# PREVALENCE AND FACTORS ASSOCIATED WITH INITIATION OF ISONIAZID PREVENTIVE THERAPY AMONG CHILDREN BELOW FIVE YEARS LIVING WITH PERSONS DIAGNOSED WITH PULMONARY TUBERCULOSIS IN KISUMU COUNTY, KENYA

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# Prevalence and Factors Associated with Initiation of Isoniazid Preventive Therapy among Children below Five Years Living with Persons Diagnosed with Pulmonary Tuberculosis in Kisumu County, Kenya

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**A Thesis Submitted in Partial Fulfilment for the Requirements of the Degree of Master of Science in Public Health of the Jomo Kenyatta University of Agriculture and Technology**

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## DECLARATION

This thesis is my original work and has not been submitted for a degree in any University.

Signature……. Date ……..

**Eunice Akinyi Ouma**

This thesis has been submitted for examination with our approval as the university supervisors.

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## DEDICATION

I dedicate this thesis to my sons Tim, Ethan and Teo who have been my source of inspiration and to every child who has borne the burden of taking Isoniazid in the fight against Tuberculosis.

## ACKNOWLEDGEMENT

I sincerely thank the Almighty God for enabling me carrying out this research, my supervisors Prof. Gideon Kikuvi and Dr. Walter Otieno for their immense support and guidance throughout the study, my research assistants who took their time to collect the data not forgetting my respondents and my family for their prayers and encouragement throughout the study.

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## ABREVIATIONS AND ACRONYMS

| | |
|---|---|
| **AIDS** | Acquired Immune-Deficiency Syndrome |
| **BCG** | Bacille Calmette Guerin |
| **DLTLD** | Division of Leprosy, Tuberculosis and Lung Disease |
| **DOTS** | Directly Observed Therapy Short Course |
| **EPTB** | Extra Pulmonary Tuberculosis |
| **HCWs** | Healthcare workers |
| **HIV** | Human immune-deficiency virus |
| **HTC** | HIV testing and counseling |
| **INH** | Isoniazid |
| **IUATLD** | International Union against Tuberculosis and Lung Disease |
| **JOOTRH** | Jaramogi Oginga Odinga Teaching and Referral Hospital |
| **KAIS** | Kenya AIDS Indicator Survey |
| **KCH** | Kisumu County Hospital |
| **KNBS** | Kenya National Bureau of Statistics |
| **LMICs** | Low and Middle-Income Countries |
| **MDG** | Millennium Development Goals |
| **MOH** | Ministry of Health |
| **NASCOP** | National AIDS and STI control Programme |

| | |
|---|---|
| **NLTD** | National Lung and Tuberculosis Disease-Unit |
| **PLHIV** | People Living with HIV/AIDS |
| **PT** | Preventive Therapy |
| **PTB** | Pulmonary Tuberculosis |
| **SAE** | Serious Adverse Event |
| **TB** | Tuberculosis |
| **UNAIDS** | United Nations Programme on HIV and AIDS |
| **WHO** | World Health Organization |

## DEFINITION OF TERMS

**Active TB patient** refers to a person diagnosed with TB through radiological or biological methods and will be undergoing treatment for TB at the time of study. They usually manifest signs and/or symptoms of TB.

**Continuation phase** refers to the next 4 or 6 months of TB treatment after the intensive phase, duration of treatment depends on whether a patient is undergoing treatment for the first or subsequent time.

**Healthcare provider characteristics** refers to professional qualification, age, gender, years of work in TB-HIV clinic, special training on IPT and other health related factors that would influence IPT initiation.

**Household contacts** refer to all people who live together in the same house with the person who has PTB at least 1 month prior to TB diagnosis and during the period of illness.

**Household level factors** refers to those attributes such as age, sex, level of education and phase of TB treatment of the person with PTB that would influence IPT initiation in an exposed child.

**Intensive phase** refers to the first 2 months of treatment with anti-TB drugs.

**Isoniazid preventive therapy** refers to issuing Isoniazid (INH) to a patient with latent TB with the aim of minimizing chances of progressing to active TB.

| | |
|---|---|
| **Latent TB** | refers to a state where one has been infected with the TB causing bacteria but has no signs nor symptoms of TB disease. |

## ABSTRACT

Kenya is among the 10 out of 22 countries heavily burdened with Tuberculosis (TB) worldwide with an estimated prevalence of 266 per 100,000. Kisumu County is a TB and Human Immunodeficiency Virus (HIV) endemic zone with a prevalence of 208-306 per 100,000 and 19.3% respectively. The WHO, 2008 policy document advocated for initiation of Isoniazid Preventive Therapy (IPT) among children aged below 5 years who are household contacts of sputum positive pulmonary tuberculosis (PTB) persons. IPT prevents progression from latent TB to active TB disease. Despite the adoption and scale up of IPT policy in Kenya, initiation of children aged below 5 years in Kisumu County remains low hampering END TB elimination and control strategies. Moreover, there is paucity of data exploring the levels of IPT initiation and associated factors among children aged below 5 years in this setting. This study was conducted to determine prevalence of IPT initiation and factors associated with IPT initiation among children aged below 5 years who live in households with sputum positive PTB persons. The study was carried out at Jaramogi Oginga Odinga Teaching and Referral hospital, Kisumu County hospital, Lumumba, Migosi, and Rabuor sub-county hospitals. The research applied the cross-sectional study design. Consequently, purposive sampling was used to recruit sputum positive PTB persons (n=175) and TB clinic staff (n=35) to whom structured questionnaires were administered. Fisher's exact test was used to determine the association between categorical variables and initiation of IPT. Generalized linear model (log, negative binomial) was used to estimate the prevalence rate ratio of IPT Initiation. The $\alpha$ level of significance was set at $p<0.05$ and data was analyzed using STATA (version 14.1). The mean age of respondents was [33±SD 11.2]. Prevalence of IPT initiation was established as [70.2%; 95% C.I (63.0-76.6)] with the female respondents more likely to initiate their children on IPT [72.6%; 95% C.I (67.7-80.7)]. Multivariate prevalence rate ratio showed that respondents aged less than 25 years [aPR=1.43; 95% C.I (1.13-1.83)] were more likely to initiate the children on IPT than those aged >40 years. Respondents who resided in urban areas [aPR=1.56; 95% C.I (1.22-2.00)] and peri-urban areas [aPR=1.63; 95% C.I (1.43-1.87)] were more likely to initiate children on IPT compared to those in rural areas. Respondents with more than 5 persons in the household [aPR=2.02; 95% C.I (1.26-3.23)] were more likely to initiate children on IPT compared to those with 1-2 persons in the households. Respondents who had an average contact of 3-6 hours during the day [aPR=1.74; 95% C.I (1.11-2.73)] and >6 hours contact [aPR=1.66; 95% C.I (1.06-2.58)] were more likely to initiate the children on IPT compared to those with less than 3 hours contact time. Respondents who slept with the children in the same room [aPR=1.50; 95% C. I (1.22-1.85)] were more likely to initiate the children on IPT compared to those who did not sleep with them in the same room. The Ministry of health (MOH) and collaborates should advocate for health promotion activities unlimited to sensitization among sputum positive PTB persons with children aged below 5 years to help bolster IPT initiation in rural areas. Nonetheless, further studies need to examine the correlates of IPT initiation and predictors of missed opportunity to IPT initiation among children aged below 5 years sputum positive PTB persons.

# CHAPTER ONE

# INTRODUCTION

## 1.1 Background Information

Tuberculosis (TB) remains a major global public health problem, recognized as being second only to HIV/AIDS as the greatest cause of mortality. It is a bacterial airborne disease caused by an infectious agent, *Mycobacterium tuberculosis* and is the leading cause of morbidity and mortality among people living with HIV (PLHIV) worldwide (Zumla *et al.*, 2015). This makes TB an important public health problem that requires intervention.

According to WHO 2015 report, globally there were an estimated 9.6 million incident cases of TB, equivalent to 133 cases per 100,000 populations in 2014. 85% of these cases occurred in the developing world with Asia and African regions each contributing 58% and 28% respectively. Overall, 83% of all TB cases in 2014 reportedly occurred in the 22 high burden countries. Of these countries, 9 are found in Africa and include South Africa, Nigeria, Ethiopia and Kenya among others.

According to WHO report of 2016, globally, 10.4 million people were estimated to have fallen ill with TB in 2015, among which one million (10%) were children. TB remained among the top ten causes of mortality globally in the same year (WHO, 2016) with an estimated 1.4 million people dying from this preventable, treatable and curable disease. Kenya continues to bear the regional burden of TB disease. In 2015, Kenya reported nearly 7,000 TB cases among under 5 year olds TB in children (DLTLD, 2015).

Isoniazid preventive therapy is the use of Isoniazid (INH) to sterilize latent infection with *Mycobacterium tuberculosis* and thus prevent progression to active disease. Prophylaxis with INH has been demonstrated to significantly reduce the incidence of TB in children aged below five years who are household contacts of sputum positive PTB persons and in people living with HIV (PLHIV) through prevention of disease progression.

The WHO and International Union Against TB and Lung Disease (IUATLD) recommend TB preventive therapy in HIV infected persons, children below five years exposed to active sputum positive adults diagnosed with TB among others. Children are highly susceptible to TB infection, which mostly occurs following exposure from an infectious adult (WHO, 2011). Once exposed children are at a higher risk of progressing to TB disease. The scenario is worsened when coupled with HIV infection. HIV infection alone will increase the risk of a HIV positive individual getting TB by a factor of 30, as compared to a HIV negative individual. There is therefore an urgent need to protect this highly susceptible group.

In Kenya, TB is the leading cause of morbidity and mortality among persons infected with HIV. Kenya is one of the 22 high TB burden countries in the world with a national prevalence of 266 (range 189-281) per 100,000 population, and an incidence of 81,518 (MOH, 2015). Forty-five percent (36,817) were new sputum positive cases. Children contributed 8.5% (6,968) with county variations ranging from 4.6% in Murang'a to 17.8% in Turkana; 52.6% of the children being below the age of 5 years, and 47.4% between 5-14 years of age.

Recognizing the high prevalence of TB in the country, especially in the wake of HIV epidemic, and in line with WHO's interim policy on TB and HIV collaborative activities, The Kenya Ministry of Health (MOH) through the National Tuberculosis, Leprosy and Lung Disease (NTLD) unit, recommends IPT for all children below the age of five years who are in close contact with an infectious smear or culture positive TB case. According to WHO report of 2016, about 1.2 million children aged 5 years and below were household contacts of sputum positive pulmonary TB patients and hence were eligible for IPT, however only 87,236 children (7.1%) were initiated on IPT.

The status of Isoniazid Preventive Therapy (IPT) initiation against tuberculosis (TB) among children under five years of age in Africa is still behind other regions of the world. According to the World Health Organization, only 17% of African countries reported initiating IPT against TB in children under five years of age in 2017. In addition, the coverage of IPT in Africa is estimated to be much lower than the global average of 29%. This means that most children in Africa are not receiving the recommended IPT against TB. Inadequate resources and funding are major barriers to

the implementation of IPT, as well as a lack of awareness among healthcare providers and caregivers.

Similarly, Isoniazid Preventive Therapy (IPT) initiation against Tuberculosis (TB) among children under 5 years in East Africa is still low. While there has been steady progress in recent years, only a small percentage of eligible children are receiving IPT. In many countries, the number of eligible children receiving IPT is still below 20%. Several contributing factors have been identified that limit the initiation of IPT in East Africa. These include inadequate health infrastructure, limited access to health services, inadequate health staff training, and limited resources for TB control. Additionally, many parents are unaware of the benefits of IPT for their children, and healthcare providers often lack the skills and knowledge to properly diagnose and treat TB in young children.

While it is highly recommended for high-risk groups, including young children under five years of age, initiation of IPT in Kenya remains low. The initiation of IPT in children is still low with a national initiation of 5.5% among children aged below five years with a household contact of sputum positive PTB against an adult initiation of 33% (DLTLD, 2015). This demonstrates the need for IPT to be met by the country, especially Kisumu County, one of the high TB burden regions in Kenya. As of 2015, it is estimated that only 18% of eligible children under five years have been initiated on Isoniazid Preventive Therapy in Kisumu. This figure is far below the WHO recommended target of 80%. As a result, this study determines the prevalence of IPT initiation and factors associated with IPT initiation among children aged below 5 years who live in households with sputum positive PTB persons.

### 1.2 Statement of the Problem

Children especially pre-school age spend a lot of time with their family members who may be a source of TB infection. This risk often depends on the child's age and the status of the sputum smear of the adult diagnosed with TB. Consequently, the World Health Organization recommends that every child below the age of five who has a household contact with an infectious TB case should receive IPT for at least six months after the active TB disease is ruled out. The National Tuberculosis Program has

implemented strategies that target high-risk groups, such as children to ensure that they are tested for TB and receive appropriate treatment, including IPT. Moreover, Kenya Expanded Programme for Immunization among other programs have also been adopted to assist improve the outcome of IPT initiation. A child's risk of developing TB can therefore be minimized by approximately 60%.

Nonetheless, initiation of Isoniazid Preventive Therapy among children below five years is still a huge public health concern in Kenya. In 2015, Kenya reported 6,968 cases (8.5%) of TB in children aged 0-14 years of which 52.6% of the cases occurred among those below 5 years of age. A higher rate of mortality, 5.2%, was also reported among children aged below five years compared to older children aged 6-14 years who had a mortality rate of 4.6% (Owiti *et al.*, 2015). As of 2015, it was estimated that only 18% of the estimated proportion of eligible children under five years have been initiated on Isoniazid Preventive Therapy in Kisumu County. This figure is far below the WHO recommended target of 80%.

Determining and addressing the factors associated with initiation of Isoniazid Preventive Therapy among children aged below five years who are household contacts of smear positive PTB persons assists in monitoring progress towards achieving SDG 3, target 3.3 that intends to achieve 80% and 90% reduction in the TB incidence death rates respectively by 2030 globally and in this case, Kisumu County. Many studies have been conducted to assist in explaining the factors associated with initiation of IPT among children under five, but there is paucity of knowledge on the factors that impede the initiation of IPT in Kisumu County both at household and facility levels.

Therefore, the aim of the study is to determine factors associated with initiation of Isoniazid Preventive Therapy among children aged below five years who are household contacts of smear positive PTB persons to strengthen public health intervention and improve the outcomes of IPT initiation.

### 1.3 Justification of the study

Whereas national guidelines are clear on IPT provision in healthcare settings, it is not however clearly known the extent to which adults with smear positive PTB or healthcare level factors would influence initiation of IPT within the confines of a TB

clinic. Reports of IPT initiation in resource poor settings are scarce, and where available, they are poorly documented. Additionally, different circumstances in relation to patient service needs at the time of presentation to a health service point may determine the acceptance or decline of IPT for children. Furthermore, information about the status of actual IPT initiation among children less than five-year-old exposed to adults with sputum positive TB in Kisumu County is still minimal. An insight to the household, healthcare level factors that would influence initiation of IPT among children below five years exposed to sputum positive TB will assist healthcare workers in provision of quality TB prevention services. Parents and other adult clients would use the same information to ask about IPT whenever they visit the clinic. Insights on prevalence inform healthcare policies, identify areas of improvement, and develop strategies to improve access to IPT among children in this age group. Additionally, the study highlighted gaps in healthcare level characteristics that require strengthening to achieve targeted levels of IPT in children. Insights on prevalence.

## 1.4 Objectives

### 1.4.1 Broad Objective

To determine the prevalence and factors associated with initiation of Isoniazid Preventive Therapy among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County

### 1.4.2 Specific Objectives

1. To determine the prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County.
2. To determine the household level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County.
3. To determine the healthcare level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County.

## 1.5 Research questions

1. What is the prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County?
2. What are the household level factors associated with IPT initiation among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County?
3. What are the healthcare level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons in Kisumu County?

## 1.6 Limitations of the study

1. The study was conducted in a few selected hospitals due to time and cost constraints.
2. The selected facilities might have served different catchment areas.

## 1.7 Conceptual/Operational Framework

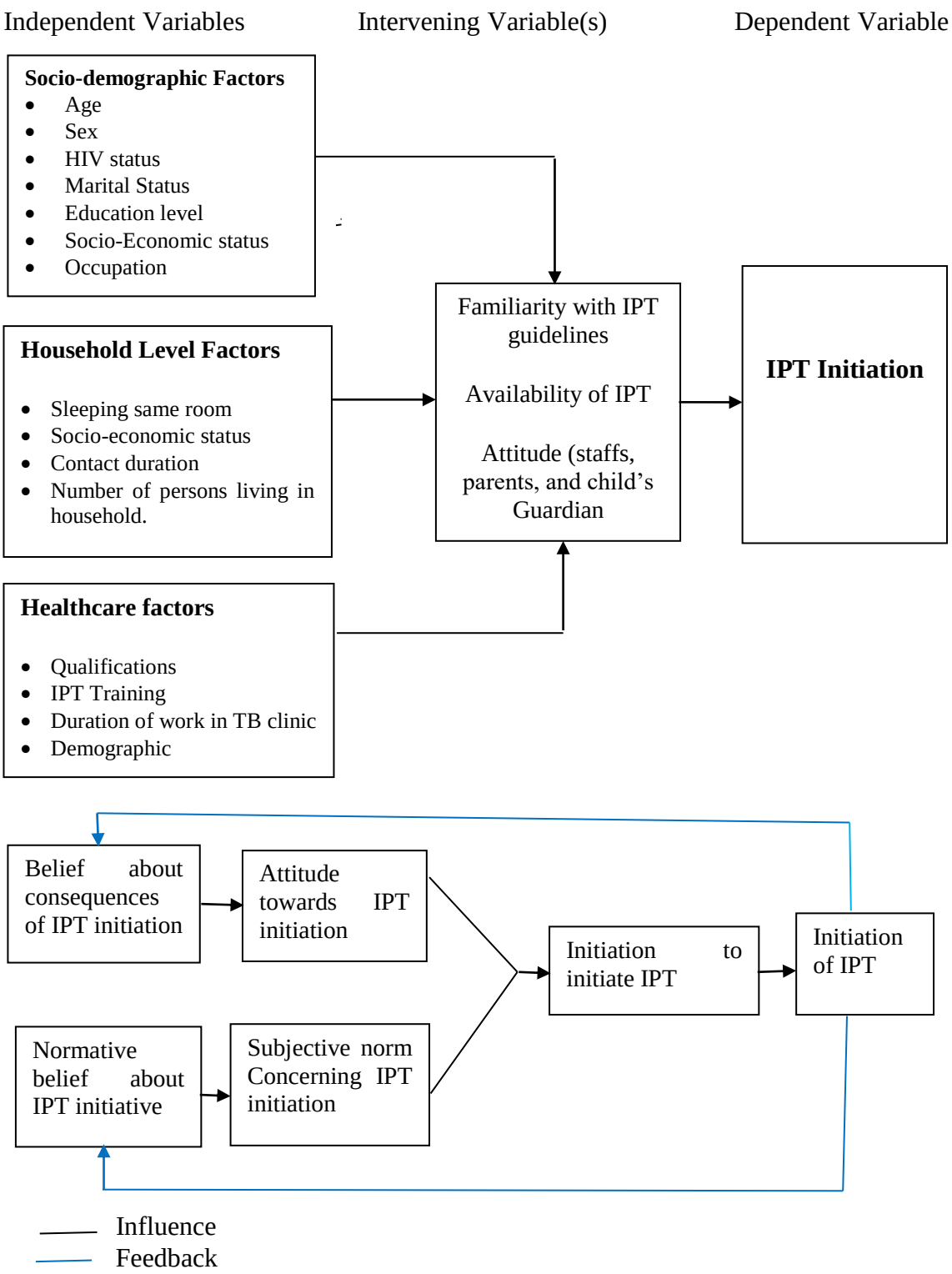


**Figure 1.1: Conceptual Framework**

# CHAPTER TWO

# LITERATURE REVIEW

## 2.1 Aetiology, Mode of Transmission and Management of TB

Tuberculosis is an infectious disease whose causative agent is commonly the bacillus *Mycobacterium tuberculosis*. Other causative agents of Tuberculosis include *Mycobacteria africanum*, *Mycobacteria bovis* and *Mycobacteria microti*. It typically affects the lungs but can affect other sites as well. *Mycobacterium is* a widespread bacterial pathogen that is capable of prolonged survival within individuals in a state of latency or inactivity (Banu, 2009). TB is transmitted primarily by airborne droplets from person to person, and an infection is acquired when a person with active TB disease expel the bacteria in the air often during coughing. Transmission through the gastrointestinal tract and transdermally have also been reported. Factors that determine the transmission rate of Tuberculosis include the amount of bacilli expelled, the length of time an individual is exposed to air that contains the bacilli and the immunity of the exposed person (Herchline, 2016). Generally, nearly 90% of those infected with latent TB will never become ill (WHO, 2004). However, under certain conditions, the risk of progression to active TB disease is increased by factors such as smoking, alcohol consumption, malnutrition, poor ventilation, overcrowding, HIV infection, diabetes mellitus, Intravenous drug use, immunosuppressive therapy, end stage renal disease, low body weight, chronic malabsorption syndrome, age below five years and malignancies (Herchline, 2016).

TB in children is often difficult to diagnose given that they hardly expectorate any sputum during coughing, thus, a high index of suspicion and a good clinical acumen is required to suspect TB in a child. The typical presentation of pulmonary tuberculosis include cough, fever, night sweats, weight loss, hemoptysis and chest pain. Presentation of extrapulmonary TB is often varied depending on the body system that has been affected. Diagnosis of tuberculosis encompases different stategies which include screening tests such as Mantoux Tuberculin Skin Test (TST) which uses a Purified Protein Derivative and Interferon-Gamma Release Assay (IGRA), an antigen based blood test. To make a diagnosis of TB, a sputum sample can be obtained on which tests

such as Acid Fast Bacilli smear, culture, molecular testing (GeneXpert, HAIN) and Nucleic Acid Amplicafication Tests can be done. Imaging modalities such as chest xray and CT scan are also helpful in the diagnosis of TB.

Once a diagnosis of TB is made, treatment entails 6 months of drug therapy which includes 2 months of intensive phase involving treatment with four drugs with anti tuberculous activity and a four month continuation phase with two drugs. The duration of treatment is longer for drug resistant TB and extrapulmonary TB. Stategies in prevention of TB include use of BCG vaccine, environmental infection control measures, use of personal protective devices like masks especially among healthcare workers and treatment of latent TB infection using Isonazid (Herchline, 2016; MOH, 2013).

**2.2 Isoniazid Preventive Therapy (IPT)**

Isoniazid is given to individuals with latent TB infection to prevent progression to active TB disease. Screening for and exclusion of active TB is paramount and critically important before initiating IPT. In adults, the absence of a current cough of any duration, night sweats, fever and weight loss and additionally, history of exposure to sputum positive household contact and failure to thrive in children (Owiti *et al.*, 2015), can identify the subset of population who have a very low probability of having active TB disease and thus can reliably be initiated IPT.

Evidently, short course INH has been demonstrated to have greater benefits to adult population and children. A study conducted among children in South Africa found out that prophylaxis with INH has early survival benefit and reduces incidence of TB in children with HIV. Furthermore, IPT decreases mortality from TB in children, improve quality of life in adults and prevent further transmission in the community (Zar *et al.*, 2007).

IPT has been shown to be effective in preventing progression of latent TB to active disease among children below five years exposed to household contacts with sputum positive PTB. In a study done in Pakistan, none of the children who were contacts of TB patients and completed IPT developed TB, however challenges encountered were low enrolment and a therapy completion rate of 60% (Jafri *et al.*, 2015). Similarly, a meta-

analysis of eight randomised controlled trials showed significant reduction in the risk of developing TB, with a risk ratio of 0.65 (p= 0.004). The risk of developing TB among children below 15 years was reduced by 59% ( RR,0.41 ; p< 0.001) (Ayieko *et al.*, 2014). A study done in Uganda (Jaganath *et al.*, 2013) which enrolled 490 children aged up to 15 years showed that 99% of the children who were on IPT did not develop TB disease although in Nairobi Kenya, it was found out that IPT offered 50% protection to exposed contacts from developing TB disease. IPT therefore offers adequate protection to children aged below five years who are in close contact to persons with sputum positive PTB (Okwara, 2015).

### 2.3 Prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.

In most countries, health seeking behavior of the child will lie solely on the caretaker, who most of the time will determine when to visit a health facility, what to ask for and eventually whether to administer medications when these are prescribed. Preventive therapy services require supervision of clients for adherence, and convincing parents or guardians that their children who are essentially well take these medications is often difficult (Rowe *et al.*, 2005).

It is approximated that every year, 1 million new cases of tuberculosis (TB) occur in children aged <15 years worldwide, where 75% of these is accounted for by the 22 high-burden TB countries (WHO, 2013). Young children in close contact with a smear-positive pulmonary TB cases are at high risk of latent tuberculous infection (LTBI) and development of TB disease. It is estimated that up to 43% of infected children aged <12 months and 24% of those aged 1–5 years develop TB disease (Nelson & Wells, 2004). In addition, children aged < 5 years are at a higher risk of developing disseminated forms of TB, including miliary TB and TB meningitis, frequently resulting in death (Marais *et al.*, 2009). Screening the household contacts of an infectious source case to identify children with TB disease is a recommendation by the World Health Organization to enable prompt treatment and to provide IPT for household contacts who do not have disease.

India, in the world, has one of the highest TB burdens (WHO, 2011). The Revised National TB Control Programme (RNTCP) of the Indian Government recommends screening of household contacts, especially children aged <6 years, of all smear-positive pulmonary TB cases (Pothukuchi *et al.*, 2011). A previous situational analysis revealed that among 84 household child contacts aged <6 years of 253 smear-positive PTB index patients, only 16 (19%) had been initiated on IPT (Banu Rekha *et al.*, 2009) . Despite recommendation for IPT initiation in children with no evidence of active TB disease for 6 months, implementation of IPT in children is suboptimal in India (Lobue & Menzies, 2010).

A study conducted in South Africa revealed that only 1% of children identified as eligible for IPT had been initiated (Van Wyk *et al.*, 2010). IPT uptake, among South African child contacts aged <5 years, ranges from <5% (Susan Van Wyk *et al.*, 2011) to 21% in routine health care settings (S Van Wyk *et al.*, 2010) to 73% in clinical research settings, while adherence is approximately 24% (Du Preez *et al.*, 2011; Marais *et al.*, 2004)

A prospective study conducted in Hawassa, Southern region of Ethiopia, concluded that compliance to IPT in children is poor and the finding was associated with the parents' perception of low importance of chemoprophylaxis (Tadesse *et al.*, 2016). Similar sentiments were expressed by parents to children in an adherence study by (Garie, Yassin & Cuevas, 2011) that demonstarted a 29.3% and 37.8% which is poor and very poor compliance to IPT respectively. Sixty seven percent of the parents to children with poor compliance indicated the main reason as the drugs not being necessary when the child is healthy (Garie, Yassin, & Cuevas, 2011).

Another study in urban communities of Cape Town, South Africa, revealed healthcare workers raising concerns of the children being accompanied to the clinic by an extended family member, who may not make decisions regarding the childs' treatment (Skinner *et al.*, 2013). The study further found that a better understanding of IPT among patients may show parents the range of potential exposures to TB that children may face and prevent the spread of misinformation, such as the fear of possible side effects. Newer and shorter preventive therapy regimens may be easier to understand, more acceptable and less susceptible to misconception.

Finally adoption of delivery methods such as 'DOTS Strategy' being employed by the TB programs would go a long way in increasing initiation of IPT (Tadesse *et al.,* 2016). It not only eliminates stigma associated with childhood TB, but also ensures that the parent/guardian receives the correct information offered by health care providers. In 2015, Kenya as a country reported initiation rate of 3.6% (29,924) in adults and 10% (7,934) in children of the targeted populations respectively (MOH, 2015) .

## 2.4 Household level factors associated with IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.

**C**hildren carry approximately 15% of the global tuberculosis disease burden, leading to an estimated 1 million cases of childhood TB annually (Nelson & Wells, 2004). There is growing evidence that a significant number of new TB cases in Africa result from recent transmission and casual contact. Identifying problem areas in child contact management within the TB program may help to reduce childhood TB and ultimately assist in curbing the expanding TB epidemic (Graham & Triasih, 2013).

The global public health campaigns to control TB put much focus to reduce transmission by early case finding and treatment of highly infectious patients (Graham *et al.*, 2014). As children often have paucibacillary TB, their risk of transmission is low and, thus, they have largely gone unnoticed. The burden of childhood TB can be significantly reduced by active contact tracing and diligent prescribing of chemoprophylaxis to patients in whom active TB has been excluded (Marais *et al.*, 2004). The rationale behind contact screening is twofold. First, it provides TB preventive therapy to high-risk individuals, such as young children and HIV-infected individuals. Secondly, it actively traces contacts who have TB and treats them appropriately (Graham *et al.*, 2014).

The urban poor populations living in informal settlements have disproportionately higher incidences of childhood TB, compared to adult TB cases (Marais *et al.*, 2009). Sixty percent of child TB exposures occur in their households. Infected children experience rapid disease progression and severe forms of disease, hence poorer outcomes (Pothukuchi *et al.*, 2011).

Socio-economic factors identified which represent wider societal influences over which a patient has little or no control include issues related to poverty, competing social commitments and service availability, that is distance to facilities and supply of drugs, are also widely recognized as critical factors determining patients' health behavior (Ngamvithayapong *et al.*, 1997). Other studies examining adherence to HIV and TB medication in developing countries also identify medication related costs, especially financial costs for transport and food, and competition from other livelihood responsibilities (Wasti *et al.*, 2012).

Personal factors related to people's characteristics such as age and sex are believed to have a major influence on their adherence behaviour. Gust and colleagues observed that the case non-adherent group include a greater proportion of younger men and persons with higher education(Gust *et al.*, 2011). Mosimaneotsile *et al.* (2010) and Ngamvithayapong *et al*. (1997) also found that women were more likely to be adherent than men. Gust reports that substance use is also associated with poor adherence (Gust *et al.*, 2011).

Munseri and colleagues explain the low adherence rate for women compared to men in their studies setting (Tanzania), stating the perception that IPT is linked to HIV, and women in the study did not want their HIV status to be disclosed in fear of separating from their spouses. This further illustrates the complex interactions between the different major factors whereby gender values in specific socio-cultural settings influence how stigma attached to TB and HIV plays out to induce a differential ability of men and women to disclose their status (Munseri *et al.*, 2008).

Individual beliefs are core factors contributing to the adherence of IPT. Some individual "micro-level" beliefs include fear of INH side effects, understanding of IPT and its importance, and belief in INH safety. Three studies focused on patients' understanding of the effect and the repercussions of defaulting or not adhering to IPT treatment (Ngamvithayapong *et al.*, 1997; Rowe *et al.*, 2005; Szakacs *et al.*, 2006) . Other related reasons include misunderstanding about the duration of IPT, which also highlights the importance of counselling prior to enrolment. However, Ngamvithayapong and colleagues also observe that patients were successful in adhering despite the lack of accurate knowledge (Ngamvithayapong *et al.*, 1997).

Family and other social support related factors mainly include the nature of relationships with family members, the wider community, and others taking IPT, as well as the adverse effects of stigma that emanates from these relationships influence IPT initiation (Rowe *et al.*, 2005). Relationships with family and friends appear to determine whether patients feel comfortable about taking IPT(Gust *et al.*, 2011). Stigma may also make patients ashamed to ask their employers for permission to attend their TB treatment. This impedes early treatment and facilitates progression of Latent to Active TB (Ngamvithayapong *et al.*, 1997). In some families, responsibilities of parenthood could work as a motivating factor to adhere to treatment while in other families responsibilities such as taking care of children could reduce the possibility of adherence. Support and encouragement from spouse, family and community health workers and concern for family members facilitate initiation and adherence to IPT (Szakacs *et al.*, 2006).

The reception received by participants when attending health services (Rowe *et al.*, 2005), including whether effective communication takes place (Gust *et al.*, 2011) and has a major impact on the patient's adherence to treatment. The relationship with health providers, specifically in terms of the nature of the advice, and whether it's given or not given (Mindachew *et al.*, 2011).

### 2.5. Health care level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.

The role of human resource in the provision of IPT cannot be overemphasized. These services can only be provided by health professionals notably a physician, medical doctor, clinical officer, or a nursing officer. Kenya, like many African countries, experience significant shortage of professional health workers. In a study conducted in a large TB clinic with high TB case load in South Africa (Van Wyk *et al.*, 2010) discovered that one reason for poor performance in provision of IPT to children resulted from insufficient knowledge of management of contacts amongst health workers. Similarly, (Banu, 2009) in an Indian study through focussed group discussions among health workers, it emerged that poor documentation and a lack of detailed knowledge on required procedures contributed significantly to poor IPT delivery. In a qualitative study carried out among HIV Clinics in South Africa, barriers to IPT use were found to be

primarily derived from Health Care Workers uncertainty on the benefits and risks of IPT as well as poor knowledge on the IPT guidelines (Lester *et al.*, 2010).

It is the responsibility of health workers to educate TB patients and their relatives about the disease. It is essential to obtain the patient's co-operation over the required treatment. An understanding, sympathetic and concerned attitude on the part of the healthcare worker is essential in passing the message across. Health education is a prerequisite for high cure rates and default prevention. It should be provided every time the patient receives care from the health care provider and should focus on improving adherence and detecting any untoward events that may compromise the health of the child. In addition, health education should be able to detect any index case that may be in the family (Owiti *et al.*, 2015).

A study in Gauteng, South Africa, identified knowledge gaps and inexperience as a major hindrance to IPT provision to both children and the adult population. During a focussed group discussion, doctors reported that although they had heard about IPT, they were unaware of its efficacy in preventing TB, or rather, the evidence is equivocal. Moreover, IPT was not a routine practice, thus most were unfamiliar with IPT and were reluctant to prescribe (Lester *et al.*, 2010). Despite the recommendation of IPT by WHO/UNAIDS for PLWHIV since 1993, initiation remains low (Balcells *et al.*, 2006). The fear of emerging isoniazid resistant TB was one of the reason cited for limited scale up among program managers and healthcare providers (Hiransuthikul *et al.*, 2005) however, it has been shown that there is no significant increased risk of resistance to isoniazid (Getahun *et al.*, 2010).

The healthworkers' fear of poor adherence to IPT among patients has been reported (Mindachew *et al.*, 2014). Other health workforce related barriers include; a feeling among some physicians that IPT is not beneficial, concerns for increased work load for health care workers, undesired side effects of isoniazid, unclear direction of the national policy and the notion that IPT did not provide a survival benefit (Maartens *et al.*, 2009). This is despite the fact that IPT has been shown to decrease the risk of death by 54% (Zar *et al.*, 2007).

Further, in the wake of high demands for care of TB and HIV co-infection, healthcare workers may not consider IPT particularly important due to controversies such as increased burden on the already overstretched health system, development of INH resistance if widely used as well as diversion of attention from other health priorities as have been encountered during program assesment in South Africa (Wood, 2014). These factors and many more often influence the initiation of IPT and thus prevention of TB in children.

Previous studies have identified several barriers to IPT implementation in low and middle-income countries (LMICs). These include inconsistent drug supply, clinical practices, poor record keeping systems, difficulties ruling out active TB due to poor availability of diagnostics, lack of knowledge and clarity among clinicians, as well as weak integrati04on of HIV and TB activities (Lester *et al.*, 2010) (WHO, 2011). Among these barriers, recent literature has emphasized health care worker perceptions, knowledge, and practices as the primary area to be addressed if IPT initiation rates are to be improved (Lester *et al.*, 2010). Furthermore, in contrast to previous findings focusing on patient adherence as a barrier to IPT uptake, it has been highlighted that clinician use of IPT among PLHIV is actually the key problem (Balcells *et al.*, 2006; Berhe *et al.*, 2014; Lester *et al.*, 2010). In a recent facility based cross-sectional study on IPT adherence among PLHIV in Ethiopia, 89.5% of sampled HIV patients on IPT (N=381) had taken at least 80% of their prescribed INH doses. This study concluded that the level of adherence to IPT in Ethiopia was high. Based on these study findings, barriers to provision of IPT on the provider side must be understood in order to improve IPT coverage rates (Berhe *et al.*, 2014). As a critical gateway to initiation of IPT, active TB must be excluded. In contrast, it is not easy to diagnose symptomatic TB in children given their clinical presentation. This requires attention to history provided by the caregiver or parent during clinic visit, and a high index of suspicion or clinical acumen from the attending healthcare provider. The requirement to rule out TB is perceived as a potential barrier by majority of clinical staff thus the call for point-of-care testing. Further, the desire to have an assisted exclusion of TB using chest radiograph by clinicians in Gauteng, delayed or led to loss-to-follow up of contact cases since these services were sought off site (Lester *et al.*, 2010).

In summary, the findings presented by Zar *et al.* (2007) and Jafri *et al.* (2015) are consistent in establishing the influence of IPT initiation in minimizing the TB cases among children aged under five years. The studies found that IPT initiation reduced mortality among this age group and none of the children who were contacts of TB patients in Pakistan and completed IPT developed TB respectively. Even though the study by Jaganath *et al.* (2013) in Uganda indicated that nearly all the children who were on IPT never developed TB disease, the study done by Okwara (2015) in Kenya indicated that only half of the exposed contacts where protected by initiation of IPT from developing TB disease. This shows a significant difference in the implication of IPT initiation between the two countries which is fueled by various factors. The problem of suboptimal implementation of IPT among children in India despite the recommendation is brought out by Lobue and Menzies in their study.

Similarly, in South Africa, Van Wyk *et al.* (2010) established that only 1% of IPT eligible children had been initiated. This shows the magnitude of the problem faced in achieving both the global and national target of IPT initiation. Consequently, other studies like that presented by Tadesse *et al.* (2016) in Hawassa, Ethiopia, associated poor IPT with parents' perception of low importance of chemoprophylaxis. This study further found that IPT initiation among children was 64.3%, however, those completing the 6 months course were 80%, this is relatively higher than the findings of Van Wyk *et al.* Poor compliance have also been attributed to the perception that the drug is not necessary when the child is considered healthy (Garie, Yassin, & Cuevas, 2011).

Marais *et al.* (2009) identified high disproportionate incidences of childhood TB among children living in urban poor informal settlements, which unmasks a factor that potentially influences the initiation of IPT. A gap that was identified at facility level that influenced IPT initiation among children under five waas insufficient knowledge of management of contacts among health workers (Van Wyk *et al.,* 2010). Other facility level gaps that came out from the reviewed studies are the poor documentation, lack of detailed knowledge on the appropriate procedures and inexperience. Notably, the studies suggest fear of emerging IPT resistant TB which has been linked to minimal scale up among healthcare providers and program managers. This is despited the fact that IPT has been shown to significantly minimze the risk of developing TB among children under five years.

## 2.6 Theoretical Preposition

### 2.6.1 Theory of Reasoned Action/Planned Behavior

Theory of Planned behavior is useful in predicting one's behavior in taking up disease prevention interventions. According to the theory, intention is the immediate antecedent of behavior and is itself a function of an individual's attitude toward the behavior, subjective norm (what others will think) and perceived behavioral control. These determinants follow respectively from beliefs about the behavior's likely consequences about normative expectations of important others and about the presence of factors that control behavioral performance. Empirical support for the theory comes from a host of correlational studies demonstrating its ability to predict intentions and behavior as well as from interventions, showing that changes in behavioral, normative and control beliefs can produce changes in intentions and that these changes in intentions are reflected in subsequent behavior (Ajzen & Fishbien, 1980).

The Theory of Reasoned Action provides a comprehensive framework for understanding the influence of attitudes, subjective norms, and intentions on the initiation of IPT against TB in this population. By understanding the influence of these factors, the study can better identify and target interventions that can increase the likelihood of a successful outcome.

Due to subjective norms of this theory, persons with pulmonary tuberculosis in households with under-five are expected to plan and seek for biomedical intervention (IPT initiation) to prevent TB associated morbidity and mortality among children aged below 5 years. Conversely, this type of pressure and expectation can lead to development of bad attitudes and poor health seeking behavior thereby prompting persons diagnosed with PTB in contact with children aged below 5 years not to seek for the much-needed biomedical intervention.

The Theory of Reasoned Action has been shown to be more successful in predicting health behaviors than the Health Belief Model. The Theory of Reasoned Action considers multiple factors that may influence health behaviors, including beliefs and attitudes, subjective norms, and perceived behavioral control. It also emphasizes the importance of intention in predicting behavior. The Health Belief Model does not take

into account the role of intention and does not emphasize the importance of the social context in which behavior takes place. Therefore, the Theory of Reasoned Action is a better choice for this study.

# CHAPTER THREE

# MATERIALS AND METHODS

## 3.1 The study area

This study was conducted in Kisumu County. This area was chosen because it serves a region with a high HIV prevalence of 19.0% and TB prevalence of 306 per 100,000 populations (NASCOP, 2014). The county is in Western part of Kenya; it borders Siaya County to the west, Vihiga County to the north, Nandi County to the northeast, Kericho County to the east, Nyamira County to the south and Homa Bay County to the southeast. It runs along the shores of Lake Victoria to the northern west and southern of Winam gulf. It has an estimated population of 968,909, and occupies an area of 2,085.9sqKm, with a population density of 460 persons per square kilometers (KNBS, 2010).

The study was conducted within the TB outpatient clinics of five selected hospitals within Kisumu County. These hospitals included Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), Kisumu County Hospital (KCH), Lumumba, Migosi, and Rabuor hospitals. The high TB case load in facilities around Kisumu town led to the selection of these specific health facilities for the study.

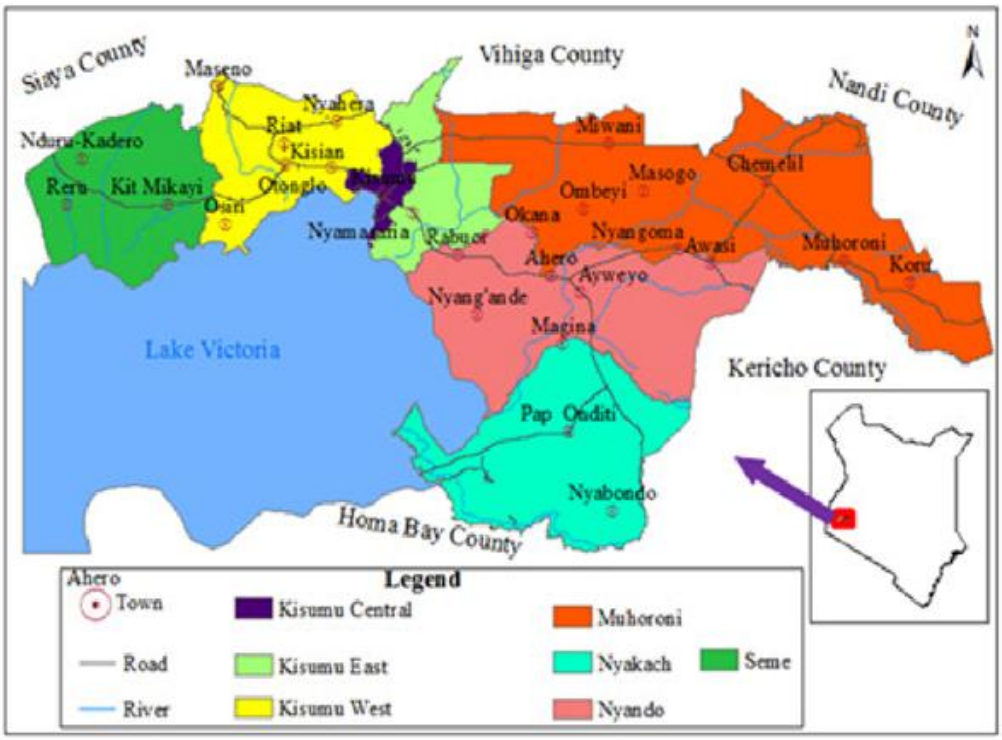


**Figure 3.1: Study area as an inset in the map of Kenya** (Source: ArcGIS)

### 3.2 Study design

A descriptive cross-sectional design was used to conduct the study.

### 3.3 Study Population

The study targeted sputum positive PTB patients with household contacts aged five years and below enrolled in TB clinics at JOOTRH, KCH, Lumumba, Migosi, and Rabuor hospitals in Kisumu County as well as staff working within these TB clinics. These facilities were selected because of high TB case load.

### 3.4 Inclusion criteria

1. Sputum positive PTB persons with household contacts aged five years and below enrolled for TB care within the selected TB clinics in Kisumu County/ Staff working in the selected TB clinics.
2. Ability to provide an informed consent.
3. Persons aged 18 years and above.

### 3.5 Exclusion criteria

1. Sputum positive PTB persons with household contacts aged below five years and are on transit to other counties.
2. Persons who are very sick and are unable to consent and respond the questionnaire

### 3.6 Sample size determination

The target population was TB patients enrolled for TB care within the selected TB clinics. In 2015, the National TB program reported 81,518 TB cases nationally. In the absence of County segregation in TB caseloads or notification in the national report, the researcher opted to use national estimates of IPT initiation in children of 6.0%. The Cochran formula for sample size determination the sample size for the study since it determines the minimum sample size needed in order to achieve a desired level of statistical power for the study. Additionally, it takes into account the population size, the effect size, the level of confidence desired, and the level of significance desired. This formula ensures that the study is properly powered and that the results are meaningful and valid.

The Cochran equation for proportion for determining the sample size was as follows:

$$N = \frac{DZ^2P(1-P)}{e^2}$$

Where:

N- The required sample size

D- Design effect estimated to be 1.7 where cluster sampling method was used.

$Z^2$- Confidence interval 95% (the standardized z-score or multiplier=1.96)

P-(6.0%) proportion of children taking up IPT in Kenya (DLTLD, 2015)

$e^2$ - Margin of error 5%

$Z^2$ - 3.8416

P - 0.06

$e^2$ - 0.0025

(1-P) - 0.94

$$N = \frac{1.7 \times 3.8416 \times 0.06 \times 0.94}{0.0025}$$

$$= 148$$

N = 171 (after factoring in 15% non-response rate). All the 171 and an additional 4 respondents completed the questionnaires. Data was therefore collected from 175 participants.

### 3.7 Sampling technique

#### 3.7.1 Proportionate stratification

Proportionate sampling technique was used to determine the number of smear positive TB individuals in contact with children below five years at Jaramogi Oginga Odinga Teaching and referral hospital, Kisumu County Hospital, Lumumba, Migosi and Rabuor sub-county hospital that would be interviewed. It ensures that the sample accurately represents the population in terms of the proportions of each subgroup. This allows the study to draw more accurate conclusions about the population, rather than relying on a randomly selected sample that may not be representative of the population. Additionally, proportionate sampling helped to ensure that the sample size is large enough to provide reliable results. Assumption on the proportion of units in each stratum was dependent on the registered number of smear positive PTB persons in contact with children below five years per health facility as shown in the table 3.1.

**Table 3.1: Sample determination for each stratum for PTB persons**

| Health Facility | Sputum positive PTB patients | Proportion (%) | Sample size |
|---|---|---|---|
| JOOTRH (Referral) | 112 | 31% | 53 |
| Kisumu County hospital (County) | 83 | 23% | 39 |
| Lumumba (Sub-County) | 54 | 15% | 26 |
| Migosi (Sub-County) | 60 | 17% | 29 |
| Rabuor (Sub-County) | 51 | 14% | 24 |
| **TOTAL** | **360** | **100** | **171** |

### 3.7.2 Purposive Sampling

Purposive sampling technique was used to select sputum positive PTB persons with at least one under-five child for each stratum. It allows for purposefully selecting a sample of participants who are likely to have information or insights that are relevant to the topic of the study. Additionally, purposive sampling is used to select a sample that will allow researchers to understand a variety of perspectives from different stakeholders, such as healthcare providers, families, and other affected individuals. This is beneficial in understanding how different factors interact to influence the initiation of IPT against TB among children below 5 years in Kisumu.

All smear positive PTB adult patients attending TB clinic each day were approached. Those in contact with children aged below 5 years were selected and recruited. Structured questionnaire was administered to those who consented. Thirty-five (35) health care providers; 8 from JOOTRH, 8 from KCH, 7 from Migosi, 6 from Lumumba and 6 from Rabuor hospital working at the TB clinics were purposively selected for the study.

### 3.8 Data collection instruments

The study adopted primary data collection technique. Structured questionnaires were developed and administered to sputum positive TB persons with children aged below five years household contacts. Self-administered structured questionnaire was used to collect data from the staff within the TB clinics at the selected h012ealth facilities. The questionnaires were pre-tested at Ahero sub county hospital TB clinic in Nyando sub-

county. A sample size of nine persons with PTB and two hospital staff (5% of actual sample size) were recruited for the pretesting. Pre-tested data was used to assess the data collection tool. This data was excluded from the final analysis.

### 3.9 Data collection

Data was collected from respondents during their clinic revisits. Treatment of TB requires that patients who are in the intensive phase of treatment go back to the clinic weekly (after every seven days) for clinical examination and pill refills, while those on continuation phase do so fortnightly (after every 14 days) with a few cases doing so after one month (28-day cycle) according to national guidelines on the management of TB (DLTLD, 2013). This kind of arrangement gave the researcher an opportunity to access all the patients who were enrolled in the various facilities at least once in a month. The questionnaires were administered at the end of patient clinical examination and dispensing medications following successful consenting process. Questionnaires were also administered to the entire TB clinic staff in the five selected hospitals. Social desirability bias was corrected by using anonymous surveys. Proportionate sampling and random enrollment of respondents was used to minimize bias.

### 3.10 Data Processing and Analysis

All collected questionnaires were checked daily for completeness, quality, duplication, inconsistencies, appropriateness, and accuracy. Data was keyed in Access (database) cleaned and validated for analysis. Frequencies were calculated for categorical variables. Wealth quintiles were created by a combination of socioeconomic variables including assets, household characteristics and utilities. A household wealth index was created as a linear combination of these factors and then households were classified into five groups (poorest, poorer, middle, richer and richest). Fisher's exact test was used to determine the association between categorical variables and initiation on IPT. Generalized linear model (GLM; log family, negative binomial distribution) was used to model IPT initiation since the prevalence was greater (>10%), thus logistic regression with odds ratios was not appropriate measure of effect to estimate the prevalence ratio of IPT Initiation. Explanatory variables that were significant at bivariate analysis $P< 0.2$ were further incorporated in the final multivariable regression model using backward

elimination and retaining predictors significant at $P<0.05$. Potential confounding effect was examined for each covariate by two-way interactions. Data analysis was done using STATA version 14.1 (STATA Corporation, College Station, Texas, USA).

**Table 3.2: Data Analysis Plan**

| Objective | Independent Variable | Dependent Variable | Measures of Effect | Statistical Test |
|---|---|---|---|---|
| To determine prevalence of IPT initiation among children aged below 5 years in contact with smear positive PTB persons | No. of children aged below 5 years. | IPT initiation | Prevalence Rate | *Descriptive statistics*<br>Numerator=#initiated on IPT<br>Denominator=Total # of children aged below 5 years in contact with smear +ve PTB persons |
| To determine household level factors associated with initiation on IPT among children aged below 5 years of smear +ve PTB persons | Education level<br>Marital status<br>Occupation<br># of <5 ‘s<br># of persons living in the household | IPT initiation | Prevalence Rate Ratio | *Inferential Statistics*<br>Multilevel- Mixed-effect Models<br>Generalized Linear Model (GLM, log negative binomial) |
| To determine health care level factors associated with IPT initiation | Demographics<br>Qualifications<br>Trainings<br>Duration of work | IPT Initiation | Prevalence Rate Ratio | *Inferential Statistics*<br>Fishers Exact Test<br>Generalized Linear Model (GLM, log negative binomial) |

### 3.11 Ethical considerations

The researcher sought permission from the Ministry of Health through the Institutional Review Board of the University of Eastern Africa, Baraton (appendix 5), JOOTRH ethical review committee (appendix 6) and the health department of Kisumu County (appendix 7). Verbal consent was also provided by all the hospital in-charges where the

data was to be collected prior to data collection. A written informed consent was obtained from the participants (persons with PTB and TB clinic staff) before collecting data and the researcher ensured privacy and confidentiality of all the information obtained. The potential risks to participants in the study were minimal. There was the risk of stress and anxiety due to discussions about TB and possible infection acquired by the child. To minimize this risk, the consenting and interview sessions were conducted in a secluded private space.

### 3.12 Validity and Reliability

1. Pretesting of the questionnaires was done to ensure that data collected was reliable and valid. Errors noted during the pre-tests were corrected. Pre-test was conducted in Ahero Sub-county Hospital since it exhibits the similar characteristics to the selected facilities in the study.
2. The research assistants were trained on the data tools and the data collection process. They were also able to communicate in all the three most common languages spoken by residents of the study area which included English, Luo and Kiswahili. This ensured that they consented and administered the questionnaires in the language best understood by the respondents.
3. The research assistants performed self-quality control checks on the questionnaires to ensure all the responses were provided before releasing the respondent.

# CHAPTER FOUR

# RESULTS

## 4.1 Socio-Demographic Characteristics of Respondents

The mean age of the respondents was 33.2 [SD± 11.2] with 48(27.4%) of the respondents aged between 25-29 years. Out of 175 respondents in the study, 95 (54.3%) were female and 52(29.7%) of the respondents had no post-primary education. One hundred and three (58.9%) of the respondents were in a monogamous marriage. Ninety-four (53.7%) of the respondents resided in urban settlement with 92(52.6%) of the respondents being unskilled in their occupation. Forty (22.8%) of the respondents belonged to the richer social economic status while 106(60.6%) of the respondents were living with 3-5 persons in the same household. Majority of the respondents, 134(76.6%) were parents to the children aged below 5 years with 75(42.9%) having about 3-6 hourly contact during the day and 107(61.1%) sleeping with the children aged below 5 years in the same room (Table 4.1).

## Table 4.1: Characteristics of the respondents

| Characteristics (N=175) | Overall n (%) |
|---|---|
| **Mean Age** (33.2 ± 11.2) | |
| **Sex** | |
| Male | 80(45.7) |
| Female | 95(54.3) |
| **Level of Education** | |
| Incomplete primary education | 44(25.1) |
| Complete primary education | 29(16.6) |
| No post-primary education | 52(29.7) |
| Secondary education and above | 50(28.6) |
| **Marital Status** | |
| Married monogamy | 103(58.9) |
| Married polygamy | 23(13.1) |
| Divorced/Separated/Single | 49(28.0) |
| **Age group (Years)** | |
| <25 | 30(17.1) |
| 25-29 | 48(27.4) |
| 30-34 | 41(23.4) |
| 35-40 | 19(10.8) |
| >=40 | 37(21.1) |
| **Residence** | |
| Urban | 94(53.7) |
| Peri-urban | 33(18.8) |
| Rural | 48(27.5) |
| **Occupation** | |
| Skilled | 83(47.4) |
| Unskilled | 92(52.6) |
| **Relationship to the child** | |
| Parent | 134(76.6) |
| Relative/caretaker | 41(23.4) |
| **Social economic Status** | |
| Poorest | 37(21.1) |
| Poorer | 31(17.7) |
| Middle | 38(21.7) |
| Richer | 40(22.8) |
| Richest | 29(16.6) |
| **Number of persons in the household** | |
| 1-2 | 26(14.9) |
| 3-5 | 108(61.7) |
| >5 | 41(23.4) |
| **Average time of contact during the day** | |
| <3 hours | 29(16.6) |
| 3-6 hours | 75(42.9) |
| > 6 hours | 71(40.5) |
| **Sleep with the child in the same room** | |
| Yes | 107(61.1) |
| No | 68(38.9) |

### 4.2 The prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.

The overall prevalence rate of IPT initiation among children aged below 5 years was 70.3 % (n=123) with 69(72.6%) IPT initiation among female PTB contacts compared to 54(67.5%) among male PTB contacts as shown in Figure 4.1 below.

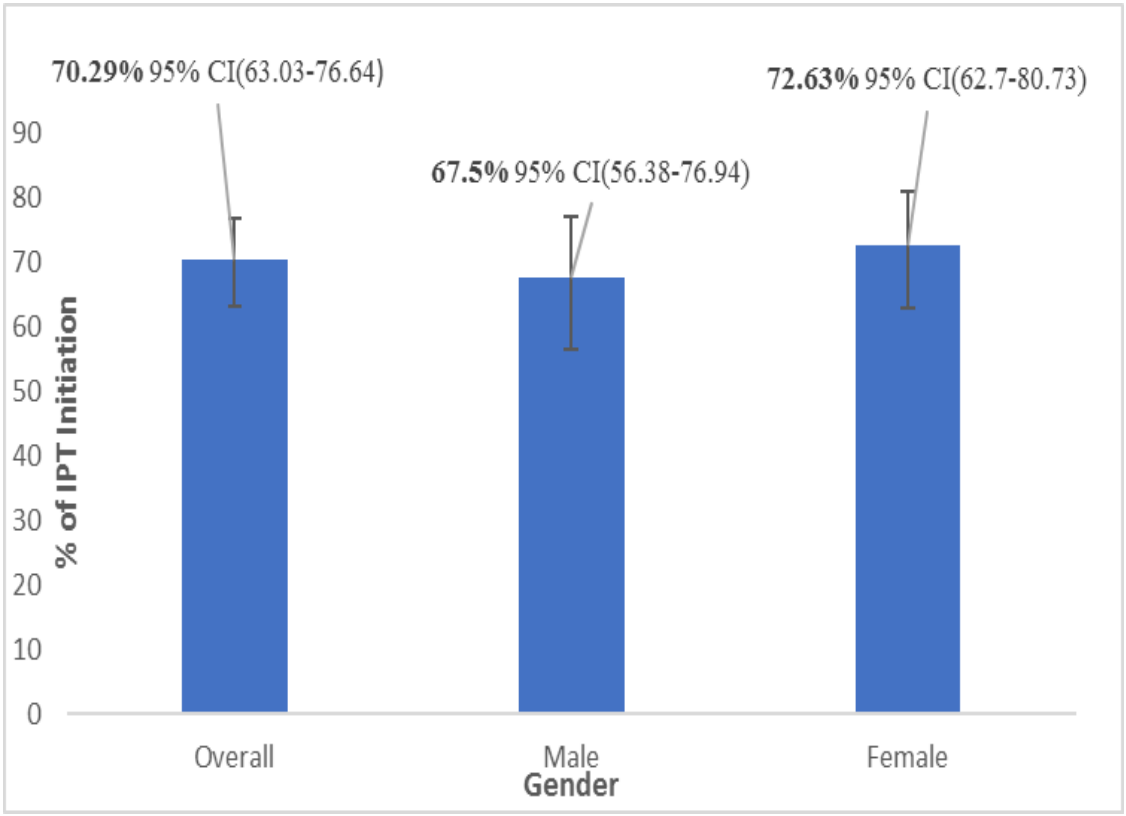


**Figure 4.1: The Prevalence of IPT initiation among children aged below five year**

### 4.3 Socio-demographic factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.

A bivariate prevalence rate ratio was performed to determine the association between socio-demographic factors and initiation of IPT among children aged below 5 years. The analysis showed that respondents with incomplete secondary level of education and

above secondary (Crude PR=1.43; 95%CI 1.20-1.70; P<0.001) and (Crude PR=1.49; 95%CI 1.09-2.02; P=0.011) respectively, were more likely to initiate their children on IPT as compared to those with incomplete primary level of education. Respondents whose age group was <25years (Crude PR=1.43; 95%CI 1.02-1.99; P=0.038) were more likely to initiate their children on IPT compared to those of >=40 years age group. Moreover, respondents who resided in urban and peri-urban areas (Crude PR=1.89; 95%CI 1.49-240; P<0.001) and (Crude PR=1.66; 95%CI 1.35-2.05; P<0.001) respectively, were more likely to initiate their children on IPT compared to those who resided in rural areas. Notably, respondents who were skilled in their occupation (Crude PR=1.24; 95%CI 1.12-1.37; P<0.001) were more likely to initiate their children on IPT as compared to those of unskilled occupation (Table 4.2).

**Table 4.2: Socio-demographic factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.**

| Socio-demographic factors | Overall N(%) | Initiated n(%) | Not Initiated n(%) | Crude PR(95% CI) | P-value |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Male | 80(45.7) | 54(67.5) | 26(32.5) | Ref | |
| Female | 95(54.3) | 69(72.6) | 26(27.4) | 1.08(0.98-1.18) | 0.127 |
| **Level of Education** | | | | | |
| Primary incomplete | 44(25.1) | 23(52.3) | 21(47.7) | Ref | |
| Primary complete | 29(16.6) | 22(75.8) | 7(24.1) | 1.45(0.96-2.19) | 0.076 |
| No post-primary education | 52(29.7) | 39(75.0) | 13(25.0) | 1.43(1.20-1.70) | <0.001 |
| Above secondary | 50(28.6) | 39(78.0) | 11(22.0) | 1.49(1.09-2.02) | 0.011 |
| **Marital Status** | | | | | |
| Married monogamy | 103(58.9) | 83(80.5) | 20(19.4) | 1.57(0.98-2.53) | 0.059 |
| Married polygamy | 23(13.1) | 15(65.2) | 8(34.8) | 1.27(0.75-2.17) | 0.364 |
| Divorced/Separated/Single | 49(28.0) | 25(51.0) | 24(48.9) | Ref | |
| **Age group (Years)** | | | | | |
| <25Yrs | 30(17.1) | 22(73.3) | 8(26.7) | 1.43(1.02-1.99) | 0.038 |
| 25-29Yrs | 48(27.4) | 39(81.2) | 9(18.8) | 1.58(0.99-2.51) | 0.052 |
| 30-34 Yrs | 41(23.4) | 31(75.6) | 10(24.4) | 1.47(0.95-2.29) | 0.086 |
| 35-40 Yrs | 19(10.8) | 12(63.2) | 7(36.8) | 1.23(0.68-2.21) | 0.487 |
| >=40 Yrs | 37(21.1) | 19(51.4) | 18(48.6) | Ref | |
| **Residence** | | | | | |
| Urban | 94(53.7) | 78(82.9) | 16(17.0) | 1.89(1.49-2.40) | <0.001 |
| Peri-urban | 33(18.8) | 24(72.7) | 9(27.3) | 1.66(1.35-2.05) | <0.001 |
| Rural | 48(27.5) | 21(43.7) | 27(56.3) | Ref | |
| **Occupation** | | | | | |
| Skilled | 83(47.4) | 65(78.3) | 18(21.6) | 1.24(1.12-1.37) | <0.001 |
| Unskilled | 92(52.6) | 58(63.0) | 34(36.9) | Ref | |
| **Relationship to the child** | | | | | |
| Parent | 114(73.6) | 91(79.8) | 23(20.2) | 1.13(0.93-1.37) | 0.224 |
| Relative/caretaker | 41(26.4) | 29(70.7) | 12(29.3) | Ref | |

PR- Prevalence ratio, CI- Confidence Interval

### 4.4 Household level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.

To determine the household level factors associated with initiation of IPT among under-fives, a bivariate prevalence rate ratio was performed. The analysis showed that, respondents whose social economic status were middle and richer (Crude PR=1.66; 95% CI 1.16-2.36; P=0.005) and (Crude PR=1.74; 95% CI 1.23-2.46; P=0.002) were more likely to initiate their children on IPT compared to those from the poorest social economic position. Respondents who had 3-5 people in the household (Crude PR=2.02; 95% CI 1.17-3.47; P=0.011) were more likely to initiate their children on IPT compared to those who had 1-2 number of persons in the household. Moreover, respondents whose average time of contact during the day was 3-6 hours (Crude PR=1.65; 95% CI 1.01-2.71; P=0.046) were more likely to initiate their children on IPT compared to those whose average time was less than 3 hours (<3). Notably, respondents who sleep with their children in the same room (Crude PR=1.54; 95% CI 1.04-2.27; P=0.032) were more likely to initiate their children on IPT compared to those who did not sleep with the children in the same room (Table 4.3).

**Table 4.3: Household level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.**

| Household level factors | Overall N (%) | Initiated n (%) | Not Initiated n (%) | Crude PR (95% CI) | P-value |
|---|---|---|---|---|---|
| **Social economic Status** | | | | | |
| Poorest | 37(21.1) | 17(45.9) | 20(54.0) | Ref | |
| Poorer | 31(17.7) | 20(64.5) | 11(35.4) | 1.40(0.80-2.44) | 0.230 |
| Middle | 38(21.7) | 29(76.3) | 9(23.6) | 1.66(1.16-2.36) | 0.005 |
| Richer | 40(22.8) | 32(80.0) | 8(20.0) | 1.74(1.23-2.46) | 0.002 |
| Richest | 29(16.6) | 25(86.2) | 4(13.7) | 1.87(0.97-3.62) | 0.061 |
| **Number of persons in the household** | | | | | |
| 1-2 | 26(14.8) | 10(38.4) | 16(61.5) | Ref | |
| 3-5 | 108(61.7) | 84(77.8) | 24(22.2) | 2.02(1.17-3.47) | 0.011 |
| >5 | 41(23.4) | 29(70.7) | 12(29.2) | 1.83(0.99-3.38) | 0.050 |
| **Average time of contact during the day** | | | | | |
| <3 hours | 29(16.6) | 14(48.2) | 15(51.7) | Ref | |
| 3-6 hours | 75(42.9) | 60(80.0) | 15(20.0) | 1.65(1.01-2.71) | 0.046 |
| > 6 hours | 71(40.5) | 49(69.0) | 22(30.9) | 1.42(0.92-2.21) | 0.108 |
| **Sleep with the child in the same room** | | | | | |
| Yes | 107(61.1) | 87(81.3) | 20(18.7) | 1.54(1.04-2.27) | 0.032 |
| No | 68(38.9) | 36(52.9) | 32(47.1) | Ref | |

PR- Prevalence ratio, CI- Confidence Interval

### 4.5. Healthcare level factors associated with initiation of IPT among children aged below five years who are household contacts of smear positive PTB persons.

Fishers exact test was used to test for health level factors associated with initiation on IPT among under -fives in contact with index smear positive persons. Persons with 3-5 years, 1-3 years, and less than one-year experience, have a significant association with the prevalence of IPT initiation at the health facility (Fisher's exact test: P=0.017; P=0.013 and P<0.001 respectively). Annually, quarterly and having no training have a significant association with the prevalence of IPT initiation at the health facility (Fisher's exact test: P<0.001; P=0.001 & P<0.001 respectively).

Isoniazid stock outs, refusal by parents to bring children to the facility, lack of TB screening facilities for children, shortage of staff and inadequate training on IPT have a significance association with the prevalence of IPT initiation at the health facility (Fisher's exact test: P=0.001; P<0.001; P<0.001; P=0.001 & P=0.002 respectively). Formal Training on IPT has a significance association with the prevalence of IPT initiation at the health facility (Fisher's exact test P<0.001 (Table 4.4).

**Table 4.4: Health facility level factors associated with IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.**

| | JOOTRH n (%) N=8 | Kisumu CRH n(%) N=5 | Lumumba n(%) N=5 | Migosi n(%) N=7 | Rabuor SCH n(%) N=8 | P-value |
|---|---|---|---|---|---|---|
| **Prevalence of IPT initiation** | 86.8 | 59.5 | 60.7 | 93.6 | 38.5 | |
| **Years of experience** | | | | | | |
| <1 year | 0(0.0) | 1(20.0) | 4(80.0) | 0(0.0) | 0(0.0) | <0.001 |
| 1-3 year | 4(50.0) | 2(40.0) | 0(0.0) | 0(0.0) | 6(75.0) | 0.013 |
| 3-5 year | 3(37.5) | 2(40.0) | 1(20.0) | 7(100.0) | 2(25.0) | 0.017 |
| 5-10 year | 1(12.5) | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0.999 |
| **Formal Training on IPT** | | | | | | |
| Yes | 8(100.0) | 5(100.0) | 1(20.0) | 7(100.0) | 8(100.0) | <0.001 |
| No | 0(0.0) | 0(0.0) | 4(80.0) | 0(0.0) | 0(0.0) | |
| **Frequency of training** | | | | | | |
| Annually | 1(12.5) | 0(0.0) | 0(0.0) | 0(0.0) | 7(87.5) | <0.001 |
| Biannually | 1(12.5) | 1(20.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0.622 |
| Quarterly | 0(0.0) | 0(0.0) | 3(75.0) | 0(0.0) | 1(12.5) | 0.001 |
| No training | 6(75.0) | 4(80.0) | 0(0.0) | 7(100.0) | 0(0.0) | <0.001 |
| **Challenges in provision of IPT*** | | | | | | |
| Stock outs of IPT | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 5(62.5) | 0.001 |
| Parental refusal to bring children to facility | 8(100.0) | 3(60.0) | 2(40.0) | 9(100.0) | 2(25.0) | <0.001 |
| Lack of TB Screening facilities for children | 2(25.0) | 2(40.0) | 0(0.0) | 0(0.0) | 7(87.5) | <0.001 |
| Shortage of staff | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 5(62.5) | 0.001 |
| Inadequate training on IPT | 0(0.0) | 1(20.0) | 3(60.0) | 0(0.0) | 0(0.0) | 0.002 |

**NB:** *Multiple responses were allowed

### 4.6. The Association between health level factors and prevalence of IPT initiation who are household contacts of smear positive PTB persons.

To determine the healthcare level factors associated with initiation of IPT among children aged below 5 years, a bivariate negative binomial regression was performed. The analysis revealed that respondents with 5-10 years of experience increased the prevalence of IPT initiation as compared to those with < 1 year of experience (β= 0.4520;95% CI 0.2677-0.6364; P<0.001). The increase was by 57.2%. Conversely, the prevalence of initiation was reduced due to IPT stock outs, inadequacy/lack of familiarity with TB screening algorithm in the facilities, shortage of staff and inadequate training on IPT (β= -0.3110;95% CI -0.5141- -0.1079; P=0.003), (β= -0.2258;95% CI -0.4208- -0.0309; P=0.023), β= -0.3110;95% CI -0.5141- -0.1079; P=0.003) and (β= -0.2130;95% CI -0.3436- -0.0823; P=0.001) respectively. The decreases were by 26.7%, 20.21%, 26.73%, and 19.18% respectively. (Table 4.5).

**Table 4.5: Association between health facility level factors and prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.**

| Prevalence of Initiation | % margin effect | Coefficients | [95% Confidence Interval] | | P-Value |
|---|---|---|---|---|---|
| **Years of Experience** | | | | | |
| < 1 year | Ref. | Ref. | | | |
| 1-3 year | 15.19 | 0.1414 | -0.0891 | 0.3721 | 0.229 |
| 3-5 year | 19.57 | 0.1788 | -0.0147 | 0.3723 | 0.070 |
| 5-10 year | 57.15 | 0.4520 | 0.2677 | 0.6364 | **<0.001** |
| **Stock outs of IPT** | 26.7 | -0.3110 | -0.5141 | -0.1079 | **0.003** |
| **Lack of TB screening facilities** | 20.21 | -0.2258 | -0.4208 | -0.0309 | **0.023** |
| **Shortage of staff** | 26.73 | -0.3110 | -0.5141 | -0.1079 | **0.003** |
| **Inadequate training on IPT** | 19.18 | -0.2130 | -0.3436 | -0.0823 | **0.001** |

**Note:** The results are from negative binomial regression. Negative coefficient implies reduction in net change and positive coefficients implies increase in net change. The % marginal effect is calculated as $(e^b - 1) * 100\%$ where b is the value for the coefficient.

### 4.7 Multivariate analysis of factors associated with initiation of Isoniazid Preventive Therapy among children aged below five years who are household contacts of smear positive PTB persons.

A multivariate prevalence rate ratio revealed that respondents aged less than 25 years (<25) (Adjusted PR=1.43; 95% CI 1.13-1.83; P=0.003) were more likely to initiate their children on IPT compared to those of aged 40 years and above.

Notably, respondents who reside in urban and pre-urban (Adjusted PR=1.56; 95%CI 1.22-2.00; P<0.001) and (Adjusted PR=1.63; 95%CI 1.43-1.87; P<0.001) respectively, were more likely to initiate their children on IPT compared to those who reside in rural areas. Respondents who had more than five persons in the household (Adjusted PR=2.02; 95% CI 1.26-3.23; P=0.003) were more likely to initiate their children on IPT compared to those with 1-2 persons in the household.

Moreover, respondents who had 3-6 hours and more than six hours average time of contact during the day (Adjusted PR=1.74; 95% CI 1.11-2.73; P=0.016) and (Adjusted PR=1.66; 95% CI 1.06-2.58; P=0.024) were more likely to initiate their children on IPT compared to those who had less than three hours average time of contact during the day. Respondents who sleep with the child in the same room (Adjusted PR=1.50; 95% CI 1.22-1.85; P<0.001) were more likely to initiate their children on IPT compared to those who did not sleep with their child in the same room.

**4.6. Multivariate analysis of factors associated with initiation of Isoniazid Preventive Therapy among children aged below five years who are household contacts of smear positive PTB persons.**

| | Overall N(%) | Initiated n(%) | Not Initiated n(%) | Adjusted PR (95% CI) | P-Value |
|---|---|---|---|---|---|
| **Level of Education** | | | | | |
| **Primary incomplete** | 44(25.1) | 23(52.3) | 21(47.7) | Ref. | |
| **Primary complete** | 29(16.6) | 22(75.8) | 7(24.1) | 0.98(0.66-1.47) | 0.943 |
| **Secondary incomplete** | 52(29.7) | 39(75.0) | 13(25.0) | 1.11(0.88-1.40) | 0.367 |
| **Above secondary** | 50(28.6) | 39(78.0) | 11(22.0) | 1.08(0.81-1.44) | 0.569 |
| **Marital Status** | | | | | |
| **Married monogamy** | 103(58.9) | 83(80.5) | 20(19.4) | 1.30(0.85-2.00) | 0.219 |
| **Married polygamy** | 23(13.1) | 15(65.2) | 8(34.8) | 1.23(0.95-1.59) | 0.104 |
| **Divorced/Separated/Single** | 49(28.0) | 25(51.0) | 24(48.9) | Ref. | |
| **Age group (Years)** | | | | | |
| **<25 Yrs** | 30(17.1) | 22(73.3) | 8(26.7) | 1.43(1.13-1.83) | 0.003 |
| **25-29 Yrs** | 48(27.4) | 39(81.2) | 9(18.8) | 1.36(0.99-1.86) | 0.057 |
| **30-34 Yrs** | 41(23.4) | 31(75.6) | 10(24.4) | 1.15(0.77-1.71) | 0.478 |
| **35-40 Yrs** | 19(10.8) | 12(63.2) | 7(36.8) | 1.19(0.57-2.49) | 0.628 |
| **>=40 Yrs.** | 37(21.1) | 19(51.4) | 18(48.6) | Ref. | |
| **Residence** | | | | | |
| **Urban** | 94(53.7) | 78(82.9) | 16(17.0) | 1.56(1.22-2.00) | <0.001 |
| **Peri-urban** | 33(18.8) | 24(72.7) | 9(27.3) | 1.63(1.43-1.87) | <0.001 |
| **Rural** | 48(27.5) | 21(43.7) | 27(56.3) | Ref. | |
| **Occupation** | | | | | |
| **Skilled** | 83(47.4) | 65(78.3) | 18(21.6) | 1.08(0.88-1.32) | 0.458 |
| **Unskilled** | 92(52.6) | 58(63.0) | 34(36.9) | Ref. | |

| | Overall N(%) | Initiated n(%) | Not Initiated n(%) | Adjusted PR (95% CI) | P-Value |
|---|---|---|---|---|---|
| **Social economic Status** | | | | | |
| **Poorest** | 37(21.1) | 17(45.9) | 20(54.0) | Ref. | |
| **Poorer** | 31(17.7) | 20(64.5) | 11(35.4) | 1.20(0.66-2.18) | 0.530 |
| **Middle** | 38(21.7) | 29(76.3) | 9(23.6) | 1.29(0.82-2.02) | 0.262 |
| **Richer** | 40(22.8) | 32(80.0) | 8(20.0) | 1.07(0.53-2.17) | 0.835 |
| **Richest** | 29(16.6) | 25(86.2) | 4(13.7) | 1.13(0.51-2.49) | 0.758 |
| **No. of persons in the household** | | | | | |
| **1-2** | 26(14.8) | 10(38.4) | 16(61.5) | Ref. | |
| **3-5** | 108(61.7) | 84(77.8) | 24(22.2) | 1.44(0.95-2.19) | 0.081 |
| **>5** | 41(23.4) | 29(70.7) | 12(29.2) | 2.02(1.26-3.23) | 0.003 |
| **Average time of contact during the day** | | | | | |
| **<3 hours** | 29(16.6) | 14(48.2) | 15(51.7) | Ref. | |
| **3-6 hours** | 75(42.9) | 60(80.0) | 15(20.0) | 1.74(1.11-2.73) | 0.016 |
| **> 6 hours** | 71(40.5) | 49(69.0) | 22(30.9) | 1.66(1.06-2.58) | 0.024 |
| **Sleep With the child in the same room** | | | | | |
| **Yes** | 107(61.1) | 87(81.3) | 20(18.7) | 1.50(1.22-1.85) | <0.001 |
| **No** | 68(38.9) | 36(52.9) | 32(47.1) | Ref. | |
| **Period worked in TB Clinic** | | | | | |
| **<1yr** | 52(30.1) | 44(84.6) | 8(15.4) | Ref. | |
| **1-3 Yrs** | 12(6.9) | 8(66.7) | 4(33.3) | 1.13(0.59-2.16) | 0.708 |
| **3-5 Yrs** | 108(62.4) | 69(63.8) | 39(36.1) | 0.92(0.56-1.53) | 0.773 |
| **5-10 Yrs** | 1(0.6) | 1(100.0) | 0(0.0) | 1.76(0.45-6.91) | 0.415 |
| **Stock outs of IPT** | 5(100.0) | 5(100.0) | 0(0.0) | 1.11(0.72-1.70) | 0.628 |
| **Lack of TB screening facilities** | 34(100.0) | 30(88.2) | 4(11.8) | 0.85(0.36-2.00) | 0.720 |
| **Shortage of staff** | 28(100.0) | 26(92.8) | 2(7.2) | 1.29(0.42-3.91) | 0.652 |
| **Inadequate training on IPT** | 51(100.0) | 44(86.3) | 7(13.7) | 1.19(0.72-1.97) | 0.480 |

# CHAPTER FIVE

# DISCUSSION, CONCLUSION AND RECOMMENDATIONS

## 5.1 Discussion

### 5.1.1 Socio demographic characteristics associated with initiation of IPT among Under- fives.

The socio demographic factors associated with IPT initiation among children below five years according to this study were level of education, age group, place of residence (rural or urban) and occupation of caregiver. This study showed that sputum positive PTB persons with no post-primary education were more likely to initiate their children on IPT than those with incomplete primary education. A number of studies have shown that higher educational status is associated with a higher initiation of preventive therapies like IPT (Bugvi *et al.*, 2014; Jani *et al.*, 2008; Mohammed, 2016)**.**

However, a study in Nairobi County contrasted the above findings noting that children whose caregivers had attained secondary school level of education were less likely to receive IPT compared with children of caregivers who had no or lower level of education. It showed that more educated caregivers were more likely to decline IPT initiation for their children citing pill burden whereas those who were less educated were reported to follow instructions of the health workers (Peninah, 2016). Gust and colleagues also observed that the case non-adherent group includes a greater proportion of persons with higher education level (Gust *et al.*, 2011).

This study found that those caregivers aged less than 25 years were more likely to initiate their children on IPT compared to those above 40 years of age. However, a study in Zimbabwe revealed that age groups less than 29 years had a significantly lower initiation of IPT when compared to the older cohorts of clients (Abrams & Strasser, 2015; Bekezela, 2017; Newton *et al.*, 2008). Similar findings by Gust and colleagues observed that the case non-adherent group includes a greater proportion of younger men (Gust *et al.*, 2011).

The implication of this study finding is that younger caregivers may be more likely to take proactive steps to protect their children from TB, such as initiating them on IPT. This could indicate that younger caregivers may be more aware of the risks of TB and the benefits of IPT, or that they may be more likely to follow through with recommended treatments for their children. Additionally, it could also imply that interventions to increase awareness and utilization of IPT among older caregivers may be needed.

The study further found that respondents who resided in urban and peri-urban areas were more likely to initiate their children on IPT compared to those who resided in rural areas. A study in South India revealed that household contacts in rural localities were less likely to be screened for TB disease and/or initiated on IPT compared to those in urban localities (Pothukuchi *et al.*, 2011). In another Malawian study, of actively screened child contacts, 39% of children came to the hospital for screening, of which only 40% (16% of total) returned for screening results or medication (Zachariah *et al.*, 2003). Overcrowding is a risk factor for TB infection and is common in urban and peri-urban settings as confirmed by a study in urban Gambia which noted that three quarters of cases and 60% of controls in the study were from households that were in the highest crowding category-reflecting the likelihood of IPT initiation in urban areas (Hill *et al.*, 2006).

### 5.1.2 The prevalence of IPT initiation among children aged below five years who are household contacts of smear positive PTB persons.

This study established 70.2% prevalence rate of IPT initiation among respondents who were likely to initiate children and among these respondents, female participants were more likely to initiate their children. They had the highest under five IPT initiation rate of 72.6% compared to 67.5% among males. This was supported by the demographic aspects of the caregivers since majority in this study were educated, skilled, married, of age group 25-29 years and resided in the urban areas. A study in Ethiopia of 221 children eligible for IPT, 64.3% (142) received IPT, 80.3% (114) successfully completed six months of therapy. No child developed active TB while on IPT. Contact screening is a good entry point for delivery of IPT to children at risk

and should be a routine practice as recommended by the WHO despite the implementation challenges (Tadesse *et al.*, 2016). Children whose caregivers had a history of being on IPT had an increased likelihood of initiation according to a study in Nairobi (Peninah, 2016).

It is estimated that around 10% of the world's tuberculosis (TB) cases occur in children 0–14 years of age (Nelson & Wells, 2004). Young children living with a tuberculosis patient are at a high risk of Mycobacterium tuberculosis infection and disease. WHO guidelines promote active screening and Isoniazid Preventive Therapy (IPT) for such children under 5 years, until now this well-established intervention is still not completely embraced in endemic countries (Rutherford *et al.*, 2012). Of the 184 children who were screened in a study of IPT Programme in South Africa, 59% (*n*=108) were documented as having started IPT, 2 started full TB treatment and for 40% (*n*=74) there was no documentation of further management or follow-up. The last represents missed opportunities for providing TB preventive therapy in a community where TB is rife (Black *et al.*, 2018).

A number of important initiatives have been facilitated by the childhood TB subgroup of the WHO Stop TB partnership aimed at greater emphasis on childhood TB by National TB programmes (NTP) that includes screening children living with an infectious case followed by the provision of preventive therapy (PT) for those cleared of TB disease (WHO, 2011). However, for a variety of reasons, these recommendations, including preventive therapy provision, are rarely fully implemented in high-burden countries. This is important, as a large proportion of childhood TB occurs in children younger than 5 years who would have been eligible for PT (Du Preez *et al.*, 2011). Literature review regarding barriers to implementation of PT found that there are a myriad of factors, including difficulties in screening, poor adherence, fear of increasing INH resistance and poor acceptability among primary caregivers and healthcare workers (Rutherford *et al.*, 2012).

Current strategies to reduce the burden of TB in children in endemic countries focus on the identification and treatment of infectious adult cases and Bacillus Calmette–

Guerin (BCG) vaccination(Marais *et al.*, 2009). These methods are insufficient to control childhood TB (Lawn *et al.*, 2006). A study from Guinea-Bissau emphasized the need for child contact focused TB prevention measures as it reported a 66% higher mortality among children exposed to TB at home than unexposed children from the same community (Gomes *et al.*, 2011). In children under 6 years of age, the initiation of INH preventive therapy is low, even with active case finding in Malawi (Zachariah *et al.*, 2003).

The benefits of preventive therapy have been recognized since the 1950s. Studies indicate that to attain TB eradication by 2050, preventive measures must be included in TB programmes (Dye & Williams, 2007). The most widely adopted preventive therapy regimen is Isoniazid Preventive Therapy (IPT) using daily isoniazid (INH) for at least 6 months. In general, IPT is safe and well tolerated by children and adolescents; major potential serious adverse events (SAE), including hepato-toxicity and pyridoxine deficiency, are rare in children (Donald, 2010). Following infection, infants and young children (<5 years) are at the highest risk of progression to disease. Review of the pre-chemotherapy literature shows that 40–50% of infected infants (0–11 months), 10–20% of children aged 1 year and 10% of children aged 2–4 years progress to disease (Marais *et al.*, 2004).

### 5.1.3. Household level factors associated with initiation of IPT among Children aged below 5 years.

The household level factors associated with initiation of IPT among children aged below 5 years as was established by this study was determined by the number of persons living in the household and by the likelihood of caregivers sleeping with the child in the same room. Studies in developed and developing countries show that the most effective means of case identification is at the household contact level (Becerra *et al.*, 2005; Zachariah *et al.*, 2003).

Studies have shown that risk of contracting TB was associated with the number of people living together in the household also referred to as overcrowding (Hermans *et al.*, 2010; Hill *et al.*, 2006; Lönnroth *et al.*, 2008). Studies have shown that increased household size was found to be an important factor in infection with TB and

overcrowding has been documented as a risk factor for TB in a variety of settings (Coker *et al.,* 2006; Mangtani *et al.,* 1995). This study is consistent with the fact that overcrowding is a risk factor for TB and revealed that respondents who had between 3 and 5 persons in the household were more likely to initiate their children on IPT compared to those who had 1-2 persons in the household as they may have felt that the children were likely to contract TB.

It was noted in this study that respondents who sleep with their children in the same room were more likely to initiate their children on IPT compared to those who did not sleep with their children in the same room. Children who are exposed to an infectious adult with TB and are asymptomatic, require IPT regardless of the TST result (Khan & Starke, 1995). Studies have shown that children exposed to patients who are sputum positive and/or have extensive lung involvement are at high risk of infection. Children who sleep in close proximity to a source case and those whose source case is a female family member are also at increased risk, more than five times higher in some reports hence a higher likelihood of initiation to IPT (Kenyon *et al.,* 2002; Lienhardt *et al.,* 2003; Lockman *et al.,* 1999). The younger children often sleep closer to their mothers hence these caregivers are likely to perceive the risk they pose to the children hence have them initiated on IPT as compared to those who do not sleep in proximity with the under five-year-old.

Family and other social support related factors mainly the nature of relationships with family members, the wider community, and others taking IPT, as well as the adverse effects of stigma that emanates from these relationships influence IPT initiation (Rowe *et al.,* 2005). Relationships with family and friends appear to determine whether patients feel comfortable about taking IPT (Gust *et al.,* 2011). It is worth noting that several factors influence IPT initiation including the long duration of IPT, TB/HIV collaborative activities and multidrug chemo prophylactic regimens. Additional barriers to initiation of and adherence to IPT include stigma related to TB, community misconceptions around the role of IPT and social problems, such as substance abuse and domestic violence among others.(Skinner *et al.,* 2013).

### 5.1.4. Healthcare level factors associated with initiation of IPT among Children aged below 5 years who are household contacts of smear positive PTB persons.

Healthcare level factors that were assessed in this study were health workers' years of experience, training on IPT, duration of working in TB clinic, refusal by parents to bring children to the facility, lack of TB screening facilities for children, IPT stock outs and shortage of staff. Research has shown surprisingly low levels of acceptability and knowledge of preventive therapy (PT) in Health Care Workers. In Australia, 17% of patient caregivers were told by their doctors not to give PT to their children (Alperstein *et al.*, 1998), while in India, in a setting where PT had been emphasized, only 27% of cases were told of the need to screen and treat their child contacts by a Health Care Worker (Banu Rekha *et al.*, 2009). These studies are consistent with the findings of this research that established that;

This study showed that health workers with more experience had a higher prevalence of initiating their patients to IPT than those with little experience. One possible explanation is that health workers with more experience have a greater knowledge and understanding of IPT. They may be more familiar with the benefits and risks of IPT and are more likely to initiate it in appropriate cases. Additionally, with more experience, health workers may feel more confident in their ability to properly administer IPT to patients, leading to increased initiation of IPT.

Another possible reason is that health workers with more experience may be more aware of the importance of IPT in preventing the spread of tuberculosis (TB). They may have a greater understanding of the impact of TB on communities and may be more likely to initiate IPT in appropriate cases to help prevent its spread. Furthermore, experienced health workers may have better communication skills and may be able to better explain the benefits of IPT to patients, leading to increased initiation of IPT. It could mean that newer health workers may need more support and guidance in initiating IPT. This could mean that mentorship programs or shadowing opportunities with more experienced health workers could be beneficial in increasing the initiation of IPT by newer health workers.

Formal training on IPT had a significant association with the prevalence of IPT initiation at the health facility according to this study. In America, international medical graduates were significantly less likely to prescribe PT to a client and to believe that PT was protective against TB disease compared to American medical graduates (Hirsch-Moverman *et al.*, 2006). In South Africa, it was found that Health Care Workers lacked knowledge and experience of IPT (Lester *et al.*, 2010). In order to implement IPT and monitor this activity efficiently, all health workers must be adequately trained and sensitized on the importance of contact screening and they must be effective in passing on this information to the community (Pothukuchi *et al.*, 2011). Indian health care workers (HCWs) claimed poor guidelines and system difficulties made PT programmes hard to implement, and fear of being blamed for causing unnecessary adverse events in children was also mentioned (Banu Rekha *et al.*, 2009). Thai doctors cited fears of adverse events and expressed concern over an increase in resistance to INH and a lack of resources to conduct proper screening (Tornee *et al.*, 2005). The findings of this study are hence like the studies highlighted.

The study also found out that Isoniazid stock outs and lack of TB screening facilities for children had a significant association with the prevalence of IPT initiation at the health facility. Unavailability of Tuberculin Skin Test (TST), lack of staff expertise to interpret test results, additional transport costs, time required to complete the screening process and increased staff workload have all been described as barriers to IPT delivery (Rutherford *et al.*, 2012). This finding is similar across other studies. The reason given for not initiating IPT in 19 screened children was due to shortages of INH tablets at the peripheral health centers in South India District. In addition, the necessary tools for diagnosis of tuberculosis such as chest radiography and TST must be made available in health facilities along with Isoniazid tablets, in appropriate doses and adequate quantities (Pothukuchi *et al.*, 2011).

Kenya, like many African countries, experiences significant shortage in professional health workers. A study in Ethiopia indicated that initiation and adherence to IPT is facilitated by interactions with a clinician that include counseling therefore patients who had received explanation about IPT were 8 times more likely to be adherent

(Mindachew *et al.,* 2011). Previous studies conducted in Kenya and Zambia, confirm that the inadequacy and poor quality of physicians' interpersonal skills negatively affect adherence to treatment (Bartlett *et al.,* 1984). In a study conducted in a large TB clinic with high TB case load in South Africa (Van Wyk *et al.,* 2010), it was discovered that one reason for poor performance in provision of IPT to children resulted from insufficient knowledge of contact management by health workers similarly study showed that lack of training on IPT had a negative impact on the intiation of IPT among children below the age of five.

## 5.2 Conclusion

- The study established a relatively fair prevalence rate of IPT initiation among children aged below 5 years which reflects an improvement from previous statistics. This places Kisumu County at a better position of achieving the WHO's recommended IPT initiation target of 80%. The lower prevalence of IPT initiation among male PTB contacts is a point of concern.
- Various household level factors were determined to influence IPT initiation among this age group in Kisumu County. Notably, younger population were more likely to initiate IPT among under-fives compared to the elderly. Other household level factors that had been established by previous studies were still discovered to be significantly associated with IPT initiation in Kisumu. These household factors include level of education, area of residence, number of people in the households and sputum positive PTB persons sleeping with children aged below 5 years in the same room.
- A lot is yet to be done at the facility level to improve the outcomes of IPT initiation among under five children in Kisumu. The findings of this study show gaps that need to be addressed at the health care facilities. Isoniazid stock outs, refusal by parents to bring children to the facility, lack of TB screening facilities, shortage of staff and inadequate training on IPT have a significant association with the prevalence of IPT initiation in Kisumu.

## 5.3 Recommendation for Practice

1. **Prevalence and Household level factors**

   This study recommends that the Ministry of Health (MOH) and collaborates to advocate for health promotion activities i.e., sensitization among smear positive PTB persons with children aged below 5 years to help bolster IPT initiation especially in rural areas. This should include social behavioral change messaging among the health care workers and general population.

2. **Health Facility level factors**

   Incorporation of in-depth patient education during routine clinic visits

   Ensuring staff working at TB clinics are well equipped and knowledgeable on current guidelines. Ministry of Health (MOH/GOK) and collaborates should procure IPT and ensure its availability to avoid stock outs and ensure adequate training of staff on TB screening and modalities of management especially among staff with fewer years of experience.

## 5.4 Recommendations for Further Research

Future studies need to look at:

1. Barriers and facilitators of adherence to IPT among children aged below 5 years in contact with sputum positive PTB persons.
2. Predictors of missed opportunity to IPT initiation among children aged below 5 years in contact with sputum positive PTB persons.
3. Loss to follow up among under-five in contact with sputum positive PTB persons initiated on IPT.

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## APPENDICES

### Appendix I: Questionnaire (Persons with PTB)

MODULE 1: INDIVIDUAL SOCIO-DEMOGRAPHIC CHARACTERISTICS

TB clinic No. _____Serial No: _____ Date _____

1. Individual demographic characteristics of the index

a. Sex of the index

1= Male

2= Female

b. What is the highest level of education that you attained?

1= No formal education 2=primary incomplete 3=Primary complete

4=secondary incomplete

5=above secondary

c. Current marital status of the index:

1=Married monogamy.

2= Married polygamy

3= Divorced

4= Separated

5= Single

d. Relationship to the child

1= Parent

2= Sibling

3=Aunt /Uncle

4= Grand parent

5= Caretaker

6= other specify

e. Date of birth of respondent - -/- -/- - - - (dd/mm/yyy)

f. Age of the respondent ___ ___ years

g. Area of residence:

1=urban

2= rural

3= peri-urban)

h. Occupation

1=farmers

2= fishermen

3= salaried

4= skilled labor,

5= unskilled labor

i. Do you smoke?

0=No

1= Yes

j. Do you take alcohol?

0= No

1=Yes

**MODULE 2; HOUSEHOLD LEVEL CHARACTERISTICS**

a. Do you own a television?

1=No

2=Yes

b. Do you own a fridge?

1=No

2=Yes

c. Do you own a bicycle?

1=No

2=Yes

d. Do you own a motorbike?

1=No

2=Yes

e. What is your main source of cooking fuel?

1= Firewood

2= Charcoal

3= Gas

4= Electric cooker

f. Do you own any car?

1= No

2=Yes

g. What material is the floor of your house made of?

1= Mud

2= Cement

3= Tiles

h. What material is the roof of your house made of?

1= Grass

2= corrugated iron sheets

3=Asbestos

4= Tiles

i. What is your source of drinking water?

1=Running tap water

2=Borehole water

3=Rain water

4= Water vendor

j. How many cows do you own?

1= none 2= 1-3 3 = 4-6 4= 7-10 5=> 10

k. Approximately how many persons live with you in the household?

1=1-2

2=3-5

3=>5

l. Sex of the household head/single parenthood

1= Male

2= Female

m. How many children under-five years old do you live with in the same house?
__ ___

n. Has any of the children under five years old been initiated on IPT?

0= No

1= Yes

o. How many children under five years old that you live have been initiated on IPT? ___ ___

p. Number of rooms in the house?

1=1

2=2-3

3=>3

q. What is the average time of contact with the under-five during the day?

1=< 3 hours

2= 3-6 hours

3=> 6 hours

r. Do you sleep with the under five year old in the same room?

0=No

1= Yes

**MODULE 3: KNOWLEDGE ON TB.**

a. What is your main source of information about TB?

1= Radio

2= Television

3= Newspapers

4= Health center

5= Community Health Workers

6= Friends/Neighbors

7= Others_____

b. What causes TB?

1= Bacteria

2= Virus

3= Germs

4= Unknown

5= Others _____

c. How is TB spread?

1= Airborne

2=Food borne

3= Water borne

4=Skin contacts

5=Kissing

6=Sex

7=Breastfeeding

8=Unknown

9=Others _____

**MODULE 4: INDEX CASE TB DIAGNOSIS AND TREATMENT**

a. Duration since TB diagnosis (Months)?

1= < 1

2= 1 < 2

3= 2 < 4

4= 4 < 6

5= >6

b. For how long did you have the symptoms of TB prior to diagnosis (months)

1= < 1

2= 1-2

3 = > 3

c. How was the TB diagnosis made?

1= Chest X-ray

2= Sputum report

3= both chest X-ray and sputum report

d. HIV status of respondent?

1=Positive 2= Negative

3= Unknown

e. Is this the first time you are on treatment for TB?

0=No

1= Yes

f. What challenges have you experienced with TB treatment?

1= Too long

2=Bad taste

3=Too many drugs

3= Too many hospital visits

4= Side effects

5=Stigma

6= Others__

g. Have you missed any of your TB doses?

0= No

1= Yes

h. If yes, why did you miss a dose?

1=Forgot

2= Stock out

3=Travelled

4=Side effects

5= others (specify) _____

i. Have you ever been asked to take your children < 5yrs for TB check at the health center after being diagnosed with TB?

0= No

1=Yes

j. If yes, what was the source of information?

1= TB clinic

2=Community Health Worker

3= Friend/ Neighbor

4=other, specify _____

**Appendix II: Key Informant Questionnaire (Health Care)**

a. Name of health facility: _____

b. Type of health facility:1= Referral hospital

2= County hospital

3=Sub county hospital

4= others, specify_____

c. Code of respondent __ __

d. Age of respondent :1=20 -29

2= 30- 39

3= 40-49

4= 50-59

5= 60 and above

e. Sex of respondent :1= Male

2= Female

f. Occupation of respondent :1= Doctor

2=Nurse

3=Clinical officer

4=Pharmacist

5=Community health worker

6= other health professionals (specify) _____

g. What is the highest level of schooling you reached to become a practicing health care provider?1= Doctorate

2=Master's degree

3= Bachelor's degree

4= Diploma

5= Certificate

6=No formal certificate/ qualification

h. For how long have you been working as a health care provider (years)?

1= < 1

2= 1-3

3= 3-5

4= 5-10

5=> 10

i. For how long have you been working in the TB clinic (Years)?

1= < 1

2 = 1-3

3=3-5

4= 5-10

5= >10

j. Have you received any formal training on Isoniazid Preventive Therapy? 0= No

1= Yes

k. If YES, who offered this training?

1=in –house training

2= MOH Trainer of trainers

3= External partners (e.g. NGOs)

4= others, specify _____

l. How often are these trainings held?

1= quarterly

2= bi annually

3= annually

4= No training schedule available

5 = others, specify _____

m. Do you have guidelines on IPT at your TB clinic?

0= No 1= Yes

n. Are there strategies put in place to enhance IPT initiation among the children aged below 5 years in your facility? 0= No

1= Yes

o. If yes, what are some of these strategies?

1=Referrals from other partners

2=Community sensitization and mobilization

3=Staff friendliness

4=Shorter turn-round for the participant at the clinic

5=Availability of TB screening machines

6= others, specify: _____

p. What are the challenges you face in the provision of IPT to children aged below 5 years?

1=Stock outs of IPT

2=Parental/ guardian refusal to bring the children to the facility

3=Lack of TB screening facilities for the children

4=Shortage of staff

5=Lack/ Inadequate training on IPT

6=others, specify_____

**Appendix III: Consent Forms**

**INFORMED CONSENT ENGLISH VERSION**

My name is Eunice Ouma, a postgraduate student at Jomo Kenyatta University of Agriculture and Technology (JKUAT). I am carrying out a study to find out the influence of adults diagnosed with sputum positive Tuberculosis (TB) in close contact with children below five years and the influence of healthcare providers in the initiation of Isoniazid Preventive Therapy (IPT).

Children especially those below five years are at greatest risk of acquiring TB and commonly get infected with TB by inhaling TB causing bacteria from older persons living with them whenever they cough, sneeze, or laugh. Isoniazid is a drug used to treat TB and has been shown to help in preventing TB, if taken by a person at risk of developing TB. Children below five years who are household contacts with persons diagnosed with sputum positive pulmonary TB are hence at risk of being infected with TB which may progress to disseminated disease and even death. As an adult with sputum positive pulmonary TB / healthcare worker dealing with TB, you will be asked some personal information, household/work related information and your views in regard to IPT. This will be done by administering a questionnaire.

The information that you shall provide will be held in confidence and used only for the purpose of the study. The questionnaires will be kept in a secure place and no names will be recorded in the questionnaires. Participating in this study is voluntary; you may choose not to take part in the study. The results obtained from this study will inform the health care sector on ways of improving IPT initiation so as to reduce occurrence of TB disease in children.

If you have understood the above information and agree to participate in this study, please sign below:

Name of subject (please print)

_____

Signature/Thumbprint of subject Date and time.

Name of Witness

_____

Signature of witness Date and time

Name of person obtaining the consent

_____

Signature of person obtaining consent Date and time

**INFORMED CONSENT KISWAHILI VERSION**

Jina langu ni Eunice Ouma, mimi ni mwanafunzi wa shahada ya uzamili katika chuo kikuu cha Kilimo naTeknolojia cha Jomo Kenyatta (JKUAT). Ninafanya utafiti kutambua athari ya watu wazima waliogunduliwa na kifua kikuu kupitia makohozi hasa wanaoishi na watoto chini ya miaka mitano na athari kwa wahudumu wa afya katika matumizi ya dawa ya Isoniazid ya kuzuia kifua kikuu (IPT). Watoto wachanga hasa wale walio chini ya miaka mitano wako katika hali hatari ya kupata kifua kikuu na hasa kwa kupumua ndani chembechembe zinazosababisha kifua kikuu kutoka kwa watu wazima wanaoishi nao wanapokohoa, kupiga chafya au hata kucheka. Isoniazid no mojawapo ya dawa inayotumika kutibu kifua kikuu na imeonekana kuwa bora zaidi kwa kuzuia kifua kikuu kwa wale walio kwenye hatari ya kupata ugonjwa wa kifua kikuu. Watoto walio chini ya miaka mitano wanaoishi na wale walio na ugonjwa wa kifua kikuu uliotambulika kupitia makohozi wako katika hali ya hatari ya kuambukizwa ugonjwa wa kifua kikuu ambao huenda unaweza kusababisha kifo ikizidi sana.

Kama mtu mzima aliyepata ugonjwa wa kifua kikuu kupitia makohozi au mhudumu wa afya anayeshughulika na ugonjwa wa kifua kikuu, utaulizwa kuhusu habari fulani za kibinafsi kuhusu nyumbani au kuhusiana na kazi kufuatana na maoni kuhusu IPT. Hii itafanywa kupitia kujibu maswali yaliyochapishwa.

Habari utakayopeana itawekwa kisiri na itatumika kwa ajili ya utafiti pekee. Majibu yako kwenye maswali yaliyochapishwa yatawekwa mahali salama na hakuna majina yatakayorekodiwa kwa majibu yako. Kushiriki kwa utafiti huu ni hiari yako; na unaweza kuamua kutoshiriki katika utafiti huu. Matokeo yatakayopatikana kwenye utafiti huu yatasaidia sekta ya afya katika kudumisha matumizi ya dawa yakuzuia kifua kikuu na hivyo basi kupunguza kuwepo kwa ugonjwa wa kifua kikuu kwa watoto.

Ikiwa umeelewa habari uliyoelezwa na unakubali kushiriki katika utafiti huu, tafadhali weka sahihi hapa chini:

_____

Jina la mshiriki (Tafadhali andika kwa herufi kubwa)

_____

Sahihi/Kidole-gumba cha mshiriki; Tarehe na saa

_____

Jina la Shahidi (Tafadhali andika kwa herufi kubwa)

_____

Sahihi ya shahidi Tarehe na saa

_____

Jina la anayemshirikisha mshiriki

_____

Sahihi Tarehe na saa

**INFORMED CONSENT LUO VERSION**

Nyinga en Eunice Ouma, an e tiegruok e mbalariany mar, Jomo Kenyatta University of Agriculture and Technology (JKUAT). Atimo nonro mar fwenyo yore ma jomadongo ma oseyudi gituo mar kehera mar oboo to kendo odak gi nyithindo ma hikgi pok oromo abich kod kaka jochiw thieth luwo yore mag kawoyath mar geng'o kahera miluongoni Isoniazid.

Nyithindo to ahinya ma pok oromo higni abich, ni e thuolo ma malo mar gamo tuo mar kahera e kwuom ywayo muya man gikute mag kahera koa kuom jomadongo ma oseyud gi tuo mar kahera ma gidakgo e seche ma gifuolo, gigir, kata ginyiero. Isoniazid en yath mar thiedho tuo mar kahera kendo osepuodhi nikonyo e geng'o tuo mar kahera, kaomuonye gi ng'atno mani e thuolo ma malo e yudo tuo mar kahera. Nyithindo ma hikgi pok oromo abich ma odak gi jogo ma oseyudi gi tuo mar kahera mar oboo mafwenyore ei okego nigi thuolo ma malo mar yudo tuo mar kahera ma nyalo landore mathoth kendo nyalo kelo tho. Nikech in ng'ano ma ni gi tuo mar kahera mar oboo mafwenyore ei okego, ibiro penji penjo kaluwore gi ngimani, kar dakni, giweche maluwore gi yath mar geng'o kahera, Isoniazid. Mae ibiro tim kitiyo gi penjo ma ondike e oboke.

Weche ma ichiwo ibiro kan maling'ling' kendo ibiro tiyogo e nonroni kende. Oboke ma nigi andiko kuom penjo miduoko ibiro kan kama orit maber kendo ok bi ndik nyingi kamoro amora ei obokeni. Donjo ei nonroni en kuom hero mari. Duoko kuom nonroni biro chiwo ratiro ne yore mag bero tiyo gi yath mar Isoniazid e geng'o tuo mar kahera mondo ogeng' landruok mar kahera kuom nyithindo.

Ka isewinjo weche moler kuom nonroni kendo iyie bedo jakanyo mar nonroni, ikwayi mondo iket seyi e obokeni.

_____

Nying jachiewre (Ndik maler)

_____

Seyi/ Lith lwedo mar jachiewre Tarik gi saa

_____

Nying janeno (Ndik maler)

_____

Seyi mar janeno Tarik gi saa

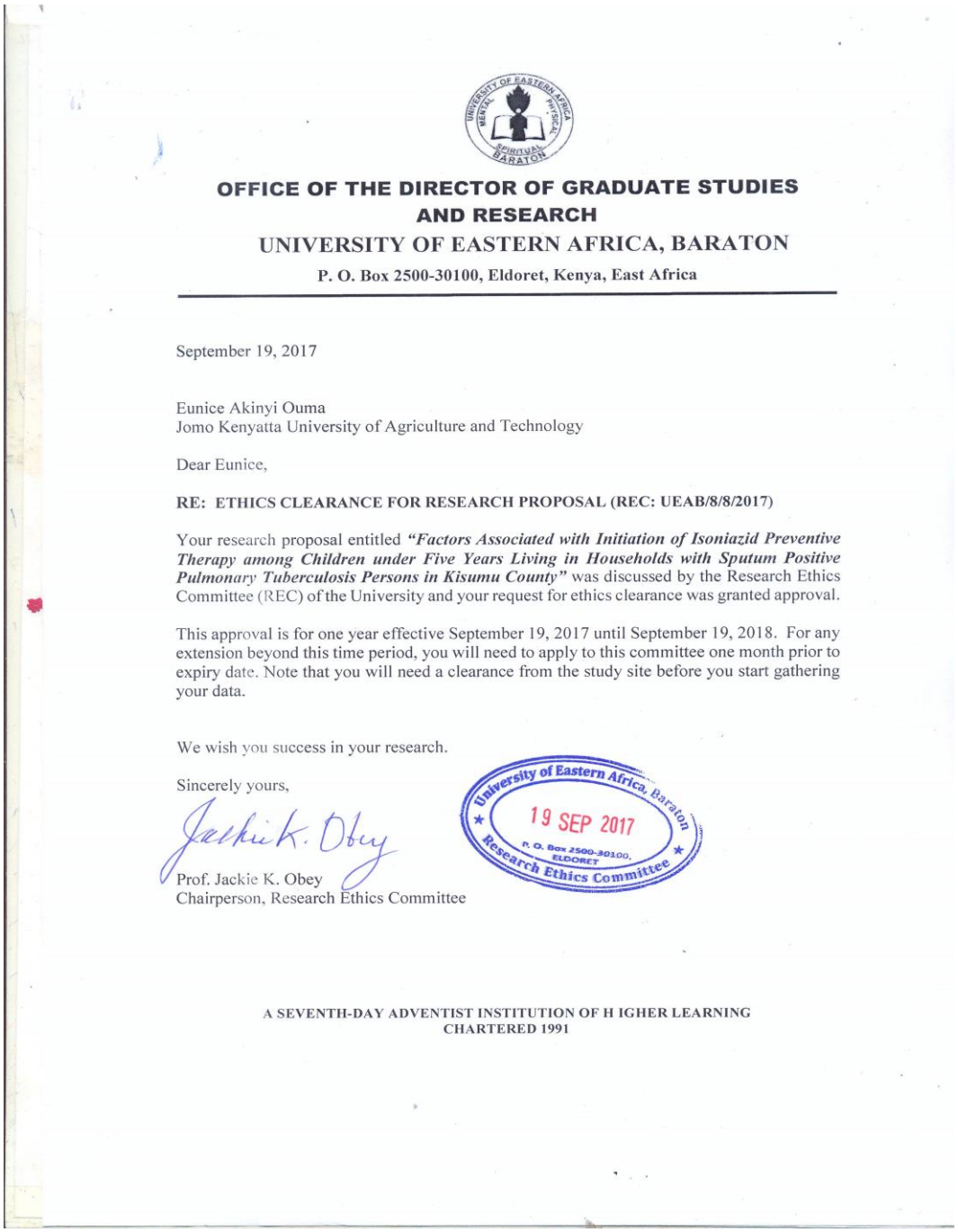
_____

Nying ng’at matayo kawo yie

_____

Seyi mar ng’at matayo kawo yie Tarik gi saa

## Appendix IV: Ethical Clearance Certificate



**OFFICE OF THE DIRECTOR OF GRADUATE STUDIES AND RESEARCH**

**UNIVERSITY OF EASTERN AFRICA, BARATON**

**P. O. Box 2500-30100, Eldoret, Kenya, East Africa**

September 19, 2017

Eunice Akinyi Ouma
Jomo Kenyatta University of Agriculture and Technology

Dear Eunice,

**RE: ETHICS CLEARANCE FOR RESEARCH PROPOSAL (REC: UEAB/8/8/2017)**

Your research proposal entitled ***"Factors Associated with Initiation of Isoniazid Preventive Therapy among Children under Five Years Living in Households with Sputum Positive Pulmonary Tuberculosis Persons in Kisumu County"*** was discussed by the Research Ethics Committee (REC) of the University and your request for ethics clearance was granted approval.

This approval is for one year effective September 19, 2017 until September 19, 2018. For any extension beyond this time period, you will need to apply to this committee one month prior to expiry date. Note that you will need a clearance from the study site before you start gathering your data.

We wish you success in your research.

Sincerely yours,

Jackie K. Obey

Prof. Jackie K. Obey
Chairperson, Research Ethics Committee

University of Eastern Africa, Baraton
19 SEP 2017
P. O. Box 2500-30100, ELDORET
Research Ethics Committee

A SEVENTH-DAY ADVENTIST INSTITUTION OF H IGHER LEARNING
CHARTERED 1991

## Appendix V: JOOTRH Ethical Approval

**MINISTRY OF HEALTH**


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

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


**Ref:** ERC.1B/VOL.I/398

**Date** 11th December, 2017

Eunice Akinyi Ouma,
**JKUAT**

Dear Eunice,

**RE: REQUEST FOR ETHICAL APPROVAL TO UNDERTAKE A STUDY ENTITLED: *"FACTORS ASSOCIATED WITH INITIATION OF ISONIAZID PREVENTIVE THERAPY AMONG CHILDREN UNDER FIVE YEARS LIVING IN HOUSEHOLDS WITH SPUTUM POSITIVE PULMONARY TUBERCULOSIS PERSONS IN KISUMU COUNTY."***

The JOOTRH ERC reviewed your protocol and found it ethically satisfactory. You are therefore, permitted to commence your study immediately. Note that this approval is granted for a period of one year (11th December, 2017 to 10th Decemberr, 2018). If it is necessary to proceed with this research beyond the approved period, you will be required to apply for further extension to the committee.

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

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

Finally, note that you will also be required to share the findings of the study in both hard and soft copies upon completion.
The JOOTRH ERC takes this opportunity to thank you for choosing the institution and wishes you the best in your endeavours.

Yours sincerely,

WILBRODA MAKUNDA
**SECRETARY – ERC,**
**JOOTRH.**

JOOTRH ETHICS & REVIEW COMMITTEE
P. O. Box 849 - 40100
KISUMU

## Appendix VI: County Government Authorisation

# COUNTY GOVERNMENT OF KISUMU

Telegrams: "PRO.(MED)"
Tel: 254-057-2020105
Fax: 254-057-2023176
E-mail: kisumucdh@gmail.com

County Director of Health,
Kisumu.
P.O. Box 721-40100,
KISUMU.

## DEPARTMENT OF HEALTH

REF: GN133 VOLIII/(203)

Date: 19th October, 2017

**CEO - JOOTRH**

**Med Supt.** – Kisumu County Hospital, Lumumba SC, Migosi SC, Rabuor SC, St.Elizabeth Chiga

**RE: RESEARCH AUTHORIZATION – EUNICE AKINYI OUMA**

The above named Jomo Kenyatta University of Agriculture and Technology student has been granted permission to carry out the research on **"Factors associated with initiation of Isoniazid Preventive Therapy among children under five years living in households with sputum positive pulmonary Tuberculosis persons in Kisumu County"** for the period ending 1st October, 2018.

This is therefore, to request you to give her your co-operation as she conducts the research.

Dr. Onyango Dickens
County Director of Health
**KISUMU COUNTY**

COUNTY DIRECTOR OF HEALTH KISUMU

*From the Desk of County Director of Health*