

**ASSESSMENT OF FACTORS THAT AFFECT DIAGNOSIS AND MANAGEMENT
OF CHILDHOOD TUBERCULOSIS AMONG HEALTHCARE WORKERS IN
SIAYA COUNTY, KENYA**

**BY
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**A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS
FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH IN
EPIDEMIOLOGY AND POPULATION HEALTH**

SCHOOL OF PUBLIC HEALTH AND COMMUNITY DEVELOPMENT

MASENO UNIVERSITY

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DECLARATION

I declare that this thesis is my original work and has not been presented to any other University or Institution for a degree or any other award.

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I would like to pay my special regards to my study respondents for their participation in this research study and willingness to share about your experience.

DEDICATION

This work is dedicated to my family for their love and support.

ABSTRACT

Every day, up to 562 children die from Tuberculosis (TB). It is one of the top 10 causes of death and leading cause of death from single infectious agent. Diagnosis of childhood TB is key to its treatment by healthcare workers (HCWs) who often overlook it due to its difficulty to diagnose and treat. In 2019, 1.2 million children fell ill with TB, with 24 of the 30 TB HBCs accounting for 87% of new TB case are found in Africa. Kenya with a case notification rate (CNR) of 426/100,000, ranked 10th globally and 4th in Sub-Saharan Africa and notified 10,051 (10.4%), while Siaya County notified 98 (5.1%) cases (< 10-15% WHO's recommendation) in 2018. Siaya county with 748/5344 deaths ranked 1st of 47 counties with >5% childhood TB in 2018. Estimating childhood TB's global burden is challenging with up to 65% of children seeking services in health facilities (HFs) remain potentially missed or overlooked each year since HCWs using standard tests fail to detect TB up to 93% of the time. The study aimed to assess factors that affect diagnosis and management of childhood TB among HCWs in Siaya County. Specifically, it set out to determine influences of socio-demographic/socioeconomic factors, level of knowledge, HF based factors and constraints to childhood TB diagnosis and management in Siaya County. This cross-sectional study utilized a mixed method approach and enrolled 241 respondents obtained from 485 HCWs. Data was collected using questionnaires and KIIs. Chi square test of association was used to determine relationship between categorical variables while adjusted odds ratio with 95% confidence levels was used to quantify the strength of the relationship. Results revealed a significant association between socio-demographic characteristics; age ($p=0.003$), highest level of education ($p=0.003$) and current employer ($p=0.047$) being significantly associated with childhood TB diagnosis and management. Chi square test of association analysis linked attendance of seminar, training or workshop on childhood TB ($p=0.012$) and HF type ($p=0.017$) to childhood TB diagnosis and management. Further, stock-outs and correct dosing ($p=0.012$) emerged as constraints to childhood TB diagnosis and management. The results presented showed that; age of the HCW, their level of education, employer and frequent seminar, training or workshop on childhood TB, HF type and constraints were associated with correct childhood TB diagnosis and management in Siaya County. It recommended that decision makers at department level should prioritize employment of young (<30 years) HCWs with diploma, increasing frequency and intensity of attendance seminar, training or workshop on childhood TB, upgrade its HFs and streamline supply chain by addressing constraints which undermined diagnosis and management of childhood TB.

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LIST OF ABBREVIATIONS AND ACRONYMS

CXR	Chest <i>x</i> -ray
ELISPOT	Enzyme- linked Immunospot
FDC	Fixed Dose Combinations
FDA	Food and Drug Administration
HBCs	High Burden Countries
HCWs	Health Care Workers
HIV	Human Immunodeficiency Virus
LTBI	Latent TB Infection
MDGs	Millennium Development Goals
MDR	Multi-Drug Resistance
MoH	Ministry of Health
NLTP	National Leprosy and TB programme
NULD	National Tuberculosis, Leprosy and Lung Disease
TB	Tuberculosis
TST	Tuberculin Skin Test
USCH	Ukwala Sub County Hospital

WHO World Health Organization

XDR Extensive Drug Resistant

DEFINITION OF TERMS

Childhood TB

Childhood TB, defined as tuberculosis in children younger than 15 years of age, which is a direct reflection of the incidence of adult tuberculosis within a community.

Healthcare worker

A healthcare worker is one who delivers care and services to the sick and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians, or even medical waste handlers.

Tuberculosis (TB)

Tuberculosis (TB) is an infectious communicable bacterial pathogen caused by the bacillus called *Mycobacterium tuberculosis* (*M. tuberculosis*); an acid fast rod shaped bacillus 0.8-5µm in length and 0.2-0.6µm in thickness, which is spread when people who are sick with TB expel bacteria into the air; for example, by coughing or sneezing.

Bacteria

Bacteria is a member of a large group of unicellular microorganisms which have cell walls but lack organelles and an organized nucleus, including some which can cause disease.

TB Infection

Means a person has Tuberculosis bacteria in their body. Usually the person's immune (defense) system can fight the bacteria, causing them to become inactive. In about 90% of people, the

bacteria will always be inactive. People with TB infection are not sick and cannot spread TB to others. This is called latent TB infection.

TB Disease

This is an illness caused by active TB bacteria. The illness may occur shortly after the bacteria enter the body, or many years later. Someone with TB disease has active TB bacteria plus signs of illness.

OPERATIONAL TERMS

Diagnosis and Management refers to the ability of health workers (medical officer, nurse or other) to continuously recognize and medically administer treatment a patient with and active *M. tuberculosis* disease.

Childhood Tuberculosis (TB) refers to TB in children younger than 15 (0-14) years of age, is a direct reflection of the incidence of adult tuberculosis within a community.

Tuberculosis management refers to the medical treatment of the infectious disease tuberculosis.

Correct diagnosis refers to identifying a disease from its signs and symptoms, reaching a decision then investigating or analyzing the cause or nature of childhood TB.

Adequate knowledge refers to a research respondent being informed of all required possible knowledge on childhood TB diagnosis and management.

Children refers to those between 0 to 14 years of age

Management refers to process of intervening during childhood TB

Clinicians refers to (Medical Officer, Clinical Officer)

Constraints refers to factors that directly affect childhood TB diagnosis and management but are not within the control of the HCW

CHAPTER ONE: INTRODUCTION

1.1 Background information

Tuberculosis (TB) is an infectious communicable bacterial pathogen caused by the bacillus *Mycobacterium tuberculosis* (Smith, 2003; WHO, 2018b). It is an acid fast rod shaped bacillus 0.8-5µm in length and 0.2-0.6µm in thickness (Delogu, Sali, & Fadda, 2013; Koch & Mizrahi, 2018; Sia & Rengarajan, 2019; WHO, 2018b). TB is spread when people who are sick with TB expel bacteria into the air; for example, by coughing or sneezing (Delogu *et al.*, 2013; Smith, 2003). Another person breathing in the bacteria may become infected with TB but will not necessarily become sick with the disease (P. Nahid *et al.*, 2019). If the bacteria go on to overcome the body's immune system, the person then becomes ill with TB (Cooper, 2009). It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB) (Lee, 2015; Perez-Velez & Marais, 2012; Thomas, 2017; WHO, 2018a). The risk of progression of infection with *M. tuberculosis* to active disease is 5–10% for immune-competent older children (15-18 years) and adults and 40–50% for children in their first 2 years of life (Narasimhan *et al.*, 2013).

TB affects people of both sexes in all age groups, but the highest burden is in men (aged ≥ 15 years) (Enos *et al.*, 2018; Grobusch & Kapata, 2018; Zhang *et al.*, 2016). A person ill with TB presents different symptoms depending on the site of the body affected (Loddenkemper *et al.*, 2016). In pulmonary TB, common symptoms are a cough with sputum production (sometimes with blood), shortness of breath and chest pain (Cowan *et al.*, 2013; Walker *et al.*, 1990). There are also general symptoms such as fever in the evening, night sweats, loss of weight, loss of appetite, fatigue and muscle weakness (Muntean, 2018). Left untreated, each person with infectious pulmonary TB will infect an average of between 10 and 15 people every year (Lin

& Flynn, 2010); (Narasimhan *et al.*, 2013; Reichler *et al.*, 2018). One in ten people infected with TB (but who are not infected with HIV) become ill with TB at some time during their life (Kwan & Ernst, 2011).

Diagnosis of childhood TB relies on thorough assessment of all the evidence derived from a careful history of exposure, clinical examination and laboratory investigations by skilled healthcare worker (HCW) (Marais & Schaaf, 2014; Sarsu & Sahin, 2016). The main tools for the diagnosis of TB are clinical assessment, and bacteriological and radiological investigation (Cudahy & Sheno, 2016; Roya-Pabon & Perez-Velez, 2016). The clinical and radiographic manifestations are less specific in children compared to adults, and are often confused with bacterial pneumonia (Carvalho *et al.*, 2018). X-ray findings may be indicative of TB but usually need confirmation by means of other tests (Bhalla *et al.*, 2015; Nachiappan *et al.*, 2017).

Microbiological confirmation of TB disease is limited by the paucibacillary nature of TB in children (Brent *et al.*, 2017; López *et al.*, 2012; Tsai *et al.*, 2013). TB cultures and newer rapid molecular tests (i.e. Xpert MTB/RIF) are used in children suspected of TB disease (Marais & Schaaf, 2014). Existing diagnostic tests for childhood TB have shortcomings, and full range of tests - including bacteriological culture and tuberculin skin testing (TST) - is often unavailable in settings where the majority of childhood TB cases occur (Venturini *et al.*, 2014). It's hypothesized that, due to the challenges encountered in the diagnosis of childhood TB (≤ 15 years of age), the actual burden of TB in children is presumed to be higher (Miggiano *et al.*, 2020). Accurate and prompt diagnosis of childhood TB is a key factor in TB treatment success by HCWs (Nathavitharana *et al.*, 2017).

TB is a treatable and curable disease (Sia & Rengarajan, 2019; Tiberi *et al.*, 2018). TB can generally be treated with a course of four standard, or first-line, anti-TB drugs (Perez-Velez & Marais, 2012; Tiberi *et al.*, 2018). There is usually an intensive two-month phase of treatment with use of all drugs, followed by a four-month continuation phase with only two drugs (Nahid *et al.*, 2019). Direct observation of treatment (DOT) intake and support to patients in different forms are recommended. If treatment is taken incorrectly or incompletely, resistance to TB drugs can be developed and a cure becomes much more difficult, or impossible in some cases (CDC, 2013). Poor and inadequate treatment has resulted in evolution of Multi-Drug Resistant TB strains that don't respond to treatment with standard first line combination of anti-TB medicines, resulting in emergence of MDR TB and Extensive Drug Resistant (XDR TB) in almost every country of the world (Chani, 2010; Phillips, 2013).

The World Health Organization (WHO) estimates that in 2019, one third of the world's population was infected with TB and that 10 million new TB cases (5.6 million men, 3.2 million women and 1.2 million children) and 1.4 million deaths from TB occurred globally (Grobusch & Kapata, 2018). Consequently, in 2019, WHO estimated 205,000 childhood TB deaths, of which 32,000 occurred in HIV-infected children (Harding, 2020). These deaths were higher than the estimated proportion of cases in children, suggesting a greater mortality rate in this age group (Dunn *et al.*, 2016; Harding, 2020).

In 2019, the 30 TB high burden countries (HBC) accounted for 87% of new TB cases globally (Harding, 2020). Twenty four (24) of the 30 TB HBCs countries globally with the highest burden of TB were in the WHO African Region (Figure 1) (Grobusch & Kapata, 2018; Jenkins, 2016). Eight countries account for two thirds of the total, with India leading the count, followed by Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa

(Kim *et al.*, 2020). Sub-Saharan Africa has a disproportionate burden of childhood TB, with two thirds of the countries in the world having childhood TB death rates $\geq 5/100,000$ located in the region (Seddon & Shingadia, 2014). In 2017, nearly 2.5 million people who contracted TB lived in sub-Saharan Africa. Kenya ranked 10th globally and 4th in Sub-Saharan Africa of the 30 TB HBCs (Yaya *et al.*, 2019).

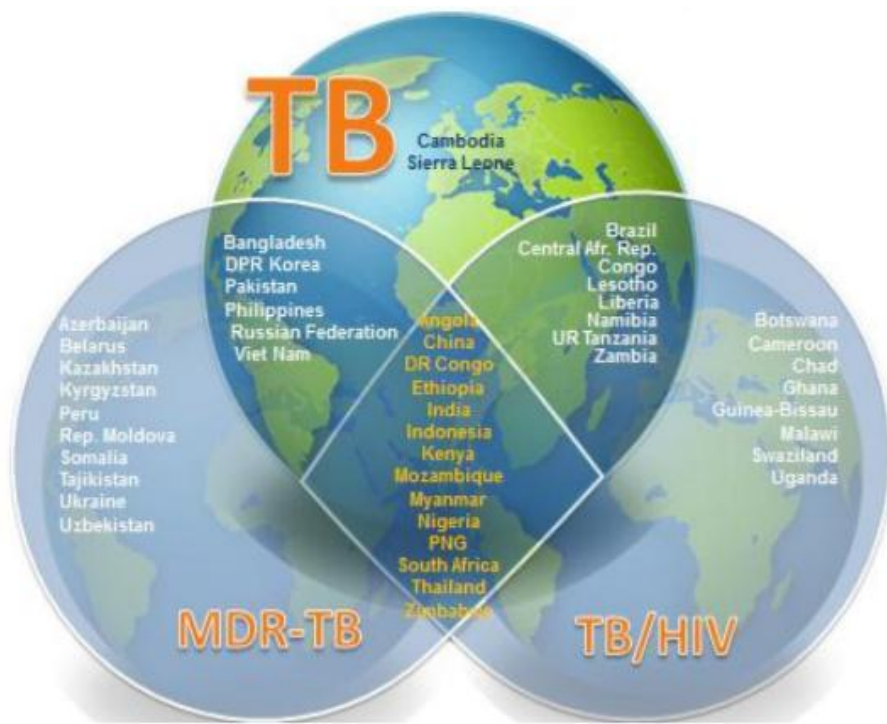


Figure 1: The 30 TB high burden countries (HBCs). Source; (Harding, 2020)

A recent (2015-2016) TB prevalence survey conducted in Kenya revealed that the burden of TB in Kenya was 426 cases per 100,000 population, with annual incidence of rate of 169,000 persons (Enos *et al.*, 2018). Kenya with a Case Notification Rate (CNR) of 426/100,000 notified 96,434 TB cases. 10,051 cases of childhood TB, representing 10.4% of all reported cases in 2018 (Figure 2) (Enos *et al.*, 2018; Harding, 2020; MOH, 2017; Zumla *et al.*, 2015).

The WHO recommends that Childhood TB cases should account for 10 to 15% of all notified cases since the prevalence of TB among contacts of infectious patients is 2.5 times higher than that of the general population (Grobusch & Kapata, 2018). However, given that most deaths from TB are preventable, the death toll from the disease is still high at 5% (503) in 2018 (Grobusch & Kapata, 2018; Muntean, 2018).

Sustainable Development Goals (SDGs) no. 3 resolved that nations should “Ensure healthy lives and promote well-being for all at all ages” with target 3.3 including ending the TB epidemic by 2030 (Aiken *et al.*, 2013; Pasquet *et al.*, 2010). Efforts to minimize the mortalities need to be accelerated if 2030 Sustainable Development Goals (SDGs) global target 3.3 set is to be realized (Annexure 2).

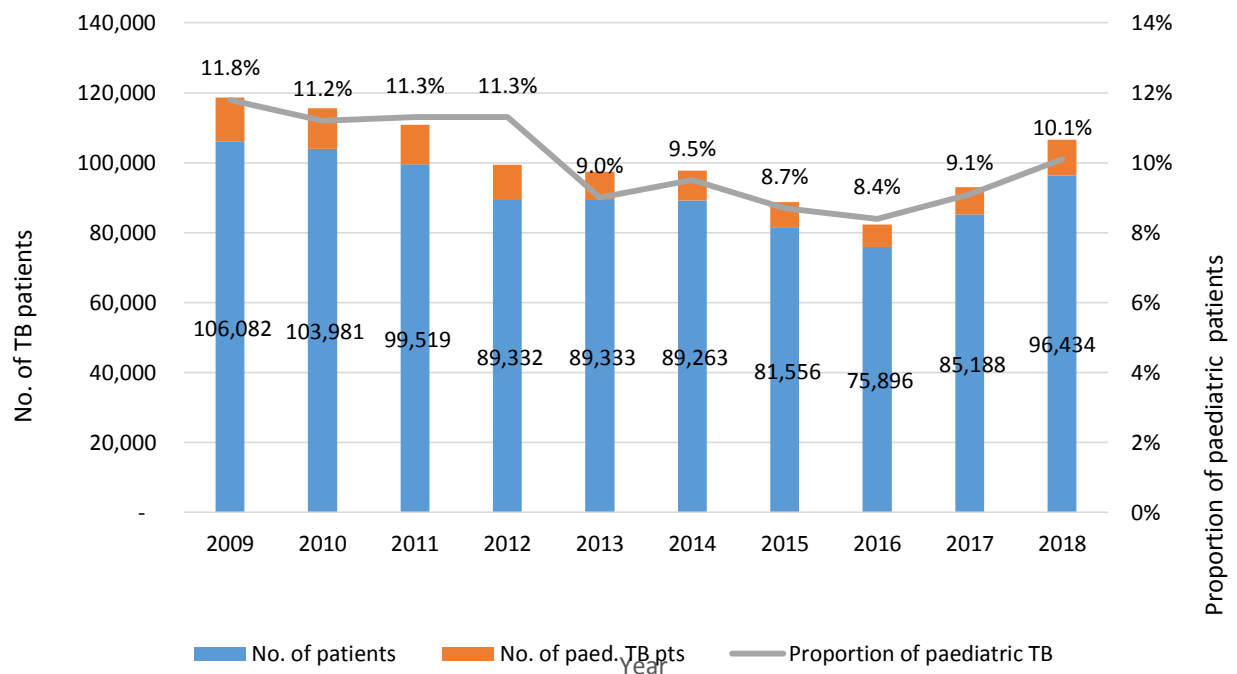


Figure 2: Kenya Pediatric TB Case notification 2009-2018: Source: NLDT-P Annual Report 2018.

In 2017, Siaya county at 14% (748/5344) ranked 1st of the 47 counties with >5% childhood TB death reporting rates (Oliwa *et al.*, 2019; Onyango *et al.*, 2018). Despite this, Siaya County with a CNR of 226/100,000 only notified 98 (5.1%) childhood TB cases and ranked 27th of the 47 counties by only contributing 26% of 10,051 case load in 2018 (Grobusch & Kapata, 2018). This is below the WHO recommendation that 10 – 15% of all notified cases should be that of childhood TB (Nduba *et al.*, 2019). There is low index of suspicion for childhood TB among HCWs and hence an estimated 65% of children with TB seeking services at HFs remain undiagnosed (Nduba *et al.*, 2019).

The extent full of TB in children has not been completely established since globally (Harding, 2020). Estimating the global childhood TB burden is challenging due to; lack of a standard case definition of a TB case as per the WHO criteria that requires a positive sputum smear, difficulty in establishing a definitive diagnosis due to varied and vague clinical presentation of TB in this age group, frequency of extra-pulmonary disease in young children, and dereliction of national tuberculosis control programs in reporting child TB cases relative to adults (Adams, Lisa, Starke, & Jeffrey, 2015; Harding, 2020). This makes accurate statistics on childhood TB cases difficult to obtain for a multitude of reasons, including under-recognition, challenges in confirming the diagnosis, and under-reporting to national TB programs (Venturini *et al.*, 2014). Additionally, there are often logistic challenges in obtaining adequate specimens from young children (Perez-Velez & Marais, 2012).

Reports by (Nathavitharana *et al.*, 2017) found that HCWs have important knowledge gaps in relation to childhood TB diagnosis, treatment. This has in turn hampered TB programmes in Kenya that often under-diagnose, under-treat, or omit all together children with TB (Grobusch & Kapata, 2018). Clinical and radiographic manifestations are less specific in children with

TB compared to adults, and are often confused with bacterial pneumonia by HCWs (Carvalho *et al.*, 2018). There is a lack of effective diagnostic tests that can detect TB in children, child-friendly drug formulations for treatment and care for children with TB and/or those in contact of someone diagnosed with TB (Perez-Velez & Marais, 2012). HCWs in Siaya County face difficulty in assessing the actual magnitude of childhood TB epidemic which may be higher than currently estimated since HCWs using standard tests fail to detect childhood TB in up to 93% of the time (Aiken *et al.*, 2013; Harding, 2020; Laserson & Wells, 2007; MOH, 2017; Rajkumar & Sathyamurthi; WHO, 2014).

1.2 Statement of the problem

Every day, up to 562 children die from TB, a preventable and curable disease. According to the WHO, at least 1.2 million children become ill with Tb every year. WHO estimates that childhood TB cases should account for 10-15% of all TB cases and this figure is estimated to be higher in the HBCs.

The true burden of childhood TB is unknown. Modelling estimates suggest that TB could be a leading cause of death in children, a “hidden epidemic”, with up to 65% of childhood TB cases seeking services in health facilities (HFs) remain potentially missed or overlooked each year due to low index of suspicion. Diagnosis of childhood TB is often challenging due to paucibacillary nature and non-specific symptoms of the disease. HCWs in HFs lacks effective diagnostics that can detect childhood TB and appropriate child-friendly fixed-dose combination drugs for treatment.

In 2017, Siaya county at 14% (748/5344) ranked 1st of the 47 counties with >5% childhood TB Death Reporting rates. Despite of this, Siaya County with a CNR of 226/100,000 only notified

98 (5.1%) childhood TB cases against 10 – 15% recommended by the WHO and ranked 27th of 47 counties in 2018 (Nduba *et al.*, 2019). This is worsened by the clinical and radiographic manifestations which are less specific in children compared to adults and are often confused with bacterial pneumonia coupled with logistic challenges in obtaining adequate specimens from young children (Perez-Velez & Marais, 2012; Roya-Pabon & Perez-Velez, 2016).

While few studies on the factors that affect diagnosis and management of childhood TB have been carried out globally and in Sub-Saharan Africa, there are no published studies of Siaya County or Kenya as a whole. Therefore, it would be difficult to address the factors that affect diagnosis and management of childhood TB among HWs in Siaya County.

1.3 Justification of the study

In 2017, Siaya county at 14% (748/5344) ranked 1st of the 47 counties with >5% childhood TB Death Reporting rates. Despite of this, Siaya County with a CNR of 226/100,000 only notified 98 (5.1%) childhood TB cases against 10 – 15% recommended by the WHO ranked 27th of 47 counties in 2018.

The study sought to identify factors that drive high deaths and low case notification rates by assessing factors influence diagnosis and management of childhood TB will be key in understanding challenges faced by HCWs in Siaya County. This will be aimed at producing solutions geared towards reducing childhood TB deaths by increasing the proportion of childhood TB cases identified, diagnosed and managed.

The findings of this study may therefore be used by the MoH, County Governments and NGOs to enrich existing knowledge on childhood TB diagnosis and management.

1.4 Study objectives

1.4.1 Main objective

To assess factors that affect diagnosis and management of childhood TB among HCWs in Siaya County.

1.4.2 Specific objective

1. To determine the socio-demographic and socioeconomic factors that affect childhood TB diagnosis and management among HCWs.
2. To determine the current level of knowledge on childhood TB diagnosis and management among HCWs
3. To establish facility based factors that affect diagnosis and management of childhood TB among HCWs
4. To evaluate the constraints to childhood TB diagnosis and management among HCWs

1.5 Research questions

1. What are the socio-demographic and economic factors that affect childhood TB diagnosis and management among HCWs in Siaya County?
2. What is the current level of knowledge on disease related factors of childhood TB diagnosis and management among HCWs in Siaya County?
3. What are the health facility based factors that affect diagnosis and management of childhood TB among HCWs in Siaya County?
4. What are the constraints to childhood TB diagnosis and management among HCWs in Siaya County?

1.6 Study assumptions

The key assumption of this study was that; unavailability of childhood TB diagnostic and management supplies, methods of diagnosis and lack of recent trainings attended were the key problems to childhood TB control and were reflected by individual HCWs and system failures. Delay in diagnosis could be related to miss-diagnosis, HCW behavior and attitude and knowledge gap on childhood TB diagnosis and management among HCWs in Siaya County.

1.7 Limitations of the study

This study was limited to HCWs stationed at the 18 HFs with direct contact to Childhood TB cases for the period of the study in Siaya County. Therefore generalization could only be made in respect to the County. Siaya County is very wide, regions like Siaya County Referral Hospital called for repeated visits during data cleaning, and this meant that an extended period was required to the expected number of respondents in order to get the required data. To mitigate this, it necessitated prior appointment bookings with respondents to enable data collection and verification to manage within the limited resources and time available.

Initially, some of the respondents were not willing to disclose whether they had knowledge on childhood TB diagnosis and management for fear of stereotyping and stigmatization. Some of the respondents also expected payment for accepting to participate in the study. To overcome these challenges, the purpose of the study was re-emphasized to them and they were assured of confidentiality.

CHAPTER TWO: LITERATURE REVIEW

2.1 Aetiology of Tuberculosis

Tuberculosis refers only to disease caused by *Mycobacterium tuberculosis* (M. Tb) for which humans are the main reservoir (Grobusch & Kapata, 2018). TB results almost exclusively from inhalation of airborne particles (droplet nuclei) containing *M. tuberculosis* (Bussi & Gutierrez, 2019; Nardell, 2016). They disperse primarily through coughing, singing, and other forced respiratory manoeuvres by people who have active pulmonary or laryngeal TB and whose sputum contains a significant number of organisms (typically enough to render the smear positive) (Bussi & Gutierrez, 2019; Nardell, 2016; Shiloh, 2016). Droplet nuclei (particles < 5 μ in diameter) containing tubercle bacilli may remain suspended in room air currents for several hours, increasing the chance of spread (Mohammad & Ghazali, 2017). How contagious patients with untreated active pulmonary TB are varies widely (Jilani *et al.*, 2020). Certain strains of *M. tuberculosis* are more contagious, and patients with positive sputum smears are more contagious than those with positive results only on culture (Proença *et al.*, 2020).

Transmission is enhanced by frequent or prolonged exposure to untreated patients/people who are dispersing large numbers of tubercle bacilli in overcrowded, poorly ventilated enclosed spaces; consequently, people living in poverty or in institutions are at particular risk (Nardell, 2016). Estimates of contagiousness vary widely; some studies suggest that only 1 in 3 patients with untreated pulmonary TB infect any close contacts; the WHO estimates that each untreated patient may infect 10 to 15 people per year (Kirenga *et al.*, 2015). However, most of those who are infected do not develop active disease. Contagiousness decreases rapidly once effective

treatment begins; organisms are less infectious even if they persist in sputum, and cough decreases (Kirenga *et al.*, 2015).

2.2 Pathophysiology of Tuberculosis

TB may occur in 3 stages: Primary infection, Latent infection and Active infection. *M. tuberculosis* bacilli initially cause a primary infection, which uncommonly causes acute illness. Most (about 95%) primary infections are asymptomatic and followed by a latent (dormant) phase. A variable percentage of latent infections subsequently reactivate with symptoms and signs of disease. Infection is usually not transmissible in the primary stage and is never contagious in the latent stage (Jilani *et al.*, 2020).

2.2.1 Primary infection

This infection requires inhalation of particles small enough to traverse the upper respiratory defences and deposit deep in the lung, usually in the sub pleural airspaces of the middle or lower lobes (Nathavitharana *et al.*, 2017). Perhaps only a single organism may suffice to cause infection in susceptible people, but less susceptible people may require repeated exposure to develop infection (Perez-Velez & Marais, 2012). To initiate infection, *M. tuberculosis* bacilli must be ingested by alveolar macrophages. Bacilli that are not killed by the macrophages actually replicate inside them, ultimately killing the host macrophage (with the help of CD8 lymphocytes) (Tsuda *et al.*, 2013). In the early weeks of infection, some infected macrophages migrate to regional lymph nodes (e.g., hilar, mediastinal), where they access the bloodstream. Organisms may then spread hematogenously to any part of the body, particularly the apical-posterior portion of the lungs (Bomanji *et al.*, 2015).

2.2.2 Latent infection

Latent infection occurs after most primary infections. In about 95% of cases, after about 3 week of uninhibited growth, the immune system suppresses bacillary replication, usually before symptoms or signs develop (Ahmad, 2011). The tuberculin skin test and interferon-gamma release blood assays (IGRA) become positive during the latent stage of infection (Roya-Pabon & Perez-Velez, 2016). Less often, the primary focus progresses immediately, causing acute illness with pneumonia, pleural effusion, and marked mediastinal or hilar lymph node enlargement. Small pleural effusions are predominantly lymphocytic, typically contain few organisms, and clear within a few weeks. This sequence may be more common among young children and recently infected or re-infected immunosuppressed patients (Bhalla *et al.*, 2015; Karkhanis & Joshi, 2012).

2.2.3 Active disease

Healthy people who are infected with TB have about a 5 to 10% lifetime risk of developing active disease, although the percentage varies significantly by age and other risk factors. In 50 to 80% of those who develop active disease, TB reactivates within the first 2 years, but it can also occur decades later (Li *et al.*, 2019). Any organ initially seeded may become a site of reactivation, but reactivation occurs most often in the lung apices, presumably because of favourable local conditions such as high oxygen tension (Nathavitharana *et al.*, 2017). Reactivation of latent infection predominates in low-prevalence areas. In a given patient, it is difficult to determine whether active disease resulted from reinfection or reactivation (Ehlers & Schaible, 2013; Guirado & Schlesinger, 2013).

2.3 Epidemiology of childhood TB

Kenya is listed by the WHO at 10th globally and 4th in sub Saharan Africa among the 30 TB HBCs (Enos *et al.*, 2018; Yaya *et al.*, 2019). Despite considerable investment done by the Kenya government and its partners in TB care and prevention in the past 20 years, TB disease is still in the top 10 leading causes of death. Identifying all people with TB disease and successfully treating and managing them is therefore an important priority for the country (Enos *et al.*, 2018). The true burden of childhood TB is unknown, but modelling estimates suggest it could be a leading cause of death in children, a “hidden epidemic”, with up to 65% of paediatric TB cases potentially missed each year (Oliwa *et al.*, 2019). Difficulties in accurately identifying cases of childhood TB and lack of good surveillance data have made it challenging to quantify the actual burden of childhood TB (Oliwa *et al.*, 2019; Perez-Velez & Marais, 2012). Although infection can be identified through skin tests or interferon gamma release assays, the non-availability of these tests should not preclude prevention therapy, once active TB has been excluded (Fry *et al.*, 2019; Pai *et al.*, 2014).

Kenya is currently experiencing the twin epidemics of TB and HIV. The country is categorized among the WHO high TB and high TB/HIV burden countries (Onyango *et al.*, 2018). Despite an overall decrease in TB incidence, the incidence among those who are HIV positive has remained persistently high (Hogan *et al.*, 2020; Mollel *et al.*, 2019). According to WHO estimates, there are 21,000 new childhood TB cases in Kenya, but only 7,648 (36%) are notified (Oliwa *et al.*, 2019). The recent Kenya TB prevalence survey with participants >15yrs revealed 75% of TB cases had presented to HFs with suggestive symptoms but were never diagnosed (Enos *et al.*, 2018). The proportion of younger children who present to HF and go undiagnosed in Kenya is presently unknown, but is presumed to be as high (Oliwa *et al.*, 2019).

Data on burden of TB amongst paediatric admissions and clinicians' diagnostic practices in resource-limited settings are also sparse, and where they exist, they mostly present data from single tertiary hospitals in better-resourced settings (Orikiriza, 2019). However, where TB is prevalent in the population one might expect to see TB more commonly amongst admissions (Enos *et al.*, 2018).

The TB epidemic among adults puts children (0 to 14 years) at risk of acquiring the disease. Although childhood TB remains a serious public health problem in Kenya, its epidemiology has been described for 2 former provinces only (Kimani *et al.*, 2021). According to Kenyan TB guidelines, diagnosing childhood TB relies on careful history and physical examination to identify suggestive signs and symptoms of cough, fever, lethargy and growth faltering, followed by investigations including chest x-ray, tuberculin skin test (Mantoux), Xpert MTB/RIF and/or culture (Oliwa *et al.*, 2019). Unfortunately, childhood TB diagnosis is complicated by low sensitivity and specificity of symptoms and lack of appropriate point-of-care diagnostic tests (López *et al.*, 2012; Marais & Schaaf, 2014). WHO recommends the use of Xpert MTB/RIF as a first-line TB diagnostic test and by 2018 there were 183 machines in Kenya in public HFs across the country (Enos *et al.*, 2018).

2.4 Influence of socio-demographic/economic factors on diagnosis and management of childhood TB.

The increased focus on addressing the social determinants of TB has been stimulated from both within and beyond the TB sector. Several studies have tried to only look at the relationship of the patient's educational level to their health status, seen as important to gain a better understanding of the causes associated with adverse health outcomes, identifying patients at

risk of such adverse outcomes and subsequently developing appropriate interventions (Braveman & Gottlieb, 2014).

A study carried out in Thailand aimed at determining the patient factors predicting successful treatment. Out of 1,241 patients studied, 81% with higher educational levels and knowledge of tuberculosis were successfully treated, the argument being that these factors are associated with better compliance to TB treatment and subsequently treatment success (Okanurak, Kitayaporn, & Akarasewi, 2008).

Several other studies have demonstrated educational levels of TB patients as significant predictors of treatment compliance. Meanwhile, a Malaysian study demonstrated that, among other factors, non-compliance was associated with completed secondary education (Braveman & Gottlieb, 2014).

2.5 HCW's knowledge on childhood TB diagnosis and management.

Low level of knowledge on childhood TB by HCWs can lead to complications and worse health outcomes increasing the transmission and delaying health seeking behavior, lack of adherence, resulting in multidrug resistance, treatment failure, and disease complication and death (Gelaw, 2016).

2.5.1 Role of health care workers

Studies have strongly support the need to specifically target HCWs and increase their acquaintance and capability in the prevention, diagnosis, control and management of childhood TB cases (Espinal *et al.*, 2000; Yonge, Otieno, Sharma, & Omedo, 2016). Other studies have

noted that beyond professional guidance, there are limited structured ways to constantly enhance the skills of HCWs regarding national guidelines for TB management.

According to (Gizaw *et al.*, 2015), on the knowledge and practice of HCWs towards TB infection control and its associated factors in Ethiopia's HFs, the study indicated that only 36.1% had poor knowledge and 51.7% unsatisfactory practice score towards TB infection control. More than six years of experience and working in HFs and TB related training were importantly associated with knowledge on TB infection control. In addition, having experience in TB clinic and TB related training were significantly associated with practice on tuberculosis infection control.

The use of primary HFs in South Africa's Free State Province, in a study carried out by (Engelbrecht *et al.*, 2016) who assessed factors associated with HCW' good TB infection control practices by using a cross-sectional self-administered survey with a sample of 202 nurses and 34 facility-based community HCWs. The study findings showed good levels of knowledge about TB. Over 80% of the studied population had affirmative attitudes towards TB infection control practices. Further analysis indicated that for every unit increase in attitudes, good practices increased 1.090 times. Thus, respondents with good levels of knowledge were more likely to have good quality practices compared to respondents with poor levels of knowledge.

Analysis of the level of knowledge and awareness among medical students and nursing staff about TB infection control by (Bhandari & Bande, 2016). A total of 88 medical students and 48 nursing staff were involved in the study. The study established that medical students had more knowledge, attitude and practice regarding TB compared to nursing staff and the

difference was found to be statistically significant. It was concluded that nursing staff need regular seminars, symposiums or meetings to improve their knowledge about TB.

Assessment of the knowledge and practices of hospital employees on TB in Northwestern Greece was carried out by (Charisis, 2014). The study used a structured questionnaire which was administered to 789 employees in Ioannina University Hospital consisting of physicians, nurses, technicians, assistants and administrators. Most employees recognized respiratory droplets as transmission route and pulmonary TB as infectious. However, very few employees acknowledged that TB is an airborne disease and that laryngeal TB is infectious. Further analysis revealed that most of the employees who had managed a suspected case used regular masks, with very few employees using high protection masks or none. For newly diagnosed patients, most of the employees supported care in special infectious disease units. In conclusion, hospital employees may lack specific knowledge on less common routes of transmission of TB and often fail to practice certain guidelines for suspected TB cases.

(Hashim, Kubaisy, & Dulayme, 2003) undertook a cross-sectional study using 500 patients and 500 HCWs randomly selected from 250 primary health care facilities all over Iraq to assess knowledge, attitudes and practices towards TB. Research findings showed that 95.5% of the HCWs were aware of TB due to their age and job duration. However, their practice was poor compared to patients with only 38.2% reported to have managed suspected TB cases perfectly. In Iraq, the national TB programme had a positive impact on knowledge of TB patients.

(Falzon *et al.*, 2011) sought to set up a baseline of TB-related understanding, attitude and practice among HCWs in Kingston and St. Andrew (KSA). Data were collected using close-ended questionnaires and analyzed using descriptive and chi-squared analysis. The study

results showed less than optimal performance on TB-related knowledge, attitudes and practices among the survey participants; less than 40% had good knowledge of TB.

Studied on knowledge level by (Alotaibi *et al.*, 2019; Noé *et al.*, 2017) identified attitudes and evaluated practices regarding TB care and control among 170 health care workers of the district of Manhiça, which is a high TB and HIV burden rural area in Southern Mozambique. Over 70% of the population approved there was stigma associated with TB and less than 30% of respondents had heard of Xpert MTB/RIF® testing. The study concluded that HCWs' knowledge gaps recognized may lead to lower quality patient care. Thus, HCW should be provided with tailored TB education to reduce the high TB burden in the rural areas in Southern Mozambique.

2.5.2 Directly observed treatment/therapy

DOT - a TB control strategy recommended by the WHO - patients are observed as they take their medicine, with the aim to increase adherence to treatment (Fiseha & Demissie, 2015; Karumbi & Garner, 2015; Wright *et al.*, 2015). Supervision of childhood TB treatment through DOT at HFs is resource-intensive and can put additional pressure on health systems, particularly in settings with a high TB burden and constrained resources (Wright *et al.*, 2015). With DOT, a trained HCW provides the prescribed anti-TB drugs and watches the patient swallow every dose (Fiseha & Demissie, 2015). A patient meets with a trained HCW every day or several times a week. The patient takes the TB medicines while the HCW watches (Mehta *et al.*, 2014). The HCWs also asks the patient about any problems or side effects with the medication. DOT is done at a time and place that is convenient for the patient (Tariq *et al.*, 2020). DOT is recommended for all patients with TB disease, including children and

adolescent's since there is no way to accurately predict or verify whether a patient will adhere to treatment without this assistance (Nahid *et al.*, 2019).

DOT is an important part of the treatment strategies for childhood TB. It is highly effective, relatively inexpensive, and is the only way to ensure that the child is adequately treated (Graham *et al.*, 2015). Although the public health ramifications of inadequate treatment of childhood TB are not as severe as those for inadequate treatment in adults, the personal health consequences of non-adherence in children can be disastrous (Habteyes Hailu *et al.*, 2015). In countries with adequate resources, DOT is considered the standard of care for children with TB disease. The goal for the world is to treat every child with TB with DOT (Starke, 1999). The National TB treatment guidelines strongly recommend using a patient-centered case management approach - including DOT - when treating children with active TB disease (Alipanah *et al.*, 2018).

DOT is especially critical for patients with drug-resistant TB, HIV-infected patients, and those on intermittent treatment regimens (Nahid *et al.*, 2019). It can also be inconvenient for patients to visit a HF daily for treatment supervision, for reasons including travel and waiting times (Wright *et al.*, 2015). DOT also adds direct (e.g. transport costs) and indirect costs (e.g. in terms of time lost) to treatment and these have been shown in several cases to be higher per case successfully treated for clinic DOT versus community-based DOT (CB DOT) (Wright *et al.*, 2015). For these reasons, CB DOT presents an alternative for policy makers, especially when the DOT provider is acceptable and accessible to the patient (Wright *et al.*, 2015). As a 2003 WHO report on community contribution to TB care pointed out, "Organized community groups, peer groups, chosen members of the community, and family members all have the

potential to act as supervisors to ensure completion of treatment and hence cure (Zhang *et al.*, 2016).

A Cochrane review, last updated in 2007, assessed the effectiveness of DOT compared to self-administered treatment (SAT) (Karumbi & Garner, 2015; Volmink & Garner, 2007). It also looked at the relative efficacy of different types of DOT delivery. It found a small benefit from CB DOT supervised at home (with providers including family members, CVs and CHWs), compared to SAT, in terms of treatment success (risk ratio (RR) 1.09, 95% CI 1.02-1.16; 1,365 participants, 3 trials (Kamolratanakul *et al.*, 1999; Walley *et al.*, 2001; Zwarenstein *et al.*, 1998). There was no benefit of clinic DOT compared to SAT (RR 0.92, 95% CI 0.78-1.08, 444 participants, 2 trials (Walley *et al.*, 2001; Zwarenstein *et al.*, 1998). There was only one randomized controlled trial (RCT) that compared treatment success between DOT delivered by a family member and clinic DOT (Wandwalo, Kapalata, Egwaga, & Morkve, 2004), and one RCT that compared cure rate between CHW-supervised DOT and clinic DOT (Lwilla *et al.*, 2003). Both studies showed no significant difference between the different DOT strategies.

Given the potential value of HF DOT as a means of treatment supervision, especially in resource-constrained settings, a systematic review assessing the effectiveness of CB DOT compared to conventional clinic DOT including all available studies is indicated to inform policies on DOT delivery (Wright *et al.*, 2015).

2.5.3 Trainings and capacity building of HCWs on childhood TB

Active participation in educational activities is essential for learning since active participation improves HCWs' level of understanding, the ability to process material, and the retention of knowledge on childhood TB diagnosis and management (Alotaibi *et al.*, 2019; Kigozi *et al.*,

2017). The importance of active learning has also been acknowledged in medical education settings, therefore, changed the traditionally passive faculty-centered environments into active HCW-centered learning environments (Coy *et al.*, 2018).

Developing human resources capacity is vital for childhood TB control in low- and middle-income countries (LMICs) (Wu *et al.*, 2017). Although investments in TB HCW training programmes have increased, it is unclear whether these are robustly evaluated (Pai *et al.*, 2014). It is widely recognized that developing human resources capacity is vital for childhood TB control in LMICs, and insufficient quality, quantity, and distribution of HCWs was highlighted as a major challenge in the WHO Global Plan to Stop TB 2006–2015 (Wu *et al.*, 2017). Inconsistent and inadequate quality of services provided by HCWs is documented as a prevalent problem that results in poor case detection and adherence to treatment, thereby hindering the progress on TB control (Gebreweld *et al.*, 2018; Sima, Belachew, & Abebe, 2019; Wu *et al.*, 2017). In line with the need for human resource capacity building, investments in training programmes have increased; for example, in 2014, the Global Fund to Fight AIDS, TB and Malaria provided 16 million person-episodes of training for HCWs, which was a ten-fold increase over the number trained in 2005 (Wu *et al.*, 2017).

In line with the need for human resource capacity building, investments in training programmes have increased. It helps answer two main questions: whether training objectives were achieved, and whether the accomplishment of those objectives resulted in enhanced performance on the job (Kumar, 2012). In addition, results of training evaluations help ensure training meets the needs of learners and organizations (Kumar, 2012).

In settings with a high burden of TB-HIV, frontline level HCWs, typically nurses, often receive limited training in childhood TB, although they are often tasked with managing childhood TB

at the primary care level (du Plessis, Black, Detjen, Hesselning, & du Preez, 2017). Without adequate knowledge and clinical skills, missed opportunities for childhood TB diagnosis, treatment and preventive therapy will continue to occur, perpetuating significant policy-practice gaps (du Plessis *et al.*, 2017; Lestari *et al.*, 2019; Rigouts, 2009).

2.5.4 Standard length of treatment of newly diagnosed case of childhood TB.

TB Treatment can be challenging for patients as it requires taking multiple drugs for at least 6 months (Abdelhadi *et al.*, 2015; Muture *et al.*, 2011). Knowledge of the standard childhood TB treatment regimen consists of an intensive phase that lasts 2 months involving 4 drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) to rapidly kill the M. Tb; and a continuation phase that last up to 4 months involving 2 drugs (isoniazid, rifampicin) that eliminate the remaining bacilli and prevent relapse (Silva *et al.*, 2020; Sotgiu *et al.*, 2015). This six- month treatment duration can adversely impact patient adherence to therapy. Poor adherence leads to the development of drug resistance and enhances the chances of relapse in such individuals (Silva *et al.*, 2020; Sotgiu *et al.*, 2015).

The major justification for using this longer treatment regimen is to reduce recurrence. In addition, previously published data do not support the use of shortened treatment regimens in adults with newly diagnosed pulmonary drug-susceptible TB (DS-TB) (Silva *et al.*, 2020). However, the long duration of DS-TB treatment is associated with non-adherence and loss to follow-up. However, the treatment success rate of multidrug-resistant tuberculosis (MDR-TB) is low (approximately 50%) with longer regimens, although recent studies involving new drugs have suggested that better results are possible also at the programmatic level (Borisov *et al.*, 2017). The development of efficacious, safe, and shorter treatment regimens for both DS-TB

and MDR-TB could significantly improve childhood TB management and treatment success rates (Silva *et al.*, 2020).

HCW's knowledge on medical treatment of childhood TB, together with correct diagnosis, represents a cornerstone in the management and control of childhood TB. It is relevant from a clinical and public health perspective, as TB is a serious contagious airborne disease (Sotgiu *et al.*, 2015). Currently, HCWs are facing daily problems related to the prescription of less effective and toxic second-line drugs, with frequent pharmacological interactions with antiretroviral drugs or medicines used to treat other comorbidities (Sotgiu *et al.*, 2015). With a timely diagnosis and knowledge of standard length of treatment with first-line anti-TBs for 6 months, most children who develop TB can be cured and onward transmission of infection curtailed. TB treatment aims to cure TB patients, prevent deaths from TB and to stop transmission of M. Tb from the infected to the host community (Cohen *et al.*, 2010).

2.5.5 Recommended dosage for first-line anti-TB drugs

The principles of TB treatment are the same for adults and children (Bass *et al.*, 1994; Lewinsohn *et al.*, 2017; Nahid *et al.*, 2016). The combination regimens used to treat active disease aim to eliminate actively replicating and dormant or near-dormant mycobacteria using a combination of minimum-toxicity drugs with different actions while preventing the emergence of drug-resistant organisms (Shehzad, Rehman, Ul-Islam, Khattak, & Lee, 2013). Treatment outcomes in all children are generally good provided treatment is started as soon as a diagnosis is made. Children generally tolerate the anti-TB medicine better than adults and their dosages are calculated according to weight (not age) (WHO, 2014).

The goals of anti- TB treatment in children are to: cure the child of TB, prevent death from TB, prevent complications arising from TB disease, prevent TB relapse/recurrence by eliminating the dormant bacilli, and prevent the development of drug resistance by using a combination of drugs and Reduce TB transmission to others (Naidoo *et al.*, 2018).

Recommended drugs used for first line treatment of TB in children are: Rifampicin (R) Isoniazid (H) or (INH) Pyrazinamide (Z) Ethambutol (E). Childhood TB treatment consists of two phases: an intensive phase with a combination of bactericidal drugs (RHZE) to kill the rapidly growing bacilli and a continuation phase with fewer drugs (RH) to eradicate the slower-growing persistent bacilli (Grobusch & Kapata, 2018). The adjunctive use of steroids in TB meningitis has been shown to reduce death and severe disability (Schutz *et al.*, 2018). A number of pharmacokinetic studies in children indicate that age is a determinant of serum levels for all the first-line anti-TB drugs and that infants and young children have lower peak serum levels than older children or adults (Justine *et al.*, 2020).

2.6 Health facility based factors' influence on diagnosis and management of childhood TB

Job aids are required to strengthen clinical management and prevention of childhood in TB endemic, resource-limited settings as many HCWs lack training and therefore confidence in childhood TB diagnosis, treatment and prevention (Grobusch & Kapata, 2018). These materials should aim to address the need to strengthen clinical diagnosis and management of childhood TB at the secondary and primary level of HFs, which is where most children with TB will first present, and where opportunities for prevention are commonly missed (Grobusch & Kapata, 2018). There is a growing recognition that while it is difficult to achieve

bacteriological confirmation of childhood TB, it is often not difficult to make a clinical diagnosis, which reduces the need to refer every child with presumptive TB to a tertiary HF for diagnosis and care (Singh *et al.*, 2021).

2.6.1 Chest radiography (X-Ray)

Diagnosis of TB is particularly challenging in young children, given the non-specific nature of their symptoms, difficulties in obtaining samples for microbiological examination and the often pauci-bacillary nature of their disease (López *et al.*, 2012; Marais & Schaaf, 2014). In everyday practice, childhood TB diagnosis relies heavily on exposure to an infectious source case or immunological evidence of *M. tuberculosis* infection, together with findings suggestive of TB on the chest radiograph (CXR). CXR remains a critical tool for diagnosing intrathoracic TB which is the most common presentation of childhood TB (García-Basteiro *et al.*, 2015). In fact, CXR signs suggestive of TB are considered essential to establish a diagnosis of probable intrathoracic TB, according to international consensus clinical case definitions (García-Basteiro *et al.*, 2015; Graham *et al.*, 2015).

CXR is a rapid imaging technique that allows lung abnormalities to be identified (Grobusch & Kapata, 2018). CXR is used to diagnose conditions of the thoracic cavity, including the airways, ribs, lungs, heart and diaphragm. CXR has historically been one of the primary tools for detecting TB, especially pulmonary TB (Bhalla *et al.*, 2015). CXR has high sensitivity for pulmonary TB and thus is a valuable tool to identify TB as a differential diagnosis for patients, especially when the CXR is read to identify any abnormality that is consistent with TB (Bhalla *et al.*, 2015; Cudahy & Shenoi, 2016; Enos *et al.*, 2018). WHO classifies TB diagnosis into bacteriologically confirmed TB, if it is based on bacteriological confirmation, or clinically

diagnosed TB, if it is based on clinical assessment including CXR, but is not confirmed by bacteriological examination (Roya-Pabon & Perez-Velez, 2016).

Childhood TB is characterized by paucibacillary disease and microbiological confirmation is only possible in <50% of pediatric cases (López *et al.*, 2012; Marais & Schaaf, 2014). CXR is therefore of great importance in identifying smear negative, culture negative TB. CXR is considered a key diagnostic tool for childhood TB in clinical management (Kaguthi *et al.*, 2014). CXR, is an important tool for triaging and screening for pulmonary TB, and it is also useful to aid diagnosis when pulmonary TB cannot be confirmed bacteriologically (Mungai *et al.*, 2021). Although recent diagnostic strategies have given specific prominence to bacteriology, CXR can be used for selecting individuals for referral for bacteriological examination, and the role of radiology remains important when bacteriological tests cannot provide a clear answer (Lagier *et al.*, 2015). Access to high-quality CXR is limited in many settings (Kretz *et al.*, 2020).

Ensuring the wider and quality-assured use of CXR for TB detection in combination with laboratory based diagnostic tests recommended by the WHO, can contribute to earlier TB diagnosis and potentially to closing the TB case-detection gap when used as part of algorithms within a framework of health-system and laboratory strengthening (Cudahy & Sheno, 2016). CXR is an important investigation for diagnosis of childhood TB (Kaguthi *et al.*, 2014). A clinical diagnosis of PTB may be made by combining suggestive history, physical examination findings and an abnormal CXR (Bhalla *et al.*, 2015). In this case, the CXR provides important support for making a clinical diagnosis of PTB in children (Rigouts, 2009).

2.6.2 The type of health facility

Kenya's health care services have been delivered through dispensaries and health centres, complemented by hospital services provided at the district, provincial and national levels. A lack of guidance on the norms and standards for these different levels has resulted vastly different capacities across the system – facilities are of different sizes and the activities offered at the respective levels of the system vary widely.

Additionally, investments have not been appropriately coordinated, with the result that service inputs are not rationalized or equitably distributed across the country. For efficient and effective service delivery, each defined level of the system is expected to provide KEPH services for a defined population cohort. Each level has both service delivery and management functions to ensure efficient and effective delivery of health services. At levels 1–3 of the system, service delivery and management functions are combined at the health facilities. Service delivery staff also carry out management functions related to planning, monitoring and supervision activities. More extensive management functions are provided at levels 4–6. Overall coordination roles are introduced at these levels, which calls for more dedicated structures.

Limited knowledge about signs and symptoms of TB, poor health seeking behavior, and poor diagnosis and disease management in health facilities result in delays in TB diagnosis and treatment, which in turn, increase the risk of TB transmission and the development of MDR-TB (Donald & Van Helden, 2009). Early diagnosis and prompt treatment are the core objectives of an effective national TB control program.

2.7 Constraints to correct diagnosis and management of childhood TB

The proposed approach to diagnosing TB in children is based on limited published evidence, and rests heavily on expert opinion. Most children with TB have pulmonary TB (G. J. Fox *et al.*, 2015). Although bacteriological confirmation of TB is not always feasible, it should be sought whenever possible by microscopy, culture or WHO-endorsed genotypic (molecular) testing (i.e. Xpert MTB/RIF) of respiratory or non-respiratory samples as indicated by clinical presentation (Weyer *et al.*, 2013). A trial of treatment with anti-TB medications is not recommended as a method of diagnosing TB in children (Villarino *et al.*, 2015).

Existing diagnostic tests for childhood TB have shortcomings, and the full range of tests - including bacteriological culture and tuberculin skin testing (TST) - is often unavailable in settings where the majority of TB cases occur (López *et al.*, 2012; Pai *et al.*, 2014). The development of affordable diagnostic tests for childhood TB in low-resource settings should be a priority for researchers and policy-makers (Orikiriza, 2019).

Novel approaches to confirmation of childhood TB have been developed and evaluated. These include more rapid culture techniques and genotypic (molecular) techniques that improve detection of *M. tuberculosis* (Eddabra & Benhassou, 2018). The development that has received most attention recently is that of the Xpert MTB/RIF assay. This is a fully automated real-time DNA based test which can detect both TB and resistance to rifampicin in less than 2 hours (Beynon *et al.*, 2018; Cox *et al.*, 2014; Mechal *et al.*, 2019).

Following successful clinical evaluation in adults with TB in a variety of settings, WHO endorsed the Xpert MTB/RIF assay in 2010 and published recommendations in 2011 (Lawn *et al.*, 2013). However, in 2011, published data from children on the performance of Xpert

MTB/RIF assay were limited and the policy statement of 2011 therefore made no recommendations for its use that were specific to children (Ardizzoni *et al.*, 2015).

Encouraging data, mainly concerned with sputum samples, are emerging from children that show an improved yield and sensitivity compared with smear microscopy, although two of these studies also considered nasopharyngeal aspirate and gastric lavage (Detjen *et al.*, 2015). However, sensitivity of Xpert MTB/RIF is still lower than culture confirmation or clinical diagnosis (Lawn *et al.*, 2013). More data are needed from children, including more evaluation of specimens other than sputum, plus operational evaluation of the role of Xpert MTB/RIF in the diagnostic evaluation of children with suspected TB (WHO, 2014).

Alongside the underuse of Xpert for the diagnosis of TB in Kenyan county referral hospitals, studies have found a general problem with the diagnosis of TB among children-very few children with suggestive symptoms get a proper history and examination as per the TB guidelines (Oliwa *et al.*, 2020). A qualitative study from Peru (a high TB burden, low-resource setting) also identified constraints to diagnosing TB in children related to ignorance and stigma; limited access to diagnostic tests; inadequately trained health centre staff; and provider shortages (Chiang *et al.*, 2015). While several studies have highlighted the challenges of implementing Xpert among adults, data addressing constraints to the use of this diagnostic among children are sparse (Chiang *et al.*, 2015).

2.7.1 Correct anti-TB drugs dosing for childhood TB

Fixed-dose combinations (FDCs) of drugs for childhood TB treatment have been advocated internationally to prevent the emergence of drug resistance attributable to inappropriate drug intake (Lienhardt *et al.*, 2011; Lima *et al.*, 2017). Use of FDCs can reduce the risk of an

incorrect dosage, simplify drug procurement, and aid in ensuring adherence without changing the drug dosage (Van Galen *et al.*, 2014). In response to evidence that children require specific dosing of TB regimens to optimize treatment effect, the WHO revised its dosing guidelines for the treatment of childhood TB in 2010, and called for “appropriately dosed, quality medicines in a child-friendly format”; however, regrettably, no interest was demonstrated by pharmaceutical companies (Faust *et al.*, 2019). Consequently, caregivers and HCWs were earlier obliged to rely on their best judgment in estimating doses, which involves splitting or crushing the bitter-tasting adult pills. This represented a tremendous challenge for both children and HCWs, leading to inaccurate dosing, poor compliance with the regimens, and ultimately poor treatment outcomes (Alipanah *et al.*, 2018; Faust *et al.*, 2019).

In 2012, Unitaid pledged US\$16.7 million to the Global Alliance for TB Drug Development (the TB Alliance), a not-for-profit drug development and delivery organization, to develop pediatric FDCs of existing TB drugs. This commitment by Unitaid led to the Speeding Treatments to End Pediatric-TB (STEP-TB) project, which engaged with the pharmaceutical sector to develop the FDCs (Aronovich & Kinzett, 2001; Faust *et al.*, 2019). The first nationwide product launch and rollout of the new FDCs was in Kenya in October 2016. Commodities arrived into the country by the middle of 2016 and the drugs were distributed to all county medical stores. The initial distribution required significant logistics, but counties would routinely order according to their needs thereafter. As distribution was ongoing, HCWs sensitizations were done countrywide, initially for county TB coordinators (CTLIC), who thereafter sensitized the sub county coordinators (SCTLIC). Training of 3,500 HCWs was supported by USAID through the TB Accelerated Response and Care activity (TB ARC) of the Centre for Health Solutions–Kenya (CHS) (Faust *et al.*, 2019; Modisakeng *et al.*, 2020).

In 2016, Kenya National TB Program altered their traditional anti-TB treatment (2RHZ/RH regimen), which comprised rifampicin (R), isoniazid (H), and pyrazinamide (Z) for 2 months followed by R and H for 4 months. In the new 2RHZE/4RH regimen, a fourth drug, ethambutol (E), was added to the intensive phase (first 2 months) of TB treatment (Enos *et al.*, 2018; Muture *et al.*, 2011). Capsules containing R and H, administered with Z tablets, were replaced by FDC tablets containing R, H, Z, and E. In the new formulation, H and Z were administered at lower doses compared to the traditional 2RHZ/RH regimen (Lima *et al.*, 2017).

Table 1: Pharmacological presentation of this scheme is a tablet containing a FDC of four drugs dosages of anti-TB medicines should be used daily for the treatment of TB in children. The 2RHZE/RH scheme is still recommended for children with TB.

Isoniazid (H)	10 mg/kg (range 7–15 mg/kg); maximum dose 300 mg/day
Rifampicin (R)	15 mg/kg (range 10–20 mg/kg); maximum dose 600 mg/day
Pyrazinamide (Z)	35 mg/kg (range 30–40 mg/kg)
Ethambutol (E)	20 mg/kg (range 15–25 mg/kg)

Non-adherence to treatment regimen and inappropriate prescription of childhood TB therapy are believed to be major contributing factors to this public health problem (Ajema *et al.*, 2020). Due to the large number of tablets used in the treatment regimens of childhood TB, FDC tablets, each combining two or more anti-TB drugs, have been manufactured since the 1980s to simplify childhood TB therapy and facilitate HCW and patient compliance with treatment

dosage recommendations (Albanna *et al.*, 2013). These FDC tablets also prevent inadvertent monotherapy, which may occur because of physician error in prescription, inadequate regimens or patient error in selectively taking only one drug (Godman *et al.*, 2020; Habteyes Hailu *et al.*, 2015).

2.7.2 Stock outs or expired childhood TB drugs and laboratory commodities.

The main factors causing inadequate childhood TB treatment are unavailability of certain anti-TB drugs and laboratory commodities (LCs) used for diagnosis of TB due to stock-outs, delivery disruptions, poor storage conditions, and poor quality and regulation of medicines (Koomen, Burger, & van Doorslaer, 2019; Tola, Anbessa, & Yikna, 2020). HFs need extensive ranges of anti-TB drugs and related TB LCs for diagnosis, prevention, and treatment of childhood TB (Tola *et al.*, 2020). Inadequate TB treatment is an important factor that can contribute to the development of multi drug-resistant (MDR)-TB strains and increase the mortality rate (Nahid *et al.*, 2019; Stosic *et al.*, 2018). In the absence of treatment with anti-TB drugs, about 70% of individuals with sputum smear-positive and 20% of people with culture-positive but smear-negative pulmonary TB died within 10 years of being diagnosed (Cox *et al.*, 2014).

Drug stock-out hinders access to effective treatment and achievement of treatment success targets (Koomen *et al.*, 2019). In 2013, shortages of anti-TB drugs were reported globally, even in the US (Acosta *et al.*, 2019; Tola *et al.*, 2020). It can result in poor medicine quality, theft, expiration, losses, and shortages. Therefore, such a shortage of commodities contributes to the spread of the TB epidemic. In TB control, stock-outs of drugs and diagnostic LCs are unacceptable (Koomen *et al.*, 2019; Tola *et al.*, 2020). All anti-TB drugs and TB diagnostic

LCs are essential for diagnosis and treatment and follow-up tests of childhood TB patients, respectively. Even though treatment with a 6-month course of first-line TB medicines cures almost 90% of TB cases, lack of access to appropriate medicines persist, especially MDR-TB (Kasozi *et al.*, 2020). Pediatric TB commodities access issues are more prominent in developing countries (Grobusch & Kapata, 2018).

Deprived commodity management in HFs leads to the waste of financial resources, shortage of some medicines, or overage of others resulting in expiration and decline in the quality of patient care (Godman *et al.*, 2020). In addition, it results in wrong decisions about order frequency and quantity, inaccurate stock records, and a lack of systematic performance monitoring. Therefore, to ensure an uninterrupted supply of anti-TB drugs and LCs, good inventory management is mandatory (Jatau *et al.*, 2015). Any imperfection interrupts service provision and the patients' appropriate use of TB drugs (Grobusch & Kapata, 2018). Along all these processes, there are problems associated with the inventory management of anti-TB commodities such as non-availability, inaccurate and lack of updated bin cards (BCs), unsatisfactory inventory management, and poor storage practice (Tola *et al.*, 2020).

The capacity of the laboratory depends on the availability of the required LCs to perform these tests, which require multiple commodities like supplies, reagents, and equipment to be available simultaneously (Tola *et al.*, 2020). However, the supply chain of LCs is a great challenge, especially in developing countries including Kenya. Medicine shortages affect countries worldwide, but in particular developing countries. The evidence to date is limited but suggests that stock outs are associated with treatment alteration and discontinuation, and with worse health outcomes, but none of these studies provides any estimates of the impact of stock outs on health outcomes (Acosta *et al.*, 2019).

Causes of drug stock outs in the medicine depots and HFs include damage, expiry and theft due to poor storage and stock management (Koomen *et al.*, 2019). Other causes are a lack of resources - which can result in late or non-payment of pharmaceutical companies; lack of skilled staff; unexpected demand due to unpredictable migration patterns; poor infrastructure, theft and corruption; and, inadequate stock monitoring (Koomen *et al.*, 2019). There are several reasons why stock outs may affect poor counties more. First, poorer counties often struggle to attract skilled and experienced staff and have worse infrastructure. Secondly, remote areas are more likely to be poorer, which generates additional demands on resources and logistics to deliver drugs to these locations.

Regarding the consequences of drug stock outs, several other studies in sub-Saharan Africa have suggested that medicine shortages may affect treatment and treatment outcomes (Barnett *et al.*, 2016; Pasquet *et al.*, 2010; Seunanden & Day, 2013). A study in Malawi showed that one of the reasons for changing the HIV treatment regimen was due to drug stock outs (Barnett *et al.*, 2016). A study in Ivory Coast found that stock outs caused 9% of the HIV treatment discontinuations and 30% of the treatment alterations. Patients who interrupted treatment because of stock outs had an increased probability of dying in comparison to patients who continued treatment (Pasquet *et al.*, 2010). (Seunanden & Day, 2013) found that TB drug stock out rates in South Africa were associated with higher death rates in 2011. Different studies done in Ethiopia show that there are intermittent supplies, shortage of anti-TB commodities, and poor utilization of recording and reporting logistic formats.

These findings for developing countries are in line with findings from studies on drug stock outs conducted in developed countries (Fox *et al.*, 2014; Jensen & Rappaport, 2010; Metzger, Billett, & Link, 2012; Tan, Moles, & Chaar, 2016). In the United States shortage of the

injectable anesthetic drug Propofol caused infection risk for 40,000 patients due to mistakes with a different dosage of the drug (Jensen & Rappaport, 2010). Moreover, lower event-free survival rates were seen in children with cancer treated on a different regimen due to drug stock outs (Metzger *et al.*, 2012). Drug stock outs may also have an impact on costs because they increase the workload for health staff, as alternative treatments have to be found. Alternative drugs can also be more costly (Tan *et al.*, 2016). This has economic consequences: A survey conducted in the United States showed that approximately US \$216 million was spent to manage drug stock outs on an annual basis (Fox *et al.*, 2014).

This knowledge and existing literature on drug stock outs, lead us to expect that TB drug stock outs have a negative impact on TB treatment outcomes. This negative impact has not yet been demonstrated in other work, like who reported a positive correlation between TB drug stock outs and TB deaths, but without further control for confounding due to observed and unobserved factors. Drug stock-out is one of the factors that hinder access to effective treatment and achievement of treatment success targets (Kasozi *et al.*, 2020). Interventions to prevent treatment interruption are, therefore, aimed at both treatment provider (HCWs) and patients (Alipanah *et al.*, 2018). On the provider side, actions include ensuring proper prescribing practices and management of side effects, providing good quality medicines, and preventing stock-outs (Hughes, 2008).

2.7.3 Health products and technologies supply chain

Logistic management is the process of selection, quantification, procurement, inventory management, storage, distribution, and use, together with an effective logistic management information system (LMIS) (Tiye & Gudeta, 2018). Access to quality and affordable essential

health products and technologies is pivotal to successful delivery of health services in Kenya. In Kenya, all TB commodities selection, quantification, and procurement are done at the Kenya Medical Supplies Authority level in collaboration with the National Tuberculosis Program/ Ministry of Health (Seunanden & Day, 2013). HFs are responsible for inventory management, storage, and distribution of commodities from store to the TB clinics and laboratory units. Inventory management is the process to order, receive, store, issue, and then reorder anti-TB and LCs with the aim to secure a sustainable supply of these commodities (Tola *et al.*, 2020). In addition, dealing with one combined formulation that contains all essential drugs simplifies drug procurement, storage and distribution, and may consequently reduce drug supply management errors and cost (Tariq *et al.*, 2020).

A confluence of factors is making procurement and supply chain management of TB medicines increasingly complicated. In addition to the risks around financing availability, challenges with decentralized procurement and changing guidelines and recommendations noted above, all of which create risks of stock-outs and new products with short shelf lives that can increase the risk of expiry are being introduced (Jatau *et al.*, 2015). There is, and will continue to be, a need for ongoing technical assistance and capacity building around procurement and supply chain management, including implementing, maintaining and responding to early warning systems that detect the potential for stock-outs and treatment interruptions (Hillier, Newton-Lewis, Nair, & Larsen, 2020).

2.8 Conceptual framework

This conceptual framework hypothesized the relationship between the variables under study, that is independent and outcome variables. In this study, the ability of HCW to correctly

diagnose and manage childhood TB in Siaya County was the outcome variable and was hypothesized to be influenced by independent variables such as HCW's socio economic/demographic profile; HCW's knowledge of childhood TB diagnosis and management; health facility based factors and HCW's constraints to childhood TB diagnosis and management. The influence of HCW's level of knowledge on correct childhood TB diagnosis and management was by looking at influence of attendance of lectures/seminars/workshops to the level of knowledge, knowledge of WHO 2010mg/kg dosage for first-line anti-TB drugs and HCWs knowledge of standard length of treatment of newly diagnosed case of childhood TB as independent variables with how it influence HCW's ability to correctly diagnose and manage childhood TB.

On HF based factors, influence of availability of chest radiography in HFS, availability of standard regimens for children in HF and type of HF as independent variables on HCW's ability to correctly diagnose and manage childhood TB was assessed. Constraints to childhood TB diagnosis and management by HCWs: Influence of correct diagnosis by HCWs, stock outs or expired drugs and procurement of supplies influence on HCWs ability to correctly diagnose and manage childhood TB was equally assessed.

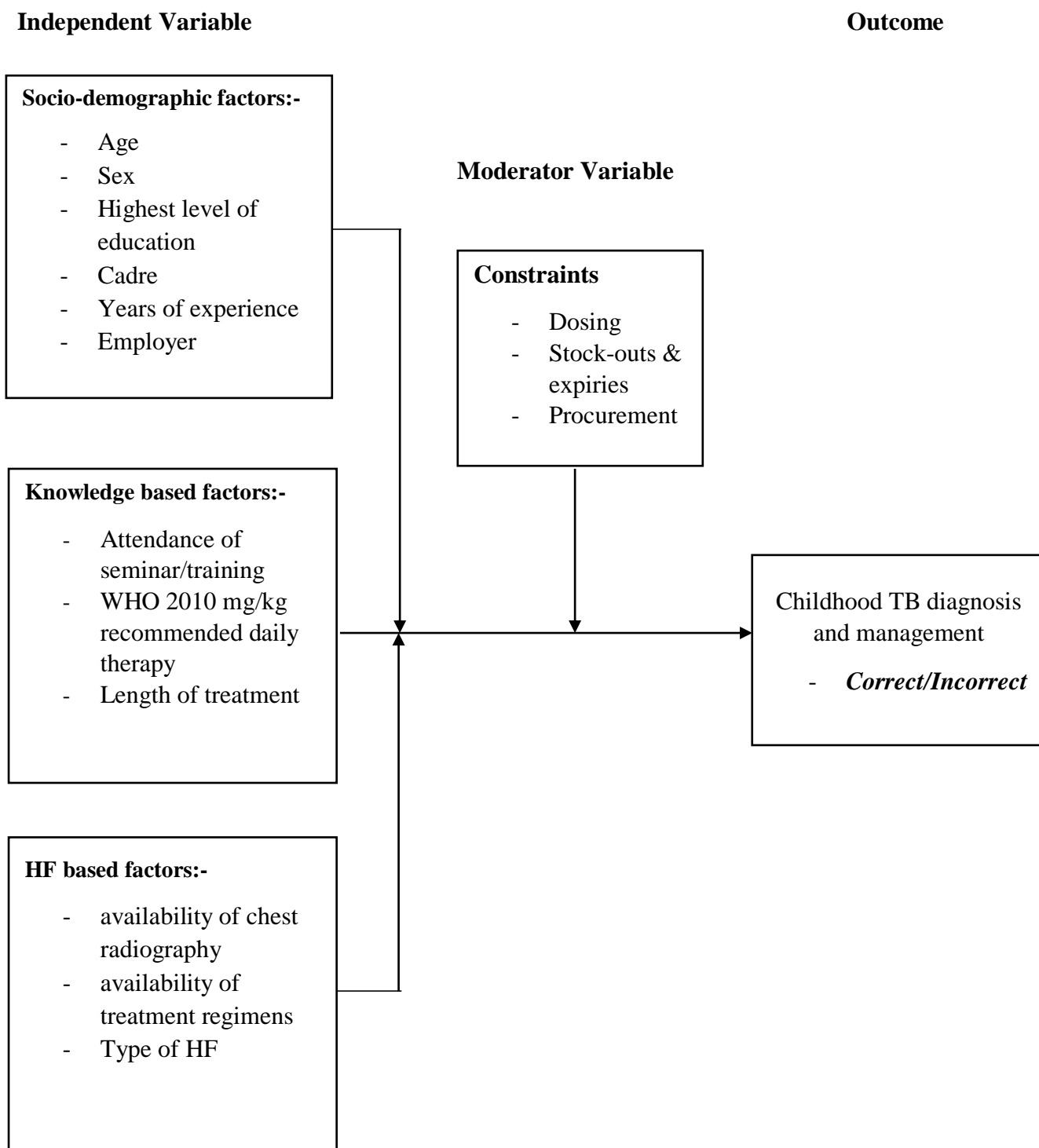


Figure 3: Conceptual framework of factors that affect diagnosis and management of childhood TB among HCWs adopted from proposed original model by Cristobal & Cristobal (2017).

CHAPTER THREE: METHODOLOGY

3.1 Study area

This study was conducted in public HF in Siaya County. To ensure representation of different categories, levels and geographical sub-counties (Figure 4) below.

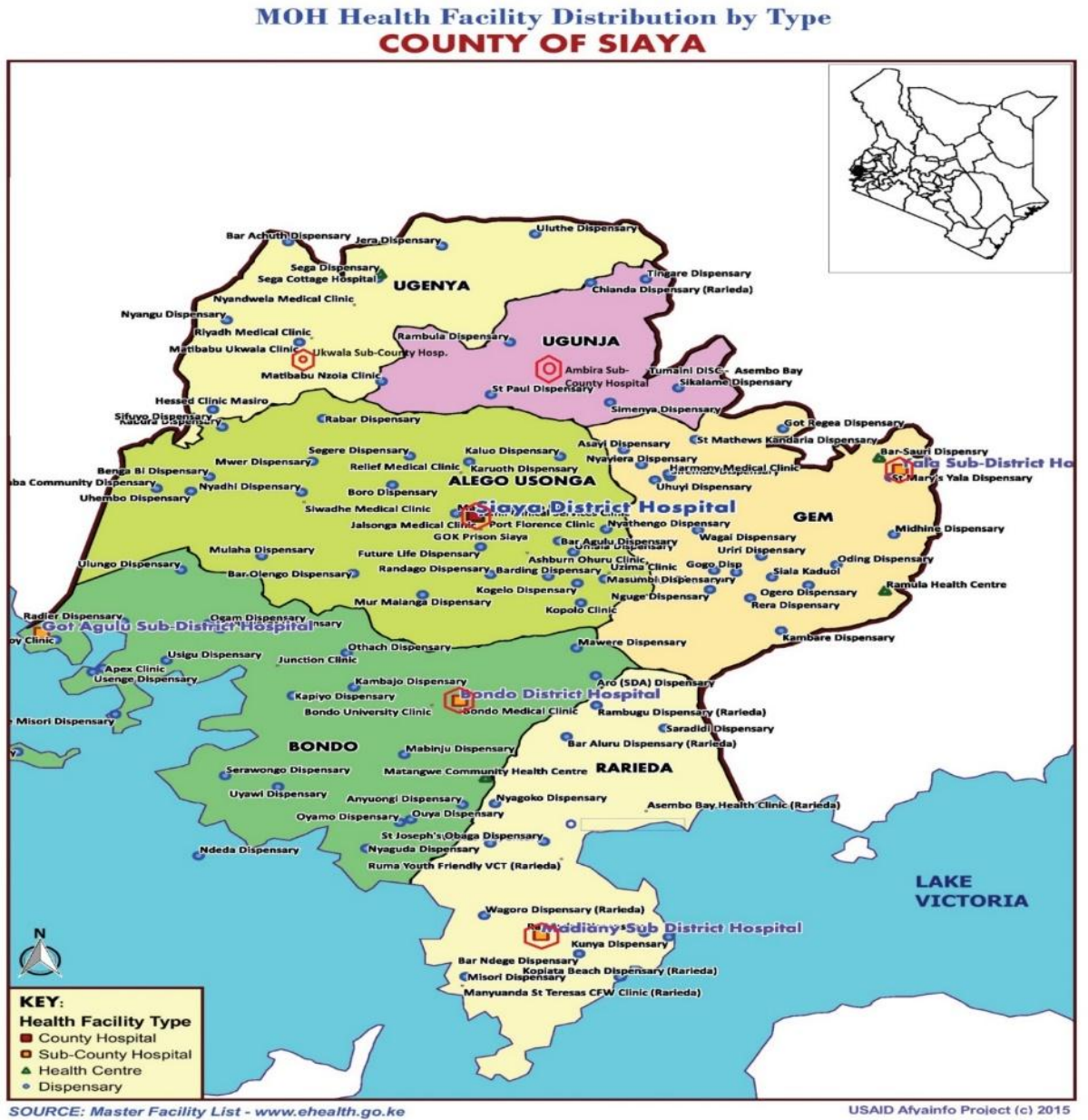


Figure 4: Figure of "Siaya County Map" showing all the 18 purposively selected HF's Source:

Master Facility List- Retrieved from www.ehealth.go.ke Copyright 2015 by USAID

In 2017, Siaya County at 14% (748/5344) ranked 1st of the 47 counties with >5% childhood TB Death Reporting rates (Onyango *et al.*, 2018). Siaya County only contributed 5.1% childhood TB cases against 10 – 15% recommended by the WHO and ranked 27th of 47 counties in 2018 (Nduba *et al.*, 2019). The eighteen (18) health facilities selected for this study contributed the highest childhood TB notification rate in 2017 (MOH, 2017).

3.2 Study design

This study was conducted through facility based cross-sectional design with primary data analysis. A descriptive research approach was chosen because it provided room for the exploration and description of phenomena in real life situation (Polit and Becker, 2010). It provided an accurate account of characteristics of particular individuals or groups. Embracing a cross sectional design approach helped describe the status of phenomena at specific point in time, amongst a specific group or population as was intended with this study.

3.3 Target population

The study targeted all HCWs (including: Doctors, Pharmacists, Nurses, Clinicians, Pharmaceutical Technologists, Laboratory Technologists and Community Health Assistants) working in 128 TB diagnostic and management HFs across six (6) sub-counties of Siaya County.

3.4 Study population

A study population is that population which the researcher needs in order to be able to generalize results (Omor, 2015). The study population was 485 HCWs working in 18 TB

diagnostic and management HFs. This was because the HFs had both high TB case identification and high number of HCWs in the region. The study respondents were those HCWs registered in the HF staff return register and were discharging duties in these HFs at the time of the study.

3.5 Sample size

Yamane's formula (Yamane, 1967) for sample size determination was used to calculate the sample size of HCWs working in the eighteen purposively sampled. Therefore, adopting Yamane's formula at 5% (0.05) margin of error and 95% confidence interval, the sample size calculated as:-

$$n = \frac{N}{1 + N(e)^2}$$

Where:

$$n = \frac{485}{1 + 485(0.05)^2}$$

$$n = 219$$

Add 10% to account for possible attrition or non-response rate.

$$n = 219 + 21.9$$

$$n = 240.9$$

$$n = 241 \text{ respondents}$$

Yamane's formula of 1967 was chosen for this study because the study population was already known.

3.6 Sampling unit

Respondents were obtained from selected dispensaries, health centers, sub county hospital and county referral hospital.

3.7 Inclusion and exclusion criteria

3.7.1 Inclusion criteria

1. HCWs who at the time of data collection had worked at 18 purposively sampled TB diagnostic and treatment centre for more than 3 months.
2. HCWs who were willing to give a written informed consent before participation in the study.

3.7.2 Exclusion criteria

1. HCWs who were not listed in the staff return register of each HF at the time of data collection.

3.8 Sampling technique

The study used purposive sampling technique to select 18 childhood TB diagnostic and management HFs based on both their high TB case identification data and high number of HCWs in the HFs that were included in this study. The researcher also applied this technique to select 6 (six) Sub-County TB and Leprosy Coordinators (SCTLs), 6 (six) Sub-County Medical Laboratory Technicians (SCMLTs) and 18 (eighteen) HF in-charges coordinating the 18 purposively sampled HFs due to their vast and in-depth knowledge in childhood TB diagnosis and management.

At the HF level, the researcher used simple random sampling technique using a sample frame of 485 HCWs. Using a table of random numbers, the first respondent was selected by blindly pointing at any number in the table of random numbers and the HCW assigned the corresponding number was included in the sample. After selecting the number, the table was then systematically followed upwards and downwards until the required number of respondents (211) was reached (Appendix VIII).

3.9 Pilot testing

Pre- testing for the questionnaire was done at Bar Sauri Health Centre, a TB diagnostic and treatment site. This facility was chosen because it is situated in Siaya County; furthermore, it serves a population which offers similar characteristics to the study target population. A sample size of 1-10% suffices, therefore in this case, a sample size of 24 respondents were recruited for pre- testing. The information gathered was cross checked with other secondary data to ensure effectiveness and accuracy of the tool.

3.10 Reliability and Validity

3.10.1 Reliability

In order to ensure reliability of the questionnaires, Reliability was calculated using Cronbach Alpha Coefficient (CAC) analysis. Both instruments were found to be reliable as they rated over 0.7. These values fell within the standard acceptable value of at least 0.7 and above which indicated the instrument was likely to yield valid and reliable results during the subsequent research undertakings. Thus, the same questionnaires were administered to the same study

respondents at different times, and chances were very high that one would get the same or a similar response. Therefore, introduction of bias was reduced.

To increase the trustworthiness of the study's findings from KIIs, the researcher employed strategies suggested by Lincoln and Guba (1985). The researcher decreased threats to credibility (quantitative researchers would use the term internal validity) by triangulating data (Triangulation of data being of critical importance to the trustworthiness of qualitative studies). As the study unfolded and particular pieces of information became known, steps were taken to validate each information item against at least one other source (e.g., a second interview) and/or a second method (e.g., an observation in addition to an interview) (Denzin, 1989; Lincoln & Guba, 1985). Using a second source or a second method produced more accurate, comprehensive, and objective findings (Silverman, 2006). For this study, interviews and field notes were compared to ensure trustworthiness.

3.10.2 Validity

Content validity of the questionnaires was achieved by all the important constructs that are identified in the literature that has been included. Content validity was computed using the Content Validity Index (CVI). Threat to external validity was minimized by virtue of the study being cross-sectional, thus reducing the possibility of attrition of study respondents, which would have otherwise compromised validity, as measurement were made at one point in time only. In addition, the use of the 10% sampling recommended for the size of the sampling frame under study helped improve external validity by improving sampling adequacy and ensuring all important elements were included.

The researcher also used good rich, thick description (Merriam, 1998), thus enabling decision making on transferability (known as external validity or generalizability in quantitative research. To increase conformability (known as objectivity in quantitative studies), the researcher attempted to control for bias by constantly comparing data, searching the literature for examples of the phenomenon, obtaining multiple viewpoints (Strauss & Corbin, 1998), searching for negative instances of the phenomenon, and checking and rechecking data (Marshall & Rossman, 1989).

3.11 Data collection instruments

After obtaining the written consent, the researcher entered the questionnaire/KIIs serial number and date of interview and proceeded from the first up to the last question using a language understood by the respondent. The respondents entered responses by ticking the appropriate response number and entering the same number into the coding box. The researcher reviewed the questionnaires and KIIs on a weekly basis to ensure they were being completed correctly and any errors were discussed with the researcher to avoid them being repeated. The process of data collection continued until every effort to contact every study respondent in the sample had been exhausted. All completed questionnaires and KIIs were kept in a safe lockable cupboard and the keys kept by the researcher until the researcher picked them up.

3.11.1 Structured questionnaire interviews

Once the HCW reported to their workstation, the researcher requested for participation in the study. A repeat visit was made whenever HCW was absent at his/her HF during the initial visit. In case HCW had relocated to a different HF within the county, he/she was traced and

interviewed. Data was collected on respondent's socio-demographics characteristics, including; sex, age, level of education. Disease related factors to assess the HCWs knowledge of childhood TB were obtained, where respondents were asked to respond to questions about causative organisms of TB, transmission, prevention and possible management. Further, facility related factors to determine the constraints to childhood TB diagnosis and management were obtained, where respondents answered questions on childhood TB diagnosis, management, availability of diagnostic and management guidelines, contact tracing and preventive therapy (Appendix II).

3.11.2 Key informant interview (KII)

A total of 30 Key Informant Interviews (KIIs) (Informants: 18 HF in-charges, 6 SCTLCS and 6 SCMLTs) were conducted. The interviews lasted an average duration of 30 minutes each. The KIIs assessed the HCWs in-depth perspective on childhood TB socio demographic and socio-economic factors, disease-based factors, facility-based factors and constraints to childhood TB diagnosis and management services. (Appendix III).

3.12 Data Processing and statistical analyses

3.12.1 Data processing

3.12.1.1 Quantitative research approach

After cleaning the information in MS Excel, data was exported to SPSS version 25.0.0. Categorical variables were analyzed and presented in frequencies and percentages (%). Pearson Chi-squared (χ^2) test for categorical variables was used to assess any bivariate and multivariate association. Adjusted Odds ratio (AOR) with 95% confidence levels was used to

quantify the strength of the relationship between intervening factors and outcome variables. Textual, figure, and tabular summaries were then used to present various outcomes with a statistical significance of $\alpha \leq 0.05$ considered.

3.12.2.2 Qualitative data analysis

Qualitative analysis occurred in three phases. First, interview transcripts were reviewed several times, searching for “recurring regularities” (Merriam, 1998). The researcher highlighted quotes and phrases from the interviews that were significant to the study. Using the constant comparative method (Glaser & Strauss, 1967), the researcher went back and forth among transcripts until categories emerged that were consistent, yet distinct (Marshall & Rossman, 1989). The researcher named these categories, coded the transcripts, and placed sections in labelled folders representing each category (Bogdan & Biklin, 1982; Merriam, 1998). Second, the researcher brought together the coded interviews and field notes and looked for relationships within and across the data sources. A table was developed to compare various coded interviews. As tentative categories emerged, the researcher tested them against the data (Merriam, 1998). The researcher also tested interview data against the mental model. Finally, the researcher integrated and refined the categories until themes solidified (Strauss & Corbin, 1998).

3.13 Ethical considerations

3.13.1 Informed consent and assent

Guidelines for the protection of human subjects were followed. Informed consent was obtained within the standard operations of the Maseno University Ethics Review Committee

(MUERC) Standard Operating Procedures (SOPs), following approval of the study procedures. Each potential respondent was read to the consent form that addressed their rights and welfare as a respondent in the study and given time to ask questions. If they agreed to participate in the study, the respondent indicated consent by either a signature or a fingerprint. Respondents were informed before the start of the interview that if they were uncomfortable, they could stop the interview at any time. All information collected during the study was kept confidential.

Research procedures was explained to respondents and written informed consent obtained before any HCW was screened for eligibility. Consent was sought after written and verbal information about the purpose and procedures of the study was given in English as appropriate. In addition, respondents were informed that participation was voluntary, and they can decline participation at any stage.

Since this study aimed at investigating factors that affect diagnosis and management of childhood TB, the study included respondents who consented directly. Ethical approval for the study was sought from MUERC. Consent forms for each study tool are included in the appendices (Appendix I).

3.13.2 Confidentiality

No study respondent will be identified by name in any report or publication derived from information collected for the study. All personal identifiers were removed from the data once in the database. Data collection forms were kept at a good clinical practice (GCP) compliant lockable storage area and all documents containing identifying information was destroyed after the project and data entry completed. Data was maintained in a de-identified electronic database that was password-protected and to which only authorized study personnel (Principal

researcher) had access. A copy of the informed consent documents was given to the respondents for their records. Rights and welfare of respondents was protected by emphasizing to them that the quality of their work would not be affected if they decline to participate in this study.

3.13.3 Risks to respondents

No major direct risks were anticipated, only the inconvenience involved in taking time to obtain consent or assent to participate in the study. Respondents' knowledge on childhood TB, diagnosis and management methods was sought. Only the principal researcher was involved in data collection. No additional risks were involved for principal researcher conducting the interviews.

3.13.4 Benefits to respondents

The main benefit to respondents was to identify and create need to fill the existing knowledge gap in childhood TB diagnosis and management of an active infection. The benefit of participation in this evaluation outweighed the risks. Furthermore, except for the potential loss of privacy associated with enrollment, the risks in this study were no greater than the risks encountered by persons during routine medical care.

3.13.5 Compensation and incentives

The researcher did not anticipate any major risks during the course of the study. Since interviews was a one-time point event, no compensation or incentives was given to respondents besides the benefits entitled to respondents.

3.13.6 Expected application of results

This study identified factors that influenced diagnosis and management of childhood TB among HCWs in Siaya County. Findings of this study would be shared with study respondents, members of the local community, as well as presented at professional conferences, and in peer-reviewed journals. Any publication of the results of this study would be governed by Maseno University research policies.

CHAPTER FOUR: RESULTS

4.0 Response rate

This chapter presented results of the study as set out in the objectives. In total, 241 HCWs responded which represented 100% response rate. A response rate of 50% is considered or deemed adequate for analysis and reporting, however, a response rate of 60% is considered good, of 70% and over is very good.

4.1 Socio-demographic characteristics of the study respondents

Table 2 summarizes data on the socio-demographic characteristics of study respondents. The study results revealed that male respondents constituted the majority of study participants 142 (59%) while female respondents were 99 (41%). Majority 139 (58%) of the respondents were aged 30 years and below, while those aged between 31-40 years were 88 (37%) with respondents above 40 years accounting for only 14 (6%). Results on their highest level of education completed revealed that holders of University/College Diploma were 174 (72%), a further 67 (28%) reported; Associate Degree 7%, Bachelor's Degree 17%, Specialized 2% and Others 1% respectively. The study results also revealed that clinical officers constituted the highest proportion of study participants 80 (33%) followed by nurses at 69 (29%). The medical laboratory officers were 34 (14%), Pharmacists were 30 (13%), medical officers were 19 (8%) while the other cadres were dental officers and TB screeners who accounted for 8 (3%). In regards to years of work experience, a majority of respondents 162 (67%) reported to be having 1 to 4 years of work-related experience obtained through working in a public HFs. This was followed by 5-9 years, <1 year, 10-14 years and >15 at 20%, 6%, 4%, and 2% respectively.

Table 2: Socio-demographic Characteristics of the Respondents (n=241)

Description of respondents:	Respondents (n=241)	Proportion (%)
<i>Gender:</i>		
Male	142	59%
Female	99	41%
<i>Age Groups (in years):</i>		
Under 30 years	139	58%
31-40 years	88	37%
41-50 years	12	4%
Over 50 years	2	1%
<i>Highest level of education completed:</i>		
University/College Diploma	174	72%
Associate Degree	18	7%
Bachelor's Degree	41	17%
Specialized/Professional graduate or Post graduate Degree	6	2%
Others (specified)	2	1%
<i>Cadre of staff:</i>		
Medical Officer/Doctor	19	8%
Nursing Officer/Counsellor	69	29%
Clinical Officer	80	33%
Medical Laboratory Officer/Technician	34	14%
Dental Officer/Community Oral Health Officer	7	3%
Pharmacist	30	13%
Pediatric TB Screener	1	0%
<i>Experience in public health facility (in years):</i>		
< 1	15	6%
1-4	162	67%
5-9	49	20%
10-14	10	4%
15+	5	2%

Data are presented as number and proportions (%) of subjects, unless otherwise indicated.

4.2 Association between socio-demographic characteristics and childhood TB diagnosis and management

The study sought to establish how socio-demographic factors like gender, age, highest level of education completed, cadre of staff and years of experience in public HFs influenced childhood TB diagnosis and management among HCWs in Siaya County. Table 3 outlined frequency distribution of socio-demographic factors and its effect on childhood TB diagnosis and management among HCWs in Siaya County. Furthermore, Chi square test of association analysis was performed to determine the influence of socio-demographic factors on childhood TB diagnosis and management (Table 4).

4.2.1 Frequency distribution of socio-demographic factors and childhood TB diagnosis and management

Table 3 showed the distribution of socio-demographic characteristics and correct or incorrect childhood TB diagnosis and management among HCWs in Siaya County. Out of 73% (n=175) respondents who were aged under 30 years, 66% (n=95) reported incorrect compared to 83% (n=80) respondents who reported correct childhood TB diagnosis and management. For those 8% (19) who were aged between 31-40 years, 9% (13) respondents reported incorrect compared to 6% (6) who reported correct diagnosis and management. While, respondents who were over 40 years 19% (47), 26% (37) respondents reported incorrect compared to 10% (n=10).

Majority 73% (n=175) respondents reported having diploma as highest level of education attained. Out of this, 66% (n=95) reported incorrect childhood TB diagnosis and management, while 83% (80) reported correct. From the 27% (n=66) who had degree level and above, 34%

(n=50) reported incorrect while 17% (16) respondents reported correct childhood TB diagnosis and management.

Regarding the current employer, of 62% (n=146) employed by MOH/partner, most 57% (n=82) respondents reported incorrect compared to 70% (n=64) who reported correct diagnosis and management. While, of the respondents employed by MOH 38% (n=89), 43% (n=62) reported incorrect compared to 30% (n=27) who reported correct childhood TB diagnosis and management. This implies that childhood TB diagnosis and management is dependent on age, highest level of education completed and current employer of HCWs (Table 3).

On gender, of 59% (n=142) male respondents, most 60% (n=87) respondents reported incorrect compared to 57% (n=55) who reported correct diagnosis and management. While, female respondents 41% (n=99), 40% (n=62) reported incorrect compared to 43% (n=41) who reported correct childhood TB diagnosis and management. This implies that childhood TB diagnosis and management is was independent on gender of HCWs.

On cadre of staff, of 41% (n=97) clinicians, most 43% (n=62) respondents reported incorrect compared to 36% (n=35) who reported correct diagnosis and management. For nurses 30% (n=73), most 32% (n=47) respondents reported incorrect compared to 27% (n=26) who reported correct. For medical laboratory personnel 14% (n=34), 12% (n=18) respondents reported incorrect compared to 17% (n=16) who reported correct. Dental officers 3% (n=7), 2% (n=3) respondents reported incorrect compared to 4% (n=4) who reported correct. And for pharmacists 12% (n=30), 10% (n=15) respondents reported incorrect compared to 16% (n=15) who reported correct childhood TB diagnosis and management (Table 3).

Table 3: Frequency of socio-demographic characteristics and childhood TB diagnosis and management

Socio-demographic Characteristics	Category	Childhood TB diagnosis and management			P value
		Total <i>n</i> (%)	Correct <i>n</i> (%)	Incorrect <i>n</i> (%)	
	n	241 (100)	96(40)	145(60)	
Gender of Respondent:	Male	142 (59)	55 (57)	87 (60)	0.676
	Female	99 (41)	41 (43)	58 (40)	
Age of respondents (in years)	Under 30	175 (73)	80 (83)	95 (66)	0.007
	31-40	19 (8)	6 (6)	13 (9)	
	Over 40	47 (19)	10 (10)	37 (26)	
Highest Level of Education Completed	Diploma Level	175 (73)	80 (83)	95 (66)	0.002
	Degree Level and above	66 (27)	16 (17)	50 (34)	
Cadre of Staff	Clinicians	97 (41)	35 (36)	62 (43)	0.403
	Nurses	73 (30)	26 (27)	47 (32)	
	Medical Lab Personnel	34 (14)	16 (17)	18 (12)	
	Dental Officers	7 (3)	4 (4)	3 (2)	
	Pharmacists	30 (12)	15 (16)	15 (10)	
Experience in public HF	< 1y	17 (7)	9 (9)	8 (6)	0.480
	1-4y	161 (67)	66 (69)	95 (66)	
	5-9y	53 (22)	18 (19)	35 (24)	
	10y +	10 (4)	3 (3)	7 (5)	
Current employer:	MoH	89 (38)	27 (30)	62 (43)	0.039
	MoH/Partner Support	146 (62)	64 (70)	82 (57)	

Data is presented as numbers and proportions (%) of subjects, unless otherwise indicated. Statistical analysis was performed using chi-square (χ^2) test. Statistical significance was set at $P \leq 0.050$. Significant P -values are indicated in bold.

4.2.2 Association between socio-demographic characteristics and childhood Tb diagnosis and management

In order to determine the association between socio-demographic characteristics and correct or incorrect childhood TB diagnosis and management, we performed Chi square test of association analysis, this weighted socio-demographic characteristics respectively (Table 4). Results showed that relative to HCWs under 30 years of age, the respondents above the age of 40 years had 0.3 lower odds of correct diagnosis and management of childhood TB (Adjusted odds ratio, AOR=0.321, 95% confidence interval, CI=0.15-0.686, $p=0.003$) compared to those above 30 years.

HCWs with degree (and above) as highest level of education attained were 0.38 times less likely to correctly diagnose and manage childhood TB (AOR=0.38, 95% CI=0.201-0.718, $p=0.003$) compared to diploma. Further, HCWs employed by MOH/Partner support were 1.8 times more likely to correctly diagnose and manage childhood TB (AOR=1.792, 95% CI=1.026-3.131, $p=0.047$) relative to respondents employed by MOH. There was no significant association between childhood TB diagnosis and management and gender ($p=0.676$), cadre of staff ($p=0.178$) and experience in public HF ($p=0.253$) (Table 4).

There was no influence of gender (AOR=1.118, 95% CI=0.663-1.887, $p=0.676$), cadre of staff (AOR=1.808, 95% CI=0.764-4.277, $p=0.178$) and HCW's experience in public HF (AOR=0.381, 95% CI=0.073-1.992, $p=0.253$) (Table 4).

Table 4: Association between socio-demographic characteristics and childhood TB diagnosis and management

Socio-demographic Characteristics	Childhood TB diagnosis and Management		Significance testing				
	Correct	Incorrect	P value	AOR	95% C.I.		P value
					Lower	Upper	
	96	145					
Gender of Respondent:	$\chi^2(1)=0.175$		0.676	1.118	0.663	1.887	0.676
Age of respondents (in years)	$\chi^2(2)=9.819$		0.007	0.321	0.150	0.686	0.003
Highest Level of Education Completed	$\chi^2(1)=9.219$		0.002	0.380	0.201	0.718	0.003
Cadre of Staff	$\chi^2(4)=4.021$		0.403	1.808	0.764	4.277	0.178
Experience in public HF	$\chi^2(3)=2.475$		0.480	0.381	0.073	1.992	0.253
Current employer:	$\chi^2(1)=4.246$		0.039	1.792	1.026	3.131	0.047

Chi square test of association analysis was performed to assess the association between socio-demographic characteristics and childhood TB diagnosis and management. HCWs were grouped into those who would carry out correct childhood TB diagnosis and management (n=96) and incorrect childhood TB diagnosis and management (n=145). Data are presented as odds ratios and 95% confidence interval (CI). Statistical significance was set at $P \leq 0.050$. Significant P values are shown in bold.

4.2.3 Emerging themes on socio-demographic factors from key informant interviews

In order to verify the results from the quantitative data analysis, KIIs were conducted with 30 members in 18 HFIs. Thematic analysis revealed four sub-themes surrounding socio-demographic characteristics and childhood TB diagnosis and management. Results showed that majority of the respondents cited age of HCWs and their qualification as important components towards childhood TB diagnosis and management. In a response, one of the respondents of KIIs stated:

“CHS, our biggest partner that support TB/HIV in the County from my own observation employs young workforce mainly from MTCs with diplomas whom they find easy to train and mentor to help them achieve their main objective. All CHS staff look young in age and a majority of them are diploma holders.” (Respondent 11)

The KII respondents indicated that terms of employment and type of employer had direct effect on childhood TB diagnosis and management in Siaya County. When asked if the type of employer mattered, one study participant quoted:

“Contact employees working in public HFIs stand a better chance of diagnosing and managing childhood TB correctly compared to those staff on permanent employment.”
(Respondent 4)

4.3 Association between knowledge based factors and childhood TB diagnosis and management

The study also set out to determine the influence of HCWs level of knowledge on childhood TB diagnosis and management. The frequency distribution of knowledge based factors and correct or incorrect childhood TB diagnosis and management among HCWs in Siaya County

were determined (Table 5). In addition Chi square test of association analysis was used to determine the influence of knowledge based factors on correct or incorrect childhood TB diagnosis and management (Table 6).

4.3.1 Frequency distribution of knowledge based factors and childhood TB diagnosis and management

Table 5 shows the distribution of knowledge based factors and childhood TB diagnosis and management among HCWs in Siaya County. Attendance of seminar/training on childhood TB in the past 12 months by a HCW showed that of 46% (n=111), 56% (n=54) respondents reported correct childhood TB diagnosis and management compared to 44% (n=42) who had not attended such fora. Few respondents 39% (n=57) who had attended seminar/training on childhood TB in the past 12 months compared to 61% (n=88) who had not attended such reported incorrect childhood TB diagnosis and management.

Regarding HCWs knowledge of WHO mg/kg recommended daily therapy, 57% (n=55) of 56% (n=135) who had no knowledge of WHO mg/kg recommended daily therapy reported correct childhood TB diagnosis and management as compared to 55% (n=80) respondents who reported incorrect diagnosis and management. For the 44% (n=106) respondents who reported having knowledge of WHO mg/kg recommended daily therapy, 43% (n=41) reported correct childhood TB diagnosis and management compared to 45% (n=65) who indicated incorrect diagnosis and management.

Majority 91% (n=220) of the respondents who reported to know the standard length of treatment of newly diagnosed childhood TB case. 94% (n=90) reported correct while 90% (n=130) respondents reported incorrect childhood TB diagnosis and management. Only 6%

(n=6) respondents who indicated not to know the standard length of treatment of newly diagnosed childhood TB case reported correct while 10% (n=15) respondents reported incorrect childhood TB diagnosis and management (Table 5). This implied that correct or incorrect childhood TB diagnosis and management is dependent on HCW's attendance of seminar/training on childhood TB in the past 12 months (Table 5).

Table 5: Distribution of the knowledge based factors on childhood TB diagnosis and management

Knowledge based factors	Category	Childhood TB diagnosis and management				P value
		Total	n (%)	Correct n (%)	Incorrect n (%)	
	n	241 (100)		96(40)	145(60)	
Attendance of seminar/training on childhood TB	No	130 (54)		42 (44)	88 (61)	0.010
	Yes	111 (46)		54 (56)	57 (39)	
WHO 2010 mg/kg recommended daily therapy	No	135 (56)		55 (57)	80 (55)	0.746
	Yes	106 (44)		41 (43)	65 (45)	
Length of treatment of newly diagnosed case	No	21 (9)		6 (6)	15 (10)	0.270
	Yes	220 (91)		90 (94)	130 (90)	

Data are presented as number and proportions (%) of subjects, unless otherwise indicated. Statistical analysis was performed using chi square (χ) test. Statistical significance was set at $P \leq 0.050$. Significant P values are indicated in bold.

4.3.2 Association between knowledge based factors and childhood TB diagnosis and management

To ascertain the influence of knowledge based factors on childhood TB diagnosis and management in Siaya County, we performed Chi square test of association analysis, that weighted knowledge based factors (Table 6). Results showed that HCWs who had attended of

seminar/training and workshops on childhood TB in the past 12 months had 1.985 higher odds of correct childhood TB diagnosis and management (AOR=1.985, 95% CI=1.176-3.349, $p=0.012$) compared to those HCWs who had not attended of seminar/training or workshops on childhood TB in the past 12 months.

There was no influence of HCW's knowledge of WHO mg/kg recommended daily therapy (AOR=0.917, 95% CI=0.545-1.544, $p=0.746$) and HCW's knowledge of the standard length of treatment in months of newly diagnosed case of childhood TB (AOR=1.731, 95% CI=0.647-4.631, $p=0.275$) (Table 6).

Table 6: Association between knowledge based factors and childhood TB diagnosis and management

Knowledge based factors	Childhood TB diagnosis and Management		Significance testing			P value	
	Correct	Incorrect	P value	AOR	95% C.I.		
					Lower		Upper
	96	145					
Attendance of seminar/training on childhood TB	$\chi^2(1)=6.671$		0.010	1.985	1.176	3.349	0.012
WHO 2010 mg/kg recommended daily therapy	$\chi^2(1)=0.105$		0.746	0.917	0.545	1.544	0.746
Length of treatment of newly diagnosed case	$\chi^2(1)=1.218$		0.270	1.731	0.647	4.631	0.275

Chi square test of association analysis was performed to assess the association between knowledge based factors and childhood TB diagnosis and management. HCWs were grouped into those who would carry out correct childhood TB diagnosis and management (n=96) and incorrect childhood TB diagnosis and management (n=145). Data are presented as odds ratios and 95% confidence interval (CI). Statistical significance was set at $P \leq 0.050$. Significant P values are shown in bold.

4.3.3 Emerging themes on knowledge based factors from key informant interviews

Thematic analysis revealed one sub-theme on knowledge based factors key to childhood TB diagnosis and management. These results from the KIIs correlate with the questionnaire results which showed that HCW's attendance of seminar/training or workshops on childhood TB in the past 12 months was the main driver to childhood TB diagnosis and management. In response to attendance of seminar/training or workshops on childhood TB in the past 12 months, one participant stated the following:

“In places where two or more trained HCWs are available, better services are provided, while in health centers where only one trained HCWs is present, the childhood TB service may be interrupted whenever the HCW is absent for various reasons.” (Respondent 8)

Another respondent emphasized the role played by training HCWs on childhood TB diagnosis and management:

“In the past, untrained HCWs were assigned in TB clinics. Untrained health workers do not properly know how to give the treatment, how to follow patients and when follow-up AFB examination should be done for TB patients.” (Respondent 12)

This was supported by a respondent who stated:

“Knowledge of the appropriate primary diagnostic test that are usually requested, skills or training level needed for someone to effectively conduct DOT and TB treatment.”

(Respondent 7)

4.4 Association between HF based factors and childhood TB diagnosis and management

The study also set out to determine the influence HF based factors on childhood TB diagnosis and management. The frequency distribution of HF based factors and childhood TB diagnosis and management among HCWs in Siaya County was determined (Table 7). In addition Chi square test of association analysis was used to determine the influence of HF based factors on childhood TB diagnosis and management (Table 8).

4.4.1 Frequency distribution of HF based factors and childhood TB diagnosis and management

Table 7 shows the distribution of HF based factors and childhood TB diagnosis and management among HCWs in Siaya County. Of the type HFs 74% (n=178), 82% (n=79) respondents reported correct childhood TB diagnosis and management compared to 68% (n=99). Of the respondents who said no on type HF was reported 18% (n=17) and 32% (n=44) to have a little significant impact on childhood TB diagnosis and management among HCWs in Siaya County.

Regarding availability of standard treatment regimens in HFs, 73% (n=70) of 76% (n=183) who indicated availability of standard treatment regimens reported correct childhood TB diagnosis and management as compared to 78% (n=113) respondents who reported incorrect diagnosis and management. For the 24% (n=58) respondents who reported non availability of standard treatment regimens in HFs, 27% (n=26) reported correct childhood TB diagnosis and management compared to 22% (n=32) who indicated incorrect diagnosis and management.

Majority 96% (n=231) of the respondents who reported availability of chest radiography in HFs. 95% (n=95) reported correct while 97% (n=140) respondents reported incorrect

childhood TB diagnosis and management. Only 5% (n=5) respondents who indicated non availability of chest radiography in HFs reported correct while 3% (n=5) respondents reported incorrect childhood TB diagnosis and management. This implied that correct or incorrect childhood TB diagnosis and management is dependent on the type of HF the HCW is stationed (Table 7).

Table 7: Distribution of HF based factors on childhood TB diagnosis and management

HF based factors	Category	Childhood TB diagnosis and management			P value
		Total <i>n</i> (%)	Correct <i>n</i> (%)	Incorrect <i>n</i> (%)	
	n	241 (100)	96(40)	145(60)	
Availability of chest radiography	No	10 (4)	5 (5)	5 (3)	0.502
	Yes	231 (96)	91 (95)	140 (97)	
Availability of standard treatment regimens	No	58 (24)	26 (27)	32 (22)	0.442
	Yes	183 (76)	70 (73)	113 (78)	
Type of HF	No	63 (26)	17 (18)	46 (32)	0.017
	Yes	178 (74)	79 (82)	99 (68)	

Data are presented as number and proportions (%) of subjects, unless otherwise indicated.

Statistical analysis was performed using chi square (χ) test. Statistical significance was set at $P \leq 0.050$. Significant P values are indicated in bold.

4.4.2 Association between HF based factors and childhood TB diagnosis and management

To determine the influence of HF based factors on childhood TB diagnosis and management among HCWs in Siaya County, Chi square test of association analysis was performed that weighted HF based factors. Results showed that the type of HF created a 2.2 times higher odds of correct childhood TB diagnosis and management (AOR=2.159, 95% CI=1.15-4.054, $p=0.017$),

suggesting that HCWs working in sub county level of hospital and above had a much higher odds of correct diagnosis and management of childhood TB compared to workers in health centre and below.

There was no influence of availability of chest radiography (AOR=0.65, 95% CI=0.183-2.308, $p=0.505$) and availability of standard treatment regimens in HFs (AOR=0.762, 95% CI=0.42-1.385, $p=0.017$) (Table 8).

Table 8: Association between HF based factors and childhood TB diagnosis and management

HF based factors	Childhood TB diagnosis and Management		Significance testing			P value	
	Correct <i>n</i> (%)	Incorrect <i>n</i> (%)	P value	AOR	95% C.I.		
					Lower		Upper
	96	145					
Availability of chest radiography	$\chi^2(1)=0.450$		0.502	0.650	0.183	2.308	0.505
Availability of standard treatment regimens	$\chi^2(1)=0.795$		0.442	0.762	0.420	1.385	0.373
Type of HF	$\chi^2(1)=5.877$		0.017	2.159	1.150	4.054	0.017

Chi square test of association analysis was performed to assess the association between HF based factors and childhood TB diagnosis and management. HCWs were grouped into those who would carry out correct childhood TB diagnosis and management ($n=96$) and incorrect childhood TB diagnosis and management ($n=145$). Data are presented as odds ratios and 95% confidence interval (CI). Statistical significance was set at $P \leq 0.050$. Significant P values are shown in bold.

4.4.3 Emerging themes on HF based factors from key informant interviews

Thematic analysis revealed HF based factors key to childhood TB diagnosis and management.

These results from the KIIs correlated with the questionnaire results which showed that type

of HF was the main drivers to childhood TB diagnosis and management. In response participants stated the following:

“As a clinician, yes, working in a sub-county hospital gives me confidence to attend to any TB patient because I am assured of availability of proper and accurate diagnostic tests like Gene Xpert and availability of childhood TB friendly regimes at my disposal. This makes it easy because it relieves me from second guessing myself as I would if I were working in a health center or dispensary.” (Respondent 19)

This finding was emphasized by another participant who reported as follows on HF based factors:-

“Diagnosis and management of childhood TB in hospitals gives better outcomes because, all Gene Xpert machines are located at this level. Equally, hospitals also act as central stores for childhood TB drugs hence after a positive diagnosis, I am guaranteed to get drugs”
(Respondent 25)

4.5 Association between constraint factors and childhood TB diagnosis and management

The frequency distribution of constraints and childhood TB diagnosis and management among HCWs in Siaya County were determined (Table 9). In addition Chi square test of association analysis was used to determine the influence of constraints on childhood TB diagnosis and management (Table 10).

4.5.1 Frequency distribution of constraint factors and childhood TB diagnosis and management

Table 9 showed the distribution of constraints and childhood TB diagnosis and management among HCWs in Siaya County. Out of 100% (n=241), respondents 26% (n=63) who identified procurement as a constraint reported 56% (n=35) correct against 44% (n=28) who reported incorrect childhood TB diagnosis and management. Respondents 35% (n=85) who identified stock-outs as a constraint reported 31% (n=26) correct against 69% (n=59) who reported incorrect childhood TB diagnosis while respondents 39% (n=93) who identified correct dosing as a constraint reported 38% (n=35) correct against 62% (n=58) who reported incorrect childhood TB diagnosis and management.

Table 9: Distribution of constraints on childhood TB diagnosis and management

Constraints	Category	Childhood TB diagnosis and management			P value
		Total <i>n (%)</i>	Correct <i>n (%)</i>	Incorrect <i>n (%)</i>	
	n	241 (100)	96(40)	145(60)	
	Procurement	63 (26)	35 (56)	28 (44)	
Constraints	Stock outs	85 (35)	26 (31)	59 (69)	0.012
	Correct dosing	93 (39)	35 (38)	58 (62)	

Data are presented as number and proportions (%) of subjects, unless otherwise indicated. Statistical analysis was performed using chi square (χ) test. Statistical significance was set at $P \leq 0.050$. Significant *P* values are indicated in bold.

4.5.2 Association between constraint factors and childhood TB diagnosis and management

To determine the constraints to childhood TB diagnosis and management in Siaya County, we performed Chi square test of association analysis, in a model that weighted constraint factors respectively (Table 10). Results showed that the three constraints had 0.342 lower odds of correct childhood TB diagnosis and management (AOR=0.342, 95% CI=0.148-0.787, $p=0.012$), suggesting that existence of challenges of stock outs and correct dosing in health facilities contributed to incorrect diagnosis and management of childhood TB.

Table 10: Association between constraints and childhood TB diagnosis and management

Constraints	Childhood TB diagnosis and Management		Significance testing			P value	
	Correct	Incorrect	P value	95% C.I.			
				AOR	Lower		Upper
	96	145					
Constraints	$\chi^2(2)=10.898$		0.012	0.342	0.148	0.787	0.012

Chi square test of association analysis was performed to assess the association constraint factors and childhood TB diagnosis and management. HCWs were grouped into those who would carry out correct childhood TB diagnosis and management (n=96) and incorrect childhood TB diagnosis and management (n=145). Data are presented as odds ratios and 95% confidence interval (CI). Statistical significance was set at $P \leq 0.050$. Significant P values are shown in bold.

4.5.3 Emerging themes on constraint factors from key informant interviews

Thematic analysis revealed three sub-themes on constraints key to childhood TB diagnosis and management. These results from the KII correlate with the questionnaire results which showed

procurement, stock-outs and correct dosing were the main drivers to correct childhood TB diagnosis and management. A respondent cited correct dosing as follows:-

“I was shocked when I was told that some children took less drugs for that long [six months] but now, once we corrected this, children got healed,. Now they do care if the duration is even one or two years” (Respondent 8)

In response to a discussion question on stock-outs, one participant stated the following:-

“Efforts to address TB LCs and drugs stock-outs remained fragmented and often outside the scope of HCWs. This is because commodities used in addressing childhood TB diagnosis and management are not procured by HFs thus HCWs only rely on distribution that is planned by NLTP. This causes delays that lead to stock-outs. (Respondent no. 30)”

CHAPTER FIVE: DISCUSSION

5.0 Introduction

This chapter focuses on the deductions of the study on the backdrop of key study variables. In this study, the researcher sought to determine the socio-demographic and socioeconomic factors that affect childhood TB diagnosis and management among HCWs, ascertain the current level of knowledge on childhood TB diagnosis and management among HCWs, establish facility-based factors that affect diagnosis and management of childhood TB among HCWs and evaluate the constraints to childhood TB diagnosis and management among HCWs.

5.1 Association between socio-demographic factors and childhood TB diagnosis and management.

This study set out to determine if the age of the HCWs had any influence on childhood TB diagnosis and management. As such, the study grouped the respondents into 3 age categories, namely, those under 30 years, 31-40 years and above 40 years. The results of the study showed that 83% and 66% of the staff under 30 years of age would correctly and incorrectly diagnose and manage childhood TB, respectively. Chi square test of association analysis revealed a significant association between age of HCWs and childhood TB diagnosis and management ($p=0.003$). This association suggested that relative to HCWs under 30 years of age, the respondents above the age of 40 years had lower odds of correct diagnosis and management of childhood TB. These findings are consistent with previous studies which found out that age may be an important factor contributing to effective learning using internet technology and should be considered when choosing platforms for HCW training on childhood TB. In addition,

other previous studies showed that socioeconomic and behavioral factors have also been shown to increase the susceptibility to TB infection (Oliwa *et al.*, 2020).

In order to understand the influence of levels of education attained by HCWs on their ability to diagnose and manage childhood TB, the study considered HCWs with a University degree and above and those with diploma certificates and below. The results showed that 83% of HCWs who had completed diploma level correctly diagnosed and managed childhood TB. Chi square test of association analysis further revealed a significant association between highest level of education completed by HCW and childhood TB diagnosis and management ($p=0.003$) suggesting that HCWs with degree (and above) as highest level of education attained were 0.38 times less likely to correctly diagnose and manage childhood TB. These results were in contrast with a study by (Gizaw *et al.*, 2015) which concluded that higher educational level, provision of training and history of TB were significantly associated with good knowledge of HCWs. These findings similarly concurred with (Oliwa *et al.*, 2020) who found that at individual level, knowledge, skill, competence and experience, as well as beliefs and fears impacted on capability (physical & psychological) as well as motivation (reflective) to diagnose TB in children and use diagnostic tests.

To further understand in the type of employer that the respondents worked for had any impact of the ability of the HCWs to diagnose and manage childhood TB, the study categorized respondent's current employer into 2 groups; MOH and MOH supported by partner NGOs. The results showed that 70% of HCWs employed by MOH/Partner correctly diagnosed and managed childhood TB. Findings from Chi square test of association revealed a significant association between HCW's current employer and childhood TB diagnosis and management ($p=0.047$) which suggested that HCWs employed by MOH/Partner support were 1.8 times

more likely to correctly diagnose and manage childhood TB. These study findings were in agreement with (Gizaw *et al.*, 2015). To enable the effective control and prevention of TB in healthcare settings in South Korea, specific and detailed guidelines by making sure all newly hired HCWs should receive baseline training for dealing with LTBI in HCWs are required.

Finally, this study sought to determine if gender (male or female), cadre (classified as clinicians, nurses, medical lab personnel, dental officers and pharmacists) and experience of HCWs (classified as <1 year, 1-4 years, 5-9 years and >10 years) would have any effect on childhood TB diagnosis and management. Findings from Chi square test of association analysis revealed no association between HCW's gender ($p=0.676$), cadre ($p=0.178$) and experience in public HF ($p=0.253$) respectively and childhood TB diagnosis and management. These results contrast with a study by () who found that at individual level, knowledge, skill, competence and experience, as well as beliefs and fears impacted on capability (physical & psychological) as well as motivation (reflective) to diagnose TB in children and use diagnostic tests. These findings similarly disagreed with (Oliwa *et al.*, 2019) who concluded that high suspicion of TB by the clinician, adequate infection-control measures by the hospital authorities and early identification of latent tuberculosis infection in HCWs by occupational specialists form the essential components of a comprehensive package to prevent TB in HCWs. Taken together, findings from this study revealed concurrence of qualitative and quantitative results and that HCW's age, level of education and current employer influences childhood TB diagnosis and management in Siaya County, Kenya.

5.2 HCW's level of knowledge on correct childhood TB diagnosis and management.

The study sought to find out if HCW's level of knowledge (*attendance of seminars/trainings or workshop on childhood TB in the past 12 months, knowledge of WHO 2010 mg/kg recommended daily therapy and knowledge of standard length of treatment of newly diagnosed case*) influenced childhood TB diagnosis and management. Overall knowledge levels of HCWs considering all the three areas of knowledge combined into a composite score revealed an association between correct diagnosis and management of childhood TB and cadre of staff, Experience (in years) in the current position, experience (in years) working in a public health facility and attendance of lectures on childhood TB in the past 12 months by HCWs. Only attendance of lectures on childhood TB by HCWs was established to significantly determine the knowledge levels on correct diagnosis and management of childhood TB at multivariate level. These findings were in agreement with (Oliwa *et al.*, 2020) who found out that at individual level, knowledge, skill, competence and experience, as well as beliefs and fears impacted on capability (physical & psychological) as well as motivation (reflective) to diagnose TB in children and use diagnostic tests.

5.2.1 Attendance of Lectures, Seminar or Workshop on Childhood Tuberculosis by HCWs on childhood TB diagnosis and management

This study investigated the influence of attendance of Lectures/Seminar/Workshop on Childhood Tuberculosis by HCWs on childhood TB diagnosis and management. Results showed that 56% of HCWs who had attended Lectures/Seminar/Workshop on Childhood TB by HCWs correctly diagnosed and managed childhood TB. Chi square test of association analysis further revealed a significant association between attendance of

Lectures/Seminar/Workshop on Childhood TB by HCWs and childhood TB diagnosis and management ($p=0.012$). This suggested that HCWs who had attended of seminar/training and workshops on childhood TB in the past 12 months had 1.985 higher odds of correct childhood TB diagnosis and management. This results were in agreement with (Oliwa *et al.*, 2019; Vries, Šebek, & Weezenbeek, 2006) who stated that childhood TB control is more likely to be achieved if the level of knowledge regarding childhood TB is increased among HCWs managing high-risk groups. Similarly, the study was also in agreement with (Brent *et al.*, 2017; Vries, Gerard, *et al.*, 2006) who noted that lack of trainings increased the risk of incorrect childhood TB diagnosis and general management.

The findings of this study was supported by (Vries, Gerard, *et al.*, 2006) while assessing Tuberculosis knowledge, attitude and practice among healthcare workers during the 2016 Hajj concluded that, HCWs should be encouraged to keep up-to-date with recent scientific literature and advances in TB management and control as well as being aware of national and international guidelines and best practices. In respect to this, less than a half of HCWs in this study reported attending a lecture, seminar or workshop on TB in the previous year which may also explain the lack of knowledge regarding recent diagnosis techniques such as Gene Xpert MTB/RIF, first-line ant-TB regimen for children and standard length of treatment in this study. While appropriate training and education of HCWs is crucial to improving their knowledge regarding childhood TB, such activities alone may not be sufficient for improving HCWs performance as well as the quality of TB control outcomes. Therefore, special attention should also be given to addressing factors beyond training such as health system, job satisfaction as well as working conditions, which could influence HCWs' knowledge regarding TB, so as not to reinforce the limitations and weaknesses of current practices. The above factors are part of

a “productivity mix” that impact on HCWs’ job motivation, productivity and performance, which may translate to HCWs not providing care according to standards and not being responsive to the needs of TB patients.

5.2.2 Knowledge of recommended WHO 2010mg/kg dosage for first-line anti-TB drugs in diagnosis and management of childhood TB

This study investigated the influence of knowledge of WHO 2010mg/kg dosages for first-line anti TB drugs in children on childhood TB diagnosis and management. Results showed that 43% of HCWs who had knowledge WHO 2010mg/kg dosages for first-line anti TB drugs in children correctly diagnosed and managed childhood TB. Chi square test of association analysis further revealed no significant association between knowledge of WHO 2010mg/kg dosages for first-line anti TB drugs in children and childhood TB diagnosis and management ($p=0.746$). The results presented here showed no link between knowledge of WHO 2010mg/kg dosages for first-line anti TB drugs in children and childhood TB diagnosis and management. These findings concurred with a Burundi study where nurses in Burundi reported that they were involved in practical work of educating patients on TB and its treatment, providing medication and related follow-up, and ensuring the patients are of good morale to complete their treatment (Alotaibi *et al.*, 2019).

This findings also contradicted (L. Adams *et al.*, 2014) when he found out that the success rate of 6-month daily regimens for new TB patients was between 84 and 86% (2 studies); however, the cure rate was only 58% in Italy, compared with 82 to 86% in Korea, Hong Kong and Africa while reviewing “Effectiveness of standard short-course chemotherapy for treating tuberculosis and the impact of drug resistance on its outcome” and concluded that the evidence

showed that treatment with daily regimens was effective for new TB cases, with a success rate of over 80%. Understanding the recommended first-line ant-TB drugs for children by HCWs should be a priority for the department of health if childhood TB control in Siaya County is to be achieved.

5.2.3 Knowledge of standard length of treatment of newly diagnosed case by HCWs on childhood TB diagnosis and management.

This study investigated the influence of knowledge of standard length of treatment of newly diagnosed case by HCWs on childhood TB diagnosis and management. Results showed that 94% of HCWs who had knowledge of standard length of treatment of newly diagnosed case by HCWs correctly diagnosed and managed childhood TB. Chi square test of association analysis further revealed no significant association between knowledge of standard length of treatment of newly diagnosed case by HCWs and childhood TB diagnosis and management ($p=0.275$).

The results presented here showed no link between knowledge of standard length of treatment of newly diagnosed case by HCWs and childhood TB diagnosis and management. These findings contradicted a study in Ethiopia (L. Adams *et al.*, 2014) that identified that the knowledge of HCWs toward MDR-TB drugs was poor (45%) in Addis Ababa, Ethiopia. This means that HCWs knowledge on standard length of treatment of newly diagnosed patient would greatly influence diagnosis and management of childhood TB patients in Siaya County.

5.3 Influence of health facility based factors on diagnosis and management of TB among HCWS

The study sought to find HF based factors (*availability of chest radiography, availability of standard treatment regimens and the type of HF*) that influences childhood TB diagnosis and management among HCWs in Siaya County.

5.3.1 Association between type of health facility and childhood TB diagnosis and management

This study set out to determine if the type of health facility had any influence on childhood TB diagnosis and management. The results of the study showed that 82% and 68% of the n=178 would correctly or incorrectly diagnose and manage childhood TB respectively. Chi square test of association analysis revealed a significant association between the type of HF and childhood TB diagnosis and management ($p=0.017$). This association suggested that HCWs working in sub county level of hospital and above had a much higher odds of correct diagnosis and management of childhood TB compared to workers in health centre and below. This findings were in agreement with (Ahmad, 2011) who postulated that treatment interruption in Kiambu County was shown to be prevalent health centers compared to sub-county hospitals due to insufficient training on commodity management in HFs.

5.3.2 Availability of chest radiography in HF and diagnosis and management of childhood TB by HCWs

The study established that 96% respondents indicated availability of chest radiography in HFs. Chi square test of association analysis did not establish any significant association between

availability chest radiography and childhood TB diagnosis and management ($p=0.505$). These findings contradicted Kirimuhuzya, (2013) who noted that despite clinician's ability to deal with TB, chest radiography was the most widely used screening tool in clinical practice that provide suggestive diagnosis in most children with TB. This findings were also in contrast with (Wu *et al.*, 2017) who in their study "Chest Radiographs for Pediatric TB Diagnosis" in Western Kenya concluded that poor agreement and high variability in classifying pediatric radiographs underscores need caution in diagnosing TB in clinical settings where bacteriological confirmation is unavailable, as in most resource limited settings. These findings suggests that HCWs should use chest radiography as a screening tool to aid in identifying possible childhood TB cases for targeted diagnosis and management.

From the above, HCWs knowledge of availability of chest radiography and its utilization in diagnosis and management of childhood TB should be supported by other bacteriological confirmatory tests like gene x-pert to aid in diagnosis and management of childhood TB. In conclusion, knowledge of childhood TB chest radiography reference did not increase the number of correct decisions to diagnose and treat childhood TB by HCWs in their operational setting in Siaya County. Further evaluation of knowledge of availability of this tool and its application in clinical practice may provide a validated triage mechanism for childhood TB management.

5.3.3 Availability of standard regimens for children in HFs on correct management of childhood TB

The study established that 73% respondents indicated availability of standard treatment regimens in HFs Chi square test of association analysis did not establish any significant

association between availability of standard treatment regimens in HFs listed by weight bands and childhood TB diagnosis and management ($p=0.373$). This findings contradicted (Kimani *et al.*, 2021) who postulated that treatment interruption in Kiambu County was shown to be prevalent during the intensive phase compared to continuation phase be due to insufficient health education and non-availability of standard regimens in HFs. These results further contradicted similar studies in HFs in south Ethiopia and Nairobi County that revealed that most of the patients interrupted treatment during the intensive phase of treatment. Since all HFs should have the basic essential requirements for TB diagnosis and treatment. This could be strengthened by consistent monthly and quarterly supervisions by the County team, and a few times by the MoH officials. A study carried out on quality of TB care in Ethiopia also revealed delivery of materials, drugs, and supplies to HFs for TB control activities being fairly good.

5.4 Constraints to correct childhood TB diagnosis and management by HCWs

Finally, this study investigated constraints to childhood TB diagnosis and management among HCWs in Siaya County with focus on; *correct dosing, stock-outs and expiries and procurement*. Both the qualitative and quantitative aspects of these constraints on childhood TB diagnosis and management was assessed.

Study findings revealed that most (56%) respondents identified correct dosing as the major constraint compared to stock-outs and expiries (44%) and procurement (26%). These findings were further confirmed by Chi square test of association analysis that found a significant relationship ($p=0.012$) between these constraints and childhood TB diagnosis and management among HCWs. This suggested that challenges of stock outs and correct dosing in health facilities

contributed to incorrect diagnosis and management of childhood TB. These findings agreed with (Kimani *et al.*, 2021) while investigating the “Effects and determinants of tuberculosis drug stock-outs in South Africa, estimated that TB stock-outs had a substantial negative effect on TB cure and success rates by district. Their results indicated that, on average, a 10% rise in the TB drug stock-out proportion resulted in a 2.14% decline in TB cure rate and a 1.43% decline in TB success rate.

Since the consequences of TB LCs and drug stock-outs for childhood TB diagnosis and treatment outcomes are severe, emphasis should be placed on further strengthening of the LCs and drugs supply chain in Siaya County. A short-term solution to ensure continuous LCs and drug supply to childhood TB patients could be a public-private partnership in which patients could confirm their TB status collect their TB drugs for free at a private pharmacy or -clinic in the case of a stock-out in the public HFs. Persistence of TB LCs and drug stock-outs in Siaya County not only hampers the effective control of TB but its unequal occurrence across sub-counties also adds to the socioeconomic inequality in TB outcomes. This suggests that efforts to reduce TB LCs and drug stock-outs are essential in the fight against the TB burden and its impact on socioeconomic inequality.

CHAPTER SIX: SUMMARY, CONCLUSIONS AND RECCOMENDATIONS

6.1 Summary

The broad objective of this study was to assess factors that affect diagnosis and management of childhood TB among HCWs in Siaya County. To accomplish that goal it became necessary to reach some prerequisite goals. The specific objectives of this study were outlined as follows:

In order to determine the socio-demographic and socioeconomic factors that affect childhood TB diagnosis and management among HCWs, results obtained from this study suggested that HCWs with degree (and above) as highest level of education attained were less likely to correctly diagnose and manage childhood TB. Similarly, HCWs employed by MOH/Partner support were more likely to correctly diagnose and manage childhood TB.

To determine the current level of knowledge on childhood TB diagnosis and management among HCWs, results revealed that HCWs who had attended of seminar, training or workshops on childhood TB in the past 12 months had higher chances of correctly diagnosing and managing childhood TB.

To establish facility based factors that affect diagnosis and management of childhood TB among HCWs, the study suggested that HCWs working in sub county level of hospital and above had a much higher odds of correct diagnosis and management of childhood TB compared to workers in health centre and below.

Finally, to evaluate the constraints to childhood TB diagnosis and management among HCWs, this study revealed that procurement, stock outs and correct dosing in health facilities contributed to incorrect diagnosis and management of childhood TB among HCWs.

6.2 Conclusion

While drawing conclusions from the findings and discussions of this study, it was necessary to observe the key study variables that informed this work in a significant measure and were found to affect diagnosis and management of childhood TB among HCWs.

1. Employment of young HCWs aged below 30 years with diploma as the highest level of education completed were associated with diagnosis and management of childhood TB.
2. Attendance of Lectures/Seminar/Workshop on Childhood TB by HCWs in the past 12 months was associated with correct childhood TB diagnosis and management.
3. Working in a sub county hospital level and above was associated with correct diagnosis and management of childhood TB compared to HCWs at health centre level and below.
4. Constraints of stock-outs and correct dosing at health facilities were associated with inability of HCWs to diagnose and manage childhood TB.

6.3 Study Recommendations.

From the study findings, the following recommendations were prescribed for both probable policy formulation and further research.

1. There is need for Siaya County department of health, MoH Kenya and health partners to prioritize more young (under 30 years) HCWs with diploma as highest level of education completed in their employment to facilitate childhood TB diagnosis and management.

2. There is need for Siaya County department of health to increase the frequency and intensity of attendance of lectures/seminars/workshops on childhood TB in form of CMEs for HCWs to enhance childhood TB diagnosis and management.
3. There is need for Siaya County department of health to enhance the ability of health centres and below to enable these HFs to correctly diagnose and manage childhood TB.
4. There is need for Siaya County department of health to streamline supply chain in order to address problems with procurement, stock out problems and correct dosing which undermined diagnosis and management of childhood TB.

6.3.1 Recommendations for policy formulation.

Currently:

- Guidelines for management of Tuberculosis and Leprosy in Kenya
- Guidelines for TB infection prevention and control for HCWs in Kenya
- National Guidelines on management of TB in children

Only encourage training/seminars/lectures post mainstream training, meaning, only basic training on childhood TB diagnosis and management by HCWs is undertaken before completion of mainstream HCW training track such as nursing, medicine and others. To scale up childhood TB diagnosis and management, and possibility of replicating, or adoption of lessons learnt in other regions, training/seminar/lectures on childhood TB diagnosis and management should be incorporated in the mainstream training of HCWs. This will ensure that at the time of entry into practice, the HCW is already knowledgeable and equipped with necessary skills for service provision.

6.3.2 Recommendations for further research

The following area emerged as a key for further investigation:

1. Research on other factors (patient related factors, disease based factors) that affect diagnosis and management of childhood TB.

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Appendix I: Informed consent form

INFORMED CONSENT FORM

Written consent for health care workers (HCWs) participating in the ‘determination of the factors that affect diagnosis and management of childhood Tuberculosis (TB)’ study,

1. Purpose of research:

The Maseno University student is doing a research study. This study is to assess the factors that affect diagnosis and management of childhood Tuberculosis (TB) among healthcare workers (HCWs). The results from this study will help seal the existing gaps in childhood TB diagnosis and management contributed to by HCWs in future.

2. What we will do:

If you agree to be in this study, we will ask questions about your knowledge on childhood TB, diagnosis and management. He/she will conduct an in-depth interview on childhood TB diagnosis and management and your responses documented for later analysis.

3. Potential benefits:

The main benefit to you will be to identify and create need to fill the existing knowledge gap among HCWs on childhood TB diagnosis and management of current or future active childhood TB case.

4. Potential risks:

There are no major direct risks anticipated during the study, only the inconvenience involved in taking the time to obtain consent or assent to participate in the study.as a result of taking part in the study.

5. Privacy and confidentiality:

The researcher will label all questionnaires and KIIs only using study codes. Information about you and your knowledge on childhood TB diagnosis and management will be kept confidential to the maximum extent allowable by law. The data collected will be stored in locked cabinets and on password-protected computers by the researcher. The researcher will use the information for research purposes only. Your name and where you live will not appear on any reports. At the end of the study, the researcher will remove all names and any other information that could identify you from the data

Your views in the interview will be held strictly confidential and will not be divulged to anybody. All interviews will take place in a private setting, no reference will be made in oral or written reports, which could link you to any information collected and your name will not appear anywhere. Only the researcher will have access to the information and all records of views shared will be stored in a locked place under the researchers' control.

6. Your rights to participate or withdraw:

Your participation in this study is completely voluntary. You can withdraw from this study at any time. If you do not want to be in this study, you will still get feedback from our study. NOTE: You will not be victimized for agreeing or refusing to participate in this study.

7. Contact information for questions and concerns:

If you have any questions about this study or feel that you been harmed in this study, you can contact Dr. Bonuke Anyona - School of Medicine or Dr. Harrysone Atieli - School of Public Health and Community Development at Maseno University, P.O. Box Private Bag, Maseno, or at +254 721 543 976 or +254 721 347 437. If you want to talk about the study with someone

who is not directly involved with this study or have questions about your rights, please contact the Chairman of the Maseno University Ethics Review Committee (MUERC) P.O. Box Private Bag, Maseno, Kenya. Telephone: + 254 57 351 622.

Respondent’s consent for participating in this study:

The above study has been explained to me. I have read the consent form/the consent form has been read to me. My questions have been answered. I agree to take part in this study.

Adult providing consent for self	Name:	Signature:	Today’s date □□/□□/□□
Witness*	Name:	Signature:	Today’s date □□/□□/□□
Study staff consenting respondent	Name:	Signature:	Today’s date □□/□□/□□
Assigned study code	MLS □□□□		

*A witness is a person independent from the study. A witness is only needed if cannot read. In that case, a respondent or parent can verbally state his/her consent in the presence of a witness who will then sign.

Appendix II: Questionnaire

FOR OFFICIAL PURPOSE ONLY	
Data Collector: _____	Questionnaire No: _____
Date Collected: _____	
(DD/MM/YYYY)	Informed Consent Received: Y/N _____
Health Facility: _____	

All questionnaires are completed anonymously. We would appreciate it if you answer all the questions and answer as honestly as possible.

Please place a check mark (✓) in the box that best answers the question. **Kindly make only one selection unless otherwise instructed.**

SECTION A: SOCIO DEMOGRAPHIC INFORMATION

1. What sex are you?

- Male
 Female

2. How old are you?

- Under 30 years
 31 – 40 years
 41 – 50 years
 Over 50 years

3. What is the highest level of education you have completed?

- University/College Diploma
 Associate Degree
 Bachelor's Degree
 Specialized/Professional graduate or Post graduate Degree (e.g. MBBS, MSc, MPH)
 Other (Please specify) _____

4. What is your current job title?

5. How long have you been working in this current position?

- < 1 year
- 1 – 4 years
- 5 – 9 years
- 10 – 14 years
- ≥ 15 years

6. How long have you been working in a public health facility?

- < 1 year
- 1 – 4 years
- 5 – 9 years
- 10 – 14 years
- ≥ 15 years

7. What type of facility do you currently work in?

- Dispensary
- Health Center
- Sub County Hospital
- County Referral Hospital

8. Who is your current employer?

- MoH
- MoH/Partner support
- Other (Please specify) _____

9. What is your current term of employment?

- Permanent and Pensionable (P&P)
- Temporary
- Contract
- Other (Please specify) _____

SECTION B: CHILDHOOD TB RELATED KNOWLEDGE AND AWARENESS

10. In the past 12 months, have you attended any lecture/ seminar/ workshop on childhood tuberculosis (TB)?

- Yes
- No

If **No** above, why?

- Not aware that the above exists
- Was committed to other duties
- Aware but did not want to attend
- Not interested

11. Who, in your opinion should be trained on Childhood TB diagnosis and management?

- All healthcare workers, regardless of the cadre
- Medical officers
- Pharmacists
- Nursing Officers (CHEWs)
- Clinical Officers
- Pharmaceutical Technologists
- Laboratory Technologists
- Other (Specify) _____

12. What is/are the main symptom(s) that are used as an indicator for infectious, active childhood TB disease? **Please check all that apply.**

- Cough ≥ 2 weeks
- Cough with blood
- Fever
- Night sweats
- Diarrheas
- Weight loss
- Don't know for certain

13. Can a child become infected with TB more than once in their lifetime?

- Yes
- No
- Don't know for certain

14. What is the standard length of treatment for a newly diagnosed case of childhood TB?

- < 1 month
- 1 – 2 months
- 3 – 4 months
- 5 – 6 months
- 7 – 8 months
- Don't know for certain

15. How can a child with TB be cured? **Please check all that apply**

- Tb cannot be cured and, only managed
- Herbal medicines
- Best without medicine
- General antibiotics
- Specific anti TB regimen
- Do not know for certain

16. What is the WHO classification criterion for a relapse case?

- A patient who remained or became smear positive again near the end of the treatment course
- A patient whose treatment was interrupted for two (2) months or more and returns to treatment with bacteriologically confirmed active TB
- A patient who was previously treated and cured, but once again has bacteriologically confirmed TB
- Do not know for certain

17. What is the WHO classification criterion for a defaulter case?

- A patient who remained or became smear positive again near the end of the treatment course
- A patient whose treatment was interrupted for two months or more and returns to treatment with bacteriologically confirmed active TB
- A patient who was previously treated and cured, but once again has bacteriologically confirmed TB
- Do not know for certain

18. In your opinion, is TB a major public health threat in Kenya?

- Yes, it is already more than just a major threat
- Yes, it poses a serious threat to Kenya
- No. Cases are controlled so there is no major concern
- No. It is not even a small threat at this time
- Do not know for certain

19. In your opinion, who are the persons most likely to become infected with TB in Kenya?

Please check all that apply.

- Homeless persons
- Children under 5 years
- Senior Citizens
- People living with HIV/AIDS
- Health care worker treating a confirmed case
- Family members of a confirmed case
- Prison Inmates

20. Under what circumstances are health education messages on TB given to patients? **Please check all that apply**

- World TB Day
- BCG Immunization
- General health promotion/ education messages delivered in clinical settings
- With suspected or confirmed cases only (i.e. no family members)
- With suspected cases and their families in a clinical setting
- With confirmed patients and their families in either a clinical or community setting
- Health education on TB is generally not done with patients

21. What is the primary diagnostic test that is usually requested in order to confirm or rule out a case of active childhood TB in children? **Please select only one answer.**

- Nasopharyngeal swab
- Chest X-ray
- Montoux test
- Sputum Smear Microscopy/ Culture
- Blood Culture
- Gene X-pert

22. What do you think are the best ways a child can be prevented from getting pulmonary TB? **Please check all that apply.**

- Immunization with BCG vaccine
- Avoid shaking hands
- Avoid sharing dishes
- Practice safe sex
- Use of Personal Protective Equipment
- Prayer
- Proper hand washing
- Through good nutrition
- Cover mouth and nose when coughing or sneezing
- Opening windows at home and work

23. In your opinion, what skill or training level is needed of someone to effectively conduct Directly Observed Treatment (DOT) with a patient with TB? **Please select only one answer.**

- Only highly qualified/ trained health care workers (e.g. physician, Public Health Nurse; Pharmacist)
- Any health care worker with clinical training (E.g. Registered Nurse; Medical Technologist)
- Any health care worker regardless of clinical training (E.g. Community Health Aide; Medical Records)
- This is not a technical activity that requires professional training in health care

24. What do you consider to be the main risk to the patient associated with incomplete or interrupted treatment course for TB? **Please select only one answer.**

- Worsening of symptoms and prolonged treatment course
- Development of drug - resistance
- Death
- There is no serious reason

SECTION C: HEALTH FACILITY RELATED FACTORS

This section aims to get an overview of all stakeholders involved in the diagnosis and management of childhood TB at county and health facility level

25. How is childhood TB diagnosed in your health facility?

- Using existing case definitions
- Using clinical algorithms/scoring systems
- On an individual basis
- Using Gene X-pert
- Unsure/don't know

26. Which diagnostic elements are generally available in your HFs and used for the diagnosis of childhood TB, and where are they available? **Tick all that apply**

- Bacteriology/histology showing M. Tb
 - Available in nearly all settings (this includes: good sample transport mechanisms available to culture labs)
 - Available in most settings (**please specify which kind of settings**)
 - Available in very few settings (**please specify which kind of settings**)
 -
 - Unsure about coverage

- X-pert MTB/RIF
- Available in nearly all settings (this includes: good sample transport mechanisms available to culture labs)
 - Available in most settings (**please specify which kind of settings**)
 - Available in very few settings (**please specify which kind of settings**)
 - Unsure about coverage
- Tuberculin skin testing (TST)
- Available in nearly all settings
 - Available in most settings (**please specify which kind of settings**)
 - Available in very few settings (**please specify which kind of settings**)
 - Unsure about coverage
- Chest radiography
- Available in nearly all settings
 - Available in most settings (**please specify which kind of settings**)
 - Available in very few settings (**please specify which kind of settings**)
 - Unsure about coverage
- Fine Needle Aspiration for detection of Lymph node TB
- Available in nearly all settings
 - Available in most settings (**please specify which kind of settings**)
 - Available in very few settings (**please specify which kind of settings**)
 - Unsure about coverage
- Clinical symptoms
- Contact history
- Response to therapy
- Other (**please describe**) _____

27. Are smears and cultures routinely collected on children in your work station?

- Yes, in nearly all settings
- Yes, in most settings

a. If yes, what specimens are collected? (**Check all that apply**)

- Gastric aspirate
- Expecterated sputum (e.g. Coughed-up sputum)
- Induced sputum
- Other (please describe)_____

b. Is there an age cutoff when sputum specimens are not collected?

- Yes, under the age of _____
- No

- No
- Unsure/don't know

28. Is drug - susceptibility testing routinely available for childhood TB cases in your HF?

- Available in nearly all settings (this includes: good sample transport mechanisms available to culture labs)
- Available in most settings (**please specify which kind of settings**)
- Available in very few settings (**please specify which kind of settings**)
- Unsure about coverage

29. What are the recommended dosages for first -line anti-tuberculosis drugs in children?

- Daily Therapy
 - Intermittent therapy
- Please tick dosage recommendations that apply**
- WHO 2006mg/kg
 - WHO 2010Mg/kg

30. Do you have standard regimens for children available, with the dosages listed by weight bands?

- Yes
- No
- Unsure/don't know

31. Do you have problems with stock-outs, expired drugs?

- Yes
- No
- Unsure/don't know

32. In your opinion, please outline the main challenges you experience regarding drug management in children

- Procurement
- Stock-outs
- Correct dosing
- Others (**Please specify**) _____

33. In your opinion, how well would you say is IPT implemented at the county level?

- Well in nearly all settings
- Well in most settings **Please specify in what kind of settings**
 - In certain sub-counties of the county
 - In urban rather than rural areas
- Generally in Tertiary Care facilities/university hospitals
- Settings managed by certain NGOs
Which _____
- Settings where expert pediatricians are available
- Well in very few settings. **Please specify in what kind of settings**
 - In certain sub-counties of the county
 - In urban rather than rural areas
- Generally in Tertiary Care facilities
- Settings managed by certain NGOs.
Which _____
- Settings where expert pediatricians are available
- Not well
- Unsure/don't know

34. Are there issues with the availability of INH for preventive therapy in children?

- Yes (**Please describe**): _____
- No
- Unsure/don't know

35. Who is included in routine contact investigations? **Please check all that apply**

- Children < 5 years of age
- Children < 15 years of age
- All household contacts
- Persons with HIV infection
- Other (**please describe**) _____
- Contact investigations are not routinely implemented

36. Is preventive therapy routinely provided to MDR child contacts in your HF?

- Yes
 - In nearly all settings
 - In most settings
 - In few settings
 - No, not recommended
 - No, not done
 - Unknown
- If yes, what kind of treatment
- INH
 - Other, specify _____

37. How well the NTLP is generally linked with other childcare providers in your county?

- Well with
 - Mother and child care services
 - Vaccinations services
 - Community child health programmes
 - Private providers
 - Other, please specify _____
- Not well
- Unknown

38. If linkages exist, what are the roles of these other providers? **Tick all that apply**

- Contact tracing
- Provision of IPT
- Referral of TB suspects
- Diagnosis
- Treatment support
- Reporting of data

Appendix III: Key informant interview guide (KII)

KEY INFORMANT INTERVIEW GUIDE (FOR HEALTH FACILITY OFFICER IN-CHARGES, SUB-COUNTY TB AND LEPROSY CO-ORDINATORS (SCTLIC) AND SUB-COUNTY MEDICAL LABORATORY CO-ORDINATORS (SCMLT)).

Name of the facility: _____

Designation of the interviewee: _____

Interviewee code number: _____

QUESTIONS

1. For how long have you worked in this health facility/sub-county?

Years _____ Months _____

2. Have you had any specific training on childhood TB diagnosis and management in the past 12 months?

3. Do you receive adequate and regular childhood TB diagnostic and management supplies?

4. Do you give DOT explanations to childhood TB patients?

5. Besides TB services work, do you have other responsibilities assigned to you?

6. Do you find your work comfortably manageable?

7. In your opinion, what do you consider as major impediments to childhood TB diagnosis and management?

8. Do other HCWs manage childhood TB according to national guidelines (e.g. diagnosis, treatment)?

9. In your opinion, what are the main programmatic challenges regarding childhood TB in your HF?

10. How often does your facility give health education to childhood TB patients/caregivers whenever they collect TB medicines?

THANK YOU

Appendix IV: Global TB Distribution

Tuberculosis worldwide

- ▶ TB is caused by the bacillus *Mycobacterium tuberculosis* that most often affects the lungs
- ▶ Multi-drug resistant TB* is a form caused by bacteria that does not respond to two of the most powerful drugs
- ▶ Treatment options for *MDR-TB are limited and expensive

In 2017

10 million new cases

1.6 million deaths

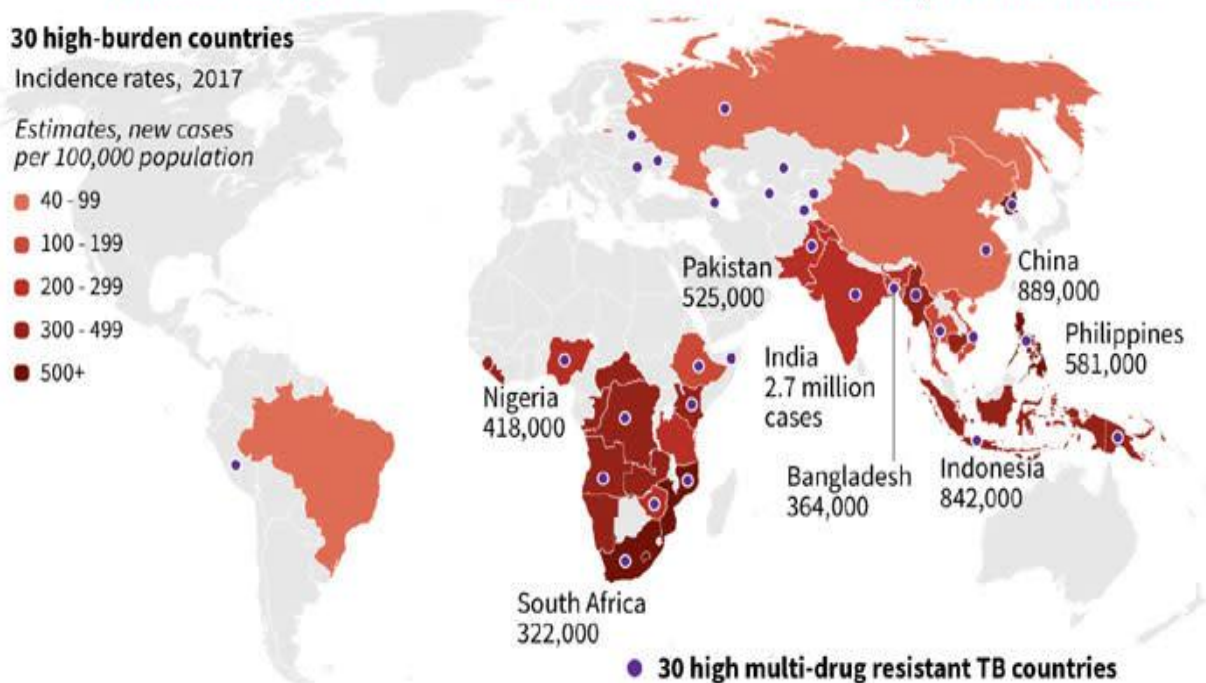
558,000 MDR-TB cases

30 high-burden countries

Incidence rates, 2017

Estimates, new cases per 100,000 population

- 40 - 99
- 100 - 199
- 200 - 299
- 300 - 499
- 500+



Source : WHO global tuberculosis report 2018

© AFP

A map showing "The 30 countries on the map that accounts for 80% of the tuberculosis cases in the world". Retrieved from <http://www.stoptb.org/countries/tbdata.asp> Copyright 2018 by WHO

Appendix V: Sustainable Development Goals

				
<p>Goal 1: End poverty in all its forms everywhere</p>	<p>Goal 2: End hunger, achieve food security and improved nutrition and promote sustainable agriculture</p>	<p>Goal 3: Ensure healthy lives and promote well-being for all at all ages</p>	<p>Goal 4: Ensure inclusive and quality education for all and promote lifelong learning</p>	<p>Goal 5: Achieve gender equality and empower all women and girls</p>
				
<p>Goal 6: Ensure access to water and sanitation for all</p>	<p>Goal 7: Ensure access to affordable, reliable, sustainable and modern energy for all</p>	<p>Goal 8: Promote inclusive and sustainable economic growth, employment and decent work for all</p>	<p>Goal 9: Build resilient infrastructure, promote sustainable industrialization and foster innovation</p>	<p>Goal 10: Reduce inequality within and among countries</p>
				
<p>Goal 11: Make cities inclusive, safe, resilient and sustainable</p>	<p>Goal 12: Ensure sustainable consumption and production patterns</p>	<p>Goal 13: Take urgent action to combat climate change and its impacts</p>	<p>Goal 14: Conserve and sustainably use the oceans, seas and marine resources</p>	<p>Goal 15: Sustainably manage forests, combat desertification, halt and reverse land degradation, halt biodiversity loss</p>
		 <p>SUSTAINABLE DEVELOPMENT GOALS 17 GOALS TO TRANSFORM OUR WORLD</p>		
<p>Goal 16: Promote just, peaceful and inclusive societies</p>	<p>Goal 17: Revitalize the global partnership for sustainable development</p>			

Appendix VI: Clearance certificate from Maseno University



MASENO UNIVERSITY ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050 Private Bag – 40105, Maseno, Kenya
Fax: +254 057 351 221 Email: muerc-secretariat@maseno.ac.ke

FROM: Secretary - MUERC **DATE:** 23rd March, 2018

TO: Felix Oloo Odhiambo **REF:** MSU/DRP/MUERC/00487/17
PGMPH/PH/0060/2014
Department of Public Health
School of Public Health and Community Development
Maseno University
P.O Private Bag, Maseno.

RE: Proposal Reference Number MSU/DRP/MUERC/00487/17 Determination of Factors that Affect Diagnosis and Management of Childhood Tuberculosis among Health Care Workers in Siaya County, Kenya

This is to inform you that the Maseno University Ethics Review Committee (MUERC) determined that the ethics issues raised at the initial review were adequately addressed in the revised proposal. Consequently, the study is granted approval for implementation effective this 23rd day of March, 2018 for a period of one (1) year.

Please note that authorization to conduct this study will automatically expire on 22nd March, 2019. If you plan to continue with the study beyond this date, please submit an application for continuation approval to the MUERC Secretariat by 15th February, 2019.

Approval for continuation of the study will be subject to successful submission of an annual progress report that is to reach the MUERC Secretariat by 15th February, 2019.

Please note that any unanticipated problems resulting from the conduct of this study must be reported to MUERC. You are required to submit any proposed changes to this study to MUERC for review and approval prior to initiation. Please advise MUERC when the study is completed or discontinued.

Thank you.


Dr. Boniuke Anyona,
Secretary,
Maseno University Ethics Review Committee.



Cc: Chairman,
Maseno University Ethics Review Committee.

MASENO UNIVERSITY IS ISO 9001:2008 CERTIFIED 

Appendix VII: Permission letter from Department of Health and Sanitation, Siaya County

COUNTY GOVERNMENT OF SIAYA



DEPARTMENT OF HEALTH AND SANITATION

E-mail: siayachd@gmail.com
PHONE:
ADJACENT TO JCC CHURCH
SIAYA TOWN

COUNTY HEALTH HEADQUARTERS
SIAYA COUNTY
P O BOX 597
SIAYA

Our Ref: SYA/CHD/RESEARCH/VOL. III (59)

27TH APRIL, 2018

The Sub-county Medical Officers of Health,
Medical Superintendents
SIAYA

RE: CLEARANCE TO CONDUCT A STUDY ON DETERMINING FACTORS THAT AFFECT DIAGNOSIS AND MANAGEMENT OF CHILDHOOD TUBERCULOSIS AMONG HEALTH CARE WORKERS IN SIAYA COUNTY

Felix Oloo Odhiambo Principal Investigator for the above referenced study has received authorization from Maseno Institution Review body MSU/DRPI/MUER/00487/17.

The study seeks to establish socio demographic level of knowledge and facility based factors that have effect on TB Management.

This is to notify you that the study has been approved by the office of the undersigned.
Kindly accord necessary assistance to the PI

Thank you.

A handwritten signature in blue ink, appearing to be 'Bobi Awino', written over a circular stamp.

Dr. Bobi Awino
DCDH (Preventive & Promotive Health Services)
SIAYA



CC: CECM – HEALTH
COH
CDH

Appendix VIII: Coded list of health facilities

Sampling Technique	Purposive Sampling	Simple Random Sampling	
Subgroups	Facility	Population	Sample
County Referral Hospital (CRH)	Siaya CRH	113	31
Sub-county Hospitals (SCH)	Yala SCH	43	15
	Bondo SCH	55	25
	Ambira SCH	39	20
	Madiany SCH	21	15
	Ukwala SCH	48	20
	Uyawi SCH	19	15
	Rwambwa SCH	21	15
	Sigomere SCH	18	15
Health Centres (HC)	Kadenge HC	11	8
	Akala HC	13	8
	Malanga HC	14	8
	Usigu HC	12	8
	Ong'ielo HC	10	8
	Manywanda HC	13	8
	Sifuyo HC	12	8
	Ligega HC	13	8
Dispensaries (Disp.)	Bar Ndege Disp.	10	6
Total	18 Health Facilities	485	241

CRH: COUNTY REFERRAL HOSP., **SCH:** SUB-COUNTY HOSP., **H.C.:** HEALTH

