features

Feature	Category	N (%)	Mean (±SD)	P values
District	Kibaha	79 (49.4%)	63.54 (±6.6)	0.859
	Rufiji	81 (50.6%)	62.45 (±4.9)	
Occupation	Community volunteer	47(29.4%)	63.00 (±6.1)	0.002
	Teachers	53(33.1%)	61.24(±5.4)	
	Clinicians	16 (10%)	64.63(±7.0)	
	Nurses	19 (119%)	63.90 (±5.7)	
	Other	25(15.6%)	64.94(±4.9)	
Sex	Male	75 (46.9%)	62.05 (±5.5)	0.748
	Female	85 (53.1%)	63.82 (±3.4)	
Age (in years)	< 30	36(22.5%)	62.71(±5.8)	0.352
	30-39	55(34.4%)	62.24(±5.9)	
	40-49	47(23.4%)	62.25(±6.3)	
	50+	22(13.4%)	61.93(±4.2)	
Education level	Primary	32 (20%)	63.19 (±6.5)	0.112
	Secondary	14(8.75%)	62.68(±2.8)	
	College	106 (66.25%)	62.78(±5.8)	
	University	8 (5%)	65.44 (±4.0)	
Duration in PCT program	<3 years	65(40.65)	62.71(±5.9)	0.174
	4-7 years	73(45.6%)	62.92(±5.7)	
	8-10 years	22(13.67%)	64.06(±5.9)	
Overall fidelity score	-	**160 (100%)**	**63.3 (±5.8)**	

3.2.4 Relationship between implementation fidelity versus geographic area

This study recruited community drug distributors (CDDs) from two districts in Pwani region which are approximately more than 200 km apart. Kibaha districts are more of an urban district compared to Rufiji which is a predominantly semi-rural area.

From the analysis, the mean fidelity score of PCT program delivery was very close between the two districts at which the score for Kibaha was a bit high 63.54 compared to that of Rufiji

which was 62.45 (See Table 3.3). The study showed that the mean fidelity score of the two groups is not statistically different (p=0.859).

3.2.5 Relationship between implementation fidelity versus sex

In this study, females scored higher than males with mean fidelity score of 63.82 compared to males who scored 62.05. The mean difference was not statistically significant at a 95% confidence interval two-sided test (p=0.748) using the student t-test. There was no difference between the two scores between males and females.

3.2.6 Relationship between implementation fidelity versus Age

We interviewed respondents whose age range was from 21 to 60 years across all groups. The ages were then categorized into 4 different groups for easy comparability of age bands as follows, less than 30 years old, between 30 to 39, 40 to 49 and lastly those 50 years old and above.

From the analysis, it was observed that there was no difference in mean fidelity scores among community drug distributors by age groups. The mean scores were as follows: those ageing less than 30 years had a mean score of 62.7, those in between 30 and 39 had a mean score of 62.24, those ageing between 40-49 had a mean score of 62.25 and lastly, those ageing more than 50 years had a mean score of 61.93. A one way ANOVA test failed to reject the null hypothesis indicating that the mean fidelity scores across the age groups were similar (p=0.352).

3.2.7 Relationship between implementation fidelity versus Occupation

Community drug distributors were categorized into 4 main groups under their occupation. The "other" group category which comprised a mixture of social workers, pharmacists and environmental health officers scored a higher fidelity score among all with a score of 64.94 followed by clinicians who scored 64.63. The nurses scored a mean fidelity of 63.9 which was higher than community volunteers who scored 63.0 while primary school teachers showed the least score of 61.24. With a one way ANOVA test we rejected the null hypothesis that all the mean fidelity scores across occupations are the same (p=0.002) and concluded that the mean score is different between some occupations. Adjustment with Bonferroni post estimation test it was proved that the fidelity scores for primary school teachers were different from a group

comprised of other categories (p=0.01) and teachers were also different to community volunteers (p=0.034).

3.2.8 Relationship between implementation fidelity versus Education level

Education level was another variable looked at among community drug distributors in this study. Individuals with university degree education showed a higher fidelity score of 65.44, those with only primary education followed up with a score of 63.19, College graduates scored a mean fidelity of 62.78 and lastly, those with at least secondary education showed a low fidelity score of 62.68. A one way ANOVA test failed to show that there is a difference between mean fidelity scores across the categories of education levels (p=0.112). The fidelity score across various education levels was similar.

3.2.9 Relationship between implementation fidelity versus Duration in the program

Using the categorized duration our results showed that those who had worked in the PCT program for a long time of 8 years or more scored higher than all with a mean score of 64.06, those with an experience of between 4-7 years scored a mean of 62.92 and lastly those with an experience of 3 years or fewer scored least with a mean score of 62.71. This observation was not statistically significant with the ANOVA test (p=0.174). The fidelity score across categories of duration was similar.

Table 5. Summary Description of the Determinants for Implementation Fidelity

Latent Variable	Number of items	Likert/Scale Used	Likert/Scale Coding	Range of Scores in %	Mean Score in %	Cronbach α value
Knowledge on PCT	7	Strongly agree, Agree, neutral, disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	54% - 97%	77.7%	0.54
Facilitation strategy	7	Strongly agree, Agree, neutral, disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	51% - 94.0%	73.5%	0.59
Quality of delivery	6	Never, Hardly ever, Some of the time, Most of the time, Always	1=Never, 2=Hardly ever, 3= Some of the time, 4=Most of the time, 5=Always	43%-80%	59%	0.32
Intervention complexity	7	Very difficult, Difficult, Neither, Simple, Very simple	1=Very difficult, 2=Difficult, 3=Neither, 4=Simple, 5=Very simple	34% - 82%	65.5%	0.76
Participant responsiveness	5	Strongly agree, Agree, Neutral, Disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	52% -100%	74.8%	0.38
Incentives	2	Strongly agree, agree, Neutral, Disagree, Strongly disagree	5=Strongly agree, 4=Agree, 3=Neutral, 2=Disagree, 1=Strongly disagree	20% - 90%	58.7%	0.36

3.3 ASSESSING IMPLEMENTATION DETERMINANTS

This study used a model framework developed by Carrol et al in 2007 which proposed that fidelity adherence should be measured through adherence construct and they explained on factors that might be enablers or barriers to improved implementation fidelity (18). This study used four of the main determinants namely facilitation strategies, intervention complexity, participants/recipient's responsiveness and quality of delivery of the PCT program. Additionally, the model suggested by Hasson et al (2012) on implementation fidelity was adopted by looking at other contextual factors which might also be good determinants of implementation fidelity. We looked on knowledge of CDDs on selected PCT program parameters as well as the effect of incentives on Implementation fidelity (See table 3.3).

The items were summed up for each determinant. They were all converted to percentages making the values to range between 0 and 100. The results showed that determinants ranged from 54 – 97 for knowledge on PCT program, 51- 94 for facilitation strategies, 56-93 for quality of delivery, 34-82 for interventional complexity, 60-96 for participants responsiveness and 20-100 for incentives.

3.3.1 Knowledge of an intervention

The mean score for knowledge on PCT program was found to be 77.73 (SD 7.5) and the scores ranged from 54 – 97.

3.3.2 Facilitation Strategies

The computed mean score for facilitation strategies was 73.52 (SD 8.0) and the scores were ranging from 51-94.

3.3.3 Quality of delivery

The computed mean score for quality of delivering the PCT program was 59.3 (SD 6.5) and the scores were ranging from 43-80.

3.3.4 Intervention Complexity

The computed mean score for interventional complexity on the PCT program was 63.5 (SD 11.3) and the scores were ranging from 34-82.

3.3.5 Participant's/recipients' responsiveness

The computed mean score for facilitation strategies was 74.8 (SD 8.4) and the scores were ranging from 52-100.

3.3.6 Incentives

The computed mean score for facilitation strategies was 58.7 (SD 14.3) and the scores were ranging from 20-90.

3.4 RELATIONSHIP BETWEEN IMPLEMENTATION FIDELITY AND ITS DETERMINANTS

Implementation fidelity is affected in many ways by enabling or moderating factors termed as determinants. Here we conducted only multiple linear regression analysis to look for the existing associations between fidelity and its determinants. Regression analysis was done in two fashions. We did a multivariable analysis of an outcome and one of the determinants adjusting for social-demographic characteristics which were age, sex, district, education level, duration in the program and occupation of the participant. And this was done for all 6 determinants considered in this study. Secondly, we run a model including an outcome, demographic features and all of the determinants together. The latter was done after a backward selection to check for most significant variables which to be eligible for inclusion in the final model. Regression diagnostic tests were done to assess final model fitness.

3.4.1 Relationship between fidelity and knowledge adjusting for social-demographic features (Table 3.5)

In this model knowledge on PCT program was statistically significant with a p-value of 0.007. This meant that for an increase in knowledge among community drug distributors there was 0.16 increase in implementation fidelity observed(Coeff: 0.16 95% CI;0.045-0.28).

3.4.2 Relationship between fidelity and facilitation strategies adjusting for social-demographic features (Table 3.5)

In this model facilitation, strategies of PCT program was not statistically significant with a p-value of 0.108. This meant that for an increase in facilitation strategies to community drug distributors there was 0.10 increase in implementation fidelity (Coeff: 0.10; 95% CI;-.021-0.21)).

3.4.3 Relationship between fidelity and quality of delivery adjusting for social-demographic features (Table 3.5)

In this model quality of delivery of the PCT, the program was statistically significant with a p-value of 0.027. This meant that for an increase in quality of delivering the intervention by abiding by standards and procedures among community drug distributors there was 0.16 increase in implementation fidelity (Coeff: 0.16; 95% CI 0.018-0.29).

3.4.4 Relationship between fidelity and interventional complexity adjusting for social-demographic features (Table 3.5)

In this model interventional complexity or the easiness of delivering the PCT program was statistically significant with a p-value of 0.012. This meant that for an increase in knowledge among community drug distributors there was 0.11 increase in implementation fidelity (Coeff: 0.11; 95% CI .025-0.20).

3.4.5 Multivariable Regression Analysis

A multiple regression model adjusted for all determinants together with significant social demographics which were obtained after the backward selection technique limiting with a benchmark probability of 0.2 was fitted.

All significant variables were fitted in this model including significant social demographics. This adjusted model showed six determinants to be significant at 95% and a p-value <0.05. The Pseudo R2 was 0.21 which suggests that 21% of the variance of implementation fidelity of the PCT program is explained by this model (Table 3.5).

There was no multicollinearity between the explanatory variables after conducting a correlation matrix analysis of significant determinants (Figure?) and the variance inflation factor suggested the same with a mean value of 1.3. Furthermore, the predicted residuals for the model shown to obey assumptions of linearity (See figure) while the test for checking the constant variance proved that there is homoskedasticity (p= 0.169).

Sex, education level, knowledge, facilitation strategies, quality of delivery, interventional complexity were proven to be statistically significant at a 95% confidence interval.

Table 6. Multivariate analysis for the significant predictors of implementation fidelity and social demographic characteristics.

Variable	**Multivariable model adjusted for social-demographic variables and single determinant**		**Multivariable model adjusted for social-demographic variables and all determinants**	
	Coefficient (95% CI)	**p-value**	**Coefficient (95% CI)**	**p-value**
Age (years)	-.044 (-0.14:.052)	0.367	-0.088 (-0.19:0.02)	0.110
Sex				
Male (reference)	0.00		0.00	-
Female	1.76 (-0.045:3.57)	0.056	1.80 (-0.034:3.47)	0.055
Occupation				
Clinician (reference)	0.00		0.00	-
Nurse	-0.73 (4.57-3.1)	0.707	0.56 (-3.18-4.30)	0.768
Volunteer	-1.62 (-4.91-1.64)	0.328	0.42 (-6.34-7.18)	0.902
Teacher	-3.39 (-6.62-0.15)	0.04	-1.79(-5.1-1.48)	0.282

Education level				
Primary (reference)	0.00		0.00	
Secondary	-0.51 (-4.22-3.19)	0.786	-2.19(-5.8-1.4)	0.230
College	-0.41 (-2.74- 1.9)	0.727	-1.21 (-7.58-5.18)	0.709
University	2.24 (-2.33-6.81)	0.334	-0.405(-8.02-7.21)	0.916
District				
Kibaha (reference)	0.00		0.00	
Rufiji	-1.089 (2.9- 0.73)	0.239	-2.28 (-4.51-0.06)	0.044
Duration	0.24 (-0.13-0.605)	0.197	0.275(0.173-0.72)	0.226
Knowledge on PCT	0.16 (0.042-0.28)	0.008	0.164 (.045-0.28)	0.007
Facilitation strategies	0.21(0.10-0.319)	0.000	0.095(-.021-0.21)	0.108
Quality of delivery	0.228(.093-0.36)	0.001	0.156(.018-0.29)	0.027
Intervention Complexity	0.328 (0.10-0.55)	0.005	0.112 (0.025-0.20)	0.012
Participant responsiveness	0.015(-0.092-0.12)	0.773	-0.106 (-.22-0.003)	0.057
Incentives	0.027(-.034-0.091)	0.389	.048(-.015-0.11)	0.133

Table 7. The final adjusted model for significant predictors of implementation fidelity in Pwani.

Fidelity	Coef.	St.Err	t-value	p-value	Sig.
Primary	Ref				
Secondary	-1.320	1.777	-0.74	0.459	
College	**-2.632**	**1.180**	**-2.23**	**0.027**	****
University	-1.190	2.265	-0.53	0.600	
Age	-0.015	0.042	-0.38	0.706	
Male	Ref				
Female	**1.805**	**0.864**	**2.09**	**0.039**	****
Kibaha	Ref				
Rufiji	-0.547	0.930	-0.49	0.624	
Duration <3yrs	Ref				
4-7 yrs	1.424	0.944	1.51	0.134	
8-10yrs	2.721	1.475	1.84	0.067	
Knowledge on PCT	**0.160**	**0.060**	**2.67**	**0.008**	*****
Facilitation strategies	**0.124**	**0.057**	**2.20**	**0.029**	****
Quality of delivery	**0.179**	**0.069**	**2.59**	**0.010**	****
Interventional complexity	**0.101**	**0.041**	**2.46**	**0.015**	****
_cons	23.543	6.644	3.54	0.001	***

*** p<0.01, ** p<0.05, * p<0.1

Table 3.6 above which comprises results from the final model adjusted for both social demographic characteristics and significant predictors of fidelity. The results are as below;

Sex: From the multivariable analysis adjusted for social demographics it was observed that females fidelity scores were 1.80 more compared to their male counterpart (Coeff 1.805, p=0.039 95% CI-0.034 - 3.47).

Knowledge: A unit increase in knowledge about an intervention have shown to increase implementation fidelity by a score of 0.16 (Coeff 0.16, p=0.008 95% CI 0.045-0.28).

Quality of Delivery: For the quality of delivery determinant it was observed that a unit increase in the quality of delivery led to 0.155 increase in implementation fidelity (Coeff 0.15, p=0.01 95% CI 0.025-0.20)

Facilitation Strategies: For the facilitation strategies it was observed that a unit increase in facilitation strategies would lead an increase 0.12 of implementation fidelity (Coeff 0.12, p=0.029 95% CI 0.013-0.23)

Interventional Complexity: A unit increase the easiness of the intervention under implementation will lead to 0.10 increase in implementation fidelity (Coeff 0.11, p=0.015 95% CI 0.025-0.20).

The findings above suggest that Interventional complexity, facilitation strategies, quality of delivery and knowledge are significant predictors of Implementation fidelity of PCT program in Pwani region. These are further discussed in the chapter below.

CHAPTER 4

4.0 DISCUSSION

4.1 INTRODUCTION

This study is among the first in Sub-Saharan Africa to evaluate fidelity level and factors that determine the fidelity/adherence in the guidelines on PCT program which aim to prevent and control NTDs amongst Community drug distributors in Pwani region, Tanzania.

From the study, significant predictors that determine adherence (fidelity) to PCT program delivery among CDDs fell into four broad categories; knowledge on PCT, Facilitation strategies, Interventional complexity and Quality of delivery. This chapter will provide insights of other scholars on these predictors.

4.2 LEVEL OF IMPLEMENTATION FIDELITY

Implementation fidelity among CDDS in Pwani has been observed to be falling in a moderate level of fidelity classification as an overall score was found to be 63.3 which is lower than the suggested level for high fidelity classification. The study shows that the community drug distributors delivers moderately the PCT program, this might be the influence of several varying factors. It is hypothesized by Dupre et al that most adopted programs are rarely implemented to a full capacity of 100% and the existing explanation for this is the modality of how these interventions are adopted in newer settings (77). Surveys have shown that providers like community drug distributors, in this case, tend to modify some components of an intervention and some even replicate some original components due to various reasons (45,77). Rogers in 2003 suggested the concept of re-invention during the implementation phase as one of the processes in adopting the new intervention that there is an alteration of the ingredients of an innovation itself and later affects the overall level of adherence and hence implementation fidelity (78,79).

Attaining high levels of fidelity in an implementation program is a function of multiple favourable circumstances enabling maximum adherence to its ingredients (80). While some interventions are quite easy to attain high implementation fidelity due to their nature, structural components and the contexts of implementation, adequacy of detailed manuals or lesson plans does not favour their intended outcomes (77).

Implementation fidelity is a proxy indicator for determining the uptake and implementation of an intervention and may signal to success or failure of an intervention to yield expected levels

of an outcome of interest (81). It is a process evaluation tool for looking in the "black box" of how the intervention is delivered (82). These study findings have paved a way for researchers in the implementation field to do more work in the assessment of fidelity across various disciplines in health where various adopted interventions are implemented. To date, there is paucity in implementation science studies in sub-Saharan Africa and Tanzania in the literature and academia to provide insights and recommendations on the implementation of adopted interventions like preventive chemotherapy of NTDs (83).

There was no notable significant gap in the mean score fidelity across categories of community drug distributors in this study, but this might be different in other geographical localities and societal contexts. Despite these findings, according to Rogers (2003), the study does not warrant that the main outcome of lowering NTD burden in this area wasn't promising but shows that adaptation of intervention could provide varying levels of fidelity in different settings (78). Thus, implementation researchers propose twin studies one with concrete ingredients measurement and the other with adaptation indicators assessment to compare the implementation fidelity and link them with outcomes measured (77) to arrive at conclusions over the findings observed.

4.3 DETERMINANTS OF IMPLEMENTATION FIDELITY

This study put forward several determinants as important predictors of implementation fidelity of the PCT program among CDDs in Pwani region. An adaptation of the modified conceptual framework explained by Carrol et al (2007) and Hasson et al provided a benchmark for the determinants assessed in this study (6,18). This also was in line with the suggestion pointed out by Fixsen et al in 2015 on the interaction between how an effective intervention, effective implementation and enabling contextual factors might lead to intended outcomes (84). In this study, the explained four predictors below had been proven to affect the implementation fidelity as explained by other authors (18).

4.3.1 Facilitation strategies

In this study, we examined PCT program needs like refresher pieces of training, manuals and guidelines availability, supervision and feedback, and an existing linkage pathway between the community drug distributors and PCT program managers and coordinators as indicators for facilitation. Our results showed that implementation strategies to facilitate the implementation exercise of intervention affects the fidelity level of PCT program.

Implementation researchers have shown the extensive significance of facilitation strategies which may encompass multidimensional disciplines like educational platforms, epidemiological parameters, organizational structures and social-behavioural influences that are affecting the intervention (85). These are said to be a continuum practice with a range of action points from distinctly approaches to holistic measures intending to exhaust the maximum potential within individuals who are delivering the program (86).

This was also the case which was demonstrated by Perry et al (2019) when they highlighted the critical role of implementation strategies to enhance practitioners while implementing an evidence-based approach in real settings and the significance of capacity building (87). It has been hypothesized that adequate facilitation strategies provide more opportunities for interaction in teams which on the other hand give room for higher fidelity of implementation of an intervention (54,88,89). Others have suggested that individual differences, organizational differences, and providers responsiveness to the intervention to be important factors to consider when planning for facilitation strategies (6).

4.3.2 Interventional complexity

We measured the ingredient of the PCT program by checking how easier for community drug distributors to deliver important components of the program. And we termed this predictor as interventional complexity but what we measured was how easy is the delivery of the PCT intervention. Our findings revealed that improved implementation fidelity was significantly related to nature and the easiness that the providers attributed to the program. This is in line with what has been suggested by both Carol et al and Hasson et al in their theoretical conceptual 4frameworks (6,18).

Moreover, another evidence reported that most interventions with clear, detailed and simplified guidelines and recommendations are easier to follow than complex, vague and non-specific ones (18). As recommended by Eboreime et al (2017) that the complexity of health systems interventions poses difficultness in maximizing and appreciating high implementation fidelity in a context it is delivered (90).

Besides, several studies have highlighted this aspect taking an example of the study in the Netherlands that a multidisciplinary team of consultants on an intervention for people with chronic illness, an intervention implemented was characterized with a lower fidelity outcome due to its complex nature (7,18,61,91). Wilson et al in 2009 pointed out the significance of keeping in check of the complexity of an intervention, they said interventions conducted

without consistency checks for putting them on the right tracks predisposes to a situation whereby many interventions might be delivered in the name of one (64,92,93).

4.3.3 Quality of delivery of PCT program

Participants in this study have shown that the quality of which the program components are administered is an important predictor of implementation fidelity. This is similar to what has been hypothesized by Carol et al (2007) that quality of delivery is an important predictor and moderator of implementation fidelity (6,18). Bragstad et al (2019) clarified that the quality of delivery is deeply concerned on the standards of which the intervention is delivered which may further influence the level of fidelity of implementation (54). Another evidences seen in Safeward intervention by James et al (2017) which was emphasizing the use of multi-dimensional techniques in assessing implementations, they emphasized on significance of clear parameters that defines the quality of an intervention to be identified as providers tends to modify the elements and work within limits of their comfort and this may predispose to implementation deviations (94). Other different studies highlighted that comprehensive training as a predictor for quality of delivery in their interventions realized that this was too an important predictor of the fidelity of a given intervention and tends to improve the adherence to the programs core items (89,95,96).

Another study in the Bahamas revealed that the quality of implementation of an HIV prevention program was significantly associated with better student outcomes in schools supporting the saying “better implementation leads to better outcomes” (35).

4.3.4 Knowledge on PCT guideline

It is suggested in the literature that comprehensive training approaches are linked to higher implementation fidelity, but on the contrary improvements in fidelity values like training and knowledge sometimes do not produce stronger program outcomes (95). In this study, we assessed knowledge about some basic components of the PCT program which any CDD is trained on before recruited in the team. Our analysis indicated a positive linear relationship between implementation fidelity and knowledge about the intervention. This is similar to what was proposed by Forgatch et al that knowledge demonstrates the proficiency of the implementers towards the intervention they are delivering (47). Knowledge about the program was also demonstrated by Wang et al. (2015) on the study on teachers implementing national HIV prevention program, teachers who failed to attend full workshops, had low levels of comfort and with no prior experience were reported to fall under low fidelity category (35,97).

Lower and moderate implementation fidelity has been reported across various disciplines like psychological and social support interventions, lacking enough knowledge and experience among care coordinators participated in the program delivering has been the reasons showing negative impacts on adherence to program values (6,52). In another study, researchers have demonstrated a further relationship between knowledge of an intervention accelerates improved dose and hence fidelity of an intervention, this was observed in a randomized clinical trial (2006) assessing behavioural skills for physical activities in adolescents and chronic diseases self-management program (48,92). It was reported also with several authors that knowledge as a technical tool and assistance to build confidence as well as skills to program implementers is a must parameter in ensuring program delivery and also in implementation evaluation practices (98–100).

4.3.5 Sex

Though not significant, we also observed that among the participants in our study, females have shown to have improved fidelity scores compared to males, This is further supported by Carol et (2007) and others who have not realized the bigger differences in implementation fidelity by sex across various programs implemented and gender isn't an important predictor of implementation fidelity (6,18).

Another study on smoking cessation exercise reported females to be good adherers to intervention compared to males while another study on HIV prevention in South Africa and the Bahamas reported females were not superiors in adhering to HIV prevention interventions proving less effect of sex on fidelity (101).

4.4 LIMITATIONS OF THE STUDY

This implementation research study was contextually-specific and may limit the generalization of the results and may not be reproducible in other areas with varying contextual factors in Tanzania and elsewhere. However, we expect that the study has opened the possibility for an implementation study in other contexts and the method we used might be subjected to updating, validation and adaptation for use in similar interventions.

Additionally, the study findings have minimal generalizability as PCT programs in the country run in an isolated form within a government network. This study used government health centres and primary schools since the program does not encompass non-governmental health facilities and primary schools. Children in non-governmental schools are barely reached with the program.

The study methodology also relied on memory recalling of the study participants this predisposes to recall bias and social desirability bias, this led us to recommend for an observational study in determining fidelity levels of interventions in future studies.

The tool used was with closed-ended questions and this limited the amount of information collected from these providers compared to an open-ended question that could be employed with a mixed-method design or a purely qualitative study.

Measurement of the fidelity score value was challenging as there is no standardized agreeable scale to represent and grade implementation fidelity as a scoring parameter. This has been the case even for other implementation researchers failing to have standard reference ranges to allow comparability and even judgment making of observed values. This limitation predisposes to low internal consistency metrics as there was no enough time to do rigorous content validity and selection of relevant items for each sub-domain that makes up fidelity.

Lastly, this study did not go beyond the interaction between implementation fidelity and its determinants, some works of literature have shown the existence of interaction among the determinants themselves and how that affects fidelity. The fidelity effect we observed may be a mixture of the combined effects of these determinants.

4.5 STRENGTH OF THE STUDY

Despite the limitations prescribed above the study is one among the very first implementation research work to be conducted in Tanzania and peculiar at looking at the PCT program implemented to prevent and control NTDs. Many of the evaluation work in NTDs looks on monitoring of resources and evaluating impacts. This study has shown some light on the use of Implementation science principles in evaluating evidence-based practices in the healthcare set up preferably measuring providers perspectives and attitudes.

Furthermore, the study design and data collection procedures for the study adhered to the principles of Implementation research by employing a theoretical framework for implementation research. This ensured the validity of the study findings and provided more insights to implementation researchers in employing guided and modifiable theories or frameworks in developing implementation research evaluation tools.

CHAPTER 5

5.0 INTRODUCTION

This last chapter presents the general conclusion and main recommendations from the study findings. These general conclusions and recommendations are laid out by the chronology of our specific objectives.

5.1 CONCLUSION

In conclusion, the community drug distributors in Pwani demonstrated moderate implementation fidelity on the PCT program delivery. These community drug distributors provided an evaluation of how the PCT program is delivered on their perspectives and perceptions. Despite the success observed in MDA programs implemented nationwide with many districts claiming to have lowered the burden to less than 1% Rufiji included, this is somewhat contrary with our findings as most providers seemed to be delivering moderately the PCT program. This might explain the disparity of NTD burdens across communities in Tanzania receiving the same intervention of PCT annually using the same guideline. Further undertakings are needed to include all other categories within a healthcare system that are part of the intervention left out on this work and perhaps the beneficiaries of the intervention to be included as well.

This study showed that knowledge of an intervention, Facilitation strategies, Interventional complexity and Quality of implementation delivery are strong predictors of high implementation fidelity.

These fidelity determinants have shown to be important parameters in predicting the implementation fidelity. Our study did not go beyond the interaction between fidelity and determinants, some works of literature have shown the existence of interaction among determinants. The fidelity effect we observed may be a mixture of the combined effects of these determinants.

5.2 RECOMMENDATIONS

1. We recommend the evaluation of other implementation outcomes at various levels of implementation of programs especially those already in policy implementation phases. The evaluation outcomes might be organizational, providers or recipients of the intervention to give a broader picture of the intervention process and provide a platform for evaluating how science translates to real practice.
2. It is recommended that future implementation researchers adopt validated tools or validate more tools in measurement of implementation fidelity and other implementation outcomes. Constructs from theoretical frameworks should be validated to ensure the reliability and consistency of the items used for measuring to allow transferability and repeatability of the findings.
3. Implementation fidelity and other outcomes seemed to be swiftly measured through mixed-method designs and preferably to be observational rather than interviews which limit the information collected or else tools to be expanded with as many items possible to cater for various angles of an intervention to be assessed fully.

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APPENDICES

APPENDIX 1: PLAGIARISM DECLARATION



PLAGIARISM REPORT

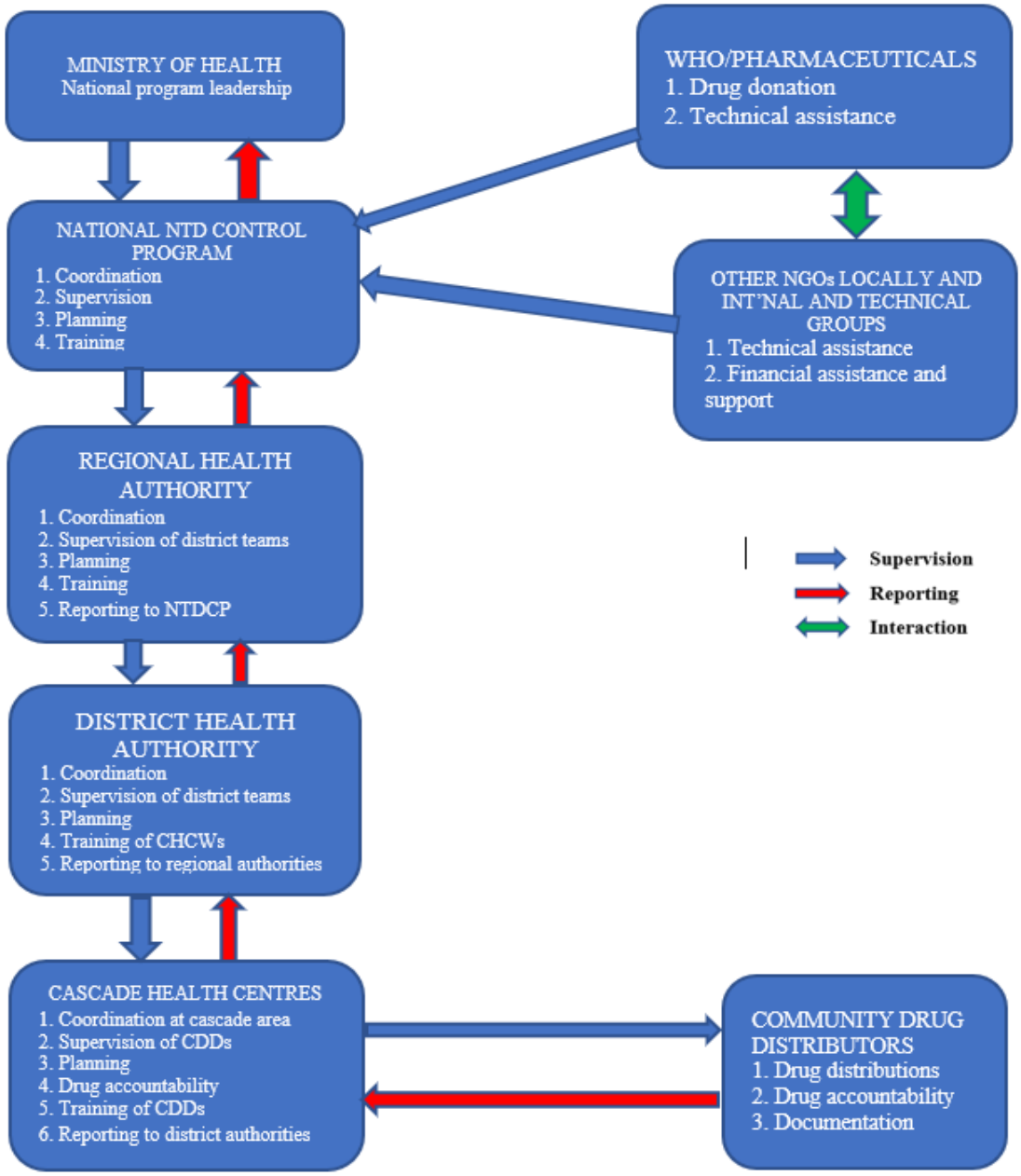
I, **MUHIDIN KASSIM MAHENDE** (Student number: 948538) am a student registered for the degree of **MSc EPIDEMIOLOGY-IMPLEMENTATION SCIENCE in the academic year 2018/2019.**

I hereby declare the following:

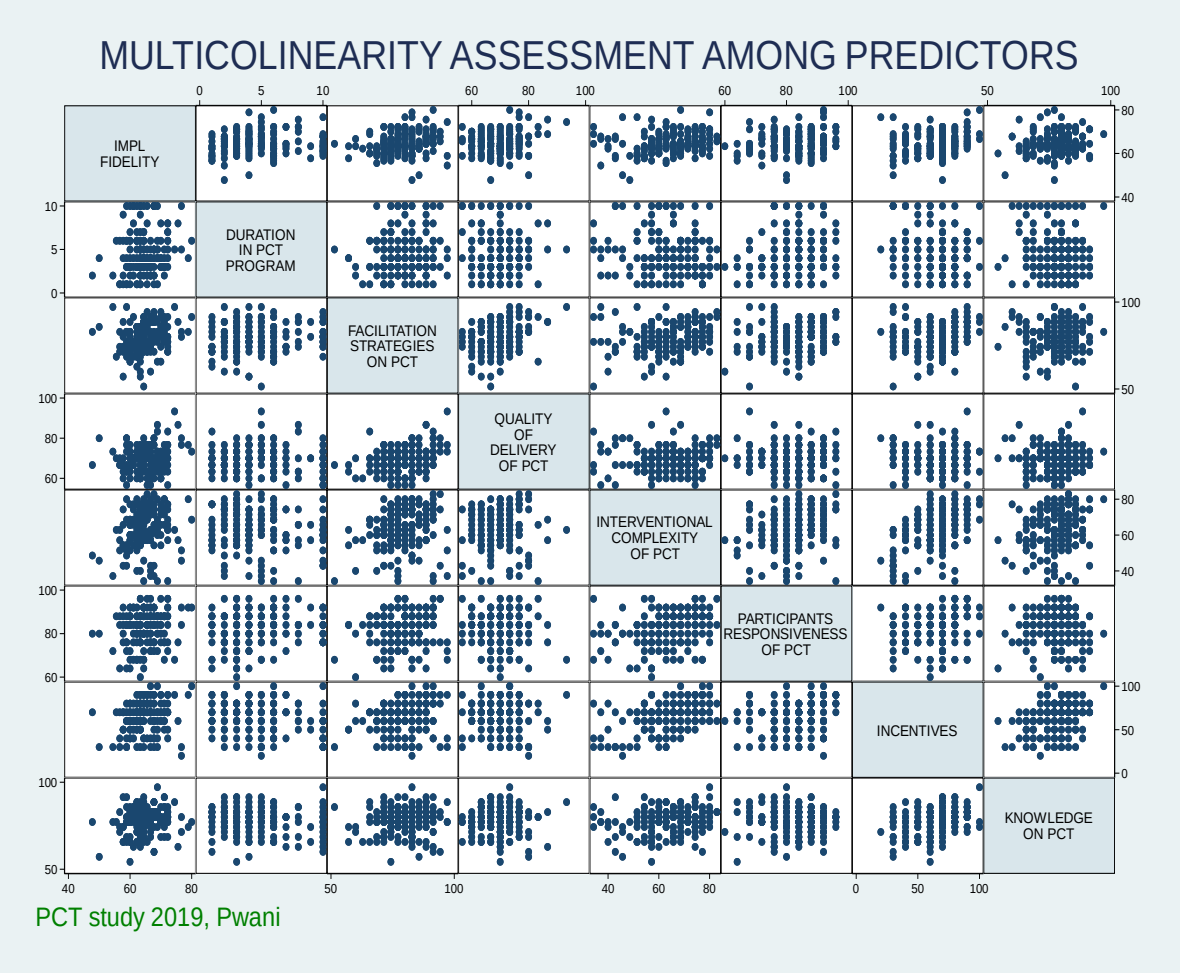
- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have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

Signature:  Date: 10th November 2020

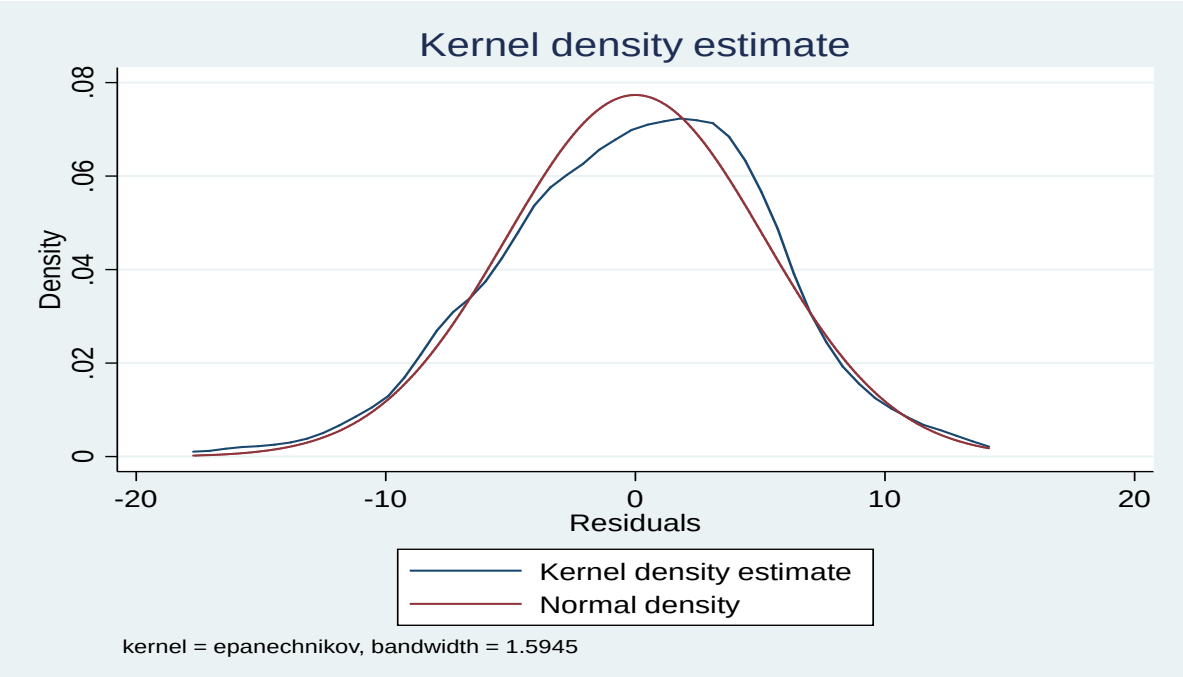
APPENDIX 2: PCT DELIVERY PLATFORM IN TANZANIA

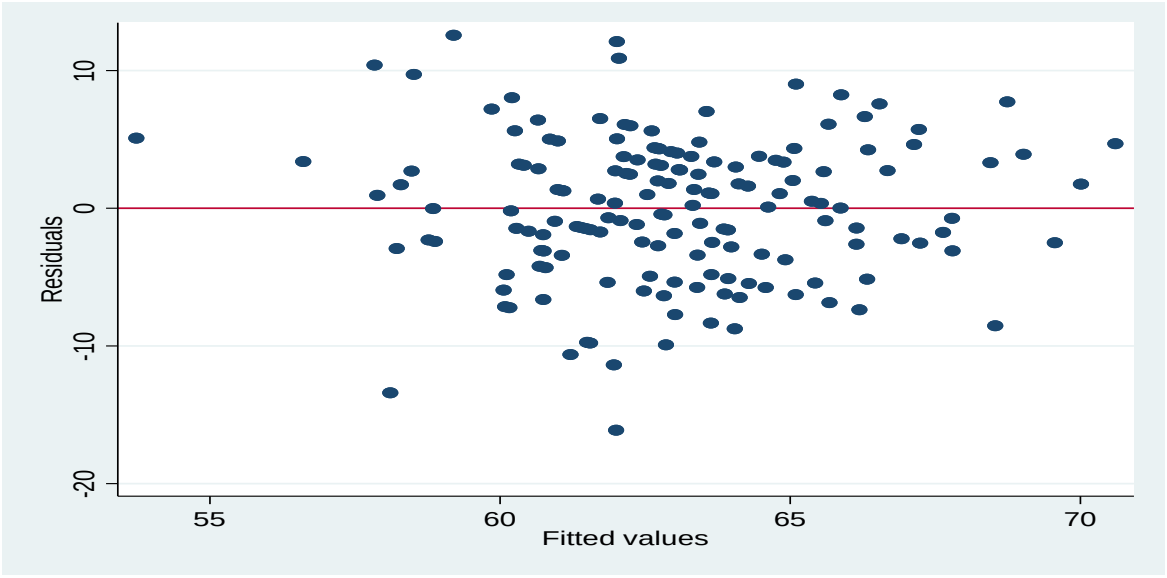


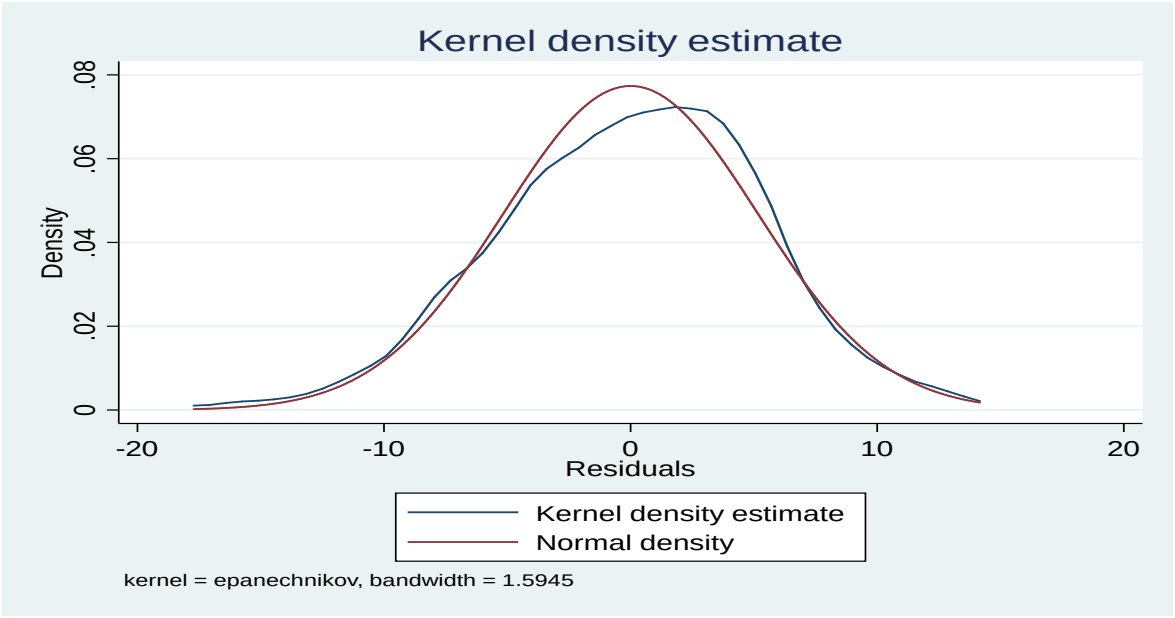
APPENDIX 3: MULTICOLINEARITY CHECKING

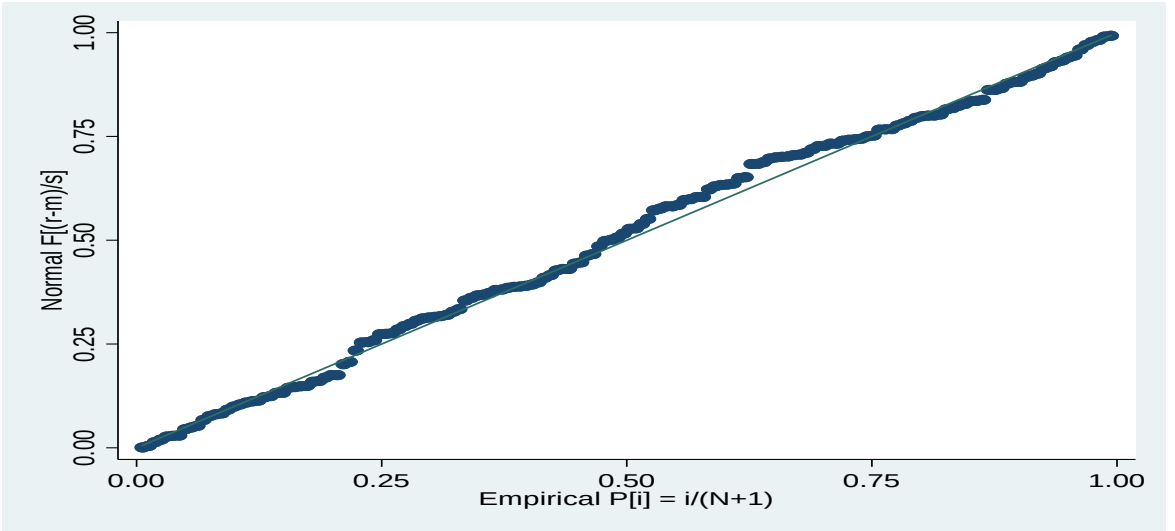


APPENDIX 4: MODEL RESIDUAL NORMALITY ASSUMPTION ASSESSMENT




Residuals
10
0
-10
-20
55
60
65
70
Fitted values


Kernel density estimate
Density
.08
.06
.04
.02
0
-20
-10
0
10
20
Residuals
Kernel density estimate
Normal density
kernel = epanechnikov, bandwidth = 1.5945


Normal F[(r-m)/s]
1.00
0.75
0.50
0.25
0.00
0.00
0.25
0.50
0.75
1.00
Empirical P[i] = i/(N+1)

APPENDIX 5: QUESTIONNAIRE_english

Participant ID: …….

Date of Interview: …… /….. /……. [DD/MMM/YYYY]

SECTION 1: DEMOGRAPHIC CHARACTERISTICS.

1. **Age of participant** [ ] [Put complete years]

2. Sex [1] Male [2] Female

3. Occupation: [1] Clinician [2] Nurse [3] Community Volunteer [4] Teacher [5] Other

If other, specify……

4. Education level [1] Primary [2] Secondary [3] College [4] University

5. District: ……

6. For how long you have been involved in the preventive chemotherapy program …… (In years)

SECTION 2: KNOWLEDGE OF PREVENTIVE CHEMOTHERAPY FOR NTD AMONG PARTICIPANTS

7. Have you been formally trained on Preventive Chemotherapy of NTDs?

[1] Yes [2] No

If yes, when [ ]

8. How long was the training in days [ ] days

I am going to read you some statements. Please think about how they apply in your life and indicate whether strongly disagree, disagree, are neutral (neither agree nor disagree), agree or strongly agree.

9. I am confident with my knowledge and skills on delivering the preventive chemotherapy program

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

10. Preventive Chemotherapy is the only strategy in preventing and control of NTDs in Tanzania

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

11. NTDs are a group of diseases which were not given priority in combating them for the past years, but they can be prevented.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

12. Some NTDs if left untreated leads to death

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

13. Some NTDs if left untreated may cause physical disabilities

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

14. **NTDs are not such a problem in this area and Tanzania at large**

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

15. Please name the NTDS that are targeted through the PC program:

(do not read out the response categories):

a. Lymphatic filariasis [1] Yes [2] No

b. Schistosomiasis [1] Yes [2] No

c. Oncocerciasis [1] Yes [2] No

d. Trachoma [1] Yes [2] No

e. Soil-transmitted helminths [1] Yes [2] No

16. I feel confident in how to administer all the drugs used in the program

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

17. If meet a child, aged 12, during MDA I will follow the following steps:

a …….

b …….

c …….

d …….

e …….

SECTION 3: FIDELITY (ADHERENCE) TO PREVENTIVE CHEMOTHERAPY OF NTDs

I. CONTENT AND COVERAGE:

18. Preventive chemotherapy is implemented in special groups only in this area.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

19. In this program, I administer drugs to everyone, including pregnant and lactating mothers

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

20. Preventive chemotherapy is the main tool for preventing and control of NTDs in this area

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

21. Before every preventive chemotherapy program, I do an awareness campaign to the community

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

22. I organize and conduct community sensitization meetings before each cycle of preventive chemotherapy

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

23. During general MDA what drugs do you distribute (do not read out response categories):

a. Ivermectin [1] Yes [2] No

b. Albendazole [1] Yes [2] No

c. Praziquantel [1] Yes [2] No

d. Azithromycin [1] Yes [2] No

e. Other [1] Yes [2] No

If Yes, Specify _____

24. In this preventive chemotherapy program, I administer all drugs as directly observed treatment (DOT)

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

25. Drugs used in the program sometimes have side effects

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

26. I put a record of the drugs I receive and distribute daily in my register always.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

27. I usually refer all participants experiencing severe adverse effects of drugs used to a nearby health facility.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

28. I would never stop the provision of drugs to participants once started.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

29. My PCT team is responsible for the provision of rescue treatment for those encountering side effects.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

30. I don't record and report any possible adverse reaction observed

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

31. I hand over all the tools to the manager after every end of the round

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

32. I am not supposed to hand over all the remaining drugs to the manager after every round.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

II. DURATION

33. Preventive chemotherapy program coverage is supposed to reach 90% by 2020

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

34. Preventive chemotherapy program should be stopped if the number of infected people goes down

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

III. FREQUENCY

35. PCT program is implemented after every 2 years in this area

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

SECTION 4: FIDELITY DETERMINANTS.

A. FACILITATION STRATEGIES

36. I adhere to the available preventive chemotherapy guideline during implementation to achieve a desirable outcome.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

37. I don't need to receive refresher pieces of training on guidelines

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

38. Do you agree that a manual/booklet on recommended guidelines for preventive chemotherapy program is very important in delivering this program

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

39. I use a guideline for drug dosage instructions in providing drug during program delivery

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

40. I receive frequent supervisions and support during program implementation from administrators

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

41. I get feedback on findings of supportive supervisions made during or after program implementation.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

42. There is adequate linkage system between drug distributors and PCT coordinating health facility managers.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

B. QUALITY OF DELIVERY

43. A clinician or a nurse is made available for each team assisting in program delivery

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

44. Recommended manuals/booklets on preventive chemotherapy of NTDs are always made available during program delivery

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

45. Drugs are usually not enough during the entire period of program delivery

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

46. Dosing poles for children dose estimation are always available during the program delivery

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

47. Weighing scales are always available during program delivery for measuring adults' weight.

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

48. Adequate number of staff/personnel is usually available to deliver the program and cover the targeted area in time

[1] Never [2] Hardly ever [3] Some of the time [4] Most of the time [5] Always

C. INTERVENTIONAL COMPLEXITY

49. Procedures for implementing preventive chemotherapy program are

[1] Very difficult [2] Somewhat difficult [3] Neither [4] Somewhat simple [5] Very simple

50. I perceive that the general information provided in the manual/booklet/guide is

[1] Very difficult [2] Somewhat difficult [3] neither [4] Somewhat simple [5] Very simple

51. The description of my responsibility and tasks in the guideline are

[1] Very difficult [2] Somewhat difficult [3] Neither [4] Somewhat simple [5] Very simple

52. The process of co-administering of more than one drug in the during program delivery to me is:

[1] Very difficult [2] Somewhat difficult [3] Neither [4] Somewhat simple [5] Very simple

53. Preparation of the crushed tablets for children swallowing in the program is:

[1] Very difficult [2] Somewhat difficult [3] Neither [4] Somewhat simple [5] Very simple

54. Covering the targeted area with the time allocated and manpower available in the program is:

[1] Very difficult [2] Somewhat difficult [3] Neither [4] Somewhat simple [5] Very simple

D. PARTICIPANTS/RECIPIENTS RESPONSIVENESS

55. Members of this community cooperate fully and respond well during the program implementation.

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

56. I am feeling comfortable with the program contents delivery requirements (guideline/manual)

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

57. I am not comfortable with the program delivery method used to distribute drugs in this area

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

58. Other members in my team are adhering to the preventive chemotherapy guidelines during program delivery

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

59. The preventive chemotherapy program is helping to prevent and control NTDs?

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

E. PROVISION OF INCENTIVES

60. I receive incentives for carrying out the PCT program

[1] yes [2] No

61. It is the government which provides incentives during delivery of the program?

[1] Yes [2] No [3] Don't know

62. The incentives provided are satisfactory in comparison to the workload done

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

63. Incentives do not enable implementers adherence to program contents delivery

[1] Strongly disagree [2] Disagree [3] Neutral [4] Agree [5] Strongly agree

End of interview

Thank you very much for participation.

APPENDIX 6: STUDY INFORMATION DOCUMENT

Study title: IMPLEMENTATION FIDELITY OF COMMUNITY DRUG DISTRIBUTORS DURING PREVENTIVE CHEMOTHERAPY (PCT) PROGRAM FOR NEGLECTED TROPICAL DISEASES IN PWANI REGION, TANZANIA.

Good day, my name is Dr Muhidin Mahende. I am an Epidemiology (Implementation science) student at the University of Witwatersrand, South Africa. I would like to invite you to participate in my research.

Introduction:

We are doing this research to evaluate the implementation fidelity of preventive chemotherapy for preventing and control of Neglected tropical diseases in Pwani region. Currently, the Ministry of Health is carrying out the preventive chemotherapy program for preventing and control of Neglected tropical diseases countrywide every year.

The purpose of this research is to collect some evidence on the successes and failures behind the preventive chemotherapy program; this will inform implementers and higher policy-making bodies on the status of the program in terms of how it is delivered.

Invitation to Participate: We are inviting all selected PCT implementing members to participate in the evaluation by participating in a survey where a structured questionnaire will be administered by an interviewer.

What is involved in the study:

Your participation will entail you to answer specific questions based on your experiences of participating in the PCT program in Pwani region. The interview will take between 15 to 25 minutes and the interviewer will transcribe your answers directly to an electronic device. Feel free to answer any questions that are comfortable to you and you can refrain from answering any question asked when you don't feel so.

Risks of being involved in the study:

There are no risks to yourself or your workplace for participation. In case of you feel uncomfortable to answer a certain question please you may refrain to do so without any penalty or consequence to you.

Benefits of being in the study: Your participation into this study will help us uncover the mystery behind the implementation of this program here in Pwani and compare the findings with other regions in Tanzania and across the world. The findings will enable decision-makers to plan better the program so that it can deliver the expected outcome. As an individual, there are no specific benefits to yourself or your working place. There are no personal benefits like gifts or allowances that will be provided for your participation.

Participation is voluntary,

Participant may discontinue participation at any time without penalty, or loss of benefits to which the Participant is otherwise entitled; that there is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless the Participant specifically consents to its retention.

Reimbursements for "out of pocket" expenses: There will be no cost incurred by you if you choose to participate but also there will be no remunerations given.

Confidentiality:

Identity of every participant in this research will not be disclosed. The information collected will be confidential during and after the completion of the study. Data collected is solely for research purpose and its only study team will have access to the data/responses.
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

Anonymity: No personal identifiers will be used in the study questionnaires. your participation will be anonymous.

Outputs:

After completing this research, a report will be composed and submitted to the University of Witwatersrand, disseminated through conferences, meeting and shared to policymaking bodies like Pwani region council, Ministry of Health Tanzania and World Health Organization.

Contact details of researcher/s:

Should you have any questions about the study, you can contact me at any time or phone me Cell No: +255683035186 or a local supervisor (Dr Nyogea) through Cell No: +255 757 741 922.

Contact details of HREC administrator and chair – for reporting of complaints/problems. The following text is recommended:

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("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. You may also get in touch with National health research ethics review committee here in Tanzania using these details, Tel 0758587885, 022 2130770 or you may email them through ethics@nimr.or.tz/nimrethics@gmail.com.

Thank you for reading this Study Information Sheet.

Date: ……../……/……..

Yours sincerely

Name: Dr. MUHIDIN MAHENDE
Email: 948538@students.wits.ac.za
Cell Phone no: +255683035186 / +27651867305
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Name: Dr. DANIEL NYOGEA
Telephone No: +255 757 741 922

Email: nyogea.daniel@gmail.com

APPENDIX 7: INFORMED CONSENT FORM English





STUDY TITLE: Implementation fidelity of community drug distributors during preventive chemotherapy (PCT) program for neglected Tropical diseases in Pwani region, Tanzania.
INSTITUTION: The University of the Witwatersrand, Johannesburg, South Africa.

I, the undersigned confirm that I was given information about the study "Implementation fidelity of community drug distributors during preventive chemotherapy (PCT) program in Pwani region, Tanzania."
I have been invited to participate in this study, I have read the above information given to me at its entirety. I had been also given pleasure to ask for any clarifications for something I did not clearly understand, all my questions were answered clearly, and I am satisfied with the responses provided.
I understand that the researcher(s) involved in this project will ensure confidentiality and that my name and the names of other providers will not be used in the study reports, and any response that I will provide will not be reported back to anybody else.
I understand that I may, at any stage, without prejudice, withdraw my consent and participation in the study.
I agree to be part of this study voluntarily without any form of persuasion.

Name of participant: _____

Signature of participant: _____

Date of consent _____
(DD-MMM-YYYY)

I confirm that the participant accepts to participate in the study voluntarily.

Name of consent provider: _____

Signature of consent provider: _____

Date of consent _____
(DD-MMM-YYYY)

A duplicate of this signed consent form has been given to a participant. ☐

APPENDIX 8: WITS HREC (MEDICAL) APPROVAL CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr Muhidin K. Mahende

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M181149

NAME: (Principal Investigator)	Dr Muhidin K. Mahende
DEPARTMENT:	School of Public Health Pwani Region, Tanzania Two districts: Rufiji and Kibaha Medical District
PROJECT TITLE:	Implementation fidelity of community drug distributors during preventive chemotherapy (PCT) program in Pwani Region, Tanzania
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr I. Maposa, Prof J. Levin and Dr D. Nyogea
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	12/03/2019

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: 20th March 2019

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 9: NIMR APPROVAL CERTIFICATE

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: ethics@nimr.or.tz

Ministry of Health, Community Development, Gender, Elderly & Children
University of Dodoma, College of Business Studies and Law
Building No. 11
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8a/Vol. IX/3010

16th January, 2019

Dr. Muhidin Kassim Mahende
C/o Dr. Daniel Simon Nyogea
NACOPHA
P. O. Box 55811
Dar es Salaam

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Implementation fidelity of community drug distributors during preventive chemotherapy (PCT) program in Pwani region, Tanzania (Mahende M. K. et al), whose supervisor is Dr. Daniel Simon Nyogea of National council for people living with HIV/AIDS (NACOPHA) has been granted ethical clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Sites: Kibaha, Kibiti and Rufiji Districts in Coastal region.

Approval is valid for one year: 16th January 2019 to 15th January 2020.

Name: Prof. Yunus Daud Mgaya

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Prof. Muhammad Bakari Kambi

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY & CHILDREN

CC: Director, Health Services-TAMISEMI, Dodoma
RMO of Coastal region
DMO/DED of respective district