UPTAKE OF TUBERCULOSIS PREVENTIVE THERAPY AMONG ELIGIBLE CHILDREN UNDER FIVE YEARS IN MOMBASA COUNTY

BY

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DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other University.

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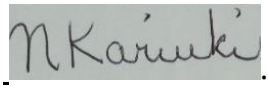
Signed:....  Date: **10th November 2021**

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DEDICATION

To God Almighty who gave me the strength and wisdom to accomplish this work.

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ABBREVIATIONS and ACRONYMS

TB	Tuberculosis
TPT	Tuberculosis Preventive Therapy
PTB	Pulmonary Tuberculosis
IPT	Isoniazid Preventive Therapy
INH	Isoniazid
ICF	Intensified Case Finding
HCW	Healthcare Worker
CHW	Community Health Worker
HIV	Human Immunodeficiency Syndrome
IGRA	Interferon Gamma Release Assay
UON	University of Nairobi
WHO	World Health Organization
NTLD	National Tuberculosis, Leprosy and Lung Disease
MTB	Mycobacterium Tuberculosis

DEFINITION OF TERMS

Tuberculosis Preventive Therapy: Treatment offered to individuals who are considered at risk of TBdisease in order to reduce that risk. Also referred to as treatment of TB infection, LTBI treatment or TBpreventive therapy.

Index case (index patient) of TB: The initially identified person of any age with new or recurrent TB in aspecific household or other comparable setting in which others may have been exposed. An index caseis the person on which a contact investigation is centred but is not necessarily the source case.

Isoniazid Preventive Therapy: refers to taking a course of isoniazid treatment in order to prevent the development of tuberculosis.

Tuberculosis:The disease state due to *M. tuberculosis*.

Active tuberculosis: refers to a disease caused by Mycobacterium*tuberculosis*in the body and is confirmed by either current clinical, radiographic or laboratory evidence.

Latent tuberculosis: A state of persistent immune response to stimulation byM. tuberculosis antigens with no evidence of clinically manifest active TB. This is also at times referred toas TB infection. There is no gold standard test for direct identification of M. tuberculosis infection in humans.Most infected people have no signs or symptoms of TB but are at risk for active TB disease. Tuberculosis exposure is usually confirmed by a positive Mantoux test and or a positive interferon gamma release assay (IGRA).

Household contact: A person who shared the same enclosed living space as the index case for oneor more nights or for frequent or extended daytime periods during the 3 months before the start ofcurrent treatment.

Infant: A child under 1 year (12 months) of age.

Child under 5: a child who has completed 59 months from birth.

Adolescent:A person aged 15–19 years.

Adult:A person over 19 years of age.

Bacteriologically confirmed pulmonary TB: TB diagnosed in a biological specimen by smear microscopy, culture or a WHO-approved molecular test such as Xpert MTB/RIF.

Xpert MTB/RIF: a molecular test that detects Mycobacterium *tuberculosis*DNA as well as mutation that confer rifampicin resistance.

Pulmonary TB: This is TB disease involving the lung parenchyma.

High TB transmission setting: A setting with a high frequency of individuals with undetected or undiagnosed active TB, or where infectious TB patients are present and there is a high risk of TB transmission. TB patients are most infectious when they are untreated or inadequately treated. Spread is increased by aerosol-generating procedures and by the presence of highly susceptible individuals.

Underweight: in adults usually refers to a body mass index < 10 years to a weightfor-age < –2 z-scores.

ABSTRACT

Background: In 2018, 10 million people were diagnosed with TB out of which 1.5 million died.Children consisted 11% of this population.Kenya is ranked in the top 30 globally for high TB endemicity.Tuberculosis preventive treatment reduces the risk of a child contracting active TB by 60%. Worldwide, only 27% of children under 5 years eligible for TB preventive treatment were started on it despite clear evidence that it reduces morbidity by 72% and mortality by 54%. In Kenya, TB preventive treatment of children below five yearswith household contact of bacterialogicallydiagnosed TB cases coverage was at 34% in 2018.This is clear evidence that uptake of TB preventive therapy by eligible children is reduced and its implementation remains difficult.Mombasa is among the top 10 counties that contributed to half of the TB cases (ranking second) and TB related deaths in Kenya.

Objectives:To determine uptake of TB preventive therapy among eligible children under five years who are household contacts of bacteriologically confirmed pulmonary TB index cases in Mombasa: Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Dispensary and Likoni Subcounty Hospital.To assess the knowledge, attitude and practice of health workers regarding TB preventive therapy in eligible children under 5 years in these hospitals and possible barriers with regard to TPT.

Study Site: The research was undertaken in Mombasa county, in the Coastal region of KenyaThe facilities in which the study was undertaken wereCoast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Dispensary and Likoni Subcounty Hospital in their respective TB clinics

Study design: Mixed methods.

Methods: This was a mixed methods research combining both qualitative and quantitative using structured questionnares with both open ended and closed ended questions. Consecutive sampling of bacteriologically confirmed TB index cases having received at least 4 weeks of treatment and living with a child under 5 years, was used to acquire the150 sample size of under five years eligible children per index case. Questionnaires were administered to recruited index

cases to evaluateuptake of TB preventive therapy in the children under 5 years and any potential barriers to TPT.The recruited index cases were then asked to bring the household contacts for evaluation. Once the children were broughtsigns and symtpoms of TB were assessed to rule out active TB. Those found to be eligible and not on TPT were referred to appropriate clinicians for initiation of TPT. Those suspected to have active TB were referred for further evaluation by clinicians. 20 in depth interviews were conducted by the reseach team to evaluate barriers of TPT uptake from a patient's perspective which were recorded, transcribed verbatim and analysed.

Among 66 HW, paper questionnaires with structured open ended and closed ended questions were also distributed by the research team to assess their knowledge, attitude and practices on TPT uptake. 20 in depth interviews were also conducted among the HWs to assess barriers of TPT uptake. 20 Key informant interviews were also conducted by the research team among regional coordinators, pharmacists'incharge, CHVs, TB clinic nurses' and TB clinics' incharge from each health facility which were recorded, later transcribed verbatim and analysed.

Data Analysis: The data was transferred directly to an electronic database and exported to R statistical software for analysis. The significance level is set at 0.05 for both children under five years and health workers.The data was summarized and presented in tables, pie charts and bar charts. Thematic coding of the qualitative data was independently carried out by the principal investigator and a qualitative consultant. A consensus on the themeswas made based on theoretical framework and summarized using representative quotes.

Results: The study enrolled 150 eligible children who were household contacts of 150 index cases aged 15 years and above. The uptake of TPT was 13.3%(20/150). The 66 health workers entailed; clinical officers, medical officers, peadetricians and nurses. The associated factors were knowledge of the health workers and index cases, attitude and practices of the health care workers. The knowledge among the health workers and index cases toward TPT was poor at 60% however, there seemed to be a good attitude and practices at 80% and 68% respectively towards TPT because it was agreed that it can prevent TB among under five children. The associated barriers to implementation of TPT included; lack of awareness on TPT, interruptedsupply of TPT drugs, resistance of caregivers/parents, cost associated with chest x ray and unavailability of Mantoux test as a screening tool.

Conclusion: The TPT uptake was poor at 13.3%. The knowledge and practice of health care workers was also poor. However, the attitude of the HWs towards TPT was found to be positive.The uptake was far much poorer majorly due to lack of awareness among the health workers and index cases/caregivers.. The barriers to TPT implementation were lack of knowledge among the HWs, cumbersome screening process, poor governance and leadership, resistance by index cases and poor socio economic status. To scale up TPT uptake there is need to create and sensitize the health workers and community at large about TPT for eligible under five household contacts.

CHAPTER 1: INTRODUCTION

1.0 Introduction

Worldwide, the most common cause of infectious related deaths is TB.The World health Organization in the year 1993 declared TB a global public health emergency(1).Tuberculosis is caused by bacilli of the genus Mycobacteriumand species Mycobacterium *tuberculosis*(2))(3)According to the figures cited in the WHO Global TB report 2019, 10 million people(range, 9.0-11.1 million) got TB, equivalent to 1132 cases (tange, 118-146) per 100 000 population. Of these, only 7 million were reported to have access to TB care. A record of 1.5 million people died from TB(1). Children at risk of being infected, are those in contact with smear positive sputum and havea 1.7 timesrisk of being infected(4). Those at high risk of getting the disease are infants and children less than five years of age(5)(6).

Worldwide, only 27% of children under 5 years, who wereeligible, were started on TB preventive treatment.Evidence shows that it reduces TB related morbidity by 72% and mortality by 52%.According to WHO, in 2018, an estimate of 150,000 people had TB with 13% being children. In TB preventive treatment of children less than five years withcontacts in the same household of bacteriologically diagnosedTB cases, coverage was at 34%(1)

In 2016,the World Health Assembly endorsed WHO's stopping TB policy.The purpose is to have a TB free worldby the year 2035.It targets to reduce 90% of patients and 95% deaths from the disease all while protecting families from catastrophic costs that push them further into poverty(7).TB preventive therapy refers to isoniazid medication to prevent progression of latent tuberculosis into active disease(8).

This research aimed at identifying the use of TB preventive therapy among eligible children under 5 years of age.The study also assessed the knowledge and practice of health workers and also explored barriers/opportunities to uptake of TB preventive therapy.

CHAPTER 2: LITERATURE REVIEW

2.0 Epidemiology of Tuberculosis

As per the National Tuberclosis, Leprosy and Lung Disease (NTLD) Program, TB cases in Kenya is estimated at 426 cases per 100,000 with 156,000 incident cases in 2018. Approximately 36% of these new cases were not diagnosed, treated or notified. Countrywide, Mombasa ranks second in the number of TB cases and is among the top 10 counties with the highest TB related deaths. The notification is also low at 25% when compared to other counties like Machakos at 136% reflecting a poor roll out of Active Case Finding in health facilities in Mombasa(9).

Brent et al., conducted a study in Coast Provincial General Hospital (CPGH) and Kilifi County Hospital (KCH) , Kenya. They study found that prospective data on childhood tuberculosis (TB) incidence and case detection rates (CDRs) are scant, and the preventable burden of childhood TB has not been measured in prospective studies. 2,042 children (<15years of age) were investigated with suspected TB by using enhanced surveillance and linked hospital, demographic, notification,and verbal autopsy data to estimate the incidence, CDR, risk factors, and preventable burden of TB among children in Kenya. Estimated TB incidence was 53 cases/100,000 children/year locally and 95 cases/100,000 children/year nationally. The estimated CDR was 0.20–0.35. Among children <5 years of age, 49% of cases were attributable to a known household contact with TB(10).

2.1 Transmission

M. tuberculosis is transmitted through airborne infectious droplet nuclei which are generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. These tiny particles (1– 5 microns in diameter) can remain suspended in the air for several hours. M. tuberculosis is transmitted through the air, not by surface contact. Transmission occurs when a person inhales droplet nuclei containing M. tuberculosis, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract and bronchi to reach the alveoli of the lungs(11) ((12))

When the patient has a positive acid-fast smear of sputum, forceful cough with copious production of thin sputum and severe upper lobe infiltrate or cavity probability of transmission is high overcrowding and poor ventilation also enhance transmission. Environmental factors such as poor ventilation and overcrowding also increase the chances of transmission. Increased frequency, duration and closeness to the contact also enhances transmission(11)(12).

Progression from latent TB to active TB disease is increased in children less than 2 years, HIV infection and immunosuppressive conditions such as malignancies and malnutrition(11)(12).

2.2 Pathogenesis of TB

The typical TB lesion is an epitheloid granuloma with central caseation necrosis. The most common site of the primary lesion is within alveolar macrophages in sub pleural regions of the lung. Bacilli proliferate locally and spread through the lymphatics to a hilar node, forming the Ghon complex. Early tubercles are spherical, 0.5- to 3-mm nodules with 3 or 4 cellular zones(11)(12)((13))

Initial lesions may heal and the infection become latent before symptomatic disease occurs. Smaller tubercles may resolve completely. Fibrosis occurs when hydrolytic enzymes dissolve tubercles and larger lesions are surrounded by a fibrous capsule. Such fibrocaseous nodules usually contain viable mycobacteria and are potential lifelong foci for reactivation or cavitation. Some nodules calcify or ossify and are seen easily on chest radiographs.If the host is unable to arrest the initial infection, the patient develops progressive, primary TB with tuberculous pneumonia in the lower and middle lobes of the lung. Purulent exudates with large numbers of acid-fast bacilli can be found in sputum and tissue. Subserosal granulomas may rupture into the pleural or pericardial spaces and create serous inflammation and effusions(11)(12)(13)

2.3 Diagnosis of TB

In children diagnosis of TB depends on taking a good thorough history and examination. The most common symptoms are cough, failure to gain weight, fever and lethargy(11). Clinical findings are commonly wheezes and crepitations over the affected lung area. With extra pulmonary TB signs and symptoms are from the affected organ.

Mantoux test, this is a tuberculosis skin test which uses purified protein derivative; it is the preferred test in children under five years. The skin test should be read 48-72 hours after injection. A positive result is an indication of exposure and other tests should be done for evaluation of TB. An induration of 5mm or more in immunosuppressed and 10mm or more in other children is considered positive. Despite having active TB, mantoux test may be negative in HIV, severe malnutrition and severe disseminated TB(11)(12)(13).

Bacteriologic examination involves detection and isolation of mycobacterium from specimens such as sputum, gastric lavage, bronchoalveolar lavage, lung tissue, lymph node tissue, bone marrow, blood, liver, CSF, urine and stool(13).

Acid fast bacilli staining can be used to confirm diagnosis initially, zielh-neelsen stain is commonly used with the use of fluorochrome stains where the bacilli stands out against a dark, non-fluorescent background.3-5mls of sputum is required for reliable results. Less than 20% of children with PTB have a positive AFB smear of sputum or gastric aspirate(11)(13).

The gold standard for detection of bacilli is culture of the mycobacterium; it identifies specific species and drug susceptibility patterns. The turnaround time is 6-8wks.The conventional media used are Lowenstein-Jensen and Middlebrook(11)(13).

Nucleic acid amplification test detects species specific genes. The turnaround time is shortened to 24-48 hours. Xpert MTB/RIF is recommended by WHO in resource limited countries(13).

Adenosine deaminase Adenosine deaminase (ADA) is a protein that is produced by cells throughout the body and is associated with the activation of lymphocytes, a type of white blood cell that plays a role in the immune response to infections. Conditions that trigger the immune system, such as an infection by *Mycobacterium tuberculosis*, the bacteria that causes tuberculosis (TB), may cause increased amounts of ADA to be produced in the areas where the bacteria are present. This test measures the amount of adenosine deaminase present in pleural fluid in order to help diagnose a tuberculosis infection of the pleurae(13).

Pulmonary chest radiographs findings in individuals with tuberculosis are not specific(11)(13).Most common findings include segmental or lobar airspace consolidation, ipsilateral hilar and mediastinal lymphadenopathy, lymphadenopathy without a parenchymal

opacity may be the only manifestation. hilar, paratracheal and subcarinal lymphadenopathy are seen in approximately 60%, 40%, 80% respectively, and/or pleural effusion. Atelectasis may occur in primary pulmonary tuberculosis, often as a consequence of tuberculous airway involvement.

Radiographic manifestation of reactivation of tuberculosis typically become apparent within 2 years of the initial infection(13).

Note that chest radiographic findings may be normal in as many as 15% of patients with primary pulmonary tuberculosis.

2.4 TB Preventive Therapy

TB preventive therapy is treatment offered to individuals who are considered at risk of TB disease in order to reduce that risk. Also referred to as treatment of TB infection, LTBI treatment or TB preventive therapy(8).

Globally, WHO 2020 TB guidelines, recommend that the treatment of LTBI regardless of HIV status is 6 or 9 months of daily isoniazid, or a 3-month regimen of weekly rifapentine plus isoniazid, or a 3 month regimen of daily isoniazid plus rifampicin. A 1-month regimen of daily rifapentine plus isoniazid or 4 months of daily rifampicin alone may also be offered as alternatives(8).

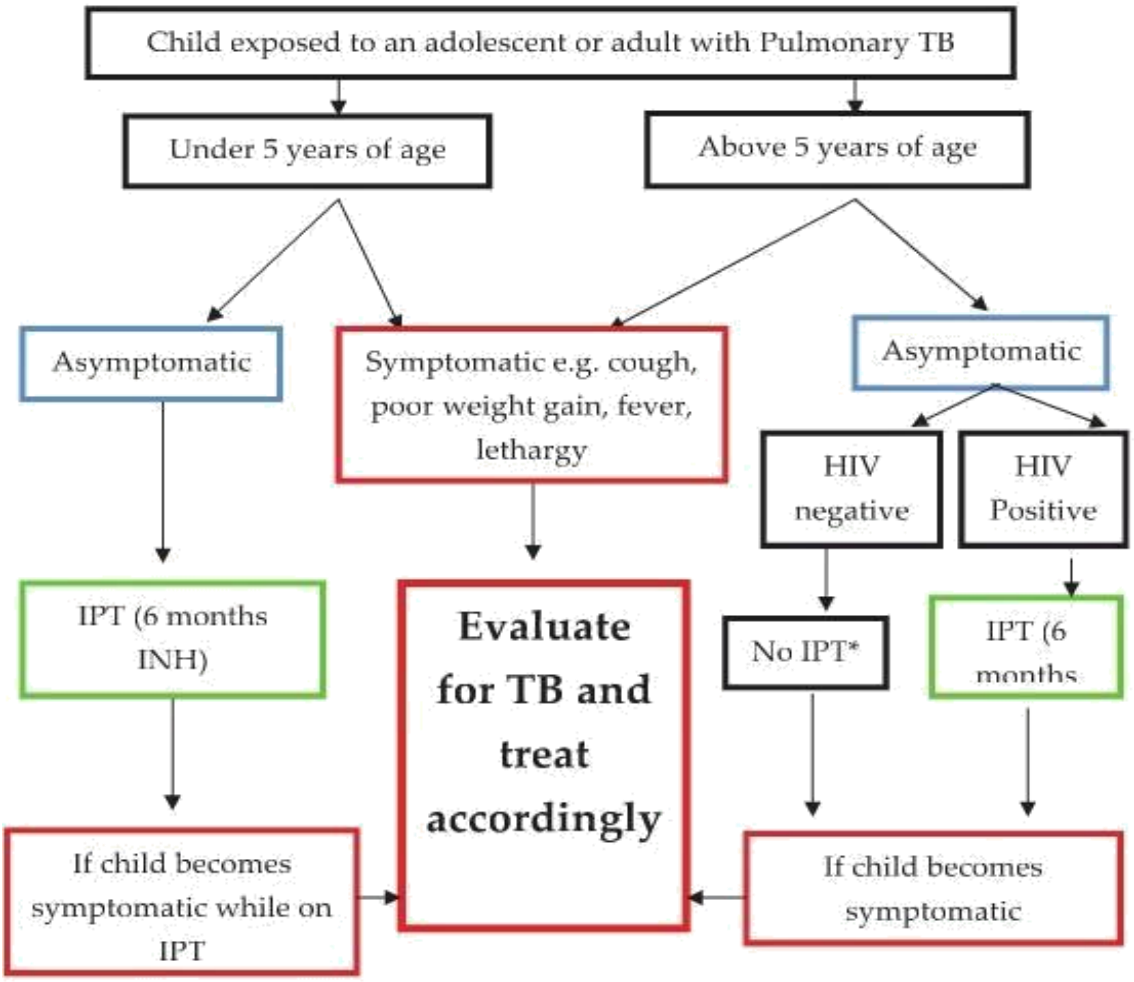
In 2020 the Ministry of Health in Kenya, revised the drugs for TB preventive therapy from a monotherapy of isioniazid of six months to include 3RH regardless of the HIV status.Table 1 belowsummarizes the drugs and the doses used in Kenya which were recently revised by the MOH.

Table1: TB preventive therapy Drugs and dosing –NTLP 2017: (14) MOH 2020 (15)

A. Daily INH for 6 months (6H)			
Weight (kg) Band	**Dose (mg)**	**Number of 100mg INH tablets**	**Number of 300mg (Adult) tablet**
<5	50	½ tablet	-
5.9 – 9.9	100	1 tablet	-

10 – 13.9	150	1 ½ tablet or	½ tablet
14 – 19.9	200	2 tablets	-
20 – 24.9	250	2 ½ tablets	-
≥25	300	3 tablets or	1 tablet
Adult	300	3 tablets or	1 tablet
Note: Syrup INH (50mg/ml) is available for younger children			
B1. Daily RH for 3 months (3RH) for children <25kgs			
Weight (kg)	**Number of tablets (RH 75/50mg)**	**How to reconstitute the medicine**	
Less than 2	One quarter	Dissolve one tablet of RH in 20 ml of safe drinking water. Once fully dissolved, give 5 ml (¼) of this solution measured with a syringe.	
2–2.9	One half	Dissolve one tablet of RH in 20 ml of safe drinking water. Once fully dissolved, give 10 ml (½) of this solution measured with a syringe.	
3-3.9	Three quarter	Dissolve one tablet of RH in 20 ml of safe drinking water. Once fully dissolved, give 15 ml (¾) of this solution measured with a syringe.	
After giving the child their dose for that day, discard the rest of the solution. Prepare a fresh solution every day.			
4–7.9	1	Dissolve one tablet of RH in 20 ml of safe drinking water. Once fully dissolved, give all this solution to the child.	
8 – 11.9	2		
12 – 15.9	3		
16 – 24.9	4		
>25	Use adult formulations		
B2. Daily RH for 3 months (3RH) for children ≥25kgs (To use Adult formulation)			
Weight (kg)	**Number of tablets (RH 150/75 mg)**		
25 – 39.9	2		
40 – 54.9	3		
55kg and above	4		

RH: Rifampicin-isoniazid fixed dose combination, INH : isoniazid



- Any child who is symptomatic should be evaluated for TB disease and treated
- *Asymptomatic HIV negative child not on IPT should be followed up every 3 months for at least 1 year
- Parent should be advised to bring the child to the hospital any time the child develops symptoms
- All child TB contacts should be offered a HIV test

Figure1; Kenya National Algorithm on Management of a Child exposed to TB (NLTP)(14)

2.4.1 Efficacy of IsoniazidPreventive Therapy

Children exposed to persons with activeTB may develop tuberculosis.With a six-month course of TB preventive therapy,the risk can be decreased by about 60 percent(16)(17).

A study done in 2014 by James Ayeko et al. where he assessed the efficacy ofisoniazid as a TB preventivemeasure in children by doing a meta-analysis of randomized controlled trials(17).Eight of these studies were put into this analysis which included10,320 participants. Combined data from these studiesindicated thatisoniazid was effective in TB prevention with a pooled RR of 0.65 (95% CI 0.47, 0.89). Only age of the participants in the sub-group analysis showed dramatic differences in the overview efficacy estimate. It indicated age could be a predictor of isoniazideffectiveness in children, there being a zero effect in children commencing isoniazid at the age younger than four months and effective in older children.Not includingthose that initiated isoniazid at four months of age or earlier showed an even stronger effect.Results on the impact of isoniazid on mortality, not including infant trials, provided an estimation of the death benefit(RR = 0.58 (95% CI 0.31, 1.09) $p = 0.092$).

The study concluded that prevention byisoniazid effectively decreaseschances of tuberculosis in children by 59 per cent.

2.4.2 Safety of IPT

Although there have been concerns about safety of IPT, there is enough proof that it is not harmful and well tolerated in children.The principalpossible side effectsarehepatotoxicity and pyridoxine deficiency which are rare(18) ((19)).However, it is mandatory to give pyridoxine together with IPT to cater for this(20).

Concerns have emerged about the risk of isoniazidresistant TB after TPT,which may hinder its implementation but a systematic review showed that it’s not statistically significant(20).

2.4.3 Determinants of Uptake of IsoniazidPreventive Therapy

In India, Singh et al, assessed uptake of isoniazid preventive therapy (IPT) among child contacts of smear-positive tuberculosis (TB) patients and its implementation challenges from healthcare providers' and parents' perspectives were using a mixed-method study design. Of 59 child contacts (<6 years) of 129 index patients, 51 were contacted. Among them, 19 of 51 (37%) were screened for TB and one had TB. Only 11 of 50 (22%) children were started and 10 of 50 (20%) completed IPT. Thematic analysis of interviews revealed lack of awareness, risk perception among parents, cumbersome screening process, isoniazid stock-outs, inadequate knowledge among healthcare providers and poor programmatic monitoring as main barriers to IPT implementation (21)

Pothukuchi et al, in 2011 estimated the number of household contacts aged <6 years, of sputum smear positive PTB patients registered for treatment under RNTCP from April to June'2008 in Krishna District, to assess the extent to which they are screened for TB disease and in its absence initiated on IPT. A cross sectional study was conducted. Households of all smear positive PTB cases (n=848) registered for treatment from April to June'2008 were included. Data on the number of household contacts aged <6 years, the extent to which they were screened for TB disease, and the status of initiation of IPT, was collected. Households of 825 (97%) patients were visited, and 172 household contacts aged <6 years were identified. Of them, 116 (67%) were evaluated for TB disease; none were found to be TB diseased and 97 (84%) contacts were initiated on IPT and 19 (16%) contacts were not initiated on IPT due to shortage of INH tablets in peripheral health centers. The reasons for non-evaluation of the remaining eligible children (n=56, 33%) include no home visit by the health staff in 25 contacts, home visit done but not evaluated in 31 contacts. House-hold contacts in rural areas were less likely to be evaluated and initiated on IPT [risk ratio 6.65 (95% CI; 3.06–14.42)(22).

Salazar- Austin et al, in 2020 conducted a pragmatic, cluster-randomized trial to determine whether contact evaluation using symptom screening improved the proportion of identified child contacts who initiated TPT, compared to TST-based screening, in Matlosana, South Africa. They randomized 16 clinics to either symptom-based or TST-based contact evaluations. Outcome data were abstracted from customized child contact management files. Contact tracing identified 550 and 467 child contacts in the symptom and TST arms, respectively (0.39 vs 0.32 per case, respectively; P = .27). There was no significant difference by arm in the adjusted proportion of

identified child contacts who were screened (52% in symptom arm vs 60% in TST arm; P = .39). The adjusted proportion of identified child contacts who initiated TPT or tuberculosis treatment was 51.5% in the symptom clinics and 57.1% in the TST clinics (difference −5.6%, 95% confidence interval −23.7 to 12.6; P = .52). Based on the district's historic average of 0.7 child contacts per index case, 14% and 15% of child contacts completed 6 months of TPT in the symptom and TST arms, respectively (P = .89). The study concluded that symptom-based screening did not improve the proportion of identified child contacts evaluated or initiated on TPT, compared to TST-based screening(23)

Chia in 2019, used a mixed-method study involving quantitative and qualitative components to assess isoniazide Preventive therapy uptake amongst child contacts of adults diagnosed with smear positive pulmonary tuberculosis in selected health facilities in Douala, cameroon. Background, clinical, health facility, community and IPT related data were collected from 9 selected health facilities using interviewer administered questionnaires. A total of 513 child contacts were included amongst which 118 (23.0%; 95% CI: 19.6- 26.9) had received IPT. This study showed that the implementation of IPT was 23%. And that few child contacts of index cases are screened for active TB and even fewer are offered IPT. The level of knowledge on the benefits of IPT, continuous emphasis, education and sensitization on the need for IPT, good index case/health worker relationship, contact tracing and reduced cost of screening were seen to facilitate the uptake of IPT(24)

In 2018, a cross-sectional study was done in Kigali, Rwanda assessing the uptake of isoniazid preventive therapy (IPT) in children with contacts of index cases with TB(25). Francine Mwayuma Birungi et al. collected data from 13 primary health centres. Approximately 136 PTB index cases had household contact with 270 children under 15years. 94 (35 %) of them were less than years old and eligible for IPT. 84 (89%, 95% CI 81-94) were started on IPT. Ten children who were eligible were not initiated on IPT because the parents/caregivers had no information on the need for IPT and those with the information declined to give their kids IPT.Poor quality services provided by both the healthcentres and unfriendly healthcare providers have also been reported as reasons not to initiate IPT.

A study on isoniazid as a preventive therapy in children less than five yearsin Ethiopia confirmed screening contacts as an entry point for IPT delivery(26).Five hundred and four index smear-positive cases of pulmonary TBwere recordedin the 28 health facilities,282 children under-five who were registered as having household contacts represented 17.9%of all household contacts.Out of these, 237 (84%) children were tested for signs of PTB,16 (6.8%) children were presumed to have TB. Of the two hundred and twenty one(221) children qualifying for IPT,142(64.3%) received itand114 (80.3%) successfully completed six months of treatment.

Of those started on IPT, completion was at a reasonable range. Issues surrounding non-completion were inadequate leadership of national intervention of TB control programs, lack of good knowledge and awareness of health workers on IPT,health workers having fear of INH toxicity, development of drug resistance and little knowledge of parents/caretakers on IPT.

Another study in was conducted in Malawi on passive versus active tuberculosis case finding and isoniazidpreventive therapy among household contacts(27).There were 985 household contacts from 189 index TB cases. The Prevalence of TB by passive case finding was 0.19% (191/100,000) among 524 household contacts, which was significantly lower than 461 actively found contacts (1.74%, 1735/100,000, $P = 0.01$). Of 126 children in the passive cohort, 22 (17%) received INH, while 25 (22%) of 113 children in the active cohort received the medication. The main reason for low intake was the cost of transport associated with chest x-ray screening.

Although the scenariofor implementation of IPT in children with HIV population is different from childhood IPT,it is important to mention a study done in Nairobi,Kenya by Peninah Mwangi in 2016 on implementation of isoniazid preventive treatment among children infected with HIV in three health facilities in Nairobi county(28).IPT uptake was found to be 53.2% which was low despite the Kenyan national guidelines since 2013 and subsequently rolled out in 2015.Those whose caregivers had pursued secondary school education were less likely to have gotten IPTrelative to those with no or lower education levels. A half of the health workers at the time of this study had not prescribed INH within the previous year. Relatively few health workers expressed concern that isoniazid was not effective enough (2%) or that the side effects were too dangerous (28.8%). Majority of the respondents (80.3%) didn't think it was better to wait until a patient gets TB and then prescribingprophylaxis. Attitude of the healthcare workers

was assessed and 81.8% of theinterviewed workers had favorable attitude towards IPT. A summary of these studies is shown in table 2 below.

Table 2: Summary of Studies on Uptake of TB Preventive Therapy

Country, Author, Year	Study Title	Study Population	Results
Bhopal, India Akash Singh et al, 2017(21)	Isoniazid Preventive Therapy among Children Living with Tuberculosis Patients: Is It Working? A Mixed-Method Study from Bhopal, India	Child contacts (<6 years) of smear-positive tuberculosis (TB) patients	IPT Uptake- 22%
Krishna, India Madhavi Pothukuchi et al 2011(22)	Tuberculosis Contact Screening and Isoniazid Preventive Therapy in a South Indian District: Operational Issues for Programmatic Consideration	Household contacts aged <6 years, of sputum smear positive PTB patients registered for treatment under RNTCP	IPT Uptake- 84%
Matlosana, South Africa, Salazar- Austin et al 2020(23)	Improving tuberculosis preventive therapy uptake.	Contact tracing identified 550 and 467 child contacts in the symptom and TST arms, respectively	IPT Uptake in symptom clinic-51.5% IPT Uptake in TST clinic- 57.1%
Douala, Cameroon Chia, A.M 2019(24)	Isoniazide Preventive Therapy Uptake amongst Child Contacts of Adults Diagnosed with Smear Positive Pulmonary Tuberculosis in Selected Health Facilities in Douala, Cameroon	513 child contacts were	IPT uptake - 23%.
Kigali, Rwanda Francine Mwanyuma Birungi et al 2018(25)	Assessment of the isoniazid preventive uptake and associated characteristics	Child <5 yrs household contacts of index cases having sputum smear positive pulmonary tuberculosis	IPT uptake -89%
Ethiopia Yared Tadesse et al 2016(26)	Uptake of isoniazid preventive therapy among under five children: TB contact investigation as an	Children under five years household contact of index cases of TB	IPT uptake-64.3%

	entry point		
Malawai Zachariah et al 2003(27)	Pasisve versus active tuberculosis case finding and isoniazid preventive therapy among household contacts in rural district of Malawi	Children under 6 years of household contacts of index cases of TB	IPT uptake in passive cohort-17% IPT uptake in active cohort- 22%
Nairobi, Kenya Peninah Muthoni Mwangi 2016(28)	Implementation of isoniazid preventive therapy among HIV infected children in three facilities in Nairobi	HIV infected children aged 1-15 yrs.	IPT uptake-53.2%

There are also studies indicating health care workers knowledge, attitude and practice on TPT. For instance, in Thailand, Hiransuthikul et al, in 2005, assessed the extent to which physicians in Thailand adhere to the Isoniazid preventive therapy guideline to optimize the implementation of national IPT program. Three hundred physicians who provided medical care for HIV-infected patients were sampled by multistage cluster sampling of public hospitals according to the region and the level of health care service. Fifty-eight (19.3%) of the surveyed physicians provided IPT; 86.2% and 34.5% of physicians who provided IPT did not do the TST or screening chest radiography for active TB, respectively. Experience with HIV patient care was significantly associated with providing IPT (29)

Rebecca et al in 2010, did a qualitative study using in-depth interviews and a focus group discussion Guateng province, South Africa in 22 clinic staff and 20 patients from 10 purposively selected HIV clinics, and a staff focus group discussion. Healthcare workers reported the primary barrier to IPT use was lack of knowledge and experience. Prescribers were unaware of the benefits of IPT and unclear about guidelines. The belief that existing screening tools are inaccurate in HIV-infected individuals and the need to refer patients to separate clinics for tuberculosis screening also emerged as barriers. No patients had heard of IPT(30).

Across-sectional descriptive study was undertaken by Abdulrazaak et al, using a standardised questionnaire administered to 51 doctors working at OdiHospital. The results showed that doctors at Odi District Hospital generally had excellent knowledge of IPT, but this was not reflected in their practice, as their mean practice score was just above an average of 50%.

Although most doctors were not trained on IPT, their attitude scores were high; only 23.5% of the doctors were trained on the IPT programme and implementation. The finding also indicated that 35% of the healthcare providers' lack of information did not comply with the national and international IPT recommendations. These could have been the reasons for the low level of IPT provision at Odi District Hospital.

Doctors at Odi District Hospital generally had excellent knowledge of IPT, but this was not reflected in their practice, as their mean practice score was just above an average of 50%. Although most doctors were not trained on IPT, their attitude scores were high; only 12 (23.5%) of the doctors were trained on the IPT programme and implementation. The finding that healthcare providers' lack of information (35%) did not comply with the national and international IPT recommendations was evident in other studies.31 These could be the reasons for the low level of IPT provision at Odi District Hospital.(31)

Teklay et al, used a mixed method approach to investoigate the barriers associated with implementation of isoniazid preventive therapy in Tigray region of Ethiopia which had low coverage(32). The main reasons for the low uptake was due to frequent interruption of isoniazid supplies raises which interrupted therapy resulting in creation of isoniazid resistance. Health managers, drug suppliers and partners working in HIV and tuberculosis programs should be committed to ensure an uninterrupted supply of isoniazid and full scale implementation of isoniazid preventive therapy to eligible people living with HIV.

Okwara et al, conducted a prospective longitudinal cohort study in informal settlings in Nairobi, where children under 5 years in household contacts with recently diagnosed smear positive TB adultsand concluded that there is high burden of TB infection and disease among under five household contacts with infectious TB cases in high burden settings and also contacts' screening and IPT strategy reduces incidence of new active TB disease in exposed contacts. Malnutrition of contacts was also associated with IPT failure(33).

Oliwa et al, carried out an observational study of 42,107 children admitted to 13 county hospitals in Kenya from 01Nov 15-31Oct 16, and 01Nov 17-31Oct 18. The findings indicated that more than half of all paediatric admissions had symptoms associated with TB and nearly two-thirds had more specific history documented. Only a few amongst them got TB tests requested. TB was

diagnosed in 2.9% of all admissions but most were inadequately investigated. This study revealed that major challenges remain in identifying and investigating TB in children in hospitals with access to Xpert MTB/RIF and a review is needed of existing guidelines(34). Table 3 below summarizes these studies.

Table 3: Literature review on healthcare worker knowledge, attitude and practice

Country, Author, Year	Study Title	Study Population	Results
Thailand Narin Hiransuthiku 2005(29)	Physician adherence to isoniazid preventive therapy guidelines for HIV-infected patients IN Thailand	Three hundred physicians who provided medical care for HIV-infected patients were sampled by multistage cluster sampling	Fifty-eight (19.3%) of the surveyed physicians provided IPT; 86.2% and 34.5% of physicians who provided IPT did not do the TST or screening chest radiography for active TB, respectively. Experience with HIV patient care was significantly associated with providing IPT.
Gauteng province, South Africa Lester, Rebecca 2010(30)	Barriers to implementation of isoniazid preventive therapy in HIV clinics: a qualitative study	22 clinic staff and 20 patients from 10 purposively selected HIV clinics.	Primary barrier to IPT use was lack of knowledge and experience. Prescribers were unaware of the benefits of IPT and unclear about guidelines. The belief that existing screening tools are inaccurate in HIV-infected individuals and the need to refer patients to separate clinics for tuberculosis screening also emerged as barriers. No patients had heard of IPT.
South Africa Ali Abdulrazaak et al 2017(31)	Knowledge, attitude and practices of doctors regarding isoniazid preventive therapy in HIV/AIDs patients at Odi District Hospital Guateng Province, South Africa	51 Doctors	43.1% excellent knowledge, 54.9% positive attitude towards IPT and 35.3% practice
Ethiopia, Gebrehiwot Teklay et al 2016(32)	Barriers in the implementation of isoniazid preventive therapy for people living with HIv in Northern Ethiopia: a mixed quantitative and qualitative study	Cross sectional study 16443 PLHIV 50 Health workers	Uptake 19.3% Contributors: irregular supply of isoniazid, fear of development or resistance, drug side effects, lack of training and guidelines reluctance to offer IPT, pill burden, lack of commitment in implementation

Kenya Jacquie N et al 2019(34)	Diagnostic practices and estimated burden of tuberculosis among children admitted to 13 government hospitals in Kenya; An analysis of two years' routine clinical data	HIV infected children aged 1-15 yrs.	Major challenges in identifying and investigating TB in children in hospitals with access to Xpert MTB/RIF
Nairobi, Kenya Okwara Florence et al, 2017(33)	Correlates of isoniazid preventive therapy failure in child household contacts with infectious tuberculosis in high burden settings in Nairobi, Kenya – a cohort study	Children under 5 years in household contact	Contacts' screening and IPT strategy reduces incidence of new active TB disease in exposed contacts. Malnutrition of contacts was also associated with IPT failure.

Framework

Based on the TPT guidelines and literatures reviewed, the researcher developed a conceptual framework for this study as shown in figure 5 below. The structure depicts barriers to uptake of TPT.

Conceptual Framework

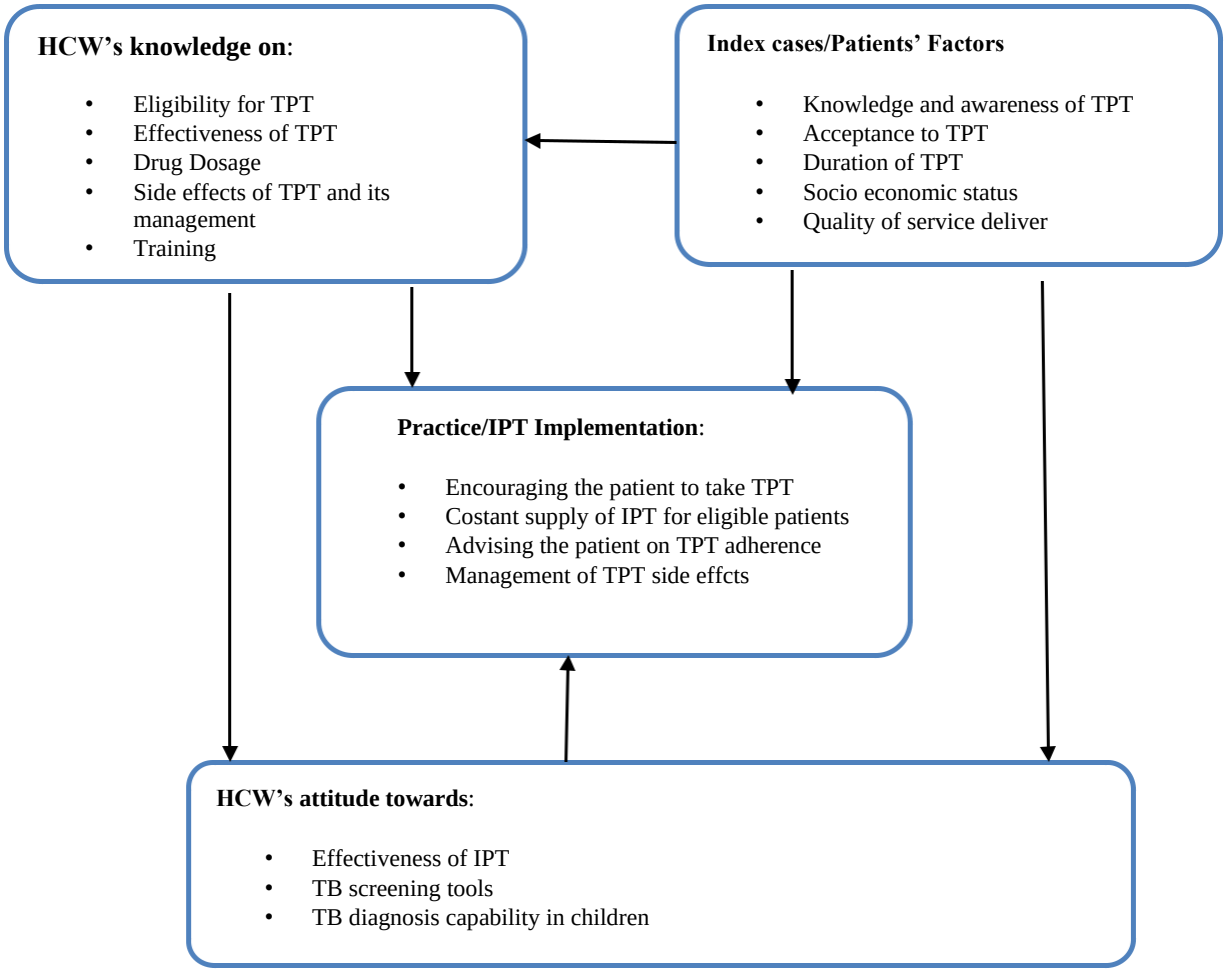


Figure 2: Conceptual framework of factors influencing TB preventive therapy implementation

2.4.4 Categories of Children who Qualify for TB Preventive Therapy according to the National Guidelines on the Management of TB in Children (NTLP) 2017

Any child who lives close to an index case of sputum smear positive pulmonary TB is at high risk of TB infection.

1. Children with HIV who are >1 year and are unlikely to have active TB on symptom based screening without having interacted with a TB case will receive IPT at 10mg/kg/day for six months (maximum 300 mg/day)
2. If the evaluation indicates no TB disease in children with HIV who are less than one year of age, only those who have had contact with a TB case, should receive six months of IPT
3. Children under the ageof 5 and exposed to infectious TB irrespective of their HIV status should be initiated on IPT after ruling out TB

NB: All children on IPT should receive pyridoxine.

However, in 2020 WHO expanded TB preventive therapy eligibility to include all children who are exposed to pulmonary TB which has recently been adopted in Kenya.

Contraindications ofIsoniazid

1. Active TB case as it would lead to drug resistance
2. Pre-existing active hepatitis(INH major toxic adverse effect is hepatitis thus it would worsen the condition)
3. Pre-existing signs and symptoms of peripheral neuropathy(INH causes peripheral neuropathy as a side effect)

2.4.5 PaediatricIntensified TB Case Finding

In 2013, Ministry of Medical Services and Public Health in Kenya introduced a paediatric intensified case finding/isoniazid preventive therapy (ICF/IPT) card which is used for children under 15 years.

2.5 Study Justification and Utility

Kenya has been ranked top30 high TB burden countries(1), thus there is need to evaluate the strategies put in place to curb the rate of infection.This is in endeavor to identify loopholes,pitfalls,strengths and weaknesses with regard to the strategies put in place.TPT is one of the major interventions which has been recommended by WHO and NTLD to minimise TB burden in children under five.Despite evidence that TB preventive therapy can reduce the risk of developing tuberculosis by 59% among children uptake is still low at 34% in Kenya (17)(1). Mombasa county is a high TB burden county, with possibly different uptake, drivers and barriers.

This study assessedthe gaps, barriers at different level of health care system and also patient derived barriers with regard to implementation of TPT uptake. This information can probbaly be used to sensitize and help create awareness among health workers on importance of TPT and provide evidence for policy makers that shall enable them to advocate for, prioritize and allocate resources towards TPT implementation programmes.

CHAPTER 3: RESEARCH QUESTIONAND STUDY OBJECTIVES

3.0 Research Question

What was the level of uptake of TB preventive therapy among eligible children under five years in Mombasa County?

3.1 Objectives of the Study

Primary Objective

1. To determine uptake of TB preventive therapy amongeligible children under five years who were household contacts of bacteriologically confirmed pulmonary TB index cases in Mombasa: Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Likoni Subcounty Hospital and Ganjoni Dispensary.

Secondary objectives

2. To assess the knowledge, attitude and practice of health workers at Coast Provincial General Hospital,Port Reitz Sub-County Hospital, Likoni Sub-County Hospital and Ganjoni Dispensary.
3. To explore barriers of uptake to TB preventive therapy.

CHAPTER 4: METHODS

4.0 Methodology

Mixed Methods.

4.1 Study Setting

The research was undertaken in Mombasa county, the second largest city in Kenya and is located in the Coastal area. According to the 2019 Kenya National Population and Housing Census, the county has a population estimate of about 1,208, 333 people. The county is considered urban even though there are few informal settlements. The county is mostly populated with middle and low income earners. The county ranks second in all TB cases in the country with pediatric TB case finding in the fourth position amongst all the forty seven counties. All the four health facilities of study are within Mombasa county. The study sites will include: Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Likoni Sub-County Hospital andGanjoni Dispensary. These four health facilities were chosen because they are situated in a high TB burden area and geographically placed in terms of population distribution in Mombasa County.

Coast Provincial General Hospital(CPGH) is a Level V referral hospital situated in the northern parts of the island of Mombasa. It also serves as a teaching hospital for Mombasa and Port Reitz medical training colleges. It caters for patients living in Mombasa and its environs including the former seven districts of Coast Province. It has a catchment area of 2.7 million patients, including other counties in the former Coast Province. The hospital has three inpatient pediatric wards with one outpatient pediatric department. There is one TB clinic which serves both adult and children and runs from Monday to Friday with a turnover of approximately one hundred patients in a month.This facility has peadiatric consultants, medical officers, interns, registred clinical officers, clinical officers interns and nurses.

Port Reitz Sub-County Hospital is a Level IV facility located in Changamwe, Mombasa County. It is the second largest government hospital in Mombasa County. It has a bed capacity of 127 and

serves a catchment population of 100,000. Initially, it was an army barracks which was later converted to a Tuberculosis hospital and subsequently into a chest hospital before finally being upgraded to a subcounty hospital at the advent on devolution in 2013. This facility also serves as a clinical officer and medical officer internship center. It is composed of: general inpatient and outpatientunits; psychiatry unit; Comprehensive Care Center; Tuberculosis clinic; laboratory; radiography unit; and an orthopaedic surgery unit. It has a TB clinic wheicer serves both adult and children. This facility has peadiatric consultants, medical officers, interns, registred clinical officers, clinical officers interns and nurses.

Likoni Sub- County Hospital is a Level IV facility located in Likoni location, about 2km from the ferry crossing on the mainland side of Mombasa county. This facility serves a catchment population of 100,000. It is composed of a laborabory, outpatient department, maternal and child health/family planning department, pharmacy, comprehensive care center, maternity and general surgical unit. On average, 140 – 150 patients are seen at this facility each week.It has a TB clinic wheicer serves both adult and children.The health workers in this facilities are registered clinical officers and nurses.

GanjoniDispensary is a Level III facility situated in Ganjoni sublocation, Island division, Mvita constituency in Mombasa County. This facility serves a catchment population on 10,000, mainly drawn from Ganjoni location and her immediate neighbours. This facility is equipped with a general outpatient department, a laboratory, a tuberculosis, and antenatal/postnatal care clinic, a family planning clinic, a nutrition clinic and a community health clinic. However, it lacks a paediatric unit. The tuberculosis clinic serves approximately 125 patients every month.It has a TB clinic wheicer serves both adult and children. This facility has registred clinical officers and nurses.

3.2 Study Population

Patient and Child sub-study

***Study population*:**

Quantitative

1. **Patient and child sub-study**

Adolescent(15yrs to <18yrs)or/and adult with TB receiving care at TB-clinic of study facility living in the same household with at least one child under five years of age.

Inclusion criteria

- Documented pulmonary TB infection of adolescent(15yrs to <18yrs) and/or adult living in the same household with at least one child under five years of age.
- On TB treatment for at least one month in the TB clinic of study facility.
- Consent for >18yrs
- Assent for 15yrs to <18yrs and consent from guardians.

***Exclusion criteri*a**

- Those unable to bring child to the clinic after recruitment
- Exposed child with active TB
- Exposed child with positive signs and symptoms
- Exposed child on treatment for active TB,
- Exposed child with contraindication to TPT.
- Adolescent(15yrs to <18yrs) without guardians.

2. Health Workerssub-study

Inclusion criteria

- Doctors and clinical officers dealing with children under five years
- Nurses in TB clinics

Exclusion criteria

- Health workers not dealing with children under five years

Qualitative

Inclusion criteria

- Key informants – regional TB coordinators, TB clinic in charge, pharmacists in charge, TB clinic nurse, CHV
- Doctors and clinical officers dealing with children under five years
- TB index cases on TB treatement for less than one month

Exclusion criteria

- Health workers not dealing with children under five years
- TB index cases on TB treatment for more than one month

4.3 Case Definition

Index case (index patient): This refers to the first new or recurring case detected with bacteriologically confirmed TB, in a person fifteen years of age and above, living in a particular household or other similar setting where a child under 5 years of age might have been exposed. An index case is the case which a contact investigation is based and not usually the source case.

Household contact: This is a child under 5 years of age who has shared the same enclosed living space for a period of 1 or more nights or has frequented the living space for extended periods of time in the presence of the index case during a period of 3 months before the commencement of treatment.

Pulmonary TB: bacteriologicallyconfirmed TB disease involving the lung parenchyma.

TPT eligibility: Any child <5yrs,asymptomatic who has been exposed to an adolescent/adult with bacteriologically confirmed pulmonary TB within the same household and receiving care in the facility of study**.**This child should have been fully physically screened and examined using the WHO algorithm for systematic screening for active TB and active TB has been excluded in the child.

TB symptom screen: children under five years with cough, fever, weight loss or fatigue of any duration or contact history with a person with activeTB, may probably have TB and evaluation for TB should be done.

Poor weight gain is defined as:reported weight loss, flattening of growth curve, confirmed weight loss of >5% from the previous visit, weight for height <-2 z-score.

4.4 Outcome Measures

- Receipt of TPT or any other TB preventive therapy confirmed from the IPT/TB preventive therapy register/card or any other physical evidence of receipt of TPT for household contacts under 5 years of age. Adolescent/adult index case knowledge, attitude and practice as well as barriers (patient-derived, health worker-facilitated and health system-facilitated) for TPT in household contacts under 5 years.
- Health worker knowledge, attitude and practices.
    i. Correct knowledge: Eligibility for TPT for household contacts under 5 years, screening for active TB,and how to rule out active TB. Drugs for TPT according to Kenyan guidelines for household contacts under 5 years include Isoniazid (INH) monotherapy for 6 months and Isoniazid Rifampicin (RH) for 3 months and knowledge on this will be assessed as follows:how to calculate dosage for a given weight (5kg) from dosage charts, formulations available (whether syrup or tablets, if can be dissolved in mouth or fluids and which fluids are acceptable), correct frequency, correct duration, correct route of administration, possible side effects and which adverse effects to counsel the parent on when giving the drug, whether the drugs should be given with or without food,correct knowledge of pyridoxine and who should receive it, correct dosage of pyridoxine; timing of follow up after initiation of TPT and what to assess and look out for during follow up.

Correct Knowledge on:
Provision of TPT

Eligibility for TPT for household contacts under five years
Drug related Number of drugs used for TPT Formulations for TPT drugs Fluids acceptable for dispersible drugs TPT drug dosages, frequency and duration TPT drug administration TPT side effects Whether given with or without food Use of pyridoxine
Guidelines and Tools for TPT TPT drug dose charts by weight band Awareness of guidelines for TPT
Child contact clinical evaluation Screening and assessing children under five for eligibility Child follow up

ii. Attitude: how much the healthcare worker agrees or disagrees with the following statements with regards to child household contacts under 5 years exposed to adolescent/adult bacteriologically confirmed pulmonary TB: all eligible children should receive TPT, TPT is effective, TPT is safe, drug resistance is a major concern when prescribing TPT, the risks of giving TPT outweigh the benefits, you comply with the Kenyan guidelines on TPT in children under 5 years, TPT reduces TB incidence and mortality, it is preferable to wait until a child under 5 years contracts TB and then treat them rather than administer prophylaxis and you are comfortable prescribing TPT.

Correct attitude on:
Benefits and effectiveness of TPT Effectiveness of TPT

Reduction of incidence and mortality by TPT
Risks and fears Safety of TPT drugs Resistance of TPT drugs
Provision of TPT All eligible children receiving TPT Compliance with guidelines Prescription of TPT

iii. Practice: With regards to bacteriologically confirmed adolescent/adult index cases, whether or not the healthcare workers do the following: inquire if index cases have child household contacts under 5 years, ask if their child household contacts under 5 years have symptoms suggestive of active TB, educate them about TPT, advise them to bring their child household contacts under 5 years for assessment and evaluation, use the TB symptom screening according to WHO to assess them for active TB, counsel the parents/caregivers on potential side effects to look out for when prescribing TB preventive drugs to child household contacts under 5 years and counsel the parents/caregivers on adherence, monitor those children under 5 years on TPT for side effects during follow up clinics and engage community health workers in case a child under 5 years on TPT cannot come for the follow up clinics.

Correct practice on:
Enquiry of household contacts under five years
Enquiry of household contacts under five years symptoms suggestive of active TB
Educating index cases on TPT
Advising index cases to bring household contacts for assessment and evaluation
Use of TB symptoms screening according to WHO to assess for active TB
Counselling parents/caregivers on potential side effects of TPT
Counselling parents/caregivers on adherence on TPT

Monitoring of household contacts on TPT
Engagement of CHVs for follow up

iv. Barriers: Healthcare worker related barriers to uptake of TB as well health system operational challenges will be captured based on yes/no responses to the following: whether it difficult to rule out active TB to decide to start TB preventive therapy drugs, whether they have TB diagnosis tools at their disposal, whether there has been any stock-out of TB preventive therapy drugs in their health facilities in the preceeding 3 months, whether improving TPT uptake rates at their facility is discussed by the supervisor, if they feel that adherence to TB preventive therapy drugs is poor among children under 5 years and TPT failure is high among the child household contacts under 5 years in their care.

Barriers
Evaluation of household contacts for TPT
Availaibility of TB diagnosis tools
Availability of TPT drugs
Discussions with supervisor on improvement of TPT uptake rates
Adherence of TPT among household contacts
TPT failure among household contacts

- Adolescent/Adult index case opinionsregarding barriers/opportunities [patient, health worker and health system] for TPT in children under 5 years (Appendix I Section 1).

4.5 Sample Sizesand Sampling Methods

4.5.1 Sample size for Index TB case- child contact pairs

The sample size will be estimated at 95% confidence level and error margin of 5%. The expected prevalence of IPT uptake for children under 5 years according to a similar study is 89% (Birungi et al, 2018). Thus the minimum number of children under five years needed for the study is given by:

$$n = Z_{\alpha/2}^2 * p*(1-p) / E^2,$$

where

n = minimum sample

p = IPT uptake (89%)

E^2 = margin of error (5%)

$Z_{\alpha/2}$= Critical value for the distribution

$$n = \frac{1.96^2*0.89*0.11}{0.05^2}$$

n=150 TB case/child contact pairs needed

A sample-size calculation based on Fisher et al., (1998) formula, requires a minimum of 150 contacts, but an additional 15 (10%) will be enrolled to cover attrition to give a total sample size of 165.

4.5.2 Sampling Method for TB Index Cases/child contact pairs

Consecutive sampling of bacteriologically confirmed TB index cases having received at least 4 weeks of treatment and living with a child under 5 years, seen at the TB clinics during hours of operation were used to acquire the sample size for children under five years. The number of TB patients selected from each of the four health facilities was proportionate to the number of TB patients for at least the previous 4 months from the day of enrolment into the study.If the adolescent/adult index cases are the parents/primary caregivers of the child household contacts under 5 years within their household, they were requested to bring them to the clinic for assessment and evaluation, regardless of whether or not the child/children are on TPT. They

were also told to carry their TPT cards or any other physical evidence showing that the child/children had been receiving TPT. Those with more than one household contact under 5 years were asked to bring all of them. If they were not the parents/primary caregivers of the household contacts under 5 years, arrangements were made with the parent/primary caregiver of the child to bring the child to the clinic for assessment and evaluation since the parents/primary caregivers were the ones best placed to give symptom screening information.

4.5.3 Sample Size for Healthcare Workers

Recruitment of Health Care Workers in the facilities of study included doctors, nurses and clinical officers in paediatric inpatient and outpatient departments (general outpatient and inpatient departments where a dedicated paediatric unit is not present), and TB. The sample size was estimated at 95% confidence level and error margin of 5%. The expected knowledge and prescription of IPT by health care workers in a similar study carried out in 3 health facilities (Peninah, 2016) is 50%; thus the minimum number of healthcare workers needed for the study was given by:

$$n = Z_{\alpha/2}^2 * p*(1-p) / E^2,$$

n = minimum sample

p = prevalence of IPT prescription

(50%) E^2 = margin of error (5%)

$Z_{\alpha/2}^2$ = critical value for the distribution

$$n = \frac{1.96^2*0.5*0.5}{0.05^2}$$

$$n = 384$$

There are 80 health care workers in the 3 health facilities. The sample size for health care workers wastherefore be adjusted for finite population using **equation (i)**

n= SS/ [1 + {(SS − 1)/Pop}]….. (**equationi)**

Thus n= 384/ [1 + {(384− 1)/80}]

n=66

The minimum number of health care workers required for the study was66.

4.5.4 Sampling Method for Healthcare Workers

Stratified simple random sampling of healthcare workers at the four health facilities of study was used to acquire sample size required. The total sample size was divided proportionately among the health facilities in relation to their staff size. For each health facility, doctors, nurses and clinical officerswereselected using consecutive convenience sampling, proportionate to the number of workers in the cadre.

4.6 Study Tools

1. Quantitative tool for index cases

Structured paper questionnaireswith both open-ended and closed-ended questions were administered by the research team to adolescents/adults with bacteriologically confirmed PTB who had received at least 4 weeks of treatment and lived with at least one child under 5 years (Appendix I) capturing the following: age, sex, number of weeks on TB treatment, whether or not they had child household contacts under 5 and how many they were,their relationship to the child, whether or not they were the parents/primary caregivers, marital status, level of education, employment status, whether or not they knew about TPT, what they knew about TPT, their source of information about this, whether or not their child household contacts had ever received TPT and reason why if they hadn't, difficulties they had faced at the facility, any other TB preventive methods they knew apart from TPT, challenges they faced coming to the facility, number of rooms in their house and how many people slept in them,whether or not they shared a bedroom with their child household contacts, whether or not they thought the government through the Ministry of Health had succeeded in creating awareness for TPT in children under 5

years and which means they thought the government could employ to improve awareness on TPT for chidren under 5 years.

The questionnaire also had a section targeting only the parents/primary caregivers of the child household contacts capturing the following: TB symptom screening questions according to the WHO algorithm, whether or not the child was on TPT (if they were on TPT, the TPT card or any other physical evidence of receipt of TPT was produced), dosage of TPT, frequency of TPT, whether or not the parent received any instructions on how to give TPT, whether or not the child is on pyridoxine, number of missed doses within the previous two weeks, the symptoms and signs the parents/primary caregivers were told to look out for, how often they were told to bring the child to the clinic for follow up, why the child was not on TPT if eligible, history of TPT within the previous 2 years and reasons for non-completion if present.

2. Tool for in-depth interviews

Open questions to explore barriers at the patient, health worker and health system levels were also asked regardless of whether or not the eligible child/children was/were receiving/not receiving TPT. The interviews of 20 adolescent/adult TB index case were recorded in audio format for qualitative purposes with regards to barriers to uptake of TPT from a healthcare seeker's perspective. These interviews were later transcribed verbatim and translated from Kiswahili to English.

Information was also retrieved from the IPT/TB preventive therapy register as well as TPT cards for the children already on TPT.

A self administered questionnaire was given to healthcare workers to assess their knowledge, attitude and practices on IPT/TB Preventive Therapy as well as barriers to TPT uptake (Appendix K).In addition, the interviews of 20 of the recruited healthcare workers wererecorded in audio format for qualitative purposes with regards to barriers to uptake of TPT from a healthcare worker's perspective. These interviews were later transcribed verbatim.

Key informants were interviewed to assess their knowledge, attitude and practices on IPT/TB Preventive Therapy as well as barriers to TPT uptake (Appendix L). These interviews were later transcribed verbatim and translated from Kiswahili to English.

4.7 Study Procedure

Phase A-Study procedure for index cases and household contacts

There wasconsecutive recruitment of adolescents/adults who had child household contacts under five years in the TB clinics with documented bacterialogically confirmed TB infection, with at least 4 weeks of TB treatment, from the triage nurse in the facilities of study. The adolescents/adults with informed consent (Appendices A-F) were asked to fill the questionnaire (Appendix I). This was done with the help of three trained research assistants. Research assistants were registered clinical officers with experience in working in a TB clinic.Adolescent/adult TB index cases living with children under 5 years of age were identified in this initial assessment and if they were the parents/primary caregivers to the eligible children, they were requested to bring the child household contacts under 5 years (whether or not they are on TPT) to the clinic for assessment and evaluation. Those with child household contactson TPT were asked to bring along TPT cards or any other physical evidence that they are receiving TPT. For those adolescent/adult index cases who were not the parents/primary caregivers to the household contacts under 5 years of age, arrangements were made by the researchers for the parents/primary caregivers to bring the children for assessment and evaluation since the parents/primary caregivers were the ones best placed to give information on TB screening.

The parents/primary caregivers who brought their children in the subsequent visit were issued with a questionnaire (Appendix I).

Child contact assessment

Once the children were brought, they were issued with a questionnaire (Appendix I Sections 1 and 2) and the child/children underwent physical examination to rule out active TB (General examination: Temperature > 37.5 [fever], weight [to confirm poor weight gain, weight loss], increased respiratory rate relative to the child's age; Respiratory examination:increased respiratory rate relative to the child's age, respiratory distress [e.g. laboured breathing, chest in-drawing {in severe disease}], percussion note - dull when lobar consolidation is present, auscultation [may be normal in early disease, and abnormal in more advanced disease {crackles, bronchial breathing}]). For those not able to bring their children for assessment, the community

health workers visited them where possible and issued the questionnaire as well as physically examine the child. Those found to be eligible and not on TPT were referred to appropriate clinicians for initiation of TPT. Those who agreed to be referred for initiation of TPT, were also advised on follow up, importance of adherence, symptoms to look out for and adverse effects to look out for (yellowness of eyes). Those suspected to have active TB were referred for further evaluation by clinicians. Those with children already on TPT were asked about the challenges, side effects, adherence, fears and opinions about TPT. In the questionnaire, the parents'/caregivers' knowledge on TPT and possible barriers such as long waiting lines, interrupted drug supplies, interpersonal experiences with healthcare workers, financial barriers, physical distance from health facilities, lack of time to bring the household contact under 5 years to the clinic due to busy work/home/school schedules, fear of stigma, pill burden, complex dosing schedules, fear of drug adverse reactions and fear of drug resistance. Behavioural information on prevention of child contacts from contracting TB if he/she knew pieces of information such as: using a mask when breastfeeding, avoiding to kiss him/her, avoiding to sleep in the same room or bed with him/her, opening windows and doors for good ventilation, and using arm protection when coughing were also captured in the questionnaire.

Qualitative – study procedure of 20 index cases

Those with children on TPT had open questions to explore the barriers/opportunities (patient, health worker and health system) for TPT in children under 5 years. Information was also retrieved from any physical records on whether or not they were on TPT.The interviews of 20 adolescent/adult TB index case were recorded in audio format for qualitative purposes with regards to barriers to uptake of TPT from a healthcare seeker's perspective. These interviews were later transcribed verbatim and translated from Kiswahili to English.

Phase B - Healthcare Workers

A HCW questionnaire (Appendix K) on knowledge, attitude and practice regarding IPT/TB preventive therapy among eligible children under five years was structured. Recruitment of Health Care Workers inpaediatric inpatient and outpatient departments (general outpatient and inpatient departments where a dedicated paediatric unit is not present), comprehensive care clinics and TB clinicswas doneandit included doctors, nurses and clinical officers in these departments. Consent for healthcare workers to be interviewed was sought (Appendix G). The

self administered questionnaire were given to them to assess their knowledge, attitude, practiceand barriers to TPT uptake. (Appendix K).

Correct knowledge was assessed as follows: eligibility for TPT for household contacts under 5 years, screening for active TB, and how to rule out active TB. Drugs for TPT according to Kenyan guidelines for household contacts under 5 years include Isoniazid (INH) monotherapy for 6 months and Isoniazid Rifampicin (RH) for 3 months and knowledge on this was assessed as follows:how to calculate dosage for a given weight (5kg) from dosage charts, formulations available (whether syrup or tablets, if can be dissolved in mouth or fluids and which fluids are acceptable), correct frequency, correct duration, correct route of administration, possible side effects and which adverse effects to counsel the parent on when giving the drug, whether the drugs should be given with or without food, correct knowledge of pyridoxine and who should receive it, timing of follow up after initiation of TPT and what to assess and look out for during follow up.

Attitude was assessed by gauging how much the healthcare worker agrees or disagrees with the following statements with regards to child household contacts under 5 years exposed to adolescent/adult bacteriologically confirmed pulmonary TB: all eligible children should receive TPT, TPT is effective, TPT is safe, drug resistance is a major concern when prescribing TPT, the risks of giving TPT outweigh the benefits, you comply with the Kenyan guidelines on TPT in children under 5 years, TPT reduces TB incidence and mortality, it is preferable to wait until a child under 5 years contracts TB and then treat them rather than administer prophylaxis and you are comfortable prescribing TPT.The questions were in a five point Likert scale evaluating the attitude of healthcare workers.

Practice was assessed as how often the healthcare worker does the following with regards to bacteriologically confirmed adolescent/adult pulmonary TB index cases: inquire if index cases have child household contacts under 5 years, ask if their child household contacts under 5 years have symptoms suggestive of active TB, educate them about TPT, advise them to bring their child household contacts under 5 years for assessment and evaluation, use the TB symptom screening according to WHO to assess them for active TB, counsel the parents/caregivers on potential side effects to look out forwhen prescribing TB preventive drugs to child household

contacts under 5 years and counsel the parents/caregivers on adherence,monitor those children under 5 years on TPT for side effectsduring follow up clinics and engage community health workers in case a child under 5 years on TPT cannot come for the follow up clinics. The questions was in a three point Likert scale evaluating the attitude of healthcare workers.

Barriers: Healthcare worker related barriers to uptake of TB as well health system operational challenges were captured based on the following: whether it difficult to rule out active TB to decide to start TB preventive therapy drugs, whether they have TB diagnosis tools at their disposal, whether there has been any stock-out of TB preventive therapy drugs in their health facilities in the preceeding 3 months, whether improving TPT uptake rates at their facility is discussed by the supervisor, if they feel that adherence to TB preventive therapy drugs is poor among children under 5 years, whether they feel that drug resistance and side effect are major risks of TPT in children under 5 years, whetherTPT failure is high among the child household contacts under 5 years in their care and whether or not they think the government through the Ministry of Health has succeeded in creating awareness for TPT in children under 5 years and which means they think the government can employ to improve awareness on TPT for chidren under 5 years.In addition, the interviews of 20 of the recruited healthcare workers' were recorded in audio format for qualitative purposes with regards to barriers to uptake of TPT from a healthcare worker's perspective. These interviews were later transcribed verbatim and translated from Kiswahili to English.

Key Informant Interviews

In-depth interviews (Appendix L) were conducted for key informants: the TB clinic In-Charges, TB clinic nurses, Pharmacy In-Charges in the four facilities, the regional TB Coordinators and community health workers in the subcounty hospitals (they are the ones who do contact tracing in the homes). The interviews were recorded using a tape recorder and transcribed verbatim and translated from Kiswahili to English.

Minimization of Bias

To avoid bias, the measures put in place were; the research assitants were trained prior to data collection to understand the information that the tool is collecting. The tools were tested before implementation of the research and necessary edits were made .

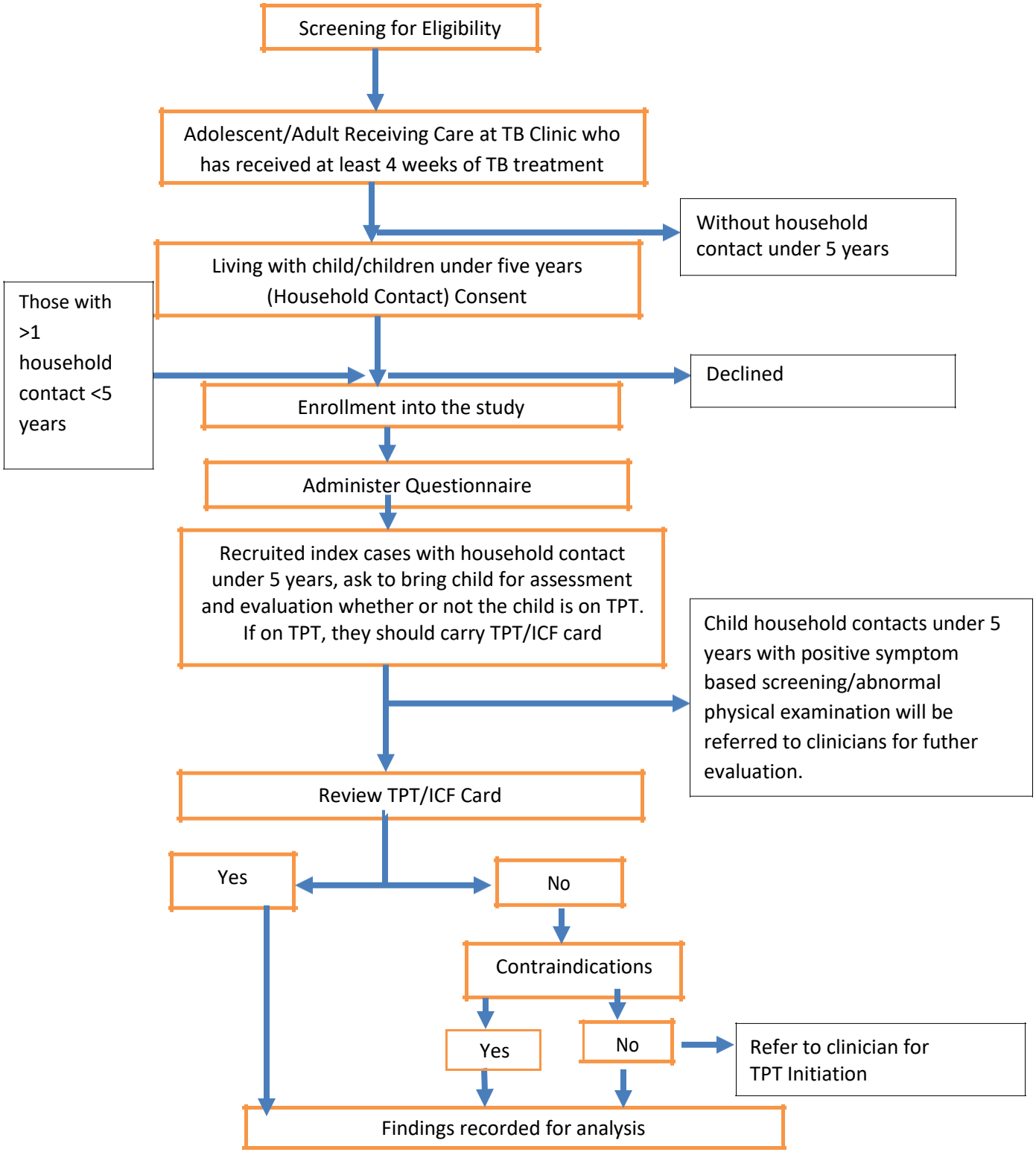


Figure3: Flowchart for enrollment of TB index cases and household contact

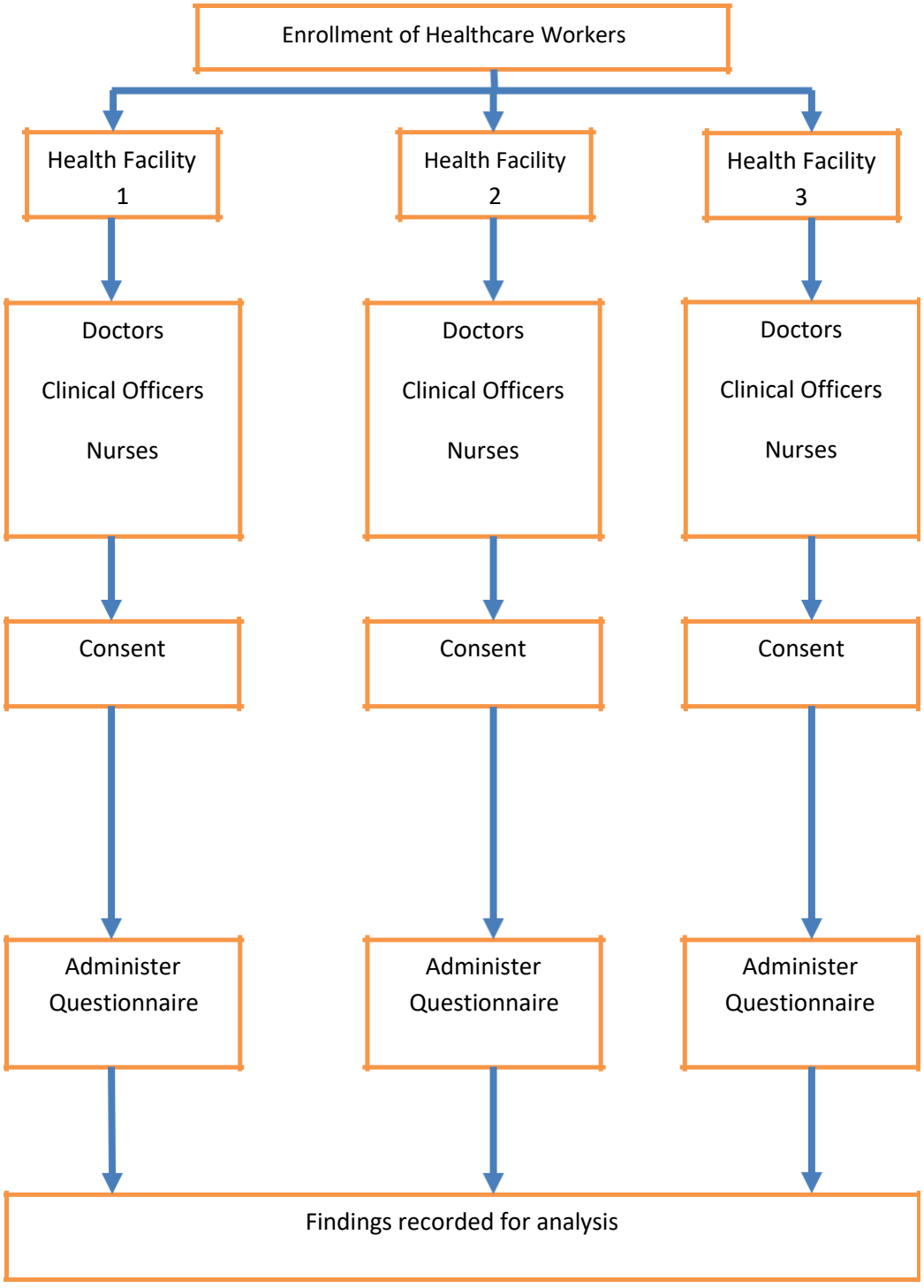


Figure 4: Flowchart for Enrollment of HCWs (Phase B)

4.8 Ethical Considerations

- Ethical approval was obtained from ethics and research committee in KNH-UONand Coast Provincial General Hospital ERC.
- Permission from the County Government ofMombasa, Port Reitz Sub County Hospital, Likoni sub county Hospital and Ganjoni Dispensary
- Consent from health workers and caregivers before enrolment.
- Copies of protocol and informed consent for approval.
- Confidentiality observed-identification codes, authorised.
- Benefits of TPT communicated to participants and those eligible referred for initiation.
- Justice, confidentiality, anonymity, safety.

4.9 Management of Data and Outline Analysis

Data was collected using structured questionnaires and entered into a Microsoft access database, protectedby password.The data collection was by using standardised questionnaires and these were entered in to a preformed password protected Microsoft Access database. Comparison of data with hard copy forms to assess for completeness and accuracy was done. The data wasanalysed usingSPSS V27 primarily using descriptive statistics.

Descriptive statistics of adolescents/adult index cases was determined and continuous variables and the interquartile range spectrum was described as medians. Categorical class variables were presented as proportions. Proportion of eligible<5yrs children who received TPT will be provided as a percentage, and a 95% confidence interval provided around the estimate.

A relationship between categorical variables was calculated using a chi-square test. Fisher's exact test will used to determine the association between knowledge, attitude and practices of healthcare workers and the uptake of TPT in the facilities of study, with statistical significance set at $p < 0.05$.

Categorical variables and correct practice and knowledge was summarized as numbers and corresponding proportions using frequency tables. Continous variables were summarized using medians and interquartile ranges. Raw qualitative data from the in-depth interviews was transcribed and the themes analyzed manually.

Knowledge, attitudeand practices among HCWs, and the barriers of uptake to TB preventive therapy was assessed as described below.

CHAPTER 5:RESULTS

5.0 Characteristics of study participants

The study identified and interviewed 150 index cases who had children under five years in the same household. Out of these index TB cases enrolled, they had 150 child contcats in total, with median child per index case (minimum, max, of the number index TB cases)

150 child household contacts were enrolled in the study (82) 51.9% were male while (76) 48.1% were females. mean age was 2.2 years. Likoni Sub county had the highest enrollment of (54) 36% followed by Port-Reitz hospital had (50) 33.3% while Coast General and Ganjoni had enrolled (23) 15.3%.

Table 4: Demographic Characteristics of enrolled children

Demographic characteristics of the enrolled children (N=150)	
Characteristic	**Frequency (%)**
Index TB Cases	150
Sex	
Male	77 (51.3)
Female	73 (48.7)
Median age = 2.2 yrs. (IQR=2.4)	
Enrolled by health facility	
Coast General Hospital	23 (15.3)
Ganjoni Dispensary	23 (15.3)
Likoni subcounty hospital	54 (36.0)
Port-Reitz hospital	50 (33.3)
TPT Uptake	
On TPT	20 (13.3)
Not on TPT	130 (86.7)

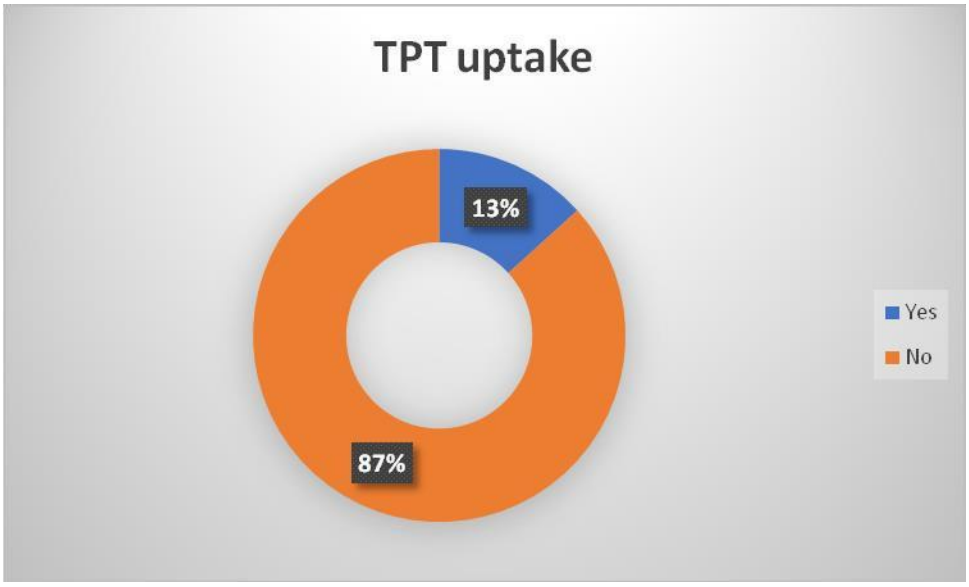
Out of 150 under five children who are eligible for TPT, (20) 13.3 were on TPT while (130) 86.7% were not on TPT.

Table 5: Household contacts per TB index case

No. of under - five contacts	No. index cases	%
1	130	87
2	12	8
3	5	3
4	3	2

The study identified 150 TB index cases who were screened for eligibility, enrolled and interviewed. Of the 150 TB index cases enrolled, they had 150 childhousehold contacts in total, with median of 1 child per index case(1 minimum, 4 maximum) of the 150 index TB cases. 130 TB index cases had one household contacts each, twelve TB index cases had two household contacts each, five TB index cases had three household contacts each and three TB index cases had four household contacts each.

Figure 5: TPT uptake in Mombasa County



In Depth interviews

Out of 20 index cases interviewed, only (2)10% were aware of TPT and their source of information was from the doctors or nurses at the TB clinic and their children were on TPT because they feared that their children may contract TB from them. The index cases mentioned some of the ways that they could prevent TB transmission to their children and this included; wearing masks (in case of lack of masks, handkerchiefs can be used), washing hands, adequate house ventilation, maintaining cleanliness in the house, coughing etiquette, avoiding crowded places and avoiding breathing near the child.

Some the challenges index cases experienced as they go to the facility for TB treatment services included; long distance to the facility, poor economic social status leading to lack of fare to the facility, lack of permission from working place, inadequate health personnel hence the time taken at the facility is long, working hours of the TB clinic, industrial strikes leading to absence of health personnel at the facility, poor service delivery, drug stock outs and stigmatization when the index cases were coming to pick the drugs.

5.1 Characteristics of Health workers interviewed

Out of 66 health workers interviewed, (22) 35.5% were males while (40) 64.5% were females. In terms of cadre, clinical officer interns were the highest in number (22) 33.3% while the least were medical officers and consultants (5) 7.6%. The rest of the health workers interviewed were medical officers' intern, registered clinical officers and nurses. Their median age was 27. The characteristics of the health workers are outlined in the table below.

Table 6: Socio Demographic Charcteristcs of health workers

Demographic characteristics of the healthcare workers (N=66)		
Characteristic	**Frequency**	**(%)**
Sex		
Male	22	36
Female	40	64

Cadre		
Registered Clinical Nurse (RCN)	11	17
Clinical officer intern	22	33
Registered clinical officer	14	21
Medical officer intern	9	14
Medical officer	5	8
Consultant paediatrician	5	8
Health facility		
Coast Provincial General Hospital	32	49
Ganjoni Dispensary	4	6
LikoniSub-county hospital	10	15
Port-Reitz Sub-county hospital	20	30
Age category		
20-29	32	56
30-39	14	25
40-59	11	19
Median age=27(IQR, 11)		

5.3 Health worker's knowledge on TPT

Knowledge was assessed by a total of 17 questions. Health care workers were assessed on questions such as awareness of existence of TB preventive therapy, available drugs, dosage and formulation, screening for TB, and monitoring of signs and symptoms for children on TB preventive therapy. Each correct answer was scored 1 and wrong answer 0. The total score was divided by 17 and multiplied by 100 to get a percentage score. The percentage score for knowledge was classified into 3 levels using Bloom's cut-off point as; Excellent: 80%-100%correct; Good: 60%-79%correct; Poor: ≤59%correct.

This is outlined in table below. 98.8% of the health workers interviewed agreed that TB can be prevented using medicine. Among the discussions, the HWs agreed to this and cited that the TPT is used to prevent TB as shown in table 4.

no, what I can say they reduce the chances of patients getting TB and they are eventually started on treatment … so, we reduce the number of cases, HW-Dr 1

In table 4 below, 97% were also aware of the number of drugs that can be used to prevent TB in children under 5 years of age which were either INH or RH drugs but only 16.7% had knowledge on the formulations of TB preventive drugs available. However, in terms of eligibility 41% of

the health workers had knowledge on children under 5 years who were eligible for TPT and this was also cited in the in-depth interviews.

I think we have like I said patients who have, we do contact tracing and we follow up on these particular patients who have contacted TB and we screen them and we give them IPT… HW-RCN 3

45.5% of the HWs were aware of how to screen or evaluate children under 5 years for eligibility for TPT and from the discussions they were comfortable due to the availability of screening tool such as chest x ray, GeneXpert, Sputum and symptom screening.

it is not so difficult because if you will follow the instructions of TB in children, it is not hard. If you will do screening very well and have the screening tool and you take the history of the child, I don't think you will have difficulties HW- RCO2

yea because from the history, you can actually have a high index of suspicion especially if there is a primary relative, first degree relative whom most likely is on treatment or he is having some cough or just a neighbor. This is somebody who stays around then maybe from the examination of the child failure to thrive and all those other things, you can be able to have a high index of suspicion and possibly start the child on investigations and then treatment HW – Dr.4

However, for those who were not comfortable, the reason given was lack of the screening tool such as Mantoux test and for those with Chest x ray, the services are not free for under fives children in the Coastal region and that many at times other respiratory infections are the ones considered while TB is ignored and it is difficult to rule out active TB, since the symptoms are hidden and presents themselves like pneumonia.

many at times when we handle our clients, we only think of the respiratory tract infections which are common in our region … and rarely do we consider TB as we treat our clients. HW- Dr 6

the symptoms are kind of hidden … and it usually sometimes present like pneumonia so you keep on treating pneumonia for some time to an extend that you decide to start on anti TBs. it is not easy to diagnose TB in children HW- RCO 3

For drug dosage, 16.7% of the health workers stated that they had knowledge on TB preventive drugs dosage and frequency for children under 5 years, 60.6% were aware of TB preventive drug dose charts by weight band, 13.6% had knowledge on where to find TPT drug dose charts by weight band and 57.6% knew about the dosage for a child weighing 5kg from the chart given.

95.5% of the health workers had knowledge that pyridoxine should be given with TPT while 59.1% were aware that pyridoxine is given to all children. Pyridoxine is to manage the side effects caused by the TPT such as neuropathy and liver damage.

I don't think so because the most common side effects of IPT is numbness, that was the common that I usually encounter on people so I don't think so. That can be prevented by pyridoxine. HW-RCO 5

Table 7: Knowledge of health workers

Knowledge	**Correct answer (N=66)**	
Purpose of TPT	Number correct	Percentage (%)
TB can be prevented using medicine	65	99
Mean percentage		**99**
Drug information on TPT		
Number of drugs that can be used to prevent TB in children under 5 years of age	64	97
Formulations of TB preventive drugs available	11	17
Fluids that are acceptable for dispersible drugs	35	55
TB preventive drugs dosage and frequency for children under 5 years	11	17
Where to find TPT drug dose charts by weight band	9	14
Dosage for a child weighing 5kg from the chart given	38	58
Pyridoxine should be given with TPT	63	96
Pyridoxine is given to all children	39	59
Mean percentage		**52**
Guidelines and tools for TPT		
Children under 5 years of age who are eligible for TPT	25	41
How to screen/evaluate these children under 5 years for eligibility for TPT	30	45
Knowledge of adverse effects to counsel parent on	36	54
Awareness of TB preventive drug dose charts by weight band	40	61

Awareness of any guidelines on prevention of TB	51	77
In Kenya, TPT is guided by WHO and MOH guidelines	47	71
Mean percentage		**58**
Child contact clinical evaluation		
Signs and symptoms to look out for during follow up	39	59
Symptoms for referral for evaluation, for child household contacts of bacteriologically confirmed TB	41	62
Mean percentage		**61**
Overall knowledge mean percentage		**60**

5.4 Health workers' attitudes towards TB preventive drugs

To measure the attitude, a total of 9 questions were asked regarding the healthcare workers attitudes towards efficacy, safety and provision of TB Preventive therapy to eligible children under 5 years.

The responses to the questions were on a three-point Likert scale comprising of "Positive", "Neutral" and "Negative". "Positive" was scored 2, "Neutral" scored 1 and "Negative" scored 0 for questions that were positively stated. For those that were negatively stated the scores were assigned as 2,1,0 for "Negative", "Neutral" and "Positive" respectively. The total score out of the maximum 18 was then multiplied by 100 to get the percentage score for attitude. The resulting percentage scores were classified into 3 levels using Bloom's cut-off point as positive attitude if scored between 80-100%, neutral attitude if scored between 60-79% and negative attitude if scored less than or equal to 59%.

The attitude of the health workers was also assessed. 93.9% of the health workers agreed that all eligible children should receive TB preventive therapy drugs and 89.2% disagreed with the statement that it is preferable to wait until a child under 5 years contracts TB and then treat them rather than administer prophylaxis because it is effective (86.4%), safe (80.3%) and reduces TB incidence and mortality (90.5%). However, the effectiveness of TPT depends on adherence and complying to the instructions so as not to cause drug resistance.

okay the usage of the drug, using a drug for long sometimes can develop to that. Sometimes you can use it for long, maybe you are not persistent, you are using it for long but you are not

adhering that is you take today, you go for a week without but you still say you are on drug, so you can develop that resistance HW -RCN 3

it depends on how it is used. As long as the one who is using it knows how to use it properly, yea … using properly means that the patient takes the drug every day and the time they are supposed to take it KII, Pharm

64.1% felt that drug resistance is a major concern prescribing TPT. In terms of risks versus the benefits 62.5% disagreed that the risks of giving TB preventive therapy drugs outweigh the benefits as shown in table 5 below.

the risk of resistance compared to the benefits of prevention, I think we would rather prevent them than, we can overlook the risk, KII-CHV

69.7% of the HWs agreed they were comfortable prescribing TPT for under-fives after ruling out active TB while 10.6% disagreed and 19.7% were not sure if they were comfortable prescribing TB preventive drugs.

no, what I can say when you are giving the preventive therapy, we look at the benefits, yea, so you will find that the benefits outweigh the risks, yea. So, start with the preventive therapy, if the other issues come up you deal with them as they come to look at the benefits HW – RCO 4

84.9% agreed to that fact that they comply with the Kenyan guidelines on TPT in children under 5 years as shown in table 5.

Table 8: Attitude of the health workers

Attitude	Positive n (%)	Neutral n (%)	Negative n (%)
Benefits and effectiveness of TPT			
TB preventive therapy drugs are effective	57 (86)	9 (14)	0
TPT reduces TB incidence and mortality	57 (91)	6 (9)	0
Mean percentage	**89**	**12**	**0**
Risks and fears on TPT drugs			
TB preventive therapy drugs are safe	53 (80)	10 (15)	3 (5)
Drug resistance is a major concern when prescribing TPT	41 (64)	7 (11)	16 (25)

The risks of giving TB preventive therapy drugs do not outweigh the benefits	40 (62)	3 (5)	21 (33)
Mean percentage	**69**	**10**	**21**
Provision of TPT			
All eligible children should receive TB preventive therapy drugs	62 (94)	2 (3)	2 (3)
I comply with the Kenyan guidelines on TPT in children under 5 years	56 (85)	9 (14)	1 (2)
It is not preferable to wait until a child under 5 years contracts TB and then treat them rather than administer prophylaxis	58 (89)	5 (8)	2 (3)
I am comfortable prescribing TB preventive therapy drugs	46 (70)	13 (20)	7 (10)
Mean percentage	**85**	**11**	**4**
Overall attitude mean percentage	**80**	**11**	**9**

5.5 Implementation of TPT by Health Workers

For practice, a total of 9 questions assessing frequency of practice were asked in relation to the healthcare workers practice in enquiring from index cases of eligible children contact, educating the index cases on TB preventive therapy, screening for active TB and monitoring those children under 5 years on TB preventive therapy drugs for side effects during follow up clinics. The responses were categorized as “Excellent”, “Good” and “Poor” with the scores of 2, 1 and 0 respectively as shown in table 6 belowThe total score out of the possible 18 was then multiplied by 100 to get the percentage score for practice. The percentage scores were then classified into 3 levels using Bloom’s cut-off point as Positive attitude if scored between 80-100%, Neutral attitude if scored between 60-79% and Negative attitude if scored less than or equal to 59%

Asked about the frequency of enquiring if index cases had a child household contact under five years 69.4% cited, yes, always, 70.3% always asked the index cases if their child household contacts under five years have symptoms suggestive of active TB and 60.9% of the health workers always advised index cases to bring their child household contacts under 5 years for assessment and evaluation. 67.2% always use TB symptom screening according to WHO to assess them for active TB. However, most the index cases reported to have heard about TPT for the first time during the interview.

In terms of counselling 74.2% always counselled the parents/caregivers on potential side effects to look out for when prescribing TB preventive drugs to child household contacts under 5 years and 87.9% always counselled them on adherence when prescribing TB preventive drugs to child household contacts under 5 years and this prevents drug resistance which can be caused by the TPT drugs.

because we always, we always educate our patients about these drugs and we educate about side effects, we educate them every time maybe when they are coming for drugs, we meet them to remind them about these drugs. So, at my facility it is difficult to have a… a failure HW, RCN 3.

because if you explain to a guardian or a parent, if he or she understands then adherence is not an issue, yes KII, RC

However, adherence totally depends with the parents/caregivers of the children are the ones who administer these drugs to the children at the frequencies indicated.

it depends with the parent, if the parent is not that careful there can be poor adherence and again if the patient is more concerned, if there is any side effect, he or she will be able to rush the child to hospital to have any, to have interventions. If the parent doesn't have that care to his/her own child, will stop the medication HW, Dr 4.

The caregivers that adhere, adhere because they wouldn't want their children to go through the pain they have gone through with the disease. HWs also mentioned that adherence is difficult due to drug stock out which is majorly caused by HW's strike hence the HW responsible in issuing or procuring the drugs is not available, lack of adequate supply, delayed supply and short expiry, ignorance among the parents an side effects of TPT on the children under five.

sometimes it is lack of proper information and at times it is just like when I have told you that this is happening you tell me, ahh, you just want to eat people's money … or you are just doing this job because you are being paid for it … yea, is just like when I am in the community, maybe I am educating them about TB, about what they will tell you, woman, for us we know it, you people are disturbing us KII, CHV

I think also there are some patients who have experienced the side effects of IPT and they tend not to use it again because of the IPT side effect KII, TB Nurse

65.2% always monitored those children under 5 years on TB preventive therapy drugs for side effects during follow up clinics and 50.8% always engaged the community health workers in case a child under 5 years on TB preventive therapy drugs cannot come for the follow up clinics.

Table 9: Practice of the health workers

Practice	**Excellent n (%)**	**Good n (%)**	**Poor n (%)**
Frequency of enquiring if index cases have child household contacts under 5 years	43 (69)	17 (27)	2 (3)
Frequency of asking if their child household contacts under 5 years have symptoms suggestive of active TB	45 (70)	15 (23)	4 (6)
Frequency of educating index cases on PT	36 (56)	20 (31)	8 (13)
Frequency of advising index cases to bring their child household contacts under 5 years for assessment and evaluation	39 (61)	20 (31)	5 (8)
Frequency of using TB symptom screening according to WHO to assess them for active TB	43 (67)	13 (20)	8 (13)
Frequency of counselling the parents/caregivers on potential side effects to look out for when prescribing TB preventive drugs to child household contacts under 5 years,	49 (74)	9 (14)	3 (5)
Frequency of counselling the parents/caregivers on adherence when prescribing TB preventive drugs to child household contacts under 5 years,	58 (95)	3 (5)	0
Frequency of monitoring those children under 5 years on TB preventive therapy drugs for side effects during follow up clinics	43 (65)	15 (23)	8 (12)
Frequency of engaging community health workers in case a child under 5 years on TB preventive therapy drugs cannot come for the follow up clinics	32 (51)	19 (30)	12 (19)
Overall practice mean percentage	**68**	**23**	**9**

5.6 Barriers to TPT uptake

Poor leadership and governance

This has led to lack of continuous supply of TB preventive drugs, inadequate staffing and lack of efforts in creation of awareness on TPT to the public.

"*because they have not taken a strong initiative in the campaigning, the awareness has not happened properly, the campaigns have not been seen, they should inform people,"* Index

Lack of health information on TPT for under-fives among the public/community:

"*for children I don't think they have done that … because like me I have known today … I have never heard, it is just today, I have heard it today,"*

Lack of health information on TPT for under-fives among the HWs

*" **do you think the health worker have good, adequa…, let me say good knowledge on TB preventive therapy for under five children? …** I: no, no they don't have … because if the caregiver themselves are not well educated, we don't expect the patient to know any better,"* HW

Myths and misconceptions: *"it is many who come that, leave alone those that come, someone can be started TB medication, when she comes to the clinic or refill of medication, she tells you, I was told this. Who told you? My neighbor meaning whatever she is being told is totally different. Total misinformation, meaning that neighbor doesn't have any information on TB and if there is one there, the neighbor meaning they are many in the community who are like that,"*
HW

Stigmatization: "*I think it is because of stigma or how the society is going to respond to the issue,"* HW

Poor socio-economic status:

Poor socio-economic status has led to lack of transport costs among the index case to go receive TB services and even take their under fives contacts for screening and are not able to afford chest x ray servies which are required to screen the under five children for eligibility.

"*for even the contacts, when we are doing contact screening for under five, they must pay for it* (chest x ray), *there is no free service there,"* KII, RC

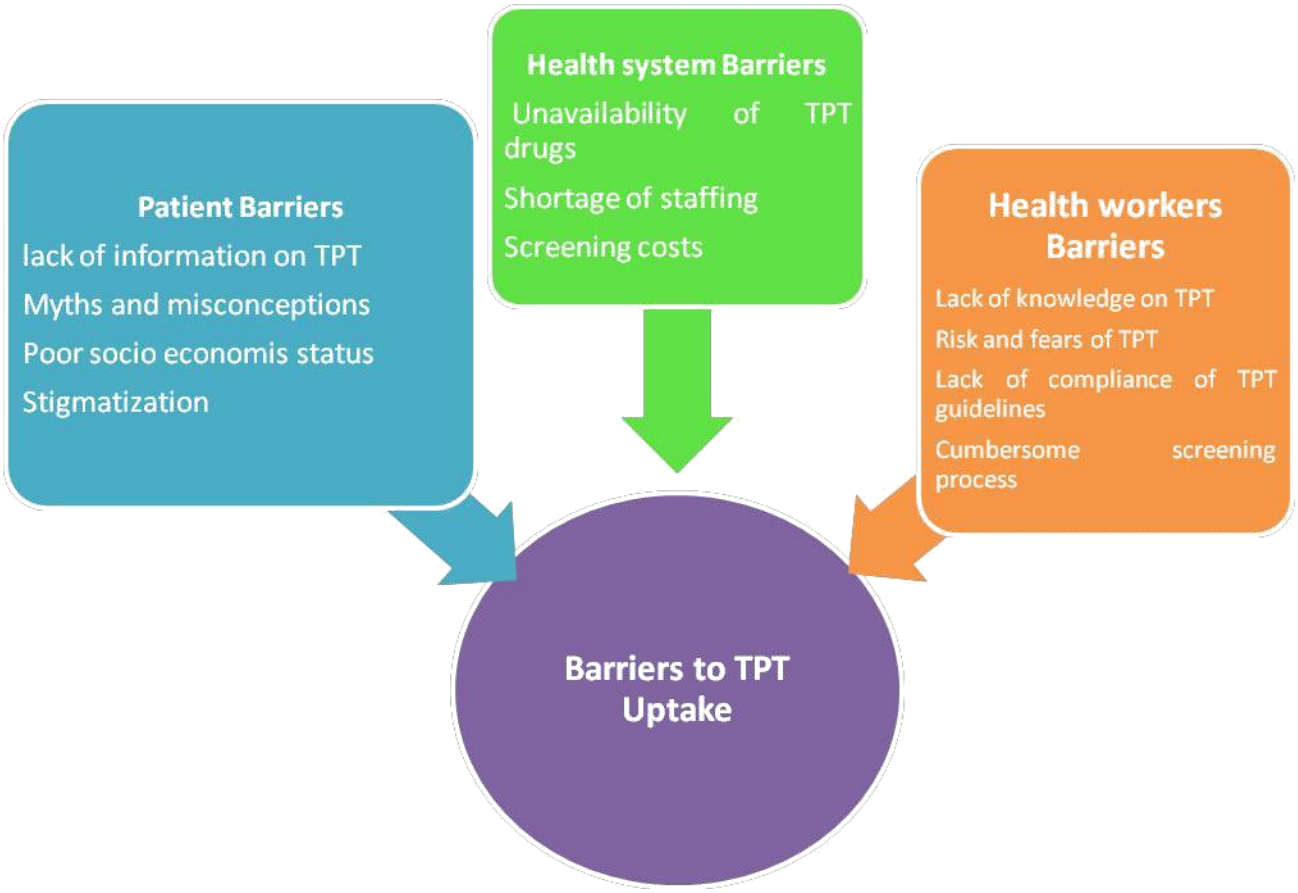


Figure 6: Barriers to TPT Intake

CHAPTER 6: DISCUSSION

The study evaluated TPT uptake among eligible children under five years in Mombasa County at Coast General, Port-Reitz hospital, Likoni sub county and Ganjoni dispensary. It also assessed the knowledge, attitude and practices of the health workers regarding TPT uptake among eligible children under five years. The study also assessed the barriers associated with TPT uptake among eligible children under five years.

In this study the TPT uptake was assessed at 13.3% among eligible children under five years in Mombasa County. The associated factors were knowledge, attitude and practices among the health workers. The analysis of this study demonstrated that the TPT uptake was poor (13.3%) despite Kenya having national guidelines on the same and being rolled out to the counties. There are studies that have found TPT uptake to be higher than what the study recorded. For instance, a study in Kenya, Nairobi County, among HIV infected children indicated that TPT uptake was at 53.2%(28). This could be attributed to the target population and the study site. The target population was HIV infected children who are a special group and there is a lot of focus in terms of financial and social support and staffing by HIV programs. The group was aged 1-15 years hence there was high probability of capturing large number of children on TPT as opposed to this study whose target group was under five years children with TB contact as a point of entry. The study site was Kenyatta National Hospital which is a level 6 hospital therefore high uptake observed was supported by increased clinical updates, assurance of INH supplies and supportive supervision and quarterly audits within the CCC. However, for the study, the study facilities were level 5, level 4 and level 3.

In India the TPT uptake was also found to be 22% (21) by Singh et al while Pothukuchi found the IPT to be lsightlyhiger at 84% and this was attributed by home visit being done by the health workers (22). In Thailand, the TPT uptake was found to be at 19.3% (29).

In Rwanda, Birungi et al, did a study and found uptake of TPT at 89% (19). This could possibly be explained by the fact that the study was done in 13 health facilities. The high uptake was also majorly due to attention being given by Rwanda NTP to TB in children in accordance with the Rwanda government’s priority intervention aimed at preventing and addressing the most

important causes of child mortality [10, 11]. Moreover, one of the indicators that the Rwanda NTP was strengthening was the number of children eligible for TPT who received it and number of children aged below 5 years old who completed TPT.

In Malawi, Zacharia et al, found the uptake to be 22% for the active cohort which was slightly higher that what the study found(27). This slight difference in TPT uptake could be explained by the large population sample which was 985 household contacts. Chia also found the TPT uptake to be 23% in Cameroon (24).

Tadesse et al, conducted a study in Ethiopia and found the TPT uptake to be at 64.3%. This study was study was conducted different geographic areas with different settings in 28 health facilities between October 2013 and June 2014(26).

Although the knowledge was poor the uptake was far much poorer as discussed above. There was a knowledge gap among HWs especially those not working in the TB clinic/program and this was evidenced by the index cases since 18 out of the 20 index cases interviewed were not aware of TPT and had heard it for the first time during the time of the interview. Similar findings were reported in Rwanda where 50% of the parents/caregivers of child household contacts who were not initiated on TPT reported their lack of information about its usefulness. In India the index cases cited inadequate knowledge to help them make informed decision on whether to initiate TPTand inadequate knowledge among HWs as a barrier to TPT implementation (25,21). However, their uptake was high (89%) and this could be due to the Rwanda NTP strategy where the health providers visit the households' index cases at the beginning of sputum smear PTB treatment for purposes of screening child contacts and initiating them on TPT. In Kenya, this strategy might not be effective because of lack of inadequate CHVs and their lack of motivation.In South Africa similar findings were reported where the HWs reported lack of knowledge and experience on TPT as a barrier to TPT implementation. However, in South Africa, some of the findings contrasted with these since Abdulrazaak et al, found that many of the HWs had good knowledge in provision of TPT which was due to the formal training they received on TB and IPT(31).

Transport cost was a limiting factor mentioned by the index cases as a challenge they experience when coming for TB services which means it can negatively affect the TPT services unlike in

Rwanda where, there has been an improvement in the ease of access to healthcare centers therefore transport cost was not a limiting factor to TPT uptake. These findings reiterate what Peninah found out in Nairobi, HIV patients had an incentive to come to the clinic already and this was independent of TPT thus removing any additional travel and time burden related to acquiring TPT medication.

Similar findings were reported by Birungi et al which showed that parents/caregivers who found unfriendly healthcare providers at the PHCs were also more likely not to initiate their children on TPT than those who found them friendly and in Cameroon, Chia found good index case and health worker relationship facilitated TPT uptake (24). Negative interactions and experience of people seeking treatment in government healthcare facilities can contribute to a reduction in subsequent medical visits and follow-ups and this could negatively affect adherence of TPT among the under-fives (32). Moreover, social stigmatization when picking up the TPT drugs as cited by one of index cases also negatively affects TPT uptake among children as also observed from study done by Birungi et al.

Garie et al, conducted a study in Southern Ethiopia, highlighted the major reason for high interruption rate was families' refusal to have an otherwise healthy child treated for six months in a TB clinic which was similar to this study. The caregivers/parents didn't understand why a healthy child was being started on TB medication(35) which were similar to this study.

This study found out that long duration of TPT (daily for 6 months) influenced non-compliance due to the pill burden which was similar to a study done in India and Kenya. In India, 75% didn't complete TPT and as suggested by one of the HWs, reducing the frequency or duration of drug intake may thus enhance initiation and completion of IPT(36). This therefore means, introduction of RH which has a short course of three months will probably result to better uptake and adherence of TPT.

Relatively few health workers expressed concern that isoniazid INH was not effective enough (13.6%) and that it was a safe drug (80.3%). However, 64.1% agreed that drug resistance could be an issue in TPT implementation since they were too dangerous.Majority, of the respondents (80.3%) did not think it was preferable to wait until a patient gets TB and then treat rather than administer prophylaxis. Our findings frame the issues similar with the study by Abdulrazaak et

al, in which fear of generating drug resistance was a third major barrier to TPT implementation(31).However, they contrasted with those of Rebecca et al in South Africa who found out that the prescribers were unaware of benefits of TPT (30).

This study found similar results to that done by Tekley et al among adults and found that most providers believed that IPT can be effective, multiple factors had impeded implementation of IPT in the region(32). Most concerns raised were about the unreliable provision of isoniazid causing fear of isoniazid resistance. Drug stock out in this study was a major barrier to TPT adherence and completion. This was reiterated by Singh et al in India (21) and Teklay et al in Ethiopia that the main barrier leading to sub-optimal implementation of IPT observed in this study was shortage of isoniazid. It seems that lack of effective systems to manage drug supply is impeding implementation of the policy. Shortage of essential drugs, such as drugs used for TB prevention have been reported as a problem in health facilities of Mombasa County.

87.9% of the HWs in this study adviced the parents/caregivers about adherence to TPT and this was similar to a study done in South Africa by Abdulrazaak where 88.2% of them advised their patients on adherence to IPT.

Chest x ray was found to be a barrier in this study because of costs associated with it yet it is hard to remove sputum in children, and due to paucibacillary factor in children it is hardly detected. A study done by Chai in Cameroon found reduced cost of screening as a facilitator of TPT uptake (24). Sensitivity and specificity of signs and symptoms screening is low because of similarity in other pulmonary diseases such as pneumonia which can be excluded by Chest x ray. Even though the specificity for chest x ray for TB diagnosis in children is low, it is of paramount importance to use chest x ray to exclude TB together with other signs and symptoms as stipulated in National and WHO guidelines. As much as chest x ray is important in excluding TB, it has it’s own limitations; availability of the chest x ray machine and interpretation of the chest x ray which requires skilled personnel therefore there is a need to have a simple and rapid diagnostic test for latent TB that will help to simplify the existing algorithm and make it more patient-friendly such as Mantoux.

These gaps could indicate that health care providers should be equipped with the knowledge, skills, and tools to counsel parents or caregivers about the importance of screening children who

are in contact with TB patients and about preventive treatment even for otherwise healthy children.

Having a policy set of guidelines for TPT, but experiencing a lack of implementation, is common in many countries. A cross-sectional email survey by WHO reported that only 28% of countries with a national policy for TPT had achieved nationwide implementation (Date et al, .2010). Lowas and coworkers had written that guidelines for practice may predispose physicians to consider changing their behavior, but unless there are other incentives or disincentives are removed, guidelines may be unlikely to effect, rapid change in actual practices.

6.1 Study strenghths and limitations

The study reviewed multiple steps in TPT implementation from identification of eligible children to screening and initiation of TPT. Qualitative and quantitative methods were used to shed light on health worker knowledge attitude and practices as well as barriers related to TPT.

The study was conducted in only four facilities within Mombasa County, whether the findings are representative of implementation of contact screening and TPT in the whole of Mombasa and the country as a whole is unknown .

Contact screening and TPT is said to be particularly useful in case of HIV positive contacts, This study however did not collect information on the HIV status of contacts and hence could not asses the status of provisionof services to the contacts who were HIV positive.

6.2 Conclusion

1. TB preventive therapy uptake was poor at 13.3% among under five household contact in Mombasa county and knowledge was far much poorer among the HWs
2. The knowledge of the health workers was at 60% and the attitude was positive at 80% and 68% of the HWs reported to be excellent in implementing TPT.
3. The poor uptake of TB preventive therapy wasprobably attributed to barriers such as poor health knowledge and awareness among the HWs and public/community, chest x ray not being free and unavailability of Mantoux test which are very important for TB screening in eligible children.

4. Other barriers of TB preventive therapy include drug stock outs, resistance by caregivers/parents, inadequate health workers, lack of motivation for CHVs and poor economic status.

6.3 Recommendations

1. TPT uptake can be scaled up by simplifying screening procedures, providing free screening services, intensifying contact tracing, educating index cases at each hospital visit, maintaining good index case/health worker relationships, improving logistics and enhancing supervision and monitoring.
2. Provide continuous health information and create awareness on TB preventive therapy drugs to HWs, TB patients and community at large through media e.g, Radios in local languages, TVs, Phone messages, Twitter, Facebook and WhatsApp, posters, billboards and brochures and through CHVs going to the community or door to door. Outreaches and road shows are also a critical way of spreading this information.
3. Frequent trainings of the HWs and CHVs which entails continuous medical education and refresher course**s**
4. Increase health workforce especially in the TB clinic
5. Affordable,available and accessible service delivery such as CXR and mantoux test.

6.4 Dissemination of results

The results compiled shall be submitted to the department of Paediatrics and Child health as hard and soft copies. These shall be presented as a poster to the faculty at the conclusion of the study. Copies of the result shall also be sent to the University of Nairobi repository for storage. The findings shall also be shared with administration of the study health facilities with the aim of notifying them on the current status of TPT uptake and the factors influencing TPT implementation in Mombasa county.

I shall also conduct CME sessions with the study hospitals on current TB preventive therapy implementation as per our national and WHO guidelines

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APPENDICES

Appendix A

Uptake of tuberculosis preventive therapy among eligible children under five years in Mombasa County.

TB Adult index case Information and Consent Form- English

Investigator: Dr. Emmanuel Macharia

Telephone number: 0712167244

Supervisors: Dr Nyambura Kariuki,Dr. Diana Marangu, University of Nairobi

Investigators statement: We are requesting you and the child who is your household contact to kindly participate in thisresearch study. The purpose of this consent form is to provide you with information you will need to help you decide whether to participate in the study. The process is called informed consent. Please read this consent information carefully and ask questions or seek clarification on any matter concerning the study with which you are uncertain.

Introduction: Tuberculosis is a contagious disease which is a major cause of morbidity and mortality. Infants and children under five years are at high risk of developing the disease. TB preventive therapy has been shown to be effective in decreasing incidence and deaths due to tuberculosis. This study seeks to establish if the child has received TB preventive therapy and establish any barriers to its implementation.

Inclusion Criteria: The study subjects shall be patients with bacteriologically confirmed and documented pulmonary TB and at least 4 weeks on treatment for TB with children under five years who are their household contacts receiving care in the TB clinics of Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital and Likoni Sub-County Hospital.

*Study procedure***:**We are kindly requesting for 15minutes of your time during which aquestionnaire will be administered, the researcher will ask the questions and fill the answers

appropriately. This interview may be recorded in audio format. If so, the researcher will inform inform you and ask for your permission. You are free to accept/decline to be recorded. You can still participate in the study if you decline to be recorded. If you are the parent/primary caregiver of the child household contact under 5 years, you will be asked to bring the child, whether or not they are on TB prentive treatment (TPT), to the clinic for TB symptom screening using the WHO algorithm. If the child is already on TPT, you will be asked to bring along the TPT card or any other physical evidence that the child is receiving TPT. The researcher will then physically examine the child and review relevant medical records. If you are not the parent/primary caregiver of the child, arrangements will be made to contact with the parent/primary caregiver for them to bring the child to the clinic. Those with more than one child household contact under 5 will be asked to bring them all to the clinic.

Benefits: If the child is eligible for TB preventive therapy and has not received it,arrangements will be made to avail it. Those children who will be found to have active tuberculosis will be initiated on treatment. Those children on TB preventive therapy and found to have side effects will be referred to a clinician for evaluation. The results of the research will be used by health workers, policy makers and program managers in this county and other counties to inform ionized preventive therapy implementation.

Risks: There will be no risks to you or the child during the study. There will be no invasiveprocedure carried out during the study that may harm the child. Refusal to participate will not jeopardize the care of the child in any way.

Voluntariness: The study will be fully voluntary. There will be no financial rewards to youfor participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise your child's care in any way.

Confidentiality: The information obtained about you and the child will be kept in strictconfidentiality. No specific information will be released to any person without your permission. We will, however, discuss general overall findings regarding all children enrolled but nothing specific will be discussed regarding the child. We will not reveal your identity or that of the child in these discussions.

Problems or questions: If you have any questions about the study or about the use of theresults you can contact the principle investigator: Dr. Emmanuel Macharia by calling 0712167244; or the supervisors: Dr. Nyambura Kariuki,Tel: 0722679119; and Dr. Diana Marangu, Tel: 0721282815.

If you have any questions on your rights as a research participant you can contact Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) BY CALLING +2542726300-19 or email uonknh-erc@uonbi.ac.ke.

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumb print in the space provided below.

I, _____ confirm that the study has been fully explained to me and I give full consent to participate in it.

TB adult index case signature/thumb print: _____

Investigators signature: _____

Date:_____/_____/2020

Appendix B

Matumiziyatibayakuzuiakifuakikuumiongonimwa Watoto wenyeumriwachiniyamiakatanokatika Kauntiya Mombasa.

Habari yaMhusikanaFomuyaIdhini

MtafitiMkuu: Dkt. Emmanuel Macharia

Nambariya Simu: 0712167244

Wasimamizi: Dkt. Nyambura Kariuki,Dkt. Diana Marangu, Chuo Kikuu cha Nairobi

Kumbusho la MtafitiMkuu: Tunauombakwaunyenyekevuushirikawakonawamtoto au Watoto katikanyumbayakokatikautafitihuu. Nia yafomuhiiyaidhinini kukupa Habari zoteunazohitakiilekufanyauamuziiwapoutawezakushirikikatikautafitihuu. Mchakatohuuunajulikanakamaidhinikamilibaadayakupatahabarizote. Tafadhali soma fomuhiiyaidhinikwamakininaulizamaswaliyoyoteutakayokuwanayokuhusujambololoteambalolita kutatiza.

Utangulizi: Ugonjwawakifuakikuuniugonjwawakuambukizwaambaonichanzokuu cha kifonaulemavu. Watoto wenyeumriwachiniyamiakatanowakokatikahatarikubwasanayakuambukizwaugonjwahuu. Tiba yakuzuiakifuakikuuimeonyeshwakuwanauwezomkubwawakupunguzamaambukiziyanavifokutok ananakifuakikuu. Utafitihuu una lengo la kuidhinishaiwapomtotoamepewatibayakuzuiakifuakikuunaiwapokunachangamotodhidiyamtotok upatatibahii.

VigezovyaUjumuishaji:
Watakaojumuishwakatikautafitihuuwatakuwawagonjwawaliodhibitishwanakusajiliwakuwanakif

uakikuunawamepokeamatibabukwaangalau wiki nnenawanaoishikatikanyumbamojana Watoto walionaumriwachiniyamiakatanonawanaopokeamatibabukatikakliniki za kifuakikuu za Hospitali Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital naLikoni Sub-County Hospital.

*TaratibuyaUtafiti***:**Tunakuombakwaunyenyekevuutuperobosaayamudawakoilituwezekukuulizam aswalimachache. Mtafitiatakuulizamaswalihayanakuandikamajibu. Mahojianohayayanawezakurekodiwakwanjiayakielekeronikikatikamfumowasauti. Mtafitiatakujuzaiwapoatatakakurekodi. Unaweza kukataa au kukubalikwahiariyako. Iwapoutakataakurekodiwa, bado unaweza kushirikikatikautafitihuu. Iwapowewendiyemzazi/mleziwamtotoanayehusika, utaagizwaumletehospitalini (hatakamaanapokea/hapokeidawa za kuzuiakifuakikuu). Iwapomtotoanapokeadawa za kuzuiakifuakikuu, utaagizwakubeba kadi yakeyakuonyeshakuwaanapokeadawahizi au Ushahidi wowotekuonyeshakuwaanapokeadawa za kuzuakifuakikuu. Mtakapofikahospitalini, atakaguliwakuonaiwapo ana ishara za ugonjwawakifuakikuukulingananautaratiburasmiwa WHO namtafitiatamuangaliamtotona pia atazitazamarekodi za kliniki. Iwapokunamtoto Zaidi yammojachiniyaumriwamiakatanokatikanyumbaunayoishi, utaagizwauwaletewotekatikaklinikihii. Iwapowewesiomzazi au mlezimkuuwamtoto, matayarishoyatafanywanamzazi/mlezimkuuwamtotoilimtotoaletwenamzazi/mlezi wake mkuu.

Faida: Iwapomtotoataidhinishwakuwaanahitajikupatatibayakuzuiakifuakikuunahajapatatibahii, maandaliziyatafanywa ilia apatedawahizi. Watoto ambaowatapatikanakuwawameambukizwakifuakikuuwatapewamatibabu. Wale watakaopatanakuadhirikanaathari za dawa za kuzuiakifuakikuuwatapewamatibabu pia. Matokeoyautafitihuuyatatumiwanawahudumuwaafya, watengenezaji sera nawakurugenziwamipangokatikakauntihiinakauntizingineilekutoa Habari yautekelezajinauidhinishajiwatibayakuzuiakifuakikuukwakutumia Isoniazid.

Hatari: Hakutakuweponahatariyoyotekwako ama kwamtotowakomkishirikikatikautafitihuu. Hakutakuweoponaupeleleziwowotevamizikatikautafitihuuambaoutahatarishahali yam toto. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Kujitolea: Utafitihuuutafanywakwanjiayakujitolea. Hakutakuweponafaidazozote za kifedhakwakoukishirikikatikautafitihuu. Uko hurukushirikikatika au kujiondoakutokautafitihuuwakatiwowote.. One is free to participate or withdraw from the study at any point. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Usiri: Habari zoteambazozitakusanywakuhusuwewenamtotozitahifadhiwakwausiriwahaliyajuu. Hakuna Habari zozotemaalumazitatolewakwayeyotebilaruhusayako. Matokeoyakijumlakuhusuwatotowoteyatajadiliwalakinifahamukuwahatutajadilihabarimaalum za mtotoyeyote. Hatutaonyeshautambulishowako au wamtotokatikamajadilianohaya.

Matatizo au Maswali: Iwapo una mawali kuhusuutafitihuu au kuhusumatumiziya matoke yautafitihuu, unaweza kumuulizamtafitimkuu, Dkt. Emmanuel Macharia kwakupiganambariyasimu 0712167244 au wasimamizi: Dkt. Nyambura Kariuki kupitianambariyasimu 0722679119 naDkt. Diana Marangukupitianambariyasimu 0721282815.

Iwapo una maswaliyototekuhusuhakizakokamamshiriki, unaweza kuwailianana Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) kwakupiganambariyasimu +2542726300-19 ama kwakutumabarua pepe kwauonknh-erc@uonbi.ac.ke.

Ili kudhitibitishakuwaumeelewamashartiyautafiti hu una kuwaumetoaidhiniyakushirikikatikautafitihuu, tafadhalitiasahihi au uwekekidolekatikanafasiiliyoachwahapachini.

Mimi, _____nathibitisha kwambanimeelezwakuhusuutafitinaninatoakibaliyakushirikikatikautafitihuu.

Sahihiya /Alama yakidole cha Mshiriki: _____

SahihiyaMtafiti: _____

Tarehe: _____//2020

Appendix C

Uptake of tuberculosis preventive therapy among eligible children under five years in Mombasa County.

Consent for Parents/Caregivers for Household Contacts under 5 years- English

Investigator: Dr. Emmanuel Macharia

Telephone number: 0712167244

Supervisors: Dr Nyambura Kariuki,Dr. Diana Marangu, University of Nairobi

Investigators statement: We are requesting you and your child under 5 years of age to kindly participate in thisresearch study. The purpose of this consent form is to provide you with information you will need to help you decide whether to participate in the study. The process is called informed consent. Please read this consent information carefully and ask questions or seek clarification on any matter concerning the study with which you are uncertain.

Introduction: Tuberculosis is a contagious disease which is a major cause of morbidity and mortality. Infants and children under five years are at high risk of developing the disease. TB preventive therapy has been shown to be effective in decreasing incidence and deaths due to tuberculosis. This study seeks to establish if the child has received TB preventive therapy and establish any barriers to its implementation.

Inclusion Criteria: The study subjects shall be patients with bacteriologically confirmed and documented pulmonary TB and at least 4 weeks on treatment for TB with children under five years who are their household contacts receiving care in the TB clinics of Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital and Likoni Sub-County Hospital.

Study procedure:We are kindly requesting for 15minutes of your time during which aquestionnaire will be administered, the researcher will ask the questions and fill the answers appropriately. This interview may be recorded in audio format. If so, the researcher will inform inform you and ask for your permission. You are free to accept/decline to be recorded. You can still participate in the study if you decline to be recorded. Your child/children, whether or not they are on TB prentive treatment (TPT), will be subjected to TB symptom screening using the WHO algorithm. If the child is already on TPT, you will be asked to bring along the TPT card or any other physical evidence that the child is receiving TPT. The researcher will then physically examine the child and review relevant medical records.

Benefits: If the child is eligible for TB preventive therapy and has not received it,arrangements will be made to avail it. Those children who will be found to have active tuberculosis will be initiated on treatment. Those children on TB preventive therapy and found to have side effects will be referred to a clinician for evaluation. The results of the research will be used by health workers, policy makers and program managers in this county and other counties to inform ionized preventive therapy implementation.

Risks: There will be no risks to you or the child during the study. There will be no invasiveprocedure carried out during the study that may harm the child. Refusal to participate will not jeopardize the care of the child in any way.

Voluntariness: The study will be fully voluntary. There will be no financial rewards to youfor participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise your child's care in any way.

Confidentiality: The information obtained about you and the child will be kept in strictconfidentiality. No specific information will be released to any person without your permission. We will, however, discuss general overall findings regarding all children enrolled but nothing specific will be discussed regarding the child. We will not reveal your identity or that of the child in these discussions.

Problems or questions: If you have any questions about the study or about the use of theresults you can contact the principle investigator: Dr. Emmanuel Macharia by calling 0712167244; or

the supervisors: Dr. Nyambura Kariuki,Tel: 0722679119; and Dr. Diana Marangu, Tel: 0721282815.

If you have any questions on your rights as a research participant you can contact Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) BY CALLING +2542726300-19 or email uonknh-erc@uonbi.ac.ke.

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumb print in the space provided below.

I, _____ confirm that the study has been fully explained to me and I give full consent to participate in it.

Parent/primary caregiver signature/thumb print: _____

Investigators signature: _____

Date:_____/_____/2020

Appendix D

Matumiziyatibayakuzuiakifuakikuumiongonimwa Watoto wenyeumriwachiniyamiakatanokatika Kauntiya Mombasa.

FomuyaIdhiniyaMzazi/MleziMkuuwamtoto/Watoto wenyeumriwachiniyamiakamitano

MtafitiMkuu: Dkt. Emmanuel Macharia

Nambariya Simu: 0712167244

Wasimamizi: Dkt. Nyambura Kariuki,Dkt. Diana Marangu, Chuo Kikuu cha Nairobi

Kumbusho la MtafitiMkuu: Tunauombakwaunyenyekevuushirikawakonawamtoto au Watoto katikanyumbayakokatikautafitihuu. Nia yafomuhiiyaidhinini kukupa Habari zoteunazohitajiilekufanyauamuziiwapoutawezakushirikikatikautafitihuu. Mchakatohuuunajulikanakamaidhinikamilibaadayakupatahabarizote. Tafadhali soma fomuhiiyaidhinikwamakininaulizamaswaliyoyoteutakayokuwanayokuhusujambololoteambalolita kutatiza.

Utangulizi: Ugonjwawakifuakikuuniugonjwawakuambukizwaambaonichanzokuu cha kifonaulemavu. Watoto wenyeumriwachiniyamiakatanowakokatikahatarikubwasanayakuambukizwaugonjwahuu. Tiba yakuzuiakifuakikuuimeonyeshwakuwanauwezomkubwawakupunguzamaambukiziyanavifokutok ananakifuakikuu. Utafitihuu una lengo la kuidhinishaiwapomtotoamepewatibayakuzuiakifuakikuunaiwapokunachangamotodhidiyamtotok upatatibahii.

VigezovyaUjumuishaji:

Watakaojumuishwakatikautafitihuuwatakuwawagonjwawaliodhibitishwanakusajiliwakuwanakifuakikuunawamepokeamatibabukwaangalau wiki nnenawanaoishikatikanyumbamojana Watoto walionaumriwachiniyamiakatanonawanaopokeamatibabukatikakliniki za kifuakikuu za Hospitali Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital naLikoni Sub-County Hospital.

*TaratibuyaUtafiti***:**Tunakuombakwaunyenyekevuutuperobosaayamudawakoilituwezekukuulizamaswalimachache. Mtafitiatakuulizamaswalihayanakuandikamajibu. Mahojianohayayanawezakurekodiwakwanjiayakielekeronikikatikamfumowasauti. Mtafitiatakujuzaiwapoatatakakurekodi. Unaweza kukataa au kukubalikwahiariyako. Iwapoutakataakurekodiwa, bado unaweza kushirikikatikautafitihuu. Mtotowako (hatakamaanapokea/hapokeidawa za kuzuiakifuakikuu) atakaguliwakuonaiwapo ana ishara za ugonjwawakifuakikuukulingananautaratiburasmiwa WHO namtafitiatamuangaliamtotona pia atazitazamarekodi za kliniki. Iwapomtotoanapokeadawa za kuzuiakifuakikuu, utaagizwakumuonyeshamtafiti kadi yakeyakuonyeshakuwaanapokeadawahizi au ushahidiwowotekuonyeshakuwaanapokeadawa za kuzuakifuakikuu.

Faida: Iwapomtotoataidhinishwakuwaanahitajikupatatibayakuzuiakifuakikuunahajapatatibahii, maandaliziyatafanywa ilia apatedawahizi. Watoto ambaowatapatikanakuwawameambukizwakifuakikuuwatapewamatibabu. Wale watakaopatanakuadhirikanaathari za dawa za kuzuiakifuakikuuwatapewamatibabu pia. Matokeoyautafitihuuyatatumiwanawahudumuwaafya, watengenezaji sera nawakurugenziwamipangokatikakauntihiinakauntizingineilekutoa Habari yautekelezajinauidhinishajiwatibayakuzuiakifuakikuukwakutumia Isoniazid.

Hatari: Hakutakuweponahatariyoyotekwako ama kwamtotowakomkishirikikatikautafitihuu. Hakutakuweoponaupeleleziwowotevamizikatikautafitihuuambaoutahatarishahali yam toto. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Kujitolea: Utafitihuuutafanywakwanjiayakujitolea. Hakutakuweponafaidazozote za kifedhakwakoukishirikikatikautafitihuu. Uko hurukushirikikatika au kujiondoakutokautafitihuuwakatiwowote.. One is free to participate or withdraw from the study

at any point. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Usiri: Habari zoteambazozitakusanywakuhusuwewenamtotozitahifadhiwakwausiriwahaliyajuu. Hakuna Habari zozotemaalumazitatolewakwayeyotebilaruhusayako. Matokeoyakijumlakuhusuwatotowoteyatajadiliwalakinifahamukuwahatutajadilihabarimaalum za mtotoyeyote. Hatutaonyeshautambulishowako au wamtotokatikamajadilianohaya.

Matatizo au Maswali: Iwapo una mawali kuhusuutafitihuu au kuhusumatumiziya matoke yautafitihuu, unaweza kumuulizamtafitimkuu, Dkt. Emmanuel Macharia kwakupiganambariyasimu 0712167244 au wasimamizi: Dkt. Nyambura Kariuki kupitianambariyasimu 0722679119 naDkt. Diana Marangukupitianambariyasimu 0721282815.

Iwapo una maswaliyototekuhusuhakizakokamamshiriki, unaweza kuwailianana Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) kwakupiganambariyasimu +2542726300-19 ama kwakutumabarua pepe kwauonknh-erc@uonbi.ac.ke.

Ili kudhitibitishakuwaumeelewamashartiyautafiti hu una kuwaumetoaidhiniyakushirikikatikautafitihuu, tafadhalitiasahihi au uwekekidolekatikanafasiiliyoachwahapachini.

Mimi, _____nathibitisha kwambanimeelezwakuhusuutafitinaninatoakibaliyakushirikikatikautafitihuu.

Sahihiya /Alama yakidole cha Mzazi/MleziMkuu: _____

SahihiyaMtafiti: _____

Tarehe:_____/___/2020

Appendix E

Uptake of tuberculosis preventive therapy among eligible children under five years in Mombasa County.

TB Adolescent Index Case Information and Assent Form for 15 - <18 Years of Age - English

Investigator: Dr. Emmanuel Macharia

Telephone number: 0712167244

Supervisors: Dr Nyambura Kariuki,Dr. Diana Marangu, University of Nairobi

Investigators statement: We are requesting you and the child who is your household contact to kindly participate in thisresearch study. The purpose of this consent form is to provide you with information you will need to help you decide whether to participate in the study. The process is called informed consent. Please read this consent information carefully and ask questions or seek clarification on any matter concerning the study with which you are uncertain.

Introduction: Tuberculosis is a contagious disease which is a major cause of morbidity and mortality. Infants and children under five years are at high risk of developing the disease. TB preventive therapy has been shown to be effective in decreasing incidence and deaths due to tuberculosis. This study seeks to establish if the child has received TB preventive therapy and establish any barriers to its implementation.

Inclusion Criteria: The study subjects shall be patients with bacteriologically confirmed and documented pulmonary TB with children under five years who are their household contacts and at least 4 weeks of treatment for TB receiving care in the TB clinics of Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital and Likoni Sub-County Hospital.

*Study procedure***:**We are kindly requesting for 15 minutes of your time during which aquestionnaire will be administered, the researcher will ask the questions and fill the answers

appropriately. This interview may be recorded in audio format. If so, the researcher will inform inform you and ask for your permission. You are free to accept/decline to be recorded. You can still participate in the study if you decline to be recorded. If you are the parent/primary caregiver of the child household contact under 5 years, you will be asked to bring the child, whether or not they are on TB prentive treatment (TPT), to the clinic for TB symptom screening using the WHO algorithm. If the child is already on TPT, you will be asked to bring along the TPT card or any other physical evidence that the child is receiving TPT. The researcher will then physically examine the child and review relevant medical records. If you are not the parent/primary caregiver of the child, arrangements will be made to contact with the parent/primary caregiver for them to bring the child to the clinic. Those with more than one child household contact under 5 will be asked to bring them all to the clinic.

Benefits: If the child is eligible for TB preventive therapy and has not received it,arrangements will be made to avail it. Those children who will be found to have active tuberculosis will be initiated on treatment. The results of the research will be used by health workers, policy makers and program managers in this county and other counties to inform ionized preventive therapy implementation.

Risks: There will be no risks to you or the child during the study. There will be no invasiveprocedure carried out during the study that may harm the child. Refusal to participate will not jeopardize the care of the child in any way.

Voluntariness: The study will be fully voluntary. There will be no financial rewards to youfor participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise your child's care in any way.

Confidentiality: The information obtained about you and the child will be kept in strictconfidentiality. No specific information will be released to any person without your permission. We will, however, discuss general overall findings regarding all children enrolled but nothing specific will be discussed regarding the child. We will not reveal your identity or that of the child in these discussions.

Problems or questions: If you have any questions about the study or about the use of theresults you can contact the principle investigator: Dr. Emmanuel Macharia by calling 0712167244; or the supervisors: Dr. Nyambura Kariuki,Tel: 0722679119; and Dr. Diana Marangu, Tel: 0721282815.

If you have any questions on your rights as a research participant you can contact Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) BY CALLING +2542726300-19 or email uonknh-erc@uonbi.ac.ke.

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumb print in the space provided below.

I, _____ confirm that the study has been fully explained to me and I give full consent to participate in it.

13 - <18 year old Patient with TB index case signature/thumb print: _____

Investigators signature: _____

Date:_____/_____/2020

Appendix F

Matumiziyatibayakuzuiakifuakikuumiongonimwa Watoto wenyeumriwachiniyamiakatanokatika Kauntiya Mombasa.

Habari naFomuyaIdhiniyaMhusikawenye Umri wa Miaka 15 - <18

MtafitiMkuu: Dkt. Emmanuel Macharia

Nambariya Simu: 0712167244

Wasimamizi: Dkt. Nyambura Kariuki,Dkt. Diana Marangu, Chuo Kikuu cha Nairobi

Kumbusho la MtafitiMkuu: Tunauombakwaunyenyekevuushirikawakonawamtoto au Watoto katikanyumbayakokatikautafitihuu. Nia yafomuhiiyaidhinini kukupa Habari zoteunazohitakiilekufanyauamuziiwapoutawezakushirikikatikautafitihuu. Mchakatohuuunajulikanakamaidhinikamilibaadayakupatahabarizote. Tafadhali soma fomuhiiyaidhinikwamakininaulizamaswaliyoyoteutakayokuwanayokuhusujambololoteambalolita kutatiza.

Utangulizi: Ugonjwawakifuakikuuniugonjwawakuambukizwaambaonichanzokuu cha kifonaulemavu. Watoto wenyeumriwachiniyamiakatanowakokatikahatarikubwasanayakuambukizwaugonjwahuu. Tiba yakuzuiakifuakikuuimeonyeshwakuwanauwezomkubwawakupunguzamaambukiziyanavifokutok ananakifuakikuu. Utafitihuu una lengo la kuidhinishaiwapomtotoamepewatibayakuzuiakifuakikuunaiwapokunachangamotodhidiyamtotok upatatibahii.

VigezovyaUjumuishaji:
Watakaojumuishwakatikautafitihuuwatakuwawagonjwawaliodhibitishwanakusajiliwakuwanakif

uakikuu, ambaowamepataangalau wiki nne za matibabuyakifuakikuunawanaoishikatikanyumbamojana Watoto walionaumriwachiniyamiakatanowanaopokeamatibabukatikakliniki za kifuakikuu za Hospitali Coast Provincial General Hospital, Port Reitz Sub-County Hospital, Ganjoni Sub-County Hospital naLikoni Sub-County Hospital.

*TaratibuyaUtafiti***:**Tunakuombakwaunyenyekevuutuperobosaayamudawakoilituwezekukuulizam aswalimachache. Mtafitiatakuulizamaswalihayanakuandikamajibu. Mahojianohayayanawezakurekodiwakwanjiayakielekeronikikatikamfumowasauti. Mtafitiatakujuzaiwapoatatakakurekodi. Unaweza kukataa au kukubalikwahiariyako. Iwapoutakataakurekodiwa, bado unaweza kushirikikatikautafitihuu. Iwapowewendiyemzazi/mleziwamtotoanayehusika, utaagizwaumletehospitalini (hatakamaanapokea/hapokeidawa za kuzuiakifuakikuu. Iwapomtotoanapokeadawa za kuzuiakifuakikuu, utaagizwakubeba kadi yakeyakuonyeshakuwaanapokeadawahizi au Ushahidi wowotekuonyeshakuwaanapokeadawa za kuzuakifuakikuu. Mtakapofikahospitalini, atakaguliwakuonaiwapo ana ishara za ugonjwawakifuakikuukulingananautaratiburasmiwa WHO natafitiatamuangaliamtotoiwapona pia atazitazamarekodi za kliniki. Iwapokunamtoto Zaidi yammojachiniyaumriwamiakatanokatikanyumbaunayoishi, utaagizwauwaletewotekatikaklinikihii. Iwapowewesiomzazi au mlezimkuuwamtoto, matayarishoyatafanywanamzazi/mlezimkuuwamtotoilimtotoaletwenamzazi/mlezi wake mkuu.

Faida: Iwapomtotoataidhinishwakuwaanahitajikupatatibayakuzuiakifuakikuunahajapatatibahii, maandaliziyatafanywa ilia apatedawahizi. Watoto ambaowatapatikanakuwawameambukizwakifuakikuuwatapewamatibabu. Matokeoyautafitihuuyatatumiwanawahudumuwaafya, watengenezaji sera nawakurugenziwamipangokatikakauntihiinakauntizingineilekutoa Habari yautekelezajinauidhinishajiwatibayakuzuiakifuakikuukwakutumia Isoniazid.

Hatari: Hakutakuweponahatariyoyotekwako ama kwamtotowakomkishirikikatikautafitihuu. Hakutakuweoponaupeleleziwowotevamizikatikautafitihuuambaoutahatarishahali yam toto. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Kujitolea: Utafitihuuutafanywakwanjiayakujitolea. Hakutakuweponafaidazozote za kifedhakwakoukishirikikatikautafitihuu. Uko hurukushirikikatika au kujiondoakutokautafitihuuwakatiwowote.. One is free to participate or withdraw from the study at any point. Kukataakushirikikatikautafitihuuhakutaadhirihuduma za matibabuyamtotokwanjiazozote.

Usiri: Habari zoteambazozitakusanywakuhusuwewenamtotozitahifadhiwakwausiriwahaliyajuu. Hakuna Habari zozotemaalumazitatolewakwayeyotebilaruhusayako. Matokeoyakijumlakuhusuwatotowoteyatajadiliwalakinifahamukuwahatutajadilihabarimaalum za mtotoyeyote. Hatutaonyeshautambulishowako au wamtotokatikamajadilianohaya.

Matatizo au Maswali: Iwapo una mawali kuhusuutafitihuu au kuhusumatumiziya matoke yautafitihuu, unaweza kumuulizamtafitimkuu, Dkt. Emmanuel Macharia kwakupiganambariyasimu 0712167244 au wasimamizi: Dkt. Nyambura Kariuki kupitianambariyasimu 0722679119 naDkt. Diana Marangukupitianambariyasimu 0721282815.

Iwapo una maswaliyototekuhusuhakizakokamamshiriki, unaweza kuwailianana Kenyatta National Hospital Ethics and Research Committee (KNH-ESRC) kwakupiganambariyasimu +2542726300-19 ama kwakutumabarua pepe kwauonknh-erc@uonbi.ac.ke.

Ili kudhitibitishakuwaumeelewamashartiyautafiti hu una kuwaumetoaidhiniyakushirikikatikautafitihuu, tafadhalitiasahihi au uwekekidolekatikanafasiiliyoachwahapachini.

Mimi, _____nathibitisha kwambanimeelezwakuhusuutafitinaninatoakibaliyakushirikikatikautafitihuu.

Sahihiya /Alama yakidole cha Mshirikimwenye Umri wa Miaka 13 - <18: _____

SahihiyaMtafiti: _____

Tarehe:_____/___/2020

Appendix G

Title of the study: Uptake of TB preventive therapy among eligible children under 5 years in Mombasa County.

Information and Consent for healthcare providers-English

Health Facility 1: Coast Provincial General Hospital

Health Facility 2: Port Reitz Sub-County Hospital

Health Facility 3: Ganjoni Sub-County Hospital

Health Facility 4: Likoni Sub-County Hospital

Investigator: Dr Emmanuel Macharia

P.O. BOX 96223 Mombasa-80100. Tel 0712167244

Supervisors: Dr Nyambura Kariuki, Dr Diana Marangu

Paediatrics and Child Health University of Nairobi.

Ethical Approval

University of Nairobi Ethical and Research Committee,

P.O BOX 20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102

Introduction: In this study I, Dr. Emmanuel Macharia from the University of Nairobi Department of Paediatrics and Child Health, will be assessing the uptake of TB preventive therapy among eligible children under 5 years in Mombasa County.

The purpose of the study is to find out the proportion of children under five years old who received TB preventive therapy and to assess the knowledge and practice of health workers regarding TB preventive therapy. Permission is requested from you to enroll you in this research

study.

Voluntary Participation and Right to Withdrawal

The following are general principles which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary.
ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal without any consequences to you.
iii. After you have understood the explanation please feel free to ask any questions that will enable you to better understand the nature of the study.

Procedure to be followed

With your permission, I will ask you some questions about your knowledge and practice regarding TB preventive therapy. All information will be handled with confidentiality and will only be used for the purpose of this study. This interview may be recorded in audio format. If so, I will inform inform you and ask for your permission. You are free to accept/decline to be recorded. You can still participate in the study if you decline to be recorded

Benefits and rewards

I will inform you of the latest guidelines for TB preventive therapy as well as the benefits of guideline adherence to the patient, to the healthcare worker and to the government. There is no reward for your participation in the study.

Discomfort and Risks

Some questions that you will be asked will be of a personal nature and may make you uncomfortable. You are free to decline to answer these questions if you so wish. You may also stop the interview at any time. Participation will require 15-20 minutes of your time and may slow service provision by yourself at the hospital**.**

Assurance of confidentiality

All information obtained from you will be kept confidential. At no point will you or your name be mentioned or used during data handling or in any resulting publications. Serial numbers will be used instead to maintain confidentiality**.**

Contacts

If you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to do so using the contact information provided below.

If you need to contact me, you can reach me by calling 0712167244. You can also contact my academic department at the Department of Paediatrics and Child Health, University of Nairobi

through my supervisors: Dr. Nyambura Kariuki,Tel: 0722679119; and Dr. Diana Marangu, Tel: 0721282815. If you'd like to contact Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study, you can do so BY CALLING +2542726300-19 or email uonknh-erc@uonbi.ac.ke.

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumb print in the space provided below.

I, _____ confirm that the study

has been fully explained to me and I give full consent to participate in it.

Healthcare Worker Participant Signature : _____

Investigators signature: _____

Date:_____/_____/2020

Appendix H

Title of the study: Uptake of TB preventive therapy among eligible children under 5 years in Mombasa County.

Information and Consent for Key Informants - English

Health Facility 1: Coast Provincial General Hospital

Health Facility 2: Port Reitz Sub-County Hospital

Health Facility 3: Ganjoni Sub-County Hospital

Health Facility 4: Likoni Sub-County Hospital

Investigator: Dr Emmanuel Macharia

P.O. BOX 96223 Mombasa-80100. Tel 0712167244

Supervisors: Dr Nyambura Kariuki, Dr Diana Marangu

Paediatrics and Child Health University of Nairobi.

Ethical Approval

University of Nairobi Ethical and Research Committee,

P.O BOX 20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102

Introduction: In this study I, Dr. Emmanuel Macharia from the University of Nairobi Department of Paediatrics and Child Health, will be assessing the uptake of TB preventive therapy among eligible children under 5 years in Mombasa County.

The purpose of the study is to find out the proportion of children under five years old who received TB preventive therapy and to assess the knowledge and practice of health workers regarding TB preventive therapy. Permission is requested from you to enroll you in this research study.

Voluntary Participation and Right to Withdrawal

The following are general principles which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary.
ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal without any consequences to you.
iii. After you have understood the explanation please feel free to ask any questions that will enable you to better understand the nature of the study.

Procedure to be followed

With your permission, I will ask you some questions about your knowledge and practice regarding TB preventive therapy. You will be able to fill out your answers in the questionnaire and the interview will be recorded in audio format and later on transcribed verbatim. All information will be handled with confidentiality and will only be used for the purpose of this study.

Benefits and rewards

I will inform you of the latest guidelines for TB preventive therapy as well as the benefits of guideline adherence to the patient, to the healthcare worker and to the government. There is no reward for your participation in the study.

Discomfort and Risks

Some questions that you will be asked will be of a personal nature and may make you uncomfortable. You are free to decline to answer these questions if you so wish. You may also stop the interview at any time. Participation will require 15-20 minutes of your time and may slow service provision by yourself at the hospital**.**

Assurance of confidentiality

All information obtained from you will be kept confidential. At no point will you or your name be mentioned or used during data handling or in any resulting publications. Serial numbers will be used instead to maintain confidentiality**.**

Contacts

If you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to do so using the contact information provided below.

If you need to contact me, you can reach me by calling 0712167244. You can also contact my academic department at the Department of Paediatrics and Child Health, University of Nairobi through my supervisors: Dr. Nyambura Kariuki,Tel: 0722679119; and Dr. Diana Marangu, Tel:

0721282815. If you'd like to contact Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study, you can do so BY CALLING +2542726300-19 or email uonknh-erc@uonbi.ac.ke.

To indicate that you understand the conditions of this study and that you consent to participate in it, please sign or put your thumb print in the space provided below.

I, _____ confirm that the study

has been fully explained to me and I give full consent to participate in it.

Healthcare Worker Participant Signature : _____

Investigators signature: _____

Date:_____/_____/2020

Appendix I

Uptake of TB preventive therapy among eligible children under five years in Mombasa County.

Questionnaire for TB index cases with children under five years household contacts – English:

Thank you for participating in this study.

SECTION 1

BIODATA

Study number: _____

Date: ____/____/_____

Contact: _____ Sex: [ ] Male [ ] Female

Number of weeks on TB treatment: _____

DEMOGRAPHICS

1. Are there any children in your house who are under 5 years of age? [ ] Yes [ ] No
2. If yes, how many? _____
3. List them below from the youngest to the oldest.

Log No.	Child Contact	Age in Months	Number
01			
02			
03			
04			
05			

06			
07			
08			
09			
10			

4. What is your relationship to the child?
   [ ] Mother

   [ ] Househelp/domestic worker

   [ ] Other (Please specify) _____

5. Are you the primary caregiver? [ ] Yes [ ] No

6. Marital status: [ ] Single

   [ ] Married

   [ ] Separated/Divorced

   [ ] Other (Please specify) _____

7. What is your level of education? _____

8. What is your employment status? [ ] Unemployed

   [ ] Employed

[ ] Retired

[ ] Student

[ ] Other (Please specify) _____

9. Are you aware of TB preventive therapy for children under five? _____

_____

(Specify if yes or no)

10. What do you understand of TB preventive therapy?_____

_____

11. If yes where did you get the information? _____

_____

(The researcher to probe further to identify if the respondent got information from health provider, peer mentor, social media, friends or others. An individual can specify)

12. Has any child under five years in your house ever used TB preventive therapy drugs?

_____ ***(Specify if yes or no)***

13. If YES, why was the child/children started on TB preventive therapy? _____

_____

_____

_____

_____

_____

_____

_____

(***The researcher to probe using questions such as: Who in the household had TB? When was treatment started for the adolescent/adult patient with TB? When was the child started on TB preventive therapy? What made you enroll the child for TPT [Did you do this out of your own initiative? Were you advised by someone to start the child on TPT*?*])***

14. If NO, why wasn't the child/children started on TB preventive therapy? __

_____

_____

_____

_____

_____

_____

_____

_____

(The researcher can probe further with questions such as: Was the child found to have active TB? Were there contraindications to TPT such as liver disease? Were you aware about TPT? Did you decline to start the child on TPT for one reason or the other? What was your reason? [fear of stigma, pill burden, fear of side effects, fear of drug resistance etc.])

15. Is there any other way, apart from from TB preventive drugs, you can use to prevent TB transmission to the child? _____***(Specify if yes or no)***

16. If YES, which ones?_____

_____

_____

_____

_____

_____

_____

_____

(Some of the most common approaches that have been adopted by individuals can include use of face masks, social distancing, adequate housing ventilation, cough etiquette, not sleeping in the same room with the child or children)

17. Number of rooms in which people sleep in your house?

_____

18. How many people live in that house?

_____

19. Do you sleep in the same room with the child/children under 5 years?

_____

_____ ***(Specify if yes or no)***

20. Which difficulties or bad experiences have you encountered now or previously when coming to this health facility?_____

_____

_____

_____

_____

_____

_____

(Probe if the difficulties or bad experiences might include finances, transport, distance, family-related, work/school-related, or others. Specify)

21. Do you think the government through the Ministry of Health has succeeded in creating awareness on TPT for under five? Why?

_____

_____

_____

_____

_____

22. In your opinion, which ways can the government through the Ministry of Health employ to improve awareness on TPT for children under 5 years? _____

_____

_____

SECTION 2*(N.B. This section applies when parents/ primary caregivers bring a child/children < 5 years who are household contacts of PTB index cases for symptom screening, physical assessment and evaluation for active TB)*

CHILD'S BIO DATA

Study number _____

Date _____/_____/_____

Date of birth _____/_____/_____

Sex: [ ] Male [ ] Female

1. Are you aware of TB preventive therapy for children under five? _____

   _____

   (Specify if yes or no)
2. What do you understand of TB preventive therapy? _____

   _____

   _____

   _____
3. If yes, where did you get the information from? _____

   _____

   _____

   _____

   (The researcher to probe further to identify if the respondent got information from health provider, peer mentor, social media, friends or others. An individual can specify)

4. Do you think it is important to give children under five years TB preventive therapy?

   [ ] Strongly agree [ ] Agree [ ] Not Sure [ ] Disagree [ ] Strongly disagree

   (To examine attitude)
5. Do you think TB preventive therapy is effective in preventing your child/children from getting TB?

[ ] Strongly agree [ ] Agree [ ] Not Sure [ ] Disagree [ ] Strongly disagree

(To examine attitude)

6. Would you agree you child/children under five years to be given TB preventive therapy?

[ ] Strongly agree [ ] Agree [ ] Not Sure [ ] Disagree [ ] Strongly disagree

(To examine attitude)

7. Is the child currently on TB preventive therapy? Yes [ ] No [ ]

(As you show the care giver a tablet/syrup of the TPT drugs, if no skip to number 8)

(If yes, the parent/primary caregiver should show the researcher the TPT card or an other physical evidence that the child is receiving TPT)

a) If yes, how much did you give? _____ ***(Practice for parents/primary caregivers)***

b) How many times in a day did you give it? _____ times ***(Practice for parents/primary caregivers)***

c) Did you receive any instructions on how to give it?_____

_____

(Practice for healthcare workers. Specify if yes or no)

d) Is the child taking pyridoxine?_____

_____

(Practice for healthcare workers. Specify if yes or no)

e) Within the past two weeks, how many doses has the child missed? _____ doses ***(Adherence. This is a patient-derived barrier)***

f) What signs and symptoms were you told to look out for?_____

_____

_____

_____

(Practice for healthcare workers)

g) How often were you told you should bring the child to the clinic?_____

_____

(Follow-up/practice for healthcare workers)

8. If no to question 7 above, what is the reason? [ ] Not aware

   [ ] Not informed by healthcare worker

   Health care worker initiated due to:

   [ ] Confirmed TB

   [ ] Suspected TB [

   ] Side effects

   [ ] Poor adherence

   Other (specify) _____

   Caregiver initiated due to:

   [ ] Side effects

   [ ] Pill burden

   [ ] Loss to follow-up

   [ ] Fear of drug resistance

   Other (specify) _____

9. a) History of TB preventive therapy use in the past 2 years. Yes [ ] No [ ]

   b) If yes, when was it started

   _____/ _____/ _____

   c) For how many months did the child take the TB preventive therapy _____months

10. If TB preventive therapy was not completed, what was the reason for non-completion?

    a) Health care worker initiated due to:_____

_____

(Confirmed TB, suspected TB, side effects, poor adherence)

Caregiver initiated due to: _____

_____

_____

(Side effects, pill burden, loss to follow-up, fear of drug resistance and other reasons. Specify)

CHILD'S CLINICAL INFORMATION

Current history of ;

Screening Questions	**Y/N**
Cough of any duration (Y/N)	
Fever (Y/N)	
Failure to thrive or poor weight gain (Y/N)	
Lethargy, less playful than usual (Y/N)	
****If "Yes" to any of the above questions, suspect TB, examine the child and use the paediatric TB diagnostic algorithm to evaluate for active disease. Rule out underlying conditions, refer if necessary***	

*If "No" to all questions, initiate workup for IPT and repeat screening on subsequent visits

Physical Examination:

MEDICAL RECORD (Measure of Outcome)

Abnormal Respiratory Signs	Y/N
Increased respiratory rate	
Respiratory distress	
Stony dull percussion note	
Added breath sounds (wheezing, crackles, bronchial breathing)	
If yes to any, refer to clinician for further evaluation	

The following information will be retrieved from the patient's records (i.e. ICF/IPT card, IPT register)

1. Date of TB preventive therapy initiation ____/____/_____
2. Reasons for not initiating TB preventive therapy?

_____

_____

_____

(Hepatitis, Peripheral neuropathy, TB preventive drugs out of stock, not documented, declined TB preventive drugs or other reasons. Specify.)

Appendix J

Questionnaire for TB index cases with children under five years household contacts – Kiswahili:

Matumiziyatibayakuzuiakifuakikuumiongonimwa Watoto wenyeumriwachiniyamiakatanokatikaKauntiya Mombasa

Asante kwakushirikikatikautafitihuu.

SEHEMU YA KWANZA

HABARI ZA MHOJIWA

NambariyaUtafiti: _____

Tarehe: _____

Nambariyasimu: _____

Jumlaya wiki ambazoumepokeamatibabuyakifuakikuu: _____

HABARI ZA KIDEMOGRAFIA

1. Je, kuna Watoto wenyeumriwachiniyamiakamitanokatikanyumbaunayoishi?

   [ ]Ndio [ ] Hapana

2. Iwapokunao, niwangapi? _____

3. Waorodheshekulingananaumriwao, kutoka yule mwenyeumrimdogokabisahadi ule wenyeumrimkubwakabisa?

Nambari	Mtotomwenye Umri wa Chini yamiaka 5	Umri katikamiezi	Idadi
01			
02			
03			
04			
05			
06			
07			
08			

09			
10			

4. Weweninanikwamtoto/Watoto hawa?
   [ ] Mama

   [ ]Shangazi

   [ ]Mjomba

   [ ]Binamu

   [ ]Nyanya/babu

   [ ] Kaka

   [ ]Mfanyikazi

   [ ]Uhusianomwingine (Taja) _____

5. Je, wewendiyemlezimkuu? [ ]Ndio [ ] Hapana

6. Hali yandoa: [ ] Sijaoa/Sijaoleka

   [ ]Nimeoa/Nimeoleka

   [ ]Tumeachana/Tumepeanatalaka

   [ ] Hali nyingene (Taja) _____

7. Je, kiwangochako cha elimunikipi? _____

8. Hali yaajira: [ ]Sijaajiriwa

   [ ]Nimeajiriwa

   [ ]Nimestaafu

   [ ] Mimi nimwanafunzi

   [ ] Hali nyingine (Taja) _____

9. Je,

   unafahamukuwakunatibayakuzuiakifuakikuukwawatotowenyeumrichiniyamiakamitano?

   _____

   _____

   (Ndio au Hapana. Taja)

10. Unaelewaninikuhusutibayakuzuiakifuakikuu? _____

    _____

    _____

    _____

11. Kama jibulakokatikaswalinambari 1 nindio, ulipatahabarihiziwapi?_____

    _____

    _____

    _____

    _____

    _____

    _____

    (Majibuyawezakuamhudumuwaafya, mshauriwarikalako, mitandaoyakijamii, marafiki au maeneomengine. Taja)

12. Je,

    kunamtotomwenyeumriwachiniyamiakamitanoambayeamewahitumiatibayakuzuiakifuakikuu? _____

(Ndio au Hapana. Taja)

13. IwapoumejibuNdiokatikaswalinambari 3,

    nikwaninimtotoalipewatibayakuzuiakifuakikuu?_____

    _____

    _____

    _____

    _____

    _____

    (mtafitianawezakuulizamaswaliilikupatataarifakwa kina)

14. Iwapoumejibuhapanakatikaswalinambari 3, nikwanini? _____

    _____

    _____

    _____

    _____

    (mtafitianawezakuulizamaswaliilikupatataarifakwa kina)

15. Je, kunanjiazingine, isipokuwakwakutumiadawa, za

    kuzuiamaambukiziyakifuakikuukwamtotowakoaliyenaumriwachiniyamiakamitano?

    _____

    (Ndio au Hapana. Taja)

16. Iwapoumejibundio, tajanjiazoteunazofahamu. _____

    _____

    _____

_____

_____

_____

_____

_____

(Kuna njiakamakuvaabarakoa, umbaliwakijamii, kutolalakwachumbakimojanamtotoaliyenaumrichiniyamiakamitano, kuhakikishakunauingizajiwahewakwachumba, adabu za kikohozi ama njiazinginemwafaka. Taja)

17. Kuna vyumba ngapi vyakulalakatikanyumbayako? _____
18. Watuwangapiwanaishikatikanyumbayako? _____
19. Je, huwaunalalakatikachumbakileambachomtoto/Watoto chiniyaumriwamiakamitanokatikanyumbayakohulala? _____ ***(Ndio au Hapana. Taja)***
20. Je, nichangamotozipizozoteumepatakufikahospitalini?_____

_____

_____

_____

(Changamoto za kifedha, changamoto za usafiri, changamoto za umbali, changamoto za kifamilia, changamoto za kikazi/kishule au changamotozingine. Taja)

21. Je, nichangamotoganiumekumbananazokatikakituohiki cha matibabuleo ama hapo mbeleni?_____

_____

_____

_____

_____

_____

_____

_____

(Laini ndefuyawagonjwa, wahudumuwaafyawakali/wakatili, hofuyaunyanyapaa, urasimukatikavituohivi, ukosefuwamadawa, au changamotozingine. Taja)

22. Je, unadhanikuwaserikalikupitiakwawizarayaafyaimefaulukatikakuhamasishawakenyakuhusutibayakuzuiakifuakikuumiongonimwawatotowenyeumriwachiniyamiakamitano? Kwa nini?***(Ndio au Hapana. Taja)***_____

_____

_____

_____

_____

23. Ni njiazipiambazounadhaniserikalikupitiakwawizarayaafyainawezakutumiailikuhamasishaw

akenyazaidikuhusutibayakuzuiakifuakikuumiongonimwa Watoto

wenyeumriwachiniyamiakamitano? _____

_____

_____

_____

_____

_____

_____

SEHEMU YA PILI (Kwa wale ambaoniwazazi/waleziwakuu)

HABARI ZA MTOTO

NambariyaUtafiti: _____

Tarehe: _____/_____/_____

TareheyaKuzaliwa: _____/_____/_____

Jinsia: [ ]Kiume [ ] Kike

1. Je, unafahamukuwakunatibayakuzuiakifuakikuukwa Watoto wenyeumrichiniyamiakamitano? _____ ***(Ndio au Hapana. Taja)***

2. Je, unaelewaninikuhusutibayakuzuiakifuakikuu? _____
   _____
   _____
   _____

3. Iwapoumejibundiokwaswalinambari 2, ulitoataarifahiziwapi? _____
   _____
   _____
   _____

   (Mtafiti anawezakuulizamaswalikwa kina ilikujuachanzo cha taarifahizi: mhudumuwaafya, mshauriwarika, mitandaoyakijamii, marafiki au mahalipengine [taja])

4. Je, nimuhimukuwapa Watoto wenyeumrichiniyamiakamitanotibayakuzuiakifuakikuu? ***(To examine attitude)***

   [ ]Ninakubalianakabisa [ ] Ninakubaliana [[ ] SinaUhakika]Sikubaliani [ ] Sikubalianikabisa

5. Je, unadhanikuwatibayakuzuiakifuakikuuinanguvu za kuzuiakifakikuukwamtoto/Watoto wako? ***(To examine attitude)***

   [ ]Ninakubalianakabisa [ ] Ninakubaliana [ ] SinaUhakika

   [ ]Sikubaliani [ ] Sikubalianikabisa

6. Je, unaweza kukubalimtoto/Watoto wakokupewatibayakuzuiakifuakikuu? ***(To examine attitude)***

   [ ]Ninakubalianakabisa [ ] Ninakubaliana] [ ] SinaUhakika

   [ ]Sikubaliani [Sikubalianikabisa

7. Je, mtotowakoanapokeatibayakuzuiakifuakikuukwawakatihuu?

   [ ]Ndio [ ] Hapana

   (Muonyeshemlezitembe/ainanyingineyadawa za kuzuiakifuukikuu, kamajibunihapana, rukahadiswalinambari 8)

   (Mzazi/mlezimkuuaonyeshe kadi yatibayakifuakikuu au Ushahidi wowotemwingineunaodhibitishakuwamtotoanapokeatibayakuzuiakifuakikuu)

   a) Kama ndio, ulimpakiwangokipi? _____ ***(Practice for parents/primary caregivers)***

   b) Ulimpatembe mara ngapi kwa siku? _____ ***(Practice for parents/primary caregivers)***

   c) Je, ulipewamaagizoyototekuhusujinsiyakumpatembehizi?

   _____

   (Ndio au Hapana. Taja. Practice for healthcare workers)

   d) Je, unampamtotowakopyridoxine?_____

   _____

   (Ndio au Hapana. Taja. Practice for healthcare workers)

   e) Katika wiki mbilizilizopita, mtotoamekosavipimo ngapi vyadawa? _____ ***(Adherence/ This is a patient-derived barrier)***

f) Je, niisharagani za ugonjwa au hadhara za dawaulifahamishwakuangaliakatikamtoto? _____ ***(Practice for healthcare worker)***

g) Uliambiwaumletewakokweny eklinikibaadayamudaupi? _____ ***(Follow-up/ Practice for healthcare workers)***

8. Iwapojibulako la swalinambari 7 nihapana, sababuyakonigani?

_____

_____

_____

(Sikufahamu, sikufahamishwanamhudumuwaafya)

Kulingananaushauriwamhudumawaafyakwasababuya:

[ ]Kuthibitishwakwamaambukiziyakifuakikuu
[ ]Kushukiwakuwanamaambukiziyakifuakikuu
[ ]Madharayadawa
[ ]Kutomezadawainavyostahili
[ ]Sababuzingine (taja) _____

Kulingananamaoniyamlezikwasababuya:

[ ]Madhara

[ ] Wingi watembe

[ ]Kutoendeleakujakliniki

[ ]Hofuyadawakukataakufanyakazi

Sababuzingine (taja) _____

9. a) Je, mtotoamepatatibayakuzuiakifuakikuukatikamiakamiwiliiliyopita? _____

(Ndio au Hapana. Taja.)

b) Kama jibunindio, matibabuhayayalianzatarehegani?_____/ _____/ _____

c) Mtotoalipatatibayakuzuiakifu akikuukwamiezi ngapi? _____

10. Iwapotibayakuzuiakifuakikuuhaikukamilishwainavtostahili, nikwanini? (Chagua)

a) Kulingananaushauriwamhudu mawaafyakwasababuya[ ]Kuthibitishwakwamaambukiziyakifuakikuu [ ] Kushukiwakuwanamaambukiziyakifuakikuu [ ] Madharayadawa[ ]Kutomezadawainavyostahili [ ] Sababuzingine (taja) _____

b) Kulingananamaoniyamlezikw asababuya: Madhara[ ] Wingi watembe [ ] Kutoendeleakujakliniki [ ] Sababuzingine (taja) _____

HABARI YA KLINIKI YA MTOTO

Je, mtotoanalalamikia ama umewezakuonayafuatayokatikamtotowako? ;

MaswaliyaUkaguzi	**Ndio/Hapana**
Kukohoa (Ndio/Hapana)	

Joto yamwilini (Ndio/Hapana)	
Kupotezaratili au Kutoongezauzitojinsiinavyofaa (Ndio/Hapana)	
Uchovu au upungufuwauchangamfu (Ndio/Hapana)	
Iwapojibuni "Ndiokwamaswaliyoyotehapojuu, shukukuwamtoto ana kifuakikuu, mkaguezaidinatumiavielekezovya TB diagnostic algorithm kutathminiiwapomtoto ana ugonjwawakifuakikuu.	

REKODI YA MATIBABU (Measures of Outcome)

Habari yaifuatayoitatolewakwarekodi za mgonjwa (Kwa mfano kadi ICF/IPT, sajiliya IPT)

1. Tareheyakuanzakwatibayakuzuiakifuakikuu ____/____/_____
2. Sababu za kutoanzatibayakuzuiakufuakikuu?

   _____

   _____

   _____

   (Hepatitis, Peripheral neuropathy, Dawa za tibayakuzuiakifuakikuukutokuwepo, sababuhaikuandikwa, mlezialikataatibayakuzuiakifuakikuu au sababuzingine. Taja)

Appendix K

Healthcare Worker Questionnaire

Thank you for participating in this study.

DEMOGRAPHICS

Date: _____/_____/_____ Age: _____ Sex: [ ] Male [ ] Female

Current position held: [ ] Medical Officer Intern

[ ] Medical Officer

[ ] Clinical Officer Intern

[ ] Registered Clinical Officer

[ ] Consultant

[ ] Nurse

KNOWLEDGE

1. Can TB be prevented using medicine? Yes [ ] No [ ]
2. If yes, which and how many drugs do you know that can be used to prevent TB in children under 5 years of age?

   _____

   _____

3. From the above drugs, which formulations are available?
   a) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   b) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   c) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   d) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup

4. Of the drugs that are dispersible, which fluids are acceptable?_____

   _____

5. Which children under 5 years of age are eligible for TB preventive therapy drugs?_____

   _____

6. How would you screen/evaluate these children for eligibility for TB preventive therapy drugs?_____

   _____

   _____

   _____

   _____

7. How do you rule out active TB in those eligible for TB preventive therapy drugs?___

   _____

   _____

   _____

   _____

   _____

8. From the drugs you mentioned above, fill in the following regarding children under 5 years?

Drug Name	Frequency	With or Without food	Adverse Effects to counsel parent on	Duration	Timing o f follow up while on TPT

9. Are you aware of TB preventive drug dose charts by weight band?

[ ] Yes [ ] No

10. If yes, where can you find these TB preventive therapy drug dose charts by weight band?_____

_____

For a child weighing 5kg, how much drug would you give from the chart below**?**_____

B. Daily Drug W			
Weight (kg)	**Dose (mg)**	**Number of 100mg tablets**	**Number of 300mg (Adult) tablet**
<5	50	½ tablet	-
5.9 – 9.9	100	1 tablet	-
10 – 13.9	150	1 ½ tablet or	½ tablet
14 – 19.9	200	2 tablets	-
20 – 24.9	250	2 ½ tablets	-

≥25	300	3 tablets or	1 tablet
Adult	300	3 tablets or	1 tablet
Note: Syrup (50mg/ml) is available for younger children			
B1. Daily Drug X for children <25kgs			
Weight (kg)	**Number of tablets (75/50mg)**	**How to reconstitute the medicine**	
Less than 2	¼	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 5 ml (¼) of this solution measured with a syringe.	
2–2.9	½	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 10 ml (½) of this solution measured with a syringe.	
3-3.9	¾	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 15 ml (¾) of this solution measured with a syringe.	
After giving the child their dose for that day, discard the rest of the solution. Prepare a fresh solution every day.			
4–7.9	1	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give all this solution to the child.	
8 – 11.9	2		
12 – 15.9	3		
16 – 24.9	4		
>25	Use adult formulations		
B2. Daily Drug X for children ≥25kgs (To use Adult formulation)			
Weight (kg)	**Number of tablets (150/75 mg)**		
25 – 39.9	2		

40 – 54.9	3
55kg and above	4

C. Weekly Drug Y (For adults and adolescents ≥15 years)

Drug Y products	**No. of Tablets**
Drug Y1 150mg tabs	6
Drug Y2 300mg tabs	3
Drug Y1 300mg + Drug Y2 300mg (FDC)	3

D. Dosage of Drug Z

Weight (kg)	**Dosage in mg**	**Number of 25mg tablets**	**Number of 50mg tablets**
<5	6.25 mg	½ tablet 3 times a week, alternate days	-
5.0 – 7.9	12.5 mg	½ tablet	-
8.0 – 14.9	25 mg	One tablet	½ of 50 mg tablet
15kg and above	50 mg	Two tablets	One 50 mg tablet

11. Should pyridoxine be given with TB preventive therapy drugs? [ ] Yes [ ] No

12. If yes, to whom?_____

13. According to our guidelines Pyridoxine is given to all children? [ ] Yes [ ] No

14. Are you aware of any guidelines on prevention of TB? Yes [ ] No [ ]

15. In Kenya, TPT is guided by ? [ ] WHO Guidelines

[ ] Kenya MOH Guidelines

[ ] Both

16. During follow up, which 4 of the following signs and symptoms should we look out for according to the National/WHO guidelines? [ ] Fever

[ ] Weight loss

[ ] Lethargy/Reduced playfulness/activity

17. For child household contacts of bacteriologically confirmed TB, a child with any of the following 4 should be referred for evaluation:

[ ] Temperature 37.5

[ ] Poor weight gain/Weight loss

[ ] Increased respiratory rate

[ ] Temperature 38.0

[ ] Any abnormal respiratory system findings

18. Where did you get this information?

[ ] Training

[ ] Colleague

[ ] Media

Other (specify) _____

ATTITUDE

1. With regards to child household contacts under 5 years exposed to adolescent/adult bacteriologically confirmed pulmonary TB:

   a) All eligible children should receive TB preventive therapy drugs

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   b) TB preventive therapy drugs are effective.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   c) TB preventive therapy drugs are safe.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   d) Drug resistance is a major concern when prescribing TB preventive therapy drugs.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   e) The risks of giving TB preventive therapy drugs outweigh the benefits.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   f) You comply with the Kenyan guidelines on TPT in children under 5 years.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

   g) TPT reduces TB incidence and mortality.

   [ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

h) It is preferable to wait until a child under 5 years contracts TB and then treat them rather than administer prophylaxis.

[ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

i) You are comfortable prescribing TB preventive therapy drugs.

[ ] Strongly Agree [ ] Agree [ ] Not sure [ ] Disgree [ ] Strongly Disagree

PRACTICE

1. With regards to bacteriologically confirmed adolescent/adult index cases:

a) Do you inquire if index cases have child household contacts under 5 years?

[ ] Yes, always [ ] Sometimes [ ] No

b) Do you ask if their child household contacts under 5 years have symptoms suggestive of active TB?

[ ] Yes, always [ ] Sometimes [ ] No

c) Do you educate them about TB preventive therapy drugs?

[ ] Yes, always [ ] Sometimes [ ] No

d) Do you advise them to bring their child household contacts under 5 years for assessment and evaluation?

[ ] Yes, always [ ] Sometimes [ ] No

e) Do you use the TB symptom screening according to WHO to assess them for active TB?

[ ] Yes, always [ ] Sometimes [ ] No

f) When prescribing TB preventive drugs to child household contacts under 5 years, do you counsel the parents/caregivers on potential side effects to look out for?

[ ] Yes, always [ ] Sometimes [ ] No

g) When prescribing TB preventive drugs to child household contacts under 5 years, do you counsel the parents/caregivers on adherence?

[ ] Yes, always [ ] Sometimes [ ] No

h) During follow up clinics,do you monitor those children under 5 years on TPT for side effects?

[ ] Yes, always [ ] Sometimes [ ] No

i) In case a child under 5 years on TB preventive therapy drugs cannot come for the follow up clinics, do you engage community health workers?

[ ] Yes, always [ ] Sometimes [ ] No

BARRIERS

23. Is it difficult to rule out active TB to decide to start TB preventive therapy drugs?

_____

24. Do you have TB diagnosis tools at your disposal?

_____

25. Has there been any stock-out of TB preventive therapy drugs at your health facility in the last 3 months? _____

26. Is improving TPT uptake rates at your facility discussed by your supervisor?

_____

27. Do you feel that TB preventive therapy drugs increase the risk of drug resistance in eligible children under 5 years?

_____

28. Do you feel that the side effects of TB preventive therapy drugs are a serious risk to children under 5 years even if they are eligible for TPT?

_____

29. Do you feel that adherence to TB preventive therapy drugs is poor among children under 5 years?_____

30. Is TPT failure is high among the child household contacts under 5 years in your care?_____

31. Do u think the government through the Ministry of Health has succeeded in creating awarenes on TPT for under five? Why?

_____

_____

_____

_____

_____

32. In your opinion, which ways can the government through the Ministry of Health employ to improve awareness on TPT for children under 5 years? _____

_____

_____

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_____

Appendix L

Key Informant Interview Guide

Thank you for participating in this study.

Date: _____/_____/_____ Age: _____ Sex: [ ] Male [ ] Female

Current position held: [ ] Regional Tuberculosis Coordinator

[ ] Pharmacy in-charge

[ ] Tuberculosis Clinic in-charge

[ ] Community Health Worker

KNOWLEDGE

1. Can TB be prevented using medicine? Yes [ ] No [ ]
2. If yes, which and how many drugs do you know that can be used to prevent TB in children under 5 years of age?

   _____

   _____

3. From the above drugs, which formulations are available?
   e) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   f) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   g) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
   h) Drug Name: _____ [ ] Tab [ ] Dispersible Tab [ ] Syrup
4. Of the drugs that are dispersible, which fluids are acceptable?_____

   _____

5. Which children under 5 years of age are eligible for TPT? _____

_____

6. How would you screen/evaluate these children for eligibility for TPT?_____

_____

_____

_____

_____

_____

_____

7. How do you rule out active TB in those eligible for TPT?_____

_____

_____

_____

_____

_____

_____

8. From the drugs you mentioned above, fill in the following regarding children under 5 years? (***To be filled by nurses***)

Drug Name	Frequency	With or Without food	Adverse Effects to counsel parent on	Duration	Timing o f follow up while on TPT

9. Are you aware of TB preventive drug dose charts by weight band?

[ ] Yes [ ] No

10. If yes, where can you find these TPT drug dose charts by weight band?

_____

_____

_____

_____

For a child weighing 5kg, how much drug would you give from the chart below***?***

_____

C. Daily Drug W			
Weight (kg)	**Dose (mg)**	**Number of 100mg tablets**	**Number of 300mg (Adult) tablet**
<5	50	½ tablet	-
5.9 – 9.9	100	1 tablet	-
10 – 13.9	150	1 ½ tablet or	½ tablet

14 – 19.9	200	2 tablets	-
20 – 24.9	250	2 ½ tablets	-
≥25	300	3 tablets or	1 tablet
Adult	300	3 tablets or	1 tablet
Note: Syrup (50mg/ml) is available for younger children			

B1. Daily Drug X for children <25kgs

Weight (kg)	Number of tablets (75/50mg)	How to reconstitute the medicine
Less than 2	¼	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 5 ml (¼) of this solution measured with a syringe.
2–2.9	½	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 10 ml (½) of this solution measured with a syringe.
3-3.9	¾	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give 15 ml (¾) of this solution measured with a syringe.
After giving the child their dose for that day, discard the rest of the solution. Prepare a fresh solution every day.		
4 – 7.9	1	Dissolve one tablet in 20 ml of safe drinking water. Once fully dissolved, give all this solution to the child.
8 – 11.9	2	
12 – 15.9	3	
16 – 24.9	4	
>25	Use adult formulations	

B2. Daily Drug X for children ≥25kgs (To use Adult formulation)

Weight (kg)	Number of tablets (150/75 mg)
25 – 39.9	2
40 – 54.9	3
55kg and above	4

E. Weekly Drug Y (For adults and adolescents ≥15 years)

Drug Y products	No. of Tablets
Y1 150mg tabs	6
Y2 300mg tabs	3
Y1 300mg + Y2 300mg (FDC)	3

F. Dosage of Drug Z

Weight (kg)	Dosage in mg	Number of 25mg tablets	Number of 50mg tablets
<5	6.25 mg	½ tablet 3 times a week, alternate days	-
5.0 – 7.9	12.5 mg	½ tablet	-
8.0 – 14.9	25 mg	One tablet	½ of 50 mg tablet
15kg and above	50 mg	Two tablets	One 50 mg tablet

11. Should pyridoxine be given with TB preventive therapy drugs? [ ] Yes [ ] No

12. If yes, to whom?_____

13. According to our guidelines Pyridoxine is given to all children? [ ] Yes [ ] No

14. Are you aware of any guidelines on prevention of TB? Yes [ ] No [ ]

15. In Kenya, TPT is guided by which guidelines?_____

_____

16. During follow up, which 4 signs and symptoms should we look out for according to the National/WHO guidelines? _____

_____

_____

_____

_____

17. For child household contacts of bacteriologically confirmed pulmonary TB,which 4 things do you check for during physical examination? _____

_____

_____

_____

_____

18. a) Are you aware of any guidelines on prevention of TB?_____

b) If yes, which ones? _____

_____

19. Where did you get this information? _____

ATTITUDE

1. a) What is your opinion on TPT? _____

   _____

   b) What makes you feel that way?_____

   _____

2. How effective is IPT?_____

   _____

   _____

   _____

3. a) Can a child on TB preventive therapy drugs develop drug resistance to TB drugs?

   [ ] Yes [ ] No

   b)What are the chances of a child on TPT developing drug resistance to TB Drugs?____

   _____

   _____

4. How comfortable are you giving TB preventive therapy to child household contacts of bacteriologically confirmed adolescent/adult pulmonary TB index cases? _____

   _____

5. How easy is it to follow TB preventive therapy guidelines? _____

   _____

6. a) It is preferable to wait until a patient gets TB and then treat rather than administer prophylaxis? [ ] Yes [ ] No

   b) If yes, why? _____

   _____

   _____

_____

_____

PRACTICE

1. Have you ever started a child under 5 years on TB preventive therapy?

_____ ***(Yes or No)***

2. If yes, did you counsel the parent/primary caregiver on side effects of TB preventive therapy? _____ ***(Yes or No)***

3. If yes to question 1 above, did you counsel the parent/primary caregiver on side adherence to TB preventive therapy? _____ ***(Yes or No)***

4. If yes to question 1 above, did you counsel the parent/primary caregiver on when to come for the follow up clinic? _____ ***(Yes or No)***

5. Have you ever referred a child under 5 years for TB preventive therapy?

_____ ***(Yes or No)***

6. Have you ever renewed an TPT prescription? _____ ***(Yes or No)***

7. Have you renewed an TPT prescription in the past 1 year? _____ **(Yes or No)**

8. If yes what were your primary considerations?

_____

_____

_____

_____

_____

_____

BARRIERS

1. How is the availability of TB preventive therapy drugs? _____

   _____

2. Has there been any stock-out of TB preventive therapy drugs at your health facility in the last 3 months?

   [ ] Yes [ ] No

3. What was/were the reason(s) for the unavailability of TB preventive therapy drugs?

_____

_____

_____

_____

_____

4. If yes, why do you feel so? _____

   _____

   _____

   _____

5. Which TB diagnosis tools do you have at your disposal? _____

   _____

   _____

_____

_____

_____

_____

(The researcher can probe further to find out which TB diagnosis tools are available such as X-Ray services, Mantoux test, sputum smear for Ziehl Neelsen [Z-N] or fluorescent staining, Sputum culture, GenExpert, IGRA etc.)

6. Do you feel that TB preventive therapy drugs increase the risk of drug resistance in eligible children under 5 years?

_____

7. Do you feel that the side effects of TB preventive therapy drugs are a serious risk to children under 5 years even if they are eligible for TPT?

_____

8. Do you feel that adherence to TB preventive therapy drugs is poor among children under 5 years?_____
9. Is TPT failure is high among the child household contacts under 5 years in your care? If yes, why?_____

_____

_____

10. Do u think the government through the Ministry of Health has succeeded in creating awarenes on TPT for under five? Why?

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11. In your opinion, which ways can the government through the Ministry of Health employ to improve awareness on TPT for children under 5 years? _____

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