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Evaluation of implementation fidelity to national guidelines on management of tuberculosis in paediatric patients in Homa-Bay County, Kenya

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2022
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UNIVERSITY OF THE WITWATERSRAND
SCHOOL OF PUBLIC HEALTH

EVALUATION OF IMPLEMENTATION FIDELITY TO NATIONAL GUIDELINES ON MANAGEMENT OF TUBERCULOSIS IN PAEDIATRIC PATIENTS IN HOMA-BAY COUNTY, KENYA.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirement for the degree of Master of Science in Epidemiology in the field of implementation science

March 21, 2022

DECLARATION

I *Sharon Cherono Kiptoon*, declare that this research report is my unaided work. It is being submitted in partial fulfillment of the requirement for the degree of Master's in Science (MSc) in Epidemiology (field of Implementation Science) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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March 21 2022

DEDICATION

To my family for their unwavering support, encouragement, and love during the entire period of my studies.

ABSTRACT

Background

Tuberculosis (TB) has been a major public health concern for a long time. Infection in children has not been given a lot of focus as in adults despite children being a vulnerable population with weaker immunity. Prognosis is worse when there is HIV/TB coinfection. The WHO rolled out guidelines for the management of TB in pediatric patients which were adopted by the Kenya Government. Health care workers then implement the guidelines. The Objectives of this study were to measure adherence to national guidelines on the management of Tuberculosis in Pediatric patients (up to 14 years) and to identify moderators affecting implementation fidelity.

Methods

A convergent parallel mixed method design was used to collect information from TB treatment sites in Homa bay County. The study was conducted during the months of August, September and October 2018.Quantitative data collected focused on Pediatric patients between ages zero and 14. A checklist based on the guidelines was designed to review 442 records in the clinics for a four-year period (2014 to 2018). Qualitative data was collected through in-depth interviews with eight Sub-County TB coordinators. Interview moderators were based on Carrol et al Implementation Fidelity framework. Summation of "yes" and "No" responses were tallied to get an adherence score for the County as a whole and for the sub-counties individually. The qualitative analysis used the thematic method in excel spreadsheets.

Results

Results showed high adherence for the County with a median of 80% (IQR 66.66-93.33%). Four of the sub-counties with normally distributed scored had a mean score of 79% and while the other four had a median score of 80% (66.66 – 93.33). Guidelines which had low implementation fidelity scores were those involving follow up tests i.e., sputum, gene X-pert and X-ray during duration of treatment. In the qualitative aspect good facilitation strategies were found to be in place from both the County and national TB programs. An attitude of fear, lack of knowledge on infection prevention, lack of skills to produce specimens for TB testing and staff shortages affected quality of treatment delivery. The health care workers reported ease in following the guidelines especially with the roll out of new guidelines which simplified diagnosis of TB in children, drugs which are dispersible and in fixed dose combination. Participant's response to the intervention was poor with both health care workers and patients expressing difficulties with direct observed therapy schedule which required frequent visits and frequent follow up tests.

Conclusion and recommendations.

In conclusion, implementation fidelity to guidelines on management of tuberculosis is high. Good facilitation strategies is a positive moderator towards achieving high implementation fidelity. The national TB program in Kenya is doing well so far in monitoring the process of guideline implementation once rolled out, however, to be able to achieve the sustainable development goal eradicating TB, further follow up is needed in the facilities to improve the

levels of adherence from 80% to 100%. Use of the conceptual framework by Carroll has proved to be a good guide in evaluating healthcare worker's performance in implementing treatment guidelines

It is recommended that health workers should undergo more sensitization on why certain guidelines have been put in place e.g., repeating sputum samples at different phases of treatment in order to improve quality of care. More training on vital procedures e.g., gastric aspirate should also be done to improve health workers' confidence and ease diagnosis of TB at younger age. Further research on implementation fidelity on other evidence based interventions would go a long way to improve service delivery and ensure other program goals are met.

ACKNOWLEDGMENTS

This work has been funded by TDR (Tropical Disease Research), the Special Program for Research and Training in Tropical Diseases, which is hosted at the World Health Organization and co-sponsored by UNICEF, UNDP, the World Bank, and WHO. TDR grant number: B40299.
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To Almighty God who has granted me good health, energy, ability to comprehend my studies and even this scholarship opportunity without which I would not have completed this research report.

To my supervisor, Prof. Latifat Ibisomi, for your valuable input, timely responses, and patience.

To the staff of Homa-bay County health department: - The director of health, County TB coordinator, sub-County TB coordinator, and the health workers in the TB treatment sites, I appreciate your cooperation and sacrifice in making my work in Homabay smooth.

To my family, I appreciate your guidance wisdom, and prayers. Thank you for believing in my abilities and encouraging me through difficult times. I appreciate you.

To all the staff in the Department of Epidemiology and Biostatistics, the administrative staff, my lecturers who were instrumental during the course work and research phase, thank you for your contribution in imparting knowledge to me.

My classmates, the 2017 cohort, you made learning a wonderful and exciting experience and made my stay in South Africa comfortable.

To you all, I am most grateful.

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LIST OF ACRONYMS

TB	Tuberculosis
DR TB	Drug resistant TB
MDR TB	Multi drug resistant TB
DOTS	Directly Observed Treatment short-course
HIV	Human Immunodeficiency Virus
USAID	United States Agency for International Development
ARV	Antiretroviral (drugs used in the treatment of HIV)
IREC	Institutional Research Ethics Committee
MTRH	Moi Teaching and Referral Hospital
NACOSTI	National Commission for Science, Technology and Innovation
TDR	Tropical Disease Research
W.H.O	World Health Organisation
BCG	Bacillus Calmette-Guerin (vaccine used against tuberculosis)
MTB/RIF	Mycobacterium tuberculosis/ Resistance to Rifampicin
Xpert MTB/RIF	The current gold standard for simultaneous rapid diagnosis of TB and detection of antibiotic resistance.

DEFINITION OF TERMS

Implementation fidelity
Implementation fidelity is defined as the degree to which an intervention is delivered as intended and is critical to successful translation of evidence-based interventions into practice.
Adherence
Refers to whether a program, intervention is being delivered the way it was written, in the right context, using the appropriate materials/guidelines. . In this study, implementation fidelity's main measurement is adherence with the remaining components being moderators of implementation fidelity.

Quality of delivery
The manner in which a program implementer e.g. teacher, health care worker, staff member, volunteer delivers a program i.e. skill, knowledge, enthusiasm.

Facilitation strategy
Structures put in place to standardize and to optimize program implementation and ensure there is uniformity in delivering the intervention e.g. standards of procedure, manuals, trainings, guidelines.

Participant responsiveness
The level to which the participants (be it implementers or those receiving the intervention) are involved in the program activities**.** Mainly, their attitudes e.g. positive and warm, or cold and non-engaging.

Intervention complexity
Refers to the description of on intervention. Is it simple and clear or complex? Detailed or vague? Specific and concise? The easier and well explained an intervention is, the easier to follow.

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CHAPTER ONE: INTRODUCTION

1.0 INTRODUCTION

In this chapter, the Epidemiology and importance of childhood TB are highlighted. Implementation fidelity is defined in relation to guidelines on the management of TB and ends with a literature review on the measurement of Implementation Fidelity.

1.1 BACKGROUND

Epidemiology of childhood tuberculosis

Tuberculosis(TB) is a major global health problem and is among the top ten causes of death worldwide from the infectious agent *Mycobacterium Tuberculosis*(1). In 2017, an estimated 1.74 million people died due to the disease(1), 250 000 of these being children(2). Focus on pediatric TB important due to several reasons. One, children suffer from severe disease and progress to disseminated TB faster than adults. Therefore, to prevent significant morbidity and mortality, early recognition and treatment are vital(3). Two, the incidence of TB in children is a reflector of local transmission rates of *Mycobacterium Tuberculosis* strains in a community. This serves as an indicator of TB control in a community(4). Trends of pediatric TB over time allow appropriate policy implementation. Finally, estimates of incidence and mortality enable countries to monitor progress towards the aims of the END TB strategy which aims to reduce TB deaths by 95% and cut new cases by 90% by 2035(5,6). Despite these reasons, Pediatric TB has been struggling against historical neglect by the global TB community. Several reasons have been attributed to this. First, childhood TB care is embedded in National TB programs in most high burden countries which run parallel to child health systems. This results in scant communication between the two and children are caught in between(7). Secondly, cases of pulmonary disease in children are less infectious as opposed to adult cases and thus they are perceived to contribute minimally to its transmission and consequently seen as low public health priority(7). Lastly, Sputum samples are mostly negative for acid-fast bacilli, and as a consequence of the requirement that only sputum positive cases are reported, there is improper recording and reporting of TB cases in children(8). Estimation of the actual burden of TB in children is therefore difficult at National and Global levels(9,10).

Kenya ranks at position 11 among the 22 high burden countries contributing 80% of the words Drug Responsive(DR) and Multidrug-Resistant(MDR)TB burden(11). The burden may be higher according to a 2015 TB survey reporting a prevalence rate of 558 per 100000, higher than 228 per 100000 reported by the World Health Organization.

According to WHO, “The most cost-effective way to stop the spread of TB in areas of high incidence is by curing it. The Direct Observed Treatment Short-Course(DOTS) is the cornerstone of TB control in both children and adults(12). Rolled out in 1994, the strategy has five principal components namely: - a political commitment from member countries to combating TB, use of quality bacteriological methods to detect cases, having an uninterrupted supply of TB medication, standard short-course chemotherapy with effective case management, and proper recording and reporting. In 2006, the STOP TB strategy was rolled out to build on and enhance DOTS to meet TB-related Millennium Development Goals(13).In 2008, a child subgroup under the STOP TB strategy was formed which worked together to publish guidelines

for the management of TB in children to be used by National TB programs(14,15). These are the guidelines that Kenya and other member states adopted. Current guidelines used in Kenya were updated in 2017(16). At the time this research report was written the guidelines of 2013 were in use(17). All aspects of TB care in Kenya are coordinated by the National TB, leprosy, and lung disease program. Diagnosis is based majorly on clinical evaluation supported by laboratory investigations such as sputum smear microscopy and chest x-ray. X-pert MTB/RIF assay was implemented in 2014 and is now widely in use for both adults and children. This test identifies *Mycobacterium* TB DNA and resistance to Rifampicin a drug used in TB treatment and produces results in 2 hours as opposed to cultures which relay results in 2 weeks. Gastric aspirate has recently been introduced in your children who are not able to cough and produce a sputum specimen. Duration of and treatment regimens follow national guidelines. Newborns have BCG immunization as part of the expanded program for immunization. HIV counseling and treatment service is offered to all children on TB treatment. Health care workers document in the TB register all that is done to the patient at different visits from diagnosis to completion of treatment. Treatment outcomes in pediatric patients have been found to be poor in Kenya and other parts of Africa(18). Data on treatment outcomes in children in Kenya has not been sufficiently described due to the challenges already described. Indeed, the focus on pediatric TB only begun when children were included in the 2011-2015 strategic plan(19). Studies conducted in Nyanza and Nairobi, from a sample of 936 and 5004 children, 20% recorded poor treatment outcomes and more severe outcomes in children under five years(20).TB/HIV co-infection was identified as a major factor. Homa Bay County is a high hotspot for pediatric TB(19).

The healthcare system in Kenya was decentralized in 2014 forming County and National levels of care. Kenya has 47 County Governments among them is Homa-Bay County. Policies and Guidelines are formed at the national level, rolled out to the County level, and implemented by healthcare workers in County hospitals.

Implementation fidelity is the degree to which an evidence-based intervention is delivered in adherence to the guidelines set out by the intervention developers. Measurement of implementation fidelity is important in providing a deeper understanding as to why evidence-based interventions report or fail to report positive outcomes. It also provides information on program implementation to evaluators and identifies deviations from guidelines in different contexts. Results of this measurement provide feedback to health care workers to improve quality of care and to program developers to modify components or increase facilitation strategies. In this study the evidence based intervention is the guidelines on management of TB. In clinical settings, health workers are the implementers of evidence based interventions to patients. In pediatric tuberculosis, they have a role in diagnosis, provision of treatment, education, and reporting of cases according to guidelines (21). The extent to which they adhere to treatment guidelines rolled out by national programs is what defines Implementation Fidelity.

1.2 PROBLEM STATEMENT

Homa Bay county records the second highest prevalence of HIV/TB co-infection in Kenya(22,23). Despite efforts by the Division of Leprosy and lung disease in Kenya, childhood mortality for TB is still high.
Good adherence to TB treatment is key to cure patients; limit drug resistance and reduce the lengthy period of treatment - which is costly and reduce suffering and death especially in children(24). In as much as patient adherence to treatment is emphasized, adherence to the guidelines of TB treatment by healthcare workers also plays a major role in achieving a cure. TB CARE II (a part of USAID bureau for global health), supported a multi-country study that included Kenya in 2012 to assess patient and provider adherence to evidence-based TB standards and guidelines(25). At the time TB guidelines, both covered adult and pediatric TB. The report identified four major areas as causes of provider non-adherence. They were: - lack of skills/knowledge, overburdened providers, poor attitude and skills of the providers, and issues of switching from old to new guidelines. A systematic review by Marieke et al., which assessed knowledge of TB treatment prescription among healthcare workers found that they did not know proper regimens, duration of treatment and were unfamiliar with local and international guidelines(26). Similar results were found in a systematic review by Langendam and colleagues(27).

It is therefore important to access healthcare worker's fidelity to the national guidelines on the management of pediatric TB to enable TB control programs to evaluate the quality of Implementation and factors associated with intervention outcomes

1.3 JUSTIFICATION

Measurement of Implementation Fidelity to National Guidelines on the management of Tuberculosis in pediatric patients in the context of Homa Bay County will provide information on the quality of care offered to pediatric patients diagnosed with TB and will enable the program implementers to identify areas of improvement. It will also add to the literature on pediatric TB and Implementation Fidelity which is minimal in Africa and the Kenyan context. The Kenyan government through the ministry of health is committed to the end TB strategy which aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB(28).
To achieve this Implementation Fidelity to the national guidelines on the management of Tuberculosis in pediatric patients needs to be measured, gaps identified, and improvements made as fidelity is the bridge between intervention and improved outcomes.

1.4 RESEARCH QUESTION, AIM, AND OBJECTIVES

1.4.1 Research question

What is the implementation fidelity to national guidelines on the management of tuberculosis in pediatric patients in Homa Bay County and what factors affect it?

1.4.2 Aim

To measure implementation fidelity to national guidelines on the management of tuberculosis in pediatric patients in Homa Bay County, Kenya, and to explore how moderating factors of Implementation Fidelity affect adherence to the guidelines

1.4.3 Specific Objectives

1. To measure implementation fidelity to national guidelines on the management of Tuberculosis in paediatric patients in Homa Bay County, Kenya

2. To explore how moderating factors affect implementation fidelity to national guidelines on the management of tuberculosis in paediatric patients in Homa-Bay County, Kenya

Implementation Fidelity framework

Several researchers have described as five components that need to be considered individually. The five components are adherence, dose, participant responsiveness, quality of delivery, and program differentiation(29). However, some of these elements have been found to overlap during measurement, posing challenges to organizations during program planning. Christopher Carroll and His colleagues did a systematic review of literature on Implementation Fidelity and designed a new framework for measurement(30). This conceptual framework was found suitable and adapted for this study.

The framework describes adherence as the main measurement in Implementation Fidelity. Within adherence, there are 4 components namely Content, Coverage, Frequency, and Duration. Content can be described as the main ingredient being delivered by the intervention. For the Kenya National guidelines on the management of tuberculosis in Pediatric patients, Content refers to whether they were tested for HIV or not, if those found positive were started on anti-retroviral treatment, Proper documentation of the date of diagnosis and that of treatment initiation, method of diagnosis, the proper classification of the type of TB, rechecking of samples used for diagnosis at intervals during the treatment, measurement of weight at the beginning and end of treatment and the end of treatment, allocating the child an appropriate outcome. Coverage, frequency, and duration are grouped as dose. Dose refers to whether the intervention was delivered to the population intended for it, as often as prescribed and for the appropriate length of time as the original design. In this study, data was collected on all four components. However only Content was used as the main measure of adherence. This formed the quantitative aspect of the study.

The framework posits that Implementation Fidelity, which is adherence is the pathway between the intervention and outcome. Achieving a high level of adherence is not easy. Some factors may influence this level. In the framework, these factors are termed, moderators. They are Intervention Complexity, Facilitation strategies, Quality of delivery, and Participant responsiveness. Exploration of these moderators formed the qualitative aspect of the study. Rachidatou et al used the Carroll framework to evaluate implementation fidelity of seasonal malaria chemoprevention in Burkina Faso(31). Mixed method study approach was used. Adherence being quantitative and moderators explored qualitatively. Components of adherence that were assessed were content coverage and schedule. Adherence was found to be good at 100%for coverage and 32% for schedule. The intervention was found to complex in terms of documentation and dishes to be washed. Quality of delivery was good with all community

distributors very responsive to instructions. Response from participants was positive and they showed enthusiasm.
This framework was adapted for this study because the components of adherence and its moderating factors are clearly defined allowing ease in the measurement of implementation fidelity.

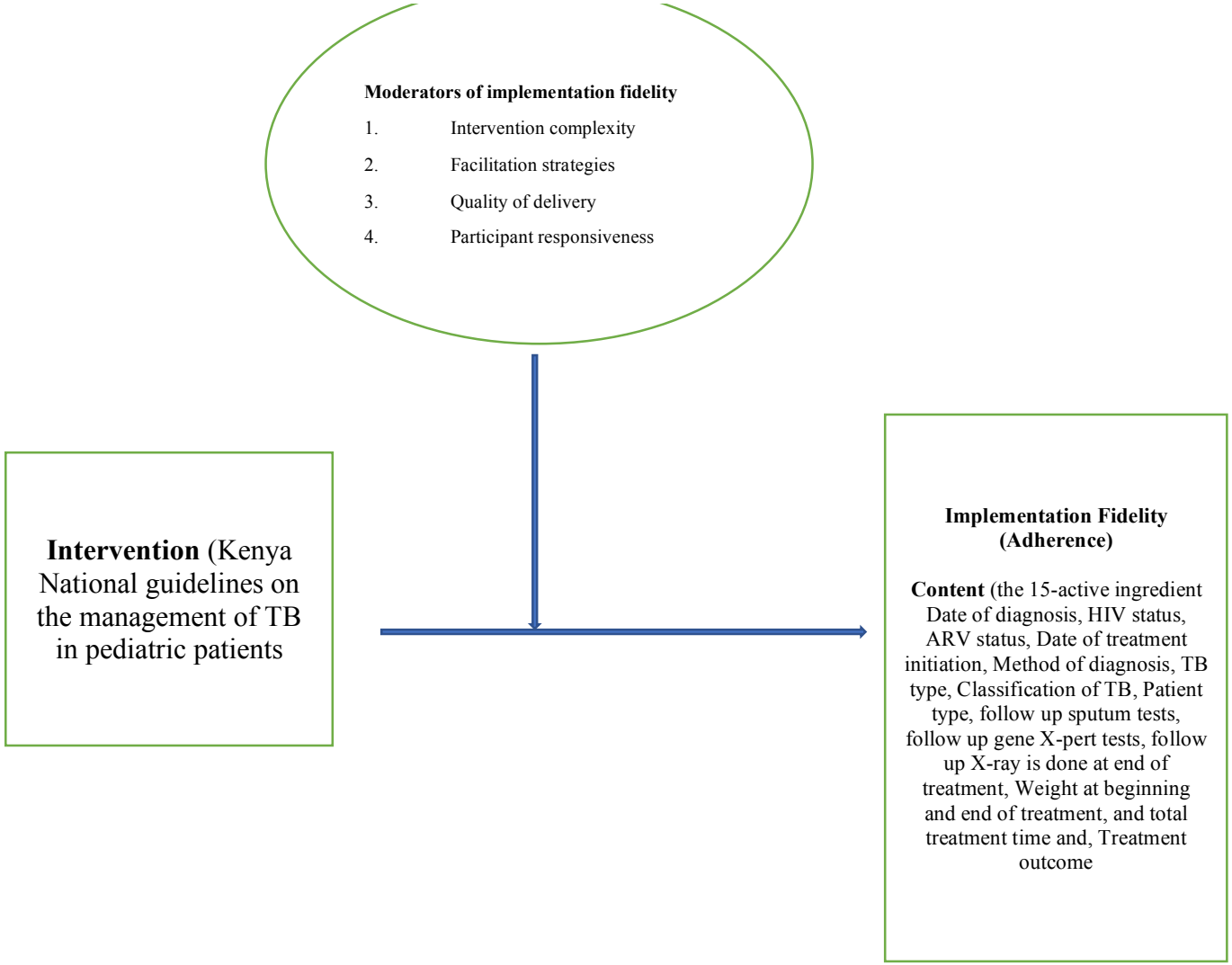

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Figure 1.1 Conceptual framework of Implementation Fidelity to Kenya National guidelines on the management of TB in paediatric patients as adapted from Carrol et al..., 2007

1.5 LITERATURE REVIEW

Young people and especially children are important populations who are more susceptible to severe TB infection and high mortality rates. The World Health Organisation describes the cut off age for childhood TB at 15 years. Children under 5 years of age bear the greatest risk of morbidity and mortality from TB infection. The curve then goes down wards in pre-school years and peaks again in adolescent years(32). Adherence to tuberculosis treatment is a strong pillar in treatment of the disease. Poor adherence will result in prolonged suffering, development of drug resistant strains, they might have treatment failure and eventually lead to death. A study by Ginenus et.al aimed to evaluate adherence status of paediatric patients receiving anti-TB treatment at a hospital in western Ethiopia(33). Age, sex and presence/absence of side effects were found to be factors affecting adherence. Small children between zero to five years, females and those who did not experience side effects adhered more to treatment.
The global tuberculosis report of 2017 pointed out that only an estimated 39% of total paediatric TB cases are notified each year(1). This is because case detection and establishment of an accurate diagnosis of active infection is a major challenge in childhood TB since the symptoms are not specific and also because children are not able to produce sputum. Integration of TB services into hospital entry points where children are attended to is one of the ways to improve case detection and diagnosis. A stepped wedge randomised control study by Lise and colleagues aimed to assess the effectiveness of such integrations(34).Hospitals in Kenya and Cameroon. Through the study, comparison between normal standard of care and integration of services will be done. Information on how many cases of paediatric TB can be diagnosed after screening at hospital entry points will go a long way in informing policy at national level. The study was expected to end and results shared in 2022.
A mixed methods study by Akash et al. estimated the yield of and adherence to TB diagnosis guidelines among children under the age of five admitted at nutrition rescue centres in India(35).The guidelines included a five point clinical assessment /screening followed by X-pert MTB/RIF testing for those suspected to have TB for confirmation. Adherence to the guidelines were found to be suboptimal. Poor screening due to poor team skills culminated in few diagnosed cases. Heath workers were also unfamiliar with guidelines and kept poor records of those on treatment and their outcomes.

Previous studies have evaluated implementation fidelity in the context of randomized control trials targeting new drugs, surgical procedures, and behavior change interventions. Compared to these trials, health service interventions are complex. They have to be operationalized among different levels of patients and practitioners(36). Also, in randomized control trials, intervention conditions are tightly controlled with numerous support towards achieving high fidelity which may not be the same scenario in the implementation of health programs. Observing high implementation fidelity during translation of evidence-based interventions into clinical practice will replicate the successful outcomes observed in controlled trials(37). Treatment manuals outline the goals and rationale of interventions as well as guidelines for administering an intervention. They serve as a mechanism by which the content of evidence-based interventions proven to be effective can be translated into the content of health care programs(38). However, having a manual does not translate to effective implementation(39). An effort must be made to assess the delivery of the intervention to correctly attribute outcomes, especially negative ones to problems with the intervention or its implementation(40). As more evidence-based practices are implemented, service providers including health practitioners are expected to be responsible for

their outcomes as part of treatment applicators. Evaluation of Fidelity of implementation can therefore be done at the practitioner level.

1.5.1 Adherence

Health care provider adherence refers to the degree to which therapists deliver an intervention as specified in the intervention manual(41). A study was done in Kenya to determine provider's and patient's adherence to TB guidelines reported that most providers felt overburdened with the workload at the clinics(25). They were not being trained when guidelines were updated and therefore, they felt they lacked knowledge and skills. Shortage of resources-materials and supplies, drugs, and staff were also identified as reasons why they did not adhere to guidelines. Measurements of adherence can be done using indirect and direct methods(37,42). Directly using Indirectly using checklists or questionnaires filled by experts or therapists or review of records and directly by observations with a trained observer(43). A systematic review found that only half of the evidence-based intervention guidelines were adhered to per-protocol(44). Possible explanations were lack of training, interventions were too complex, and that the interventions did not fit the context(45).

1.5.2 Facilitation strategies

Strategies to facilitate fidelity of implementation include distribution of manuals and guidelines to practitioners, on-the-job training, support supervision, and provision of monitoring and evaluation to providers after mentoring or supervision. Having manuals and guidelines ensures that all workers are exposed to the same content at all levels and locations especially in national health programs. A review by the TB Care II project identified a lack of policy in the management of MDR TB as one of the challenges in tools to improve adherence(46). In Malawi, the introduction of guidelines had no impact on TB case notifications attributed to poor monitoring and evaluation after implementation(47). Studies measuring fidelity by direct observation and then providing feedback helped to identify deviations which were then corrected and achieved high fidelity(48). In Zambia, a study reported that training of health-workers was done to improve performance but there was no linkage to systems addressing the barriers they faced(46). These strategies, therefore, affect the level of fidelity achieved especially in complex interventions, and may explain why some interventions get a good outcome and others do not.

1.5.3 Participant Responsiveness

Participants in a program may be those on the receiving side and those who administer it. Attitudes and perceptions of participants determine the level of fidelity achieved. A study done in Nigeria found that relationships between the health worker and patients were critical to the success of TB treatment. If a health worker is positive towards the treatment, it will positively affect the interaction between them and patients(49). Patients who felt that the health worker was rude or unhelpful reported higher rates of loss to follow up which in TB treatment would increase multidrug resistance(50,51). Evaluation of participant responsiveness is commonly through self-report(52,53). Several perspectives can be taken in the measurement of participant responsiveness: - Patients side, the provider's aspect, and whether the environment where an evidence-based intervention is conducive to have a positive response from participants(48). On the provider's aspect, the perception of the usefulness of intervention and ownership of responsibilities required of them can also be assessed(54)

1.5.4 Intervention Complexity

Simple interventions achieve higher fidelity than complex interventions(55). Guidelines that are detailed and clear are more likely to be followed as opposed to non-specific and vague guidelines. A study proposing a framework for the analysis of intervention complexity defined the construct as "the quality and quantity of non-financial resources required to implement and sustain an innovation(56). The study used the framework to analyze the complexity of the DOTS TB program. Areas found to have complexity in delivery in terms of human resources were skills required for service provision and staff supervision, Intensity of services needed due to frequency and duration of TB treatment, and management and planning requirements(56). If interventions are made inexpensive and simple, in terms of the core components or the software i.e. guidelines and human resources they lend themselves to be used in all delivery channels and overall will improve health outcomes.

1.5.5 Quality of delivery

Quality of delivery has been “defined as the extent to which a provider approaches a theoretical ideal in terms of delivery of program content(57). A health worker's preparedness to provide treatment, enthusiasm at the workplace, techniques, and methods used in delivery skills all constitute the quality of delivery. Studies in Uganda and Ghana reported low enthusiasm for TB treatment for fear of being infected with TB and consequently poor attitude to the patients(58,59). A low level of skills and knowledge leads to health workers not having the confidence to treat TB patients. Many felt that they needed training especially on new guidelines and adverse effects of treatment.

2.0 CHAPTER TWO: METHODOLOGY

2.1 INTRODUCTION

This chapter elaborates the design of this research, describes in detail the study site and study population, tools, and procedures followed in data collection. It also describes how data was managed, variables used in the analysis, and the analysis plan.

2.2 STUDY SITE

Homa Bay County is located in the Western region of Kenya. According to the 2009 census, the population was 964 000 with 44% below 15 years of age(60). It has 8 main sub-counties: - Homa Bay town, Rangwe, Mbita, Suba, Ndhiwa, Rachuonyo North, Kasipul, and Kabondo. Homa Bay town is the administrative region. The major economic activity is fishing especially Lake Victoria located in the area. This attracts a huge workforce of families who live in tiny, cramped villages in poor socioeconomic conditions. Homa Bay County has the highest prevalence of TB and HIV/AIDS (26% of the total population) in Kenya.
These factors contribute to the high pediatric and adult burden of TB in the county. Total TB treatment sites in Homa-Bay are 162 of these, 137 are government/public facilities, 4 are private and 11 are faith-based

2.3 STUDY DESIGN

To measure adherence to national guidelines on the management of tuberculosis in pediatric patients in TB treatment sites in Homa Bay County, a mixed method convergent parallel study design comprising of cross sectional quantitative and qualitative aspects was used. (Figure 2) Quantitatively, a review of treatment registers of pediatric patients for four years (January 2014 to December 2017) was conducted to measure the level of implementation fidelity. Qualitatively in-depth interviews were conducted with eight sub-county TB coordinators to explore moderators of Implementation Fidelity. Their length of work experience in the TB program ranging from four years to 11 years

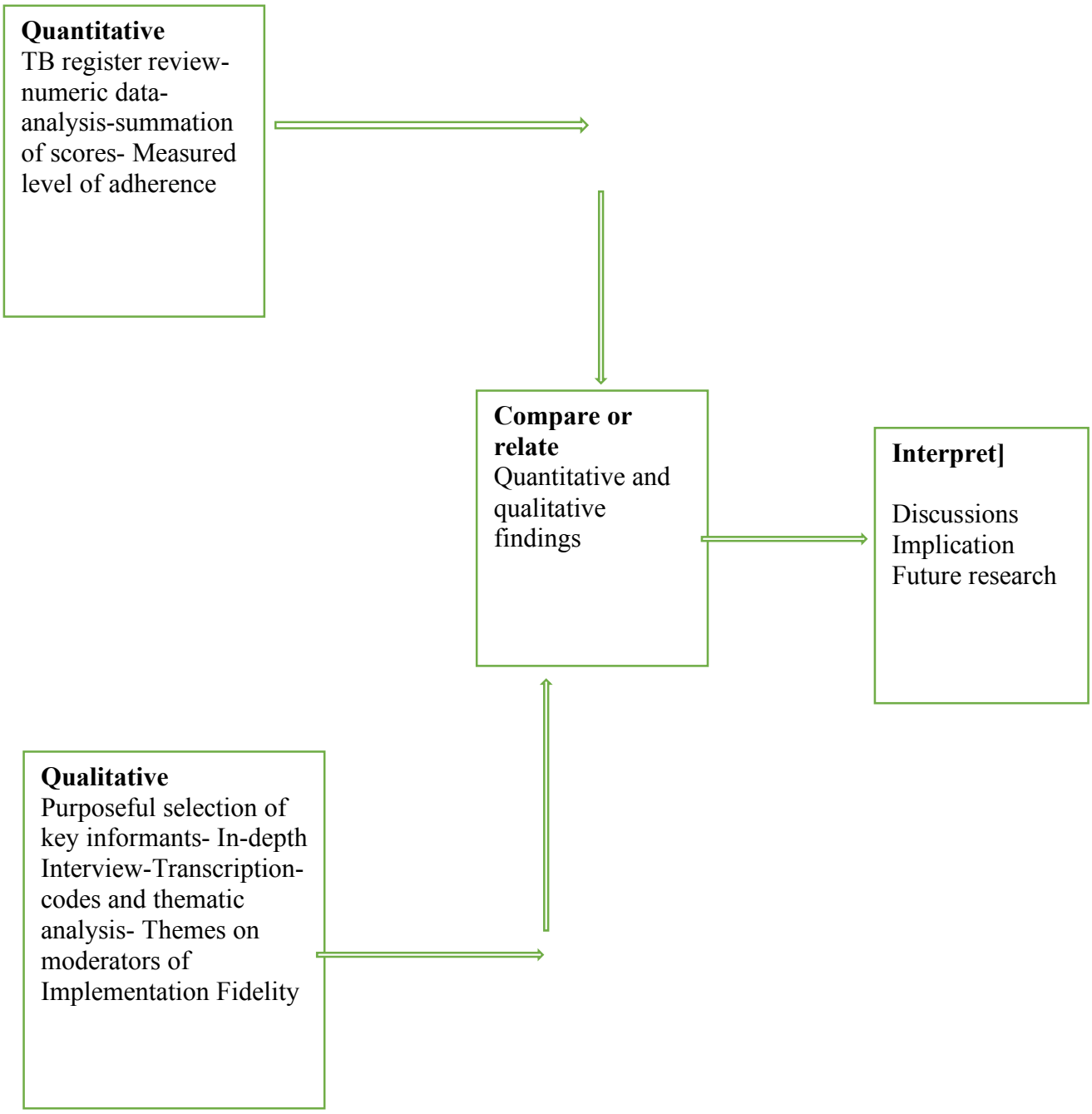

Figure 1.2 Visual depiction of Convergent Parallel study design

2.4 STUDY POPULATION

Two study populations were analyzed in this study.

1. Public TB treatment sites in Homabay County where a retrospective review of treatment records for paediatric patients was conducted from 2014 to 2017. Paediatric patients in this study were defined as those between birth and below 15 years of age corresponding to WHO considerations(9,61).
2. Sub-county TB coordinators in each of the eight sub-counties in Homa-Bay County This population was included in the study as key informants for each of the eight sub-counties. All sub-county coordinators had worked for four years or more and therefore they had sufficient experience and were conversant with the operations of the treatment sites and issues of the health workers.

2.5 STUDY SAMPLING/ SAMPLE SIZE

TB treatment records (Objective 1)
Facilities/ Record review sampling
TB registers were reviewed for the period of four years 2014 to 2017 for Objective one.
The sample size was calculated using STATA v.14 to estimate the required numbers of pediatric records to be reviewed. Assuming that 50% of health workers adhered with fidelity, at 95% confidence interval and 80% power, a minimum of 400 records were required to calculate the overall adherence score in Homa Bay County. This will translate into about 50 records from each of the eight sub-counties. All treatment records of children below 14 years of age who received treatment from 2014 to 2018 were eligible to enter the study. The records which were complete were included, those which were torn or information missing were excluded.

The records were contained in the TB treatment registers which were maintained at the facility level. Adult and pediatric patients were recorded in one register. Time constraints could not allow a visit to all treatment sites. To tackle this challenge, the research team first went through an online application called TIBU which helped identify only pediatric cases. This is a digital platform that means *"to heal"* in Kiswahili language and was introduced by the National TB program to improve data management in all treatment sites. Data from all treatment registers dating as far back as possible was uploaded onto the platform in summarized form. The software automatically remits data to the central server for analysis and reporting and can be accessed online. Data from 2014 to 2017 was reviewed. An estimate of pediatric patients treated for TB in the four years is presented in Table 2.1.

Table 2.1 Number of paediatric patients treated for TB in Homa Bay County from 2014 to 2017

Sub County	Years				
	2014	**2015**	**2016**	**2017**	**Total**
Homa Bay Town	22	16	24	26	**88**
Rangwe	12	30	23	26	**91**
Mbita	32	12	19	28	**91**
Suba	17	14	11	7	**49**
Ndhiwa	31	15	25	28	**99**
Rachuonyo North	55	37	32	43	**167**
Kasipul	56	23	26	27	**132**
Kabondo	24	22	14	12	**72**
Totals	**249**	**169**	**174**	**197**	**789**

Table 2.1 presents the total number of patients (records to be reviewed) per Sub County. Purposive sampling was carried out because the Director of Health Homa bay County had allocated two weeks in total for data collection. The County TB coordinator had already chosen some facilities which he felt had a good number of records to be reviewed in some sub-counties and other sub-counties, the team started from the TB treatment site nearest to the sub-county office, going inward to the other treatment sites until the maximum number of records possible was collected from a sub-county, putting in consideration time and remoteness of a facility. The team aimed at collecting a minimum of 50 records from each sub-county. There was a challenge on missing registers especially for the year 2014, torn pages of registers, and in-accessibility of facilities therefore it was difficult to balance the number of records collected for each year and to reach the aim of 50 records per sub-county. Records were collected from a mixture of private, public, and faith-based facilities.

In total 441 records were reviewed. The minimum number of records was 32 from Kasipul and the highest was 94 from Rachuonyo North. Records from 31 facilities were reviewed out of the total 162 facilities, two were private facilities while two were faith-based.

Table 2.2 Summary of records and health facilities in every sub-county

Sub-County	Number of records reviewed	Number of facilities visited	Total number of facilities in that Sub-County	Proportion of facilities visited
Homabay Town	48	4	14	29%
Rangwe	46	4	20	20%
Mbita	44	4	23	17%
Suba	37	4	19	21%
Ndhiwa	77	5	29	17%
Rachuonyo North	94	5	30	17%
Kasipul	32	1	12	8%
Kabondo	63	4	15	27%
Total	**441**	**31**	**162**	**19%**

Sub-county TB coordinator sampling (Objective 2)

Purposive sampling was conducted.

This is where the selection of participants is guided by the principal investigator's judgment on who is best to provide the required information (key informants). Duration of time serving in the TB program and being in a leadership position was used to determine the selection. Eligibility criteria for the key informants was duration of time in service and having a leadership role in the TB program. Those who had worked for 5 years or more at the time of study were included. Those who held no leadership role were excluded. A pilot study showed that most of the staff working in the TB clinics were employed by non-governmental organizations and whenever they found better opportunities, they would leave hence there was a high turnover of clinical staff. The eight sub-county TB coordinators were found to have been in service for a longer period and had worked in the clinics before they became supervisors therefore had a good experience and were best suited to be key informants.

In total, eight in-depth interviews were conducted.

2.6 DATA COLLECTION & TOOLS

Data was collected over a period of 3 months August, September and October 2018. A checklist and an interview guide were the data collection tools.

1. Checklist

The checklist focused on the main measurement of implementation fidelity which is adherence. It was designed in Redcap (Research Electronic Data Capture) version 7.6.3 a web-based application used to design databases and online surveys for researchers(62). The checklist followed steps outlined in the Kenya national guidelines for the management of tuberculosis in pediatric patients (2013 edition) summarized as (Appendix B).
The checklist had five sections. Section one demographics of the hospital and the patient, section two Content, covering steps on diagnosis, and treatment, section three on coverage section, section four and five collected data on frequency and duration. During analysis, only content was used as a proxy for adherence. (Appendix C)
Review of records identified what was carried out/not carried out as per the guidelines. Data was collected from TB clinic treatment registers of the pediatric patients managed during the period January 2014 to December 2017. The checklist was printed from redcap and used to fill the records. The checklist collected data on patient demographics, content (the active ingredients of the guidelines), coverage (Number of dots visits that the patient attended), Duration (total time of treatment according to the guidelines), and frequency (frequency of visits in intensive and continuation phase). Instruments were piloted by the PI in one of the health facilities in Nandi County to assess if the toolkit gathered all the information

2. Interview guide

A four-part guide, with sections exploring moderators of Implementation Fidelity to TB treatment guidelines for pediatric patients and ultimately how they related to the measured level of adherence was used (Attached as Appendix D).
Eight key informant interviews were conducted by the principal investigator with the sub-county TB coordinators in the English language. Key informants were given time to read through the information sheet and give informed consent (Appendix E).

The approximate duration of each interview was 30 minutes. Interviews collected data on Intervention complexity, quality of delivery, participant responsiveness, and facilitation strategies. Interviews were audio-recorded for transcribed by the principal investigator. Before data collection, the guide was piloted on health workers from Nandi County and adjusted accordingly

2.7 VARIABLES AND MEASUREMENT

Outcome variable Adherence scores (Continuous variable)
Each guideline earned a score of “one” if health workers adhered to it or “zero” if it was not adhered to. Each particular patient record could score a minimum of zero to a maximum of 15. The summation of these 441 scores generated the outcome variable for the quantitative aspect

which is adherence. The overall adherence score for the county was calculated. The mean of this score was then produced.

Table 2.3 List of explanatory variables

Variable	Type	Description	Coding
1.Date of diagnosis	Categorical	Date of TB diagnosis indicated in the record	"Yes" " No" "1" "0"
2.HIV	Categorical	HIV testing is done in all children diagnosed with TB. If there is a result positive or negative, the guideline was followed	"0" = No Not Tested, Data missing "1" = Yes (HIV Positive and those negative
3.ARV	Categorical	Those found HIV positive started on treatment	0" = No (Not on treatment "1" = Yes(on ARV(Anti-Retroviral treatment)
4.Diagnosis method	Categorical	Patient symptoms chest X-ray ,sputum ,Culture, biopsy od swellings, gene X-pert smears, gastric aspirate smears	0" = No "1" = Yes
5.TB type	Categorical	Pulmonary/ extra pulmonary TB	0" = No "1" = Yes
6.Total treatment time	Categorical	Appropriate treatment duration according to diagnosis e.g. Pulmonary TB =6 months, extra pulmonary eight months to one year	0" = No "1" = Yes
7.Classification	Categorical	Classification in terms of severity. two classes Severe and non-severe	0" = No "1" = Yes
8.Patient type	Categorical	5 patient types:- New, Relapse, Treatment after failure, transfer in	0" = No (Not recorded) "1" = Yes (patient has been assigned any of this category
9. weight at beginning of treatment	Categorical	Weight at beginning of treatment indicated	0" = No "1" = Yes

“treatment	Categorical	Weight at end of treatment indicated	0” = No “1” = Yes
11. Date of treatment initiation	Categorical	Date of treatment initiation indicated in the record review	0” = No “1” = Yes
12. Treatment Outcome	Categorical	Patient allocated any of the seven treatment outcomes scores one, Each score of one is aggregated together to form “Yes”	0” = No “1” = Yes
13.Follow up sputum tests	Categorical	Sputum was done three times Month one, five, and six	0” = No “1” = Yes
14.Follow up gene X-pert	Categorical	Gene X-pert was done three times Month one, five, and six	0” = No “1” = Yes
15.Follow up X-ray	Categorical	Repeat X-ray at the end of treatment	0” = No “1” = Yes

In the qualitative aspect, the four moderators of implementation fidelity were explored: - Intervention complexity, participant responsiveness, facilitation strategies, and quality of delivery. Coding of the transcripts was conducted from the codes then thematic analysis of upcoming themes was carried out. Further analysis and reporting was conducted under the four moderators.

2.8 DATA PROCESSING AND DATA ANALYSIS PLANS

2.8.1 Data processing

Objective 1
Checks to ensure the data was entered correctly were conducted and any discrepancies were removed. The data was then exported to STATA version 14 for analysis in .csv format. Data cleaning was performed in STATA V. 14 to check for missing data and errors by checking for extreme values and inconsistencies. The original data source was referenced to address all identified missing data or errors.
Objective 2
The audio records were transcribed by the primary investigator verbatim into a word document. The transcripts were then reviewed while listening to the recording’s multiple times for accuracy. For both Objectives, hard copies will be kept in a safe place under lock and key. An electronic backup will also be kept.

2.8.2 Data analysis

Objective 1 analysis.
As a broad introduction, descriptive statistics of the patients whose records were reviewed e.g., age sex, HIV status, classification of TB status, and treatment outcome were generated as categorical variables and reported using counts and percentages.

The guidelines were summarized into 15 key components which were used to generate variables. The guidelines are - Date of diagnosis, HIV status, ARV status, Date of treatment initiation, Method of diagnosis, TB type, Classification of TB, Patient type, follow up sputum tests, follow up gene X-pert tests, follow up X-ray is done at end of treatment, Weight at beginning and end of treatment, and total treatment time and, finally, Treatment outcome. Coding of the guidelines as "Yes" and "No" was done. Yes, if complete adherence to guideline and no if no adherence to the guideline. Scores for each variable were then calculated and summed up to create a fidelity score. These 15 scores were then being summed up to create an overall score for Adherence for the County. To make interpretation more meaningful, the scores were divided by a total of 15 and multiplied by 100 to present them as percentages. Checks for normal distribution of data using the Shapiro-Wilk test was conducted. The median value was calculated and presented along with interquartile ranges.
To enable comparison of one sub-county to the other, percentage adherence scores for each sub-county was then calculated by summation of scores from records evaluated from a particular sub-county and presented as a fidelity score.

Objective 2 analysis
A thematic approach was used in the initial broad coding. The broad codes were then grouped into finer codes which were categorized into themes corresponding with the four moderators of Implementation Fidelity. This was carried out by hand using excel spreadsheets as the interviews were few.
Using the moderators in the Carroll framework, health care worker's responses will be analyzed line by line to identify different codes. The codes will then be grouped under different themes and a codebook generated.

2.9 ETHICAL CONSIDERATIONS

The study protocol was submitted to the Wits University Health Research Ethics Committee (number M180146) (Appendix F) and the Moi University/Moi Teaching and Referral Hospital Ethics Review Committee (number IREC/2018/10) (Appendix G). A research permit from National Commission for Research, Science and Technology, Kenya was also obtained. The permit is not presented as part of the appendices because of challenges in communication with the office and the printout could not be obtained. Approval from the office of the Director of health Homa-Bay County to conduct record reviews in the health facilities was also obtained (APPENDIX H). An information sheet giving a detailed explanation of the study and what was required of them was provided to the participants before participation. All participants consented to the interviews and signed the approved consent forms before participation. In addition to the informed consent, participants also gave consent to allow audio recording. Participation was voluntary, and the TB coordinators were free to withdraw from the study at any moment without victimization. Any concerns and clarifications were handled. No personal identifiers were collected during the study. Signed consent forms are kept in locked filing cabinets at the Research Unit Voice recorded interviews are kept 25 in password-protected audio files. Data will be kept for two years and not made available for any member of the county health department. The sub-county TB coordinators were informed that there was no direct benefit in participating in the study, but that the information obtained could help them improve the quality of care and management of patient's pediatric TB patients in the County. Patients' records were kept confidential; no personal identifiers were collected. Patient record files were reviewed at the facilities, and TB treatment registers were never taken out of the facilities during the duration of the study.

3.0 CHAPTER THREE: RESULTS

3.1 INTRODUCTION

The results following quantitative statistical analysis of 442 treatment records from the 8 sub-counties and qualitative analysis of 8 in-depth interviews are presented in this chapter.
Findings of the quantitative aspect will be presented, followed by the qualitative.
Where applicable, tables and graphs will be used to illustrate the results.

3.2 QUANTITATIVE ANALYSIS

Objective One: To measure implementation fidelity to National guidelines on the management of Tuberculosis in pediatric patients in Homa Bay County, Kenya

Descriptive statistics of records reviewed

Age was presented in months to make the analysis of those below one year of age easier. Age distribution was skewed to the left, (*P*=<.01) Median age was 84 months (Seven years) (IQR 36-144 months).
The proportion of females (46%) was slightly lower than that of males (51%), the difference accounting for those records missing data on sex. Those who were tested for HIV and found to be positive were 46%. Of these, 91% were started on Anti-Retroviral therapy.
Pulmonary Tuberculosis was the predominant type of TB infection among the children (72%). The majority of them (42%) were diagnosed through suggestive features on chest X-ray, (19%) had positive sputum smears, and (7%) had positive gene X-pert results. The rest were diagnosed based on the symptoms they presented with.
Patients who were being treated for the first time for TB infection (New) were 96%, the rest of the (4%) had been treated before and had a relapse of the infection, had treatment failure, and were being re-treated or had been transferred from other facilities outside the County.
In terms of cure, 20% had a complete cure, a higher percentage (56%) completed treatment without any documentation of final sputum or gene X-pert results, while 35% died.
Table 3.1 gives a summary of the descriptive statistics of the records reviewed.

Table 3.1 Summary descriptive statistics

Variable	Sub-Categories	number(percentage)
Sex	Male	208(51%)
	Female	198(46%)
HIV Status	Positive	193(46%)
	Negative	213(50%)
	Not tested	13 (3%)
Type of TB	Pulmonary	316 (72%)
	Extra pulmonary	119(27%)
Type of patient	New	419(96%)
	Relapse	8(2%)
	Treatment after failure	2(0.5%)
	Transfer out	3(1.5%)
Treatment outcome	Cured	84 (20%)
	Treatment Completed	236(56%)
	Treatment Failure	3(1%)
	Died	35(8%)
	Lost to follow up	12(2%)
	Treatment completed/ Cured	2 (1%)
	Transfer out	39 (95)

Guidelines used in the measurement of adherence

The 15 guidelines used to generate the adherence scores and the percentage of records that adhered to the guidelines (Yes) and the percentage that did not adhere to the guidelines (No) are detailed in Table 3.2

For most of the guidelines, adherence to the guideline was more than 80%. However, the results show that most health care workers are not keen on ensuring that patients have all the follow-up tests done as required. These are sputum tests, gene X-pert, and follow-up X-rays. Sputum and gene X-pert are done at end of months one, five, and six of treatment for the six-month regimens, and month eight and 12 for the TB meningitis- and retreatment regimens respectively.

Table 3.2 Table showing number of records that adhered to each of the 15 guidelines

Guideline	Number of records (Frequency [N] Percentage (%)			Totals
	Yes	No	Missing	
1.Date of diagnosis	373 (84.39)	69 (15.61)	0	442
2.HIV	406 (96.90)	13 (3.10	3	442
3.ARV	176 (91.19)	17 (8.81)		193*
4.Diagnosis method	428 (98.17)	8 (1.83)	6	442
5.TB type	435 (99.77)	1 (0.23)	6	442
6.Total treatment time	360 (81.85)	82 (18.55)	0	442
7.Classification	394 (95.86)	17 (4.14)	31	442
8.Patient type	432 (99.77)	1(0.23)		442
9. weight at beginning of treatment	419(94.80)	23 (5.20)	0	442
10. Weight at end of treatment	376 (85.07)	66 (14.93)	0	442
11. Date of treatment initiation	410 (92.76)	32 (7.24)	0	442
12. TB outcome	411(98.33)	7 (1.67)	24	442
13. Follow up sputum tests	35 (7.94)	406 (92.06)	1	442
14. Follow up gene X-pert	13 (2.94)	429(97.06)	0	442
15. Follow up X-ray	12 (11)	95 (88)		107*

*The reduced number in records under ARV guideline is because it only applies to those who were HIV positive. 193 patients out of 442 were HIV positive

*The reduced number of records on follow up x-ray guidelines is because it only applies to 107 patients whose diagnosis of TB was made through chest x-ray

Composite adherence score (County)

In the 442 records analyzed, for the whole County, none obtained a score of 15 out of a possible 15, likewise, none scored a zero out of 15. The most common score was 12 which was found in 111 record reviews. Converted to percentages for easier interpretation, none of the record reviews scored 100% and none scored zero percent. The most frequent score was 80% for 111 records, followed by 73.3% for 101 record reviews. A median percentage score is 80% (P<0.01, IQR 73.33-86.66)
Table 3.3 gives a summary of the total scores/15, total percentage scores, and their frequencies.

Table 3.3 Composite adherence score for Homabay County

Records reviewed (n)	Total score (n/15)	Total score (percentage)
1	2	13.33
3	3	20
2	6	40
5	7	46.67
8	8	53.33
31	9	60
60	10	66.66
101	11	73.33
111	12	80
82	13	86.66
38	14	93.33
Total=442		

Composite adherence score (Sub County)

In the sub-counties, Ndhiwa had the least percentage adherence score 13.3%, all sub-counties had records scoring 93.3%which was the highest percentage score. The total scores for the eight sub-counties are presented in Table 3.4

Table 3.4: Composite adherence score for the eight sub-counties

Sub county (frequency/ number of records) %score							
Hogmanay Town	**Rangwe**	**Mbita**	**Suba**	**Ndhiwa**	**Rachuonyo North**	**Kasipul**	**Kabondo**
1 (40)	5(60)	1 (40)	2 (46.6)	1(13.3)	2(46.6)	1 (60)	2 (20)
1(53.3)	4(66.6)	1 (46.6)	1 (60)	1 (53.1)	2 (53.3)	8(66.6)	3 (53.3)
6 (60.9)	9 (73.3)	1(53.3)	1 (66.6)	4 (60)	8 (60)	5 (73.3)	2(60)
6 (66.6)	5 (80)	4(60)	5 (73,3)	12 (66.6)	21 (66.6)	11 (80)	2 (66.6)
18 (73.3)	16 (86.6)	6(6.66)	11 (80)	19(73.3)	29 (73.3)	6(86.6)	11 (73.3)
12 (80)	7 (93.3)	5 (73.3)	12(86.6)	25(80)	20 (80)	1(93.3)	12(80)
2(86.6)		15 (80)	5(93.3)	14 (86.6)	11 (86.6)		13(86.6)
2 (93.3)		8(86.6)		1 (93.3)	1 (93.3)		18 (93.3)
		3 (93.3)					

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Table 3.5: Table showing percentage Mean / Median adherence scores with Standard deviation/interquartile ranges

Sub county	Number of records	Mean (Standard deviation)	Median (IQR)	P-value (Shapiro-Wilk test)
Homa bay Town	48	72.77(9.80)		0.15
Rangwe	46	79.71 (10.6)		0.237
Mbita	44		80(66.66-83.33)	0.030
Suba	37		80(66.66-86.66)	0.000
Ndhiwa	77		80(73.33-80.00)	0.000
Rachuonyo North	94	72.90(9.16)		0.077
Kasipul	32	76.66(8.30)		0.802
Kabondo	63		80(73.33-93.33)	0.000

The adherence scores for Homabay town, Rangwe, Rachuonyo North, and Kasipul were normally distributed, their means and standard deviations were presented. Median and interquartile ranges were presented for the other four sub-counties- because their means were not normally distributed

3.3 QUALITATIVE ANALYSIS

This report section presents findings of the qualitative approach used to answer objective two of the research: - to explore how moderating factors affect Implementation Fidelity to National guidelines on the management of Tuberculosis in pediatric patients in Homa-Bay County, Kenya. Descriptive statistics of the participants are reported followed by key findings of the study. Findings are reported under four main themes namely: - Strategies facilitating Implementation, Participant responsiveness, Intervention Complexity, and quality of delivery.

3.3.1 Descriptive analysis

The key informants comprised eight Sub -County TB coordinators (n=8). In the findings, the key informants are referred to as "SCC" to mean Sub-County Coordinator) In terms of sex, six were male and two were female. They were all Clinical Officers. In Kenya, the term Clinical Officer describes a health practitioner who holds a diploma in Medicine and Surgery. They offer primary health care services in peripheral facilities. They are different from Medical Officer who is a Medical Doctor and holds a degree in Medicine and Surgery. Experience of leadership between four and 11 years in leadership positions and had also worked as clinicians in the clinics for a while and therefore were well versed in the TB treatment program.

Table 3.6 Socio-Demographic characteristics of study participants

Sex	N (%)
Female	2(25%)
Male	6(75%)
Age group	
25-30	2(25%)
31-35	3(37.5%)
36-40	2(25%)
41-45	1(12.5%)
Clinical experience (in years)	
0-5	3(37.5%)
6-10	4(50%)
11-15	1(12.5%)

3.3.2 Strategies facilitating Implementation

These are strategies employed to ensure that the implementation of guidelines is as uniform as possible. Every healthcare provider should receive similar training and support to ensure that what the guidelines intend to achieve are realized. Examples of these strategies are the provision of manuals in soft and hard copies, supportive supervision, on-the-job training, and continuous medical education, and giving feedback to those delivering an intervention. In the Kenyan system, guidelines are launched at the National program level and rolled out to every County for implementation.

a) Training

Our results show that training and sensitization on new updates were carried out at the National and county levels

'*After the launching, after it has been reviewed by the national team, then the launching has been done, now the guidelines are being rolled from the national level to the either if it is the county level then the facility level. So, they bring the guidelines, so from there at the...so either you can organize because always give us also outlines if we can do either an OJT (on the job training) or a CME (continuous medical education) of the guideline at the facility level' (SCC* 1)

b) Continuous mentorship

In addition to on-the-job training, the Sub County coordinators visited the facilities and observed the health care workers giving treatment. They also helped in managing very sick or complicated cases of patients and provided mentorship.

We normally go to facilities to do visitation on monthly basis, and we visit several facilities and during that visit, we do OJT (On-The-Job Training), we do mentorship to those facilities as well as we review patients who come to those...wherever we go, those visits are scheduled as per clinic visits in those facilities. So, when they have a clinic day, we join them and help in reviewing critical cases" (SCC 4)

c) Data Quality Auditing

As reported earlier in the quantitative phase of the study, treatment information of the patients is recorded in the TB treatment register found in the facility. The Sub County coordinators together with a record officer review how the health care workers fill in the registers and mentor them on how to improve the quality of data. They also ensure patients are classified correctly proper treatment outcomes are assigned to them

"That one, like for example like if it is like TB, DQA (Data Quality Analysis), we always either we can do it, combine it with HIV, so for example, if I am going to a facility, we will always involve the health records officer at the sub-county, HIV coordinator and myself for TB and HIV. We did one just last month and it was just a bit, we were just sponsored a bit by another organization in doing that, so we just want to know the level of either in terms of how they manage patients and in terms of data the quality about filling of registers, the follow-up smears are they being done well and then the outcomes are being given and the terms of HIV test done for every TB patient. If it is positive, patients are either put on ARV's or at an adequate time" (SCC 1).

d) Online Telemedicine platform

To ensure the is nationwide uniformity, the TB program in Kenya holds an online telemedicine platform called TB ECHO weekly with all healthcare workers in the program to discuss difficult

cases. The program also uses this platform to inform the health care workers of any updates to the guidelines.

we have ECHO which is just helping us to like you know it brings different cases, unique cases being discussed, it is like a video conferencing, people sit together and then you now share successful stories and also the difficult cases that are discussed, it is also a platform that can be used to relay some information that is new in terms of guidelines and SOP's (SCC 5)

e) Availability of manuals and guidelines

The study revealed that copies of guidelines were made available to the hospital management, however, the key informants felt the copies were few and some health care workers took them as personal copies.

'Maybe one per facility, which is insufficient. Also, only the focal part of TB will receive a copy and, in most cases, maybe that person receives it and make it as his own, sometimes maybe you go for supervision and ask for a guideline, they don't have, they have never seen or maybe someone has it and has kept it in his house as a copy of his own. (SCC 4)

"Like part of the tools, guidelines are rolled out copies were given to us, some in soft copies and some in hard copies and where they were few, we made more copies to ensure all of our facilities were, had such copies to utilize" (SCC 3)

3.3.3 Participant responsiveness

Participants in the study refer to health care workers as well as the patients and their parents. If participants feel an intervention is appropriate and relevant Participant Responsiveness Engage or fail to engage with an intervention depending on the extent of relevance they attach to an intervention.

The responses in this section took views from both the healthcare worker and the patient as participants in this intervention.

1. Appropriateness of guidelines to patients in Homabay

Some Heath workers think that the guidelines are appropriate in the context of Homa Bay and followed it well

"The guideline also has been positive, and it has been taken positively with the health care workers given the fact that it is not giving them hectic time to deal with the patients, one, is that commodities have been coming in good time, there is no time that we have missed commodities especially with the drugs" (SCC 7)

2. Feelings about frequent visits under direct observed therapy

Some health care workers did not see the importance of DOT (Direct Observation Therapy), frequent visits to the hospital, and repeat sputum smears hence did not follow the guidelines.

"Yes, ".... but the workers either that they don't follow the guidelines they can give a patent even for one month and then from that time they even…. they don't follow up the smears it becomes a

problem in terms of and monitoring patients also, are they improving are their side effects of drugs"(SCC 2)

Some think that either the guidelines are not appropriate because they think that every week a patient comes to the clinic is not appropriate" (SCC 3)

Frequent visits were also a concern to parents, some did not see the need to come frequently and ended up sending the children alone. The key informant felt that this affected the quality of care given to the child.

"Currently the most challenging is the caretakers of some children especially children who are not living with the real parents, you find sometimes they don't keep the appointment dates, or sometimes when they come, they are brought in late. That one I have seen mostly on children with caretakers who are not the real parents. And then sometimes you find some children come alone to the facility, you find on the diagnosis they will come with the parent or caretaker, then the subsequent visits the children come alone. Sometimes explaining some things to them becomes really difficult"

3.3.4 Intervention Complexity

This relates to core elements in the guidelines that gave the health workers and patients ease or those which proved challenging when following the guidelines.

1. Introduction of fixed dose combination for easier dosing

The health workers appreciated the new pediatric formulations of drugs that are dispersible and child friendly

"Well, initially children used not to use Ethambutol, then the Ethambutol was introduced to children at lower doses and again the pediatric foundation was now child friendly that was introduced, where at least children could now take either the dispersible tablets rather than the initial ones actually were cumbersome to take for especially children. So, for the ones that are taken now they are dispersible and easy to take, and they are also flavored so once they are dispersed in water, so children are able to take them easily" (SCC 6)

The introduction of fixed-dose combination tablets has made the prescription of drugs for the patients easier. Previously, the health workers had to add drugs to the regimen. This would end up being forgotten and children would get an under dose.

"Changes in dosages as in, okay, when I came in there was the use of 60/30 dosages then they were super boosting with the 60/60 which most of the time it got a lot of issues because like you get it a lot of issues because like you get into a facility, because of workload, health care workers tended to sometimes miss super boosting these dosages, sometimes a patient will go and get 60/60 and she has forgotten again to give the 60/30 to which they require dosages of these drugs.

So, it has brought a lot of challenges. So right now, there is a fixed-dose combination that is dispersible and easy to administer to the children. (SCC 7)

2. Improvement in diagnosis method

They also felt the change from scoring chart to active case finding improves precision in diagnosis reduces the number of children who are put on treatment when they do not have TB.

"Active Case Filing where we are looking at the patient as the patient presents but before that we were just using, there was a blank score chart and then the case score chart, so it meant if anybody scored, it was just giving you 1, 2, 3 out of 5, so if you were... then now you make a decision if there were more than 3 ticks, 3-5 then you were just making a diagnosis of TB." (SCC 1)

c) Difficulties in producing specimens for testing

Getting children to produce sputum for testing which is the gold standard in diagnosis is difficult because they are not able to follow instructions. The health workers felt that the upgrade of guidelines from taking two or three sputum samples to only taking one made diagnosis easier.

"you have to tell the patient to again produce a spot sample so initially the patient had to produce at least two samples, but currently it is one sample and that is enough for the process" (SCC 5)

On the new guidelines, to be able to obtain a sputum specimen Gastric aspiration is done. The health care workers felt that this was an invasive procedure, involves starvation of children for 6 hours which is difficult for children.

"*Well, other than that, there is a bit of diagnosis because we have some other invasive procedures that are involved in diagnosing TB in children, one, you realize that children especially under the age of 5 years are not able to produce sputum adequately and therefore there are some other invasive procedures that are involved in it and therefore some of our health care workers given that some of them have stayed for long without doing some overwhelmed procedures like inserting an MV tube, so telling them again now to insert an MV tube to aspirate gastric contents once they diagnose sometimes is a bit of a challenge to them and therefore it is called for a sort of an end training again to ensure that they are able to tell these children to be starved for 6 hrs., and again to tell these children to be a starved for 6 hrs. is again a bit of a challenge because either way you will have to refer to the main facility for instances sub-county hospital, when they are admitted, they have to be starved for like 6hrs because when you starving them at home for 6hrs and then bringing them very early in the morning sometimes is a bit of a challenge, so the component of referring them to the main hospital and then they be starved for 6 hrs. Very early in the morning the pediatric ward is down so that at least we will get the sample for Tuberculosis" (SCC 7)*

3.3.5 Quality of delivery

a) Attitude of fear)

Fear of contracting Health TB from the patients by the health care workers was a prominent theme from the key informant interviews.

"They normally just think if they are working in TB, they will get TB which is not the case. As long as there is IPC then definitely it is not a must that you develop TB but most of our health care workers still think that they are not safe when working in TB clinics". (SCC 8)

Due to the fear, they are unable to prescribe any medication or examine a patient. The patient will have to wait for the clinician in the TB treatment site in order to receive treatment.

*"[**clears throat**] Most health workers are afraid of TB and you find in some facilities they are like 'TB is for someone in particular 'even sometimes they call me, we have a TB patient what do we do, and some will even be called to go and give drugs, some are afraid of… in fact most of the health workers are afraid of TB despite all the OJT's that we do but they will just fear" (SCC 5)*

"Those who are informed about TB where it is positive, they take care of the patients but those who are not informed about TB in high volume size they are like, keep off TB, wherever they see a TB patient they fear and they refer to a specific person, in that case they have an attitude of saying that maybe I can be infected with TB if I see these patients knowing that maybe they have been seeing this patient in the ward." (SCC 6)

b) Lack of awareness on Infection Prevention control

"like in our sub-county we have a rider system, sputum working system, you can find those riders have not gone to one facility for example and the sputum sample was collected there, somebody may not feel comfortable taking that sputum sample to a fridge because they feel it may contaminate, the aspect of contamination of the sputum brings a lot of stigma or some change of attitude then you find somebody just taking that kind of a sputum, just leave it we shall call the patient tomorrow to produce it again and maybe it is difficult to produce another one and will affect diagnosis ."(SCC 2)

c) Lack of adequate skilled manpower

Staffing issues was a recurrent theme in many of the interviews. There are facilities e.g., dispensaries that have only one health worker who has to run all clinics this, in turn, affects quality of TB care. Many health facilities have NGO seconded staff who are highly trained, once the NGOs phase-out, the staff leave. Given that they are highly. Trained they leave a huge gap and thus quality of care is reduced.

"*Under staffing where one health worker has to man all areas in the facility leads to them not giving enough time to TB patients/ heavy workload comprehensive care, more focus on HIV, dwindling of staff as partner phases out (SCC 8)*

Education and counselling that is the challenge in what I have observed in TB patients because you will find one health care worker is the same one who is seeing both HIV patients and TB patients You will find HIV patients and TB patients there is adherence counselor, there is peer educator, peer educators like my sub county there are community educators and facility peer educators. All these people they are towards in assuring adherence ARVs to these patients while in TB there are only two clinicians and you will get that HIV do bill counts and they even have those forms where adherence is met but when a TB patient comes 'have you finished your drugs, let me see the packet, do you have any problem, then they are just given drugs and they go back, so that is the weakness that I have seen as much as patients are taking drugs, I think education and education in TB treatment is not done as it is supposed to be done." (SCC 1)

"The partners and currently our major employer, the partner that has employed so many staff, are again thinning down their staffs. So right now, we have a crisis of staffs, they are gone, almost you will get some labs have been closed because they don't have lab technicians (SCC 2)

d) Lack of knowledge and skills

Health workers shy away from diagnostic procedures because of feelings of inadequacy, lack of confidence and knowledge.

"*Some of them have stayed for long without doing some overwhelmed procedures like inserting an NG tube, so telling them again now to insert an NG tube to aspirate gastric contents once they diagnose sometimes is a bit of a challenge to them." (SCC 5)*

"Okay we want to embrace the issue of gastric lavage to help us in the diagnosis of TB especially for children who cannot produce sputum, but one the clinicians they fear doing gastric lavage, I don't know why. Two you can get that some of them say they don't have the confidence and the full knowledge on how to do gastric lavage" (SCC 7)

CHAPTER FOUR: DISCUSSION

4.1 INTRODUCTION

This study aimed to measure Adherence to National guidelines on the management of Tuberculosis in pediatric patients in Homa Bay County, Kenya and to explore how moderating factors of Implementation Fidelity affect adherence to the guidelines. Results of the study are discussed in this chapter as per objectives and in light of evidence existing on implementation fidelity.

4.2 MEASURING ADHERENCE

The study focused on intervention content as the only measurement of adherence. Intervention content in the study is described as the key aspects of care that the health care workers are supposed to provide to the patients. The aspects include proper diagnosis, proper administration of drugs at the right doses, frequent follow up until completion of treatment.

Overall adherence score for the County was high. Similarly adherence scores for the sub-counties was also high with four counties scoring 80% and four of them scoring 79%. The study did not measure coverage duration and frequency as measurements of adherence. Measurement of Implementation Fidelity in current perspectives advocates measurement of the four components of adherence (Content, coverage, duration and frequency) as bottom line measurements. However different studies have focused on some components and not all four. Toomey et al, measured fidelity of content and duration in a self-management intervention for patients with osteoarthritis(63). High score of content was classified as between (80-100%). The results showed high fidelity of content. Fidelity of duration was found to be low as it deviated from the 45 minutes intended in the intervention. Another study measured dose in an intervention promoting oral health in pre-school children with an average score of 64 %(64). Despite the high scores of 80% and 79% some aspects of the guidelines were not followed. Our results showed low scores in the follow up sputum, gene X-pert and X-ray guidelines. These follow up tests are important in monitoring the patient's progress and determining cure. Positive sputum or gene X-pert at month five of treatment, or an X-ray showing features of TB at the end of treatment may point to drug resistance or treatment failure whose treatment is for a longer duration, drugs are costly and are a public health concern.

Joseph et al, explored factors which could influence adherence to screening and treatment policies of TB in a work site(65). Findings reported that some health care practitioners were not familiar with the epidemiology and pathogenesis of TB. Hence the reason they were not following policies as written out.

4.3. MODERATORS OF IMPLEMENTATION FIDELITY

4.3.1 Strategies to facilitate implementation

Our findings showed that good strategies were put in place by the National TB team, TB coordinator and sub-coordinators in Homabay County like trainings, both on the job and online. There was supervision and mentorship from the County and the National program. They only lacked guidelines where they could refer to when in need.

Policymakers at the National Tuberculosis Leprosy and Lung disease program level develop guidelines and write them down as a manual, it is then distributed to the health workers to

standardize care in all facilities. In Homabay County, all facilities received copies of the manual others went even further to develop standard operating procedures which were put on the walls as summaries for easy reference. Branden et al describes how 40% of nurses used a manual in an oral intervention to achieve high adherence(64). The same study found that 93% of nurses found that training helped follow the guidelines. Training, mentorship, monitoring, and feedback came out as major facilitation strategies from the TB program has employed to standardize care for all patients

Several studies highlight the importance if support supervision in aiding the health workers adhere with fidelity

Chung et al, assessed the role performance of CHWs in Sarawak, Malaysia(66). The study showed that supervision was an important factor to good performance and poor performance contributed to poor morale and unproductivity.

4.3.2 Participant responsiveness

The Guidelines elicited different perceptions from the health care workers on the treatment of TB in paediatric patients. Some health workers felt that they were easy to follow and appropriate in the context of Homabay County while others did not.

Health care worker responsiveness to DOT (Direct Observed Therapy) and frequent patient follow ups was a concern. National TB guidelines strongly recommend a patient centred case management approach including DOT especially for those with active disease. This is because it helps reduce spread to others and reduces emergence of drug resistant TB. Luka and colleagues found that health workers with poor communication and interpersonal skills negatively affected adherence to long duration of TB treatment in patients(67).

The Implementation Fidelity framework by Carroll et al poses that uptake of an intervention depends on its acceptability and participant's non engagement with an intervention can be a major reason for its failure.

4.3.3 Intervention complexity

This study revealed that changes in the guidelines, e.g. fixed combination drugs and active case finding which made diagnosis easier lead to higher adherence. However induction of sputum through gastric aspirate was an area where they felt was complex. Lack of knowledge and skills, combined with inadequate infrastructure made it difficult to obtain sputum specimens from children. This led to low adherence because sputum testing is the gold standard when diagnosing TB.

This confirms the literature that by Carroll et al that simple specific interventions have a higher chance of being implemented with high adherence as opposed to complex interventions(30)

On the patient's aspect, formulation of drugs which are dispersible and flavoured increased the likely hood of paediatric patients taking them and actually completing long periods of treatment.

4.3.4 Quality of delivery

Carroll et al explains that an intervention delivered in an appropriate manner as intended by its implementers is deemed to have good delivery. Our study revealed that in as much as the health care workers implemented some aspects with high adherence, some factors affected their quality of delivery.

Lack of adequate staff lead to over working of the few available staff which in turn compromised quality of care. Whole some care of TB patients involve counselling on adherence, nutritional

support and contact tracing among others. Lack of staff resulted to the patient only receiving drugs and missing out on other care.

4.4 RELATING QUANTITATIVE AND QUALITATIVE ASPECTS

Findings of this study showed a high level of adherence both at the county and the sub county levels. The high levels of adherence could be attributed to several moderators. Homa-bay County in conjunction with the division of tuberculosis at a national level have put up different ways of interacting with health care workers to ensure that the guidelines are available to all and the intervention is uniformly implemented. From weekly nationwide meetings, on job trainings, support supervision and WhatsApp platforms to discuss difficult cases, the health care workers have good facilitation strategies. Simplification of the guidelines to small pocket size books ensures that everyone can understand the guidelines. Introduction of fixed dose combinations ensures that children whose medication goes with weight bands get the right dosage and pill burden is low. Few issues noted from the qualitative study account for the remainder 20% of the fidelity score. High staff turnover leaving staff overwhelmed in TB clinics, an attitude of fear to contract TB, difficulty obtaining sputum specimens in children and non-adherence by health workers and parents to frequent visits (DOTS).
Kinley et al. conducted a similar mixed method study assessing implementation fidelity of tuberculosis infection prevention control practices (IPC) in Bhutan(68). The study focused on knowledge, responsiveness and adherence to IPC (quantitative) and explored barriers and enablers to both patients and health care workers. Adherence score was 82% in healthcare workers and 93% for patients. Poor structures, understaffing, poor attitude of staff was some of the negative moderators. Good monitoring and supervision, collaboration and coordination were the positive moderators.
In Nepal, Tuberculosis prevention therapy was rolled out in line with WHO recommendation. Ashmita et al conducted a mixed method study to access implementation fidelity of the prevention program(69). The carol framework for implementation fidelity was used. Moderate level of adherence was reported at 70% of children being enrolled into the prevention program.

In Ghana, Narh-Bana and colleagues assessed the implementation fidelity of TB screening guidelines by health workers at HIV clinics. The intervention is geared towards reducing cases of TB in people living with HIV, early diagnosis and early initiation of treatment. The overall fidelity score was 79% with 53% of health care workers scoring above the median. Providers who were female, had a tertiary education and were clinicians had higher fidelity score. Components of adherence that were analyzed were content and frequency.

4.6(a) STRENGTHS OF THE STUDY

1. Use of both qualitative and quantitative methods (mixed methods) provide a deeper understanding to factors contributing to positive and negative outcomes in implementing TB treatment guidelines
2. Availability of the TIBU platform enabled a quick overview of the records to be reviewed. Manually moving from facility to facility would have been cumbersome and many records would have been missed especially from 2014/2015

4.6(b) LIMITATIONS OF THE STUDY

It is important to keep in mind the following limitations when considering the findings of this study

1. At the time this report was written, Implementation research is a fairly new field in the Kenyan context. Few studies on Implementation research have been carried out in this region therefore no reference data was available.
2. Method of sampling used in qualitative study might not be a representation of the whole county. Facilities nearest to the sub-county hospital may have been in urban set up therefore the picture in remote areas may not have been captured.
3. Missing records and torn registers especially for the year 2014 contributed to reduced number of records in some sub-counties. The presented level of adherence may not be a uniform representation of the four years.

4.5 CONCLUSIONS

Findings presented in this study provide a platform for measuring health worker's performance not only in the aspect of TB guidelines but in all other evidence-based interventions using the conceptual framework proposed by Carroll et al., (60). Use of the framework allows program managers to understand how the components of adherence interact with each other and how moderators of Implementation fidelity affect the outcomes.

Adherence to the national guidelines on the management of TB in pediatric patients was found to be high. Areas which showed low fidelity scores were guidelines which required follow up tests in the course of treatment

Findings in the qualitative phase especially participant responsiveness shed more light on the low implementation fidelity scores to follow up tests. Some health care workers did not understand the reason for frequent visits to the facility under the direct observed treatment therapy. Instead, they preferred to give in monthly doses. Similarly, Guardians of the patients did not understand the rationale behind frequent visits and felt they were costly.

Monitoring the process of implementation by program managers and stake holders is therefore recommended in implementing guidelines and standards of procedure for healthcare workers to ensure successful outcomes.

Further research needs to be done on other health interventions to build knowledge on implementation fidelity.

4.6 RECCOMENDATIONS

Based on the findings of this study, the following are the recommendations

1. Directly observed treatment (short course) and frequent clinic visits are the best strategies to reduce number of TB cases, therefore health care workers should be encouraged to follow the guideline and also to encourage patients to do so.
2. To allay the attitude of fear, more on job training , education and campaigns should be done, focused on all health care workers and not only those in TB clinics. This will ensure early diagnosis and initiation of treatment.
3. The skills which the health care workers lack should also be taught in these sessions
4. On a national/County level in order to retain staff, competitive packages should be offered in order to provide a stable environment and reduce high turn over

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APPENDICES

APPENDIX A : PLAGARISM DECLARATION



PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I ___Sharon Cherono Kiptoon___ (Student number: 1698528____) am a student registered for the degree of __ MSc. EPIDEMIOLOGY (IMPLEMENTATION SCIENCE) in the academic year _2021_.
I hereby declare the following:

1. I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
2. I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
3. I have followed the required conventions in referencing the thoughts and ideas of others.
4. 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.
5. I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: SCK_____. Date: __ MARCH ,16 ,2021

APPENDIX B: APPROPRIATE MANAGEMENT OF TUBERCULOSIS IN PAEDIATRICS AS PER NATIONAL GUIDELINES.

1. Date of diagnosis should be indicated at enrolment into treatment to enable proper follow up
2. Every child must undergo HIV testing prior to initiation of treatment.
3. If positive, treatment status should be recorded and steps made to ensure initiation of treatment if not already started.

4. Method of diagnosis indicated because it is used in follow up to ascertain cure. E.g. if sputum , follow up will involve repeat sputum samples
5. Diagnosis status-pulmonary or extra pulmonary is indicated because they have different treatment regimens.
6. Category of TB status- Non severe, severe, re-treatment, multidrug resistant all have different durations of treatment so it should be indicated.
7. Weight of the child indicated at every visit. Children's doses are calculated according to weight.

Drug	**Recommendations Average dose in mg/kg**	**Range in mg/kg**	**Maximum Dose**
Isoniazid	10	10 – 15	300 mg
Rifampicin	15	10 – 20	600 mg
Pyrazinamide	35	30 – 40	1.5 g
Ethambutol	20	15 – 25	1.6 g

8. Appropriate regimen during intensive and continuation phase as dictated by diagnosis/category of TB status as from the guidelines(16).

TB disease category	**Recommended regimen**	
	Intensive phase	**Continuation phase**
All forms of TB except TB meningitis, bone and joint TB (osteoarticular TB)	2* RHZE	4 RH
TB meningitis Bone and joint TB	2 RHZE	10 RH
*****Retreatment***	3 RHZE	5 RHE
Drug resistant TB	Refer to a DRTB specialist	

*Numeral refers to number of months of the regimen e.g. 2 HRZE refers to two months of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol

H= Isoniazid
R= Rifampicin
Z= Pyrazinamide
E= Ethambutol

9. Documentation of sputum test results, x-ray findings or any investigations after intensive phase, during continuation phase and at the end of treatment.
10. Treatment under direct observation (DOTS) requires patients to come in frequently to take medication under supervision. Health workers are required to document every visit. This will be used to calculate frequency and coverage of DOTS.
11. Documentation of duration of entire treatment in months according to guidelines.

TB disease category	***Duration of treatment***
Pulmonary Tuberculosis	6 months
TB meningitis, bone and Joint TB	12 months

Re-treatment	8 months
Drug resistant	12 months

12. Documentation of treatment outcome: Cure, treatment completed, treatment failure, Died, default or transfer out.
(Adopted from the WHO Guidance for National programs on the management of Tuberculosis in children 2014 edition(13))

Outcome	**Definition**
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion
Treatment Completed	A TB patient who completed treatment without evidence of failure *but* with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable
Treatment Failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment
Died	A TB patient who dies for any reason before starting or during the course of treatment
Lost to follow up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases “transferred out” to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
Treatment success	The sum of *cured* and *treatment completed*

APPENDIX C: PATIENT TB REGISTER DATA EXTRACTION FORM

Quantitative checklist assessing adherence to TB guidelines.

Date: ……. Hospital MFL code: …….

Section 1: Hospital and Patient Demographics

Hospital Name		
Level of Health Facility		
	County Referral	☐
	Sub-County Hospital	☐
	Health centre	☐
	Dispensary	☐

Patient demographics

1.Age at diagnosis: …….

2. Gender: ……

3. Weight; ……

4. Height: ……

5. Z score: …….

6. MUAC: …….

Section 2: Content

7.Date diagnosis was made; ……

☐ Not recorded

8.. Date of treatment initiation: ……

☐Not recorded

9. HIV status: ……

☐Not recorded

10. ARV status: ……...

☐Not recorded

11. Method(s) of diagnosis (Check all that apply)

1. Clinical diagnosis

   ☐symptomatic diagnosis
   ☐Chest x-ray

1. ☐sputum smear microscopy
   Result: ……..
2. ☐Culture / Drug susceptibility testing

Result: ……

3. ☐ Biopsy for histopathology/ Fine needle aspirate
   Result: ……..
4. ☐ Gene expert
   Result: …….

5. ☐ Gastric aspirate
   Result: ……

6. ☐ Not recorded

12. Diagnosis and type of TB

1. Pulmonary ☐
2. Extra-Pulmonary ☐
   Type: ……..

3. Not Recorded ☐

13. Category of Childs TB status

1. ☐ Non Severe
2. ☐ Severe
3. ☐ Not recorded

14. Type of patient

1. ☐ New patient
2. ☐ Relapse
3. ☐ Treatment after failure
4. ☐ Return after default
5. ☐ Transfer In
6. ☐ Other
7. ☐ Drug resistant TB
8. ☐ Not recorded

15. Intensive phase treatment regimen…
(Indicate regimen) …….

(Indicate dosage) …….

1. ☐ Appropriate as per guideline
2. ☐ Not appropriate as per guideline

16. Continuation phase treatment regimen.
(Indicate regimen) …….

(Indicate dosage) …….

1. ☐ Appropriate as per guideline
2. ☐ Not appropriate as per guideline

17. If bacteriologically confirmed, Sputum collected at end of the intensive phase

1. ☐ Yes Result…….
2. ☐ No

18. If bacteriologically confirmed, Sputum collected at mid continuation phase

1. ☐ Yes Result…….
2. ☐ No

19. If bacteriologically confirmed, Sputum collected at end of treatment

1. ☐ Yes Result……...
2. ☐ No

20. If confirmed by CXR, repeat x-ray at end of treatment

1. ☐ Done
2. ☐ Not done

Result: …….

21. Treatment outcome

1. ☐ Cured
2. ☐ Treatment completed
3. ☐ Treatment Failure
4. ☐ Died
5. ☐ lost to follow up
6. ☐ Treatment completed and cured
7. ☐ Transfer out
8. ☐ Not recorded

22. Weight at end of treatment: -

23. Date of treatment completion ……

9. ☐ Not recorded

24. Cotrimoxazole prophylaxis: …….

10.
11.

DOT Coverage

Dot Refill of drugs			
Week	**Attendance**	**Week**	**Attendance**

1	☐	2	☐
3	☐	4	☐
5	☐	6	☐
7	☐	8	☐
9	☐	11	☐
13	☐	15	☐
17	☐	19	☐
21	☐	23	☐
24	☐		

Duration

Total Time in months of treatment	
Non-Severe	
Severe	
Re-Treatment	
Multidrug Resistant	

Frequency

Frequency of clinic visits		
	Intensive Phase	**Continuation Phase**
Non-Severe		
Severe		
Re-Treatment		
Multidrug Resistant		

APPENDIX D: HEALTH WORKER INTERVIEW GUIDE ON MODERATORS OF IMPLEMENTATION FIDELITY

Qualitative interview guide collecting data on moderators of Implementation fidelity.

Date…….

Name of Sub-County …….

1. Could you tell me about your background and work experience?

2. Could you tell me about your current work in TB management?
3.Are you familiar with the guidelines on management of tuberculosis in pediatric patients?
4.Are you aware of any updates in the guidelines?
Could you tell me of the differences between the previous and the new updates?

Facilitation strategies (standardized- to ensure that everyone is receiving similar training making delivery as uniform as possible)
5 . Are there opportunities for training of health workers in TB treatment sites? Tell me more about them.
6.How does the national TB involve health workers in monitoring and evaluation of treatment to ensure all health workers are on a level ground?
7.How do you feel about stock and supplies used in management of Pediatric patients? What is positive? What is negative?

Participant responsiveness
Health worker
8.What are the views of the health workers on appropriateness of these guidelines in the management of TB in children?
9.Do they feel they are useful?
Do they feel comfortable providing all aspects of the guidelines or would they like some areas delegated? How can they be improved?
Patient
10.In respect to children, what are some of the factors that improve adherence to TB treatment?
11.What are the factors that reduce adherence to treatment?
12.Do they feel that the treatment guidelines are appropriate in their context?
Intervention Complexity
13.How do the feel about the ease in following the guidelines?
14.Are there any easy areas to follow? Are there any hard areas to follow?
15. What challenges have you or other health workers encountered when adhering to them as stipulated?

Quality of delivery – delivered in a manner appropriate to what was intended
16.Apart from treatment what other essentials of care are health workers required to provide to pediatric patients?
17.In regard to the health care workers what is being done positively?
18.What is being done negatively?
19.What would you say regarding the attitude of health workers towards treatment of TB in pediatric patients? Areas of improvement?
20.Do they have adequate skills?

APPENDIX E: PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Section a): Participant Information
Dear Sir/Madam

My name is Sharon Kiptoon. I am a master's student at the University of The Witwatersrand in Johannesburg in the Department of Epidemiology and Biostatistics. As part of the requirements of the degree, I am undertaking a research project. The title of my study is Evaluation of Implementation Fidelity to National guidelines on management of Tuberculosis in pediatric patients in Homa-Bay County, Kenya.
The aim of this research is to evaluate how health workers in Homa-Bay County, adhere to National guidelines on management of Tuberculosis in children and to identify the factors that enhance or diminish their adherence. Data for this study will be conducted for a period of 2 months.
As a health worker in Homa-Bay, your information is valuable, and I am inviting you to participate as a key informant. The activity will involve an in-depth interview between myself or a trained researcher and you in a secluded area where you will be comfortable. Questions in the interview will be on factors encouraging or diminishing proper adherence to TB guidelines in children. The interview will be recorded in audio for transcription and analysis later. The interview will take about 30-60 minutes of your time.
You will not receive any direct benefits from this study and there are no consequences or disadvantages of not participating in the study. You are free to withdraw from the study at any time. You may not answer any question if you don't want to. Information provided during the interview will be completely confidential and anonymous. You are not required to indicate your name in any section of the study.
Should you have any questions about this research, feel free to contact me through the details at the end of this form. The study will be written up as a research report which will be available online through the University library website. If you wish to receive a summary of this report, I will be happy to send it to you. If you have any questions or concerns regarding ethical procedures of this study, you are welcome to contact the Wits University Human Research Ethics Committee Telephone: +27(0) 717 1408,
Email:hrec-medical.researchoffice@wits.ac.za

Yours sincerely,
Dr. Sharon Kiptoon,
Email: kiptoon88@gmail.com,

Section b): Qualitative study consent form for key informants

Title of the project: Evaluation of Implementation Fidelity to National guidelines on management of Tuberculosis in pediatric patients in Homa-Bay County, Kenya.
Name of researcher: Dr. Sharon Kiptoon

I ……. agree to participate in this research project. The research project has been explained to me and I understand what my participation will involve. Kindly indicate your response by circling your responses.

1.	I agree that my participation will remain anonymous	YES	NO
2.	I agree that the information provided here may be Used by the researcher for the study	YES	NO
1.	I agree that the information I provide may be used Anonymously by other researchers following this Study	YES	NO

…….. (Signature)
…… (Name of participant)
……. (Date)

APPENDIX F: UNIVERSITY OF WITWATERSRAND ETHICAL COMMITTEE CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Office of the Deputy Vice-Chancellor Research & Post Graduate Affairs

MEMORANDUM
(This memo is not a clearance certificate)

TO: **Dr Sharon Kiptoon**
Department of Epidemiology and Biostatistics E-mail:
kiptoon88@gmail.com

FROM: **Mr Rhulani Mkansi**
Administrative Officer: Human Research Ethics Committee (Medical)
Tel: 011 717-1234/2656/2700
E-mail: Rhulani.Mkansi@wits.ac.za or HREC-Medical.ResearchOffice@wits.ac.za

DATE: 24 February 2018

REF: ***R14/49***

PROTOCOL NO: M180146 *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

The protocol below was considered at a meeting of the Human Research Ethics Committee (Medical) **on Friday 26 January 2018.** The Committee requires the following amendments/corrections/information from you before your application can be approved.

Project Title: Evaluation of Implementation Fidelity to National Guidelines on Management of Tuberculosis in Paediatric Patients in Nandi County, Kenya

Conditions: **Provisionally approved subject to:**
(This memo is not a clearance certificate - not yet cleared)

1. *Information Sheet:* ○ The PIS for healthcare workers suggest that the study will take the form of a questionnaire, but the questions supplied suggest that it will take the form of a semi- structured interview - please clarify.

2. *Questionnaire:* ○ The questionnaire in this study has clear identifiers (centre, age, gender, job category years of experience), please remove. Please remove TB register number. Please remove gender as well.
3. *Other:*
   ○ There may be repercussions for those who do not adhere or disagree with the guidelines - how will you protect them?

NB:

1. This memo is not a clearance certificate, no research should commence prior to obtaining a clearance certificate.
2. **Please submit two hard copies of the following to the Research Office:** ○ **Covering letter:** list all the conditions above and write your response below each condition and attach relevant documentation, highlight/track any changes made.
   ○ **Signed declaration** confirming that data has not been collected for the study. ○ **Amendments** must be sent within **3 months** after receipt of the outcome of the application. ○ The default in the research office is hard copies. **Email submission will not be considered.**
3. **Delivery Address for amendments:** ○ Research Office, Faculty of Health Sciences, Phillip Tobias Building, Third Floor, Corner York Road and 29 Princess of Wales Terrace.
4. **Office hours:** 08h30-16h30.

APPENDIX G: MOI UNIVERSITY ETHICAL COMMITTEE CLEARANCE CERTIFICATE

MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2018/10
Approval Number: 0003049

5th July, 2018

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
05 JUL 2018
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dr. Sharon Cherono Kiptoon,
University of Witwatersrand,
School of Public Health,
Private Bag 3 Wits, 2050,
JOHANNESBURG.

Dear Dr. Kiptoon,

RE: FORMAL APPROVAL

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

"Evaluation of Implementation Fidelity to National Guidelines on Management of Tuberculosis in Pediatric Patients in HomaBay County".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3049*** on 5th July, 2018, 2018. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 4th July, 2019. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	- SOM
	Principal	-	CHS	Dean	-	SON	Dean	- SOD

APPENDIX H: PERMISSION TO CONDUCT RESEARCH IN HOMA BAY COUNTY

MINISTRY OF HEALTH

Telegrams: "MOH" Homa Bay
Telephone: 21039 HOMA

When replying please quote
HOMABAY.



MINISTRY OF HEALTH,
BAY COUNTY,

P.O. BOX 52,

REF: No.MOWRA/VOLl (1)

9th April 2018

To
Dr. Cherono Kiptoon

Dear Sir/Madam,

RE RESEARCH STUDY.

Following your request to conduct a research in Homa Bay County entitled "Evaluation of Implementation Fidelity to National guideline on Management of Pediatric TB in Homa Bay County, Kenya", we are hereby pleased to inform you that your request is formally accepted, and we will be interested in working with you to make this study successful. Full authorization will be communicated once you avail ethical approval from your university

You will also be required to adhere to the hospital's norms and regulations and involve both the County Health Management Team and hospital's staff during the research period. You will also be expected to communicate your findings to the hospital's management plus the Directors' office at the end of the research.

We are looking forward to work with you in this study.



Dr.Vincent Waringa
For County Director of Health
HomabayCounty